104TH CONGRESS, 1st Session } HOUSE OF REPRESENTATIVES { REPT. 104–33 Part 2

JOB CREATION AND WAGE ENHANCEMENT ACT OF 1995

FEBRUARY 15, 1995.—Ordered to be printed

Mr. WALKER, from the Committee on Science, submitted the following

REPORT

together with

THE TRANSCRIPT FROM THE LEGISLATIVE MARKUP OF THE SCIENCE COMMITTEE

and the

ADDITIONAL, SUPPLEMENTAL, AND DISSENTING VIEWS

[To accompany H.R. 9]

[Including cost estimate of the Congressional Budget Office]

The Committee on Science, to whom was referred title III of the bill (H.R. 9) to create jobs, enhance wages, strengthen property rights, maintain certain economic liberties, decentralize and reduce the power of the Federal Government with respect to the States, localities, and citizens of the United States, and to increase the accountability of Federal officials, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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Additional, supplemental, and dissenting views.

I. AMENDMENT

The amendment is as follows:

Strike title III and insert the following:

TITLE III—RISK ASSESSMENT AND COST/BENEFIT ANALYSIS FOR NEW REGULATIONS

SEC. 3001. FINDINGS.

The Congress finds that:

(1) Environmental, health, and safety regulations have led to dramatic improvements in the environment and have significantly reduced human health risk; however, the Federal regulations that have led to these improvements have been more costly and less effective than they could have been; too often, regulatory priorities have not been based upon a realistic consideration of risk, risk reduction opportunities, and costs.

(2) The public and private resources available to address health, safety, and environmental concerns are not unlimited; those resources need to be allocated to address the greatest needs in the most cost-effective manner and so that the incremental costs of regulatory options are reasonably related to the incremental benefits.

(3) To provide more cost-effective and cost-reasonable protection to human health and the environment, regulatory priorities should be based upon realistic consideration of risk; the priority setting process must include scientifically sound, objective, and unbiased risk assessments, comparative risk analysis, and risk management choices that are grounded in cost-benefit principles.

(4) Risk assessment has proven to be a useful decision making tool; however, improvements are needed in both the quality of assessments and the characterization and communication of findings; scientific and other data must be better collected, organized, and evaluated; most importantly, the critical information resulting from a risk assessment must be effectively communicated in an objective and unbiased manner to

decision makers, and from decision makers to the public.

(5) The public stake holders must be fully involved in the risk-decision making process. They have the right-to-know about the risks addressed by regulation, the amount of risk to be reduced, the quality of the science used to support decisions, and the cost of implementing and complying with regulations. This knowledge will allow for public scrutiny and promote quality, integrity, and responsiveness of agency decisions.

(6) Although risk assessment is one important method to improve regulatory decision-making, other approaches to secure prompt relief from the burden of unnecessary and overly complex regulations will also be necessary.

Subtitle A—Risk Assessment and Communication

SEC. 3101. SHORT TITLE.

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

SEC. 3102. PURPOSES.

The purposes of this subtitle 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.

SEC. 3103. EFFECTIVE DATE; APPLICABILITY; SAVINGS PROVISIONS.

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

(b) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (3), this subtitle applies to all significant risk assessment documents and significant risk characterization documents prepared by, or on behalf of, or used by, any Federal agency in connection with Federal programs designed to protect human health, safety, and the environment.

(2) SIGNIFICANT RISK ASSESSMENT DOCUMENT OR SIGNIFICANT RISK CHARACTERIZATION DOCUMENT.—(A) As used in this subtitle, the terms "significant risk assessment document" and "significant risk characterization document" include, at a minimum, risk assessment documents or risk characterization documents included in, or in the administrative record for, each of the following:

(i) Any major rule, as defined in subtitle B, promulgated as part of any Federal regulatory program designed to protect human health, safety, or the environment.

(ii) Any proposed or final regulatory decision relating to decontamination or other clean-up plans for a facility.

(iii) Any report to Congress.

(iv) Placement of a substance or health effects value on the Integrated Risk Information System Database maintained by the Environmental Protection Agency.

(v) Any regulatory action to place a substance on any official list of carcinogens or toxic or hazardous substances.

Such terms also include any risk assessment or risk characterization that forms the basis of a final risk assessment or risk characterization guideline or protocol of general application.

(B) The terms "significant risk assessment document" and "significant risk characterization document" also include such risk assessment and risk characterization documents of agency as—

(i) are provided by an agency to the public and are likely to result in an annual effect on the economy of $25,000,000 or more; or

(ii) the head of the agency may identify, in consultation with the Director of the Office of Management and Budget.

(C) Within 15 months after the date of the enactment of this Act, each agency administering programs 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 to be considered significant risk assessment documents or significant risk characterization documents for purposes of this subtitle. In establishing such categories, the head of the agency shall consider—

(i) the benefits of consistent compliance by documents in the categories concerned with the principles under sections 3104 and 3105;

(ii) the administrative burdens of including documents in various categories concerned with the principles under section 3104 and 3105;

(iii) the need to make expeditious administrative decisions regarding documents in various 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; and

(v) such other factors as may be appropriate.

(3) EXCEPTIONS.—(A) This subtitle does not apply to the following:

(i) A situation that the head of the agency considers to be an emergency or to be necessary to maintain military readiness.

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

(iii) Any individual food, drug, or other product label or to any risk characterization appearing on any such label, if the individual product label is required by law to be approved by a Federal agency prior to use.

(iv) Any health, safety, or environmental inspections or individual facility permitting actions.

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

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

SEC. 3104. PRINCIPLES FOR RISK ASSESSMENT.

(a) IN GENERAL.—The head of each Federal agency shall apply the principles set forth in subsection (b) in order to assure that risk assessments and all of their components distinguish scientific findings from other considerations and are, to the maximum 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.

(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 laboratory and 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 include discussion of possible reconciliation of conflicting information, and as appropriate, differences in study designs, comparative physiology, routes of exposure, bioavailability, pharmacokinetics, and any other relevant factor, including the availability of raw data for review. Greatest emphasis shall be placed on data that indicate a biological basis of the 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, a Federal agency shall—

(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.

(3) 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 subtitle.

SEC. 3105. PRINCIPLES FOR RISK CHARACTERIZATION AND COMMUNICATION.

In a significant risk assessment document, each Federal agency shall assure compliance with each of the following:

(1) ESTIMATES OF RISK.—The risk characterization shall describe the populations or natural resources which are the subject of the risk assessment. If a numerical estimate of risk is provided, the agency shall, to 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 department, agency, or instrumentality); and

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

In addition to such best estimate or estimates, the risk characterization may present plausible upper-bound or conservative estimates in conjunction with plausible lower bounds estimates. Where appropriate, the risk characterization may present, in lieu of a single best estimate, multiple estimates based on assumptions, inferences, or models which are equally plausible, given current scientific understanding. To the extent practical and appropriate, the characterization shall provide descriptions of the distribution and probability of risk estimates to reflect differences in exposure variability or sensitivity in populations and uncertainties.

(2) EXPOSURE SCENARIOS.—Where relevant, the risk characterization 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 Federal agency shall provide a statement that places the nature and magnitude of risks to human health, safety, or the environment in context. Such statement shall include appropriate comparisons with estimates of greater and lesser risks that are familiar to and routinely encountered by the general public as well as other risks. The statement shall identify relevant distinctions among categories of risk and limitations to comparisons.

(4) SUBSTITUTION RISKS.—Each significant risk assessment or risk characterization document referred to in section 3103(b) shall include a statement of any significant substitution risks to human health, where information on such risks is available to the agency.

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

(A) a Federal agency provides a public comment period with respect to a significant risk assessment document, or a commenter provides a significant risk assessment document, and a summary of results of such risk assessment, and

(B) such risk assessment is consistent with the principles and the guidance provided under this subtitle,

the agency shall present such summary in connection with the presentation of the agency's risk assessment document, risk characterization document, or the regulation. 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.

SEC. 3106. GUIDELINES, PLAN FOR ASSESSING NEW INFORMATION, AND REPORT.

(a) GUIDELINES.—Within 15 months after the date of enactment of this subtitle, the President shall issue guidelines for Federal agencies consistent with the risk assessment and characterization principles set forth in sections 3104 and 3105 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) PLAN.—Within 18 months after the date of the enactment of this subtitle, each Federal agency shall publish a plan to review and, where appropriate, revise any significant risk assessment document or significant risk characterization document published prior to the expiration of such 18-month period if, based on information available at the time of such review, the head of the agency determines that the application of the principles set forth in sections 3104 and 3105 would be likely to significantly alter the results of the prior risk assessment or risk characterization. The plan shall provide procedures for receiving and considering new information and risk assessments from the public. The final plan shall set priorities for review, and where appropriate, revision of risk assessment documents and risk characterization documents based on the potential to more efficiently focus national economic resources within Federal programs designed to protect human health, safety, or the environment on the most important priorities and on such other factors as such Federal agency considers appropriate.

(c) REPORT.—Within 3 years after the enactment of this subtitle, each Federal agency shall provide a report to the Congress evaluating the categories of policy and value judgments identified under subparagraph (C) of section 3104(b)(2).

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

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

SEC. 3107. RESEARCH AND TRAINING IN RISK ASSESSMENT.

(a) EVALUATION.—The head of each covered agency shall regularly and systematically evaluate risk assessment re-

search and training needs of the agency, including the following:

(1) Research to reduce generic data gaps or redundancies, 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 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 application. 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).

(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.

(d) COVERED AGENCY DEFINED.—For purposes of this section, the term "covered agency" means each of the following:

(1) The Environmental Protection Agency.

(2) The Consumer Product Safety Commission.

(3) The Occupational Health and Safety Administration.

(4) The Department of Labor.

(5) The Department of Transportation.

(6) The Department of Energy.

(7) The Department of Agriculture.

(8) The Department of the Interior.

(9) The Food and Drug Administration.

SEC. 3108. STUDY OF COMPARATIVE RISK ANALYSIS.

(a) IN GENERAL.—(1) The Director of the Office of Science and Technology Policy shall conduct, or provide for the conduct of, a study using comparative risk analysis to rank health 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 develop and rigorously test improved methods of comparative risk analysis.

(2) Not later than 90 days after the date of the enactment of this Act, 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 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 environmental risk reduction. The study shall compare and evaluate a range of diverse environmental risks, both as to risks to and within an environmental medium and risks across environmental media.

(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 Act 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.

SEC. 3109. DEFINITIONS.

For purposes of this subtitle:

(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.

(2) RISK CHARACTERIZATION DOCUMENT.—The term "risk characterization document" means a document quantifying or describing the degree of toxicity, expo-

sure, or other risk they pose for exposed individuals, populations, or resources.

(3) BEST ESTIMATE.—The term "best estimate" means an estimate which is based 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 option designed to decrease other risks.

(5) FEDERAL AGENCY.—As used in this title, 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.

(6) DOCUMENT.—The term "document" includes material stored in electronic or digital form.

(7) PREPARE.—As used in this title, the term "prepare", when referring to risk assessment, risk characterizations, or analyses of risk reduction benefits and costs, includes both the preparation or use of such a document by an agency.

Subtitle B—Analysis of Risk Reduction Benefits and Costs

SEC. 3201. ANALYSIS OF RISK REDUCTION BENEFITS AND COSTS.

(a) IN GENERAL.—Except as provided in section 3103(b)(3) and subsection (d), the President shall require each Federal agency to prepare the following for each major rule designed to protect human health, safety, or the environment that is proposed or promulgated by the agency after the date of enactment of this Act:

(1) For each such proposed or promulgated rule, an assessment of incremental costs and incremental risk reduction or other benefits associated with each significant regulatory alternative considered by the agency in connection with the rule or proposed rule. Costs and benefits shall be quantified to the extent feasible and appropriate and may otherwise be qualitatively described.

(2) For each such proposed or promulgated rule, an identification (including an analysis of the costs and benefits) of reasonable alternatives for achieving the identified benefits of the proposed or promulgated rule, including alternatives—

(A) that require no government action;

(B) that will accommodate differences among geographic regions and among persons with different levels of resources with which to comply; and

(C) that employ performance or other market-based standards that permit the greatest flexibility in achieving the identified benefits of the proposed or promulgated rule and that comply with paragraph (3).

(3) An assessment of the feasibility of establishing a regulatory program that operates through the application of market-based mechanisms.

(4) An assessment of the aggregate effect of the rule on small businesses with fewer than 100 employees, including the effect of the net employment effect of the rule.

(5) An analysis of whether the identified benefits of the proposed or promulgated rule are likely to exceed the identified costs of the proposed or promulgated rule, and an analysis of whether the proposed or promulgated rule will provide greater net benefits to society than any of the alternatives to the proposed or promulgated rule, including alternatives identified in paragraph (2).

(6) At the time of the publication of the final major rule, a final cost-benefit analysis (to be published in the rulemaking record), including a summary of the analysis in a statement of basis and purpose.

(7) For each such proposed or promulgated rule, to the extent feasible, a comparison of any human health, safety, or environmental risks addressed by the regulatory alternatives to other greater or lesser risks chosen by the head of the agency, including at least 3 other risks regulated by the agency and to at least 3 other risks with which the public is familiar.

(8) For each final rule, an assessment of the costs and risk reduction or other benefits associated with implementation of, and compliance with, the rule, including, to the maximum extent practicable, a quantitative assessment of the cumulative financial burden that persons producing products that are regulated by the rule will bear in order to comply with the rule and with related existing standards that affect the product or other similar products produced by such persons.

(9) For each final rule, a certification by the head of the agency of each of the following:

(A) A certification that the assessments under subtitle B are based on an objective and unbiased

scientific and economic evaluation of all significant and relevant information and risk assessments provided to the agency by interested parties relating to the costs, risks, and risk reduction or other benefits addressed by the rule.

(B) A certification that incremental risk reduction or other benefits of any regulatory or non-regulatory option chosen will be likely to justify, and be reasonably related to, the incremental costs incurred by State, local, and tribal governments, the Federal Government, and other public and private entities.

(C) A certification that no regulatory or non-regulatory alternative considered by the agency or proposed to the agency during or prior to the public comment period would be more likely to achieve a substantially equivalent reduction in risk in a more cost-effective manner or would be more likely to provide flexibility to the regulated entities in achieving the objective of the regulation, along with a brief explanation of why other regulatory or non-regulatory alternatives that were considered by or proposed to the agency were found to be less cost-effective or less flexible.

(b) PUBLICATION.—For each major rule referred to in subsection (a) each agency shall publish in a clear and concise manner in the Federal Register along with the proposed and final regulation, or otherwise make publicly available, the information required to be prepared under subsection (a) of this section. The agency shall publish in the Federal Register, along with the final regulation, the certifications required by subsection (a).

(c) DEFINITIONS.—For purposes of this section:

(1) COSTS.—The term "costs" includes the direct and indirect costs to the United States Government, to State, local, and tribal governments, and to private-sector prices, wage earners, consumers, and the economy, of implementing and complying with a regulatory action.

(2) BENEFIT.—The term "benefit" means the social and economic benefits that are expected to result directly or indirectly from implementation of a rule or an alternative to a rule.

(3) MAJOR RULE.—The term "major rule" means any regulation that is likely to result in an annual increase in costs of $25,000,000 or more.

(d) SUBSTANCES AND PRODUCTS.—This section and section 3301 do not apply to any action authorizing or approving any individual substance or product. No government action shall be treated as authorizing or approving any individual substance or product for the purposes of this subsection if the results of such action are used as the basis of imposing bans, cancellations, suspensions, or revoca-

tions of any previously marketed or approved substance or product.

(e) COST/BENEFIT ANALYSIS GUIDANCE.—Within 15 months after the date of the enactment of this title, the Office of Management and Budget shall issue regulations for Federal agencies, consistent with this title, governing the development and preparation of analyses of risk reduction benefits and costs.

(f) APPLICABILITY.—

(1) IN GENERAL.—Notwithstanding any other provision of law, the requirements of this section shall supplement and, to the extent there is a conflict, supersede the decisional criteria for rulemaking otherwise applicable under the statute pursuant to which the rule is promulgated.

(2) SUBSTANTIAL EVIDENCE.—Notwithstanding any other provision of Federal law, no major rule shall be promulgated by any Federal agency pertaining to the protection of health, safety, or the environment unless the requirements of section 3201(a) and (b) are met and the certifications required therein are supported by substantial evidence of the rulemaking record.

(g) TRANSITIONAL PLAN.—Within 180 days after the date of the enactment of this title, Federal agencies, with guidance from the Office of Management and Budget, shall develop transition plans to assist the agencies, the public, and the regulated community in the implementation of this title, including any new requirements or procedures needed to supplement prior agency practice.

(h) REPORTS TO CONGRESS.—Federal agencies shall report to Congress annually whether their implementation of this title has created any significant regulatory or program management complications resulting from any differences between the certification provisions of this title and the decisional criteria for rulemaking that otherwise would have been applicable under other statute.

Subtitle C—Peer Review

SEC. 3301. PEER REVIEW PROGRAM.

(a) ESTABLISHMENT.—For regulatory programs addressing human health, safety, or the environment, the head of each Federal agency shall develop a systematic program for independent and external peer review of risk assessments and economic assessments used by the agency. 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 feasible and appropriate, include representatives of industry, universities, agriculture, labor, consumers, conservation organizations, and other public interest groups and organizations;

(2) may provide for differing levels of peer review 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.—Each Federal agency shall provide for peer review of any evaluation under section 3201(a)(9)(A) or for purposes of any significant risk or cost assessment prepared in connection with any regulation that is likely to result in an annual increase in costs of $100,000,000 or more (other than any regulation or other action taken by an agency to authorize or approve any individual substance or product). 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.—

(1) IN GENERAL.—Each peer review under this section shall include a report to the Federal agency concerned with respect to each of the following:

(A) An evaluation of the technical, scientific, and economic merit of the data and methods used for the assessment and analysis.

(B) A list of any considerations that were not taken into account in the assessment and analysis, but were considered appropriate by a majority of the members of the peer review panel.

(C) A discussion of the methodology used for the assessment and analysis.

(2) COMMENTS AND APPENDIX.—Each peer review report under this subsection shall include—

(A) all comments supported by a majority of the members of the peer review panel submitting the report; and

(B) an appendix which sets forth the dissenting opinions that any peer review panel member wants to express.

(3) SEPARATION OF ASSESSMENTS.—Peer review of human health, safety, environmental, and economic assessments may be separated for purpose of this subtitle.

(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 for purposes of judicial review of any final agency action.

(f) 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.

(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.

Subtitle D—Other Provisions

SEC. 3401. JUDICIAL REVIEW.

Compliance with the requirements of this title shall be reviewable pursuant to the Administrative Procedure Act.

SEC. 3402. PRIORITIZATION OF THREATS AND RESOURCE USE.

For any risk assessment, risk characterization, cost-benefit analysis, or peer review program prepared by, or on behalf of, any Federal agency under this title, the head of the Federal agency shall—

(1) prioritize threats to human health, safety, and the environment according to—

(A) the seriousness of the risk they pose; and

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

(2) prioritize the use of resources available to the agency under those laws to reduce those risks in accordance with the priorities established under paragraph (1), including applying the priorities to the budget, strategic planning, and research activities of the agency.

II. BACKGROUND AND NEED FOR THE LEGISLATION

Title III—Risk Assessment and Cost Benefit Analysis for New Regulations was introduced as part of H.R. 9, the "Job Creation and Wage Enhancement Act of 1995" on January 4, 1995. Title III was subsequently referred to the Committee on Science and additionally to the Committee on Commerce and to the Committee on Government Reform and Oversight.

The Risk Assessment and Cost/Benefit Analysis legislation was developed in response to the need to develop clear and consistent guidelines on the conduct of risk assessment and cost benefit analysis for programs throughout the Federal government which regulate and otherwise manage risks to human health, safety and the environment. The legislation seeks to ensure that these assessments and analyses are formulated using the best science available.

The cost of regulation runs in the hundreds of billions of dollars. The problem is that Federal regulatory costs are too often out of proportion to the problems that the regulations are designed to address. The concern in the area of health, safety and environmental regulations is that the Federal programs require expenditures of substantial economic resources on reductions in risk which are either hypothetical, exaggerated or small.

The concern with Federal risk assessment practices is that Federal risk assessment, characterization and communication is biased and based on a series of hypothetical assumptions which are designed to overstate the risks. In many contexts, Federal agencies explicitly state that their risk assessment process is designed to produce estimates that "err on the side of safety" because of scientific uncertainties and to ensure that the broadest range of the public is covered. It is generally believed that the "upper bound estimates" are highly improbable and differ from the most plausible level of risk by many orders of magnitude. Moreover, the practice of only calculating upper bound or worst case estimates of risk inappropriately collapses scientific findings with a preconceived policy judgment or bias. The perceived overstatement of risk is a serious concern among the regulated community. Many argue there should be "best estimates" or estimates of expected value in addition to upper-bound estimates to provide a more realistic benchmark.

Some Federal provisions require consideration of the costs and benefits of regulatory alternatives, although the specific language authorizing such consideration differs greatly among statutes. While these resulting regulatory decisions are judicially reviewable, the general standards of review is for courts to be deferential to Federal agencies concerning the analysis of factual issues. Moreover, many Federal statutes prohibit or do not explicitly authorize consideration of costs and benefits for determining regulatory requirements.

The Reagan Administration issued Executive Order 12291 in order to encourage agencies to at least try to assess the costs and benefits of regulatory options where statutes did not otherwise compel such an assessment. As an executive order, the assessments were not judicially reviewable. The Clinton Administration has replaced Executive Order 12291 with Executive Order 12866 which, more or less, continues the requirements of 12291.

Following is a chart from the section of Risk Management Budgeting in the Fiscal Year 1992 Budget of the United States Government which is a summary of some of the assessments performed under Executive Order 12291. The chart illustrates the problem. For some regulations, the costs per theoretical life saved are in the thousands of dollars. In other cases, the costs per theoretical life saved or cancer incidence avoided are in the millions or even bil-

lions. Many of the costs associated with the reduction of perceived risks from chemicals are also upper bound estimates and, thus, the true risk reduction is even less cost-effective—possibly by several orders of magnitude. Accordingly, many advocate giving more prominence to the consideration of the relationship between costs and benefits and setting regulatory priorities to both save money and increase protection by focusing resources on the greatest risk reduction opportunities.

TABLE C–2. RISKS AND COST-EFFECTIVENESS OF SELECTED REGULATIONS

Regulation [1]	Year issued	Health of safety?	Agency	Baseline mortality risk per million exposed	Cost per premature death averted ($ millions 1990)
Unvented Space Heater Ban	1980	S	CPSC	1,890	0.1
Aircraft Cabin Fire Protection Standard	1985	S	FAA	5	0.1
Auto Passive Restraint/Seat Belt Standards	1984	S	NHTSA	6,370	0.1
Steering Column Protection Standard [2]	1967	S	NHTSA	385	0.1
Underground Construction Standards [3]	1989	S	OSHA–S	38,700	0.1
Trihalomethane Drinking Water Standards	1979	H	EPA	420	0.2
Aircraft Seat Cushion Flammability Standard	1984	S	FAA	11	0.4
Alcohol and Drug Control Standards [3]	1985	H	FRA	81	0.4
Auto Fuel-System Integrity Standard	1975	S	NHTSA	343	0.4
Standards for Servicing Auto Wheel Rims [3]	1984	S	OSHA–S	630	0.4
Aircraft Floor Emergency Lighting Standard	1984	S	FAA	2	0.6
Concrete & Masonry Construction Standards [3]	1988	S	OSHA–S	630	0.6
Crane Suspended Personnel Platform Standard [3]	1988	S	OSHA–S	81,000	0.7
Passive Restraints for Trucks & Buses (Proposed)	1989	S	NHTSA	6,370	0.7
Side-Impact Standards for Autos (Dynamic)	1990	S	NHTSA	NA	0.8
Children's Sleepwear Flammability Ban [4]	1973	S	CPSC	29	0.8
Auto Side Door Support Standards	1970	S	NHTSA	2,520	0.8
Low-Altitude Windshear Equipment & Training Standards.	1988	S	FAA	NA	1.3
Electrical Equipment Standards (Metal Mines)	1970	S	MSHA	NA	1.4
Trenching and Excavation Standards [3]	1989	S	OSHA–S	14,310	1.5
Traffic Alert and Collision Avoidance (TCAS) Systems	1988	S	FAA	NA	1.5
Hazard Communication Standard [4]	1983	S	OSHA–S	1,800	1.6
Side-Impact Stds for Trucks, Buses and MPVs (Proposed).	1989	S	NHTSA	NA	2.2
Grain Dust Explosion Prevention Standards [3]	1987	S	OSHA–S	9,450	2.8
Rear Lap/Shoulder Belts for Autos	1989	S	NHTSA	NA	3.2
Standards for Radionuclides in uranium Mines [3]	1984	H	EPA	6,300	3.4
Benzene NESHAP (Original: Fugitive Emissions)	1984	H	EPA	1,470	3.4
Ethylene Dibromide Drinking Water Standard	1991	H	EPA	NA	5.7
Benzene NESHAP (Revised: Coke By-Products) [3]	1988	H	EPA	NA	6.1
Asbestos Occupational Exposure Limit [3]	1972	H	OSHA–H	3,015	8.3
Benzene Occupational Exposure Limit [3]	1987	H	OSHA–H	39,600	8.9
Electrical Equipment Standards (Coal Mines) [3]	1970	S	MSHA	NA	9.2
Arsenic Emission Standards for Glass Plants	1986	H	EPA	2,660	13.5
Ethylene Oxide Occupational Exposure Limit [3]	1984	H	OSHA–H	1,980	20.5
Arsenic/Copper NESHAP	1986	H	EPA	63,000	23.0
Haz Waste Listing for Petroleum Refining Sludge	1990	H	EPA	210	27.6
Cover/Move Uranium Mill Tailings (Inactive Sites)	1983	H	EPA	30,100	31.7
Benzene NESHAP (Revised: Transfer Operations)	1990	H	EPA	NA	32.9
Cover/Move Uranium Mill Tailings (Active Sites)	1983	H	EPA	30,100	45.0
Acrylonitrile Occupational Exposure Limit [3]	1978	H	OSHA–H	42,300	51.5
Coke Ovens Occupational Exposure Limit [3]	1976	H	OSHA–H	7,200	63.5
Lockout/Tagout [3]	1989	S	OSHA–S	4	70.9
Asbestos Occupational Exposure Limit [3]	1986	H	OSHA–H	3,015	74.0
Arsenic Occupational Exposure Limit [3]	1978	H	OSHA–H	14,800	106.9
Asbestos Ban	1989	H	EPA	NA	110.7
Diethylstilbestrol (DES) Cattlefeed Ban	1979	H	FDA	22	124.8
Benzene NESHAP (Revised: Waste Operations)	1990	H	EPA	NA	168.2
1,2-Dichloropropane Drinking Water Standard	1991	H	EPA	NA	653.0
Haz Waste Land Disposal Ban (1st 3rd)	1988	H	EPA	2	4,190.4

TABLE C–2. RISKS AND COST-EFFECTIVENESS OF SELECTED REGULATIONS—Continued

Regulation [1]	Year issued	Health of safety?	Agency	Baseline mortality risk per million exposed	Cost per premature death averted ($ millions 1990)
Municipal Solid Waste Landfill Standards (Proposed)	1988	H	EPA	<1	19,107.0
Formaldehyde Occupational Exposure Limit [3]	1987	H	OSHA–H	31	86,201.8
Atrazine/Alachlor Drinking Water Standard	1991	H	EPA	NA	92,069.7
Haz Waste Listing for Wood Preserving Chemicals ...	1990	H	EPA	<1	5,700,000.0

[1] 70-year lifetime exposure assumed unless otherwise specified.
[2] 50-year lifetime exposure.
[3] 45-year lifetime exposure.
[4] 12-year exposure period.
NA=Not available.

Agency Abbreviations.—CPSC: Consumer Product Safety Commission; MSHA: Mine Safety and Health Administration; EPA: Environmental Protection Agency; NHTSA: National Highway Traffic Safety Administration; FAA: Federal Aviation Administration; FRA: Federal Railroad Administration; FDA: Food and Drug Administration; OSHA–H: Occupational Safety and Health Administration, Health Standards; OSHA–S: Occupational Safety and Health Administration, Safety Standards.

Source: John F. Morrall, III, ''A Review of the Record,'' Regulation, Vol. 10, No. 2 (1986), p. 30. Updated by the Author, et. al.

The explicit purposes of the bill 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 to educate federal, state and local decision makers and the public.

2. To provide for full consideration and relevant data and potential methodologies used to assess and communicate and characterize health, safety, and environmental risk.

3. To require explanation of significant choices in the risk assessment process which will allow for better peer review and public understanding.

4. To improve consistency within the executive branch in preparing risk assessments and risk characterizations through, among other methods, further research in the risk assessment methodology.

5. To undertake for every major rule designed to protect health, safety and the environment an analysis of the costs and benefits of that regulatory action.

6. To establish a certification process by the head of each agency promulgating rules designed to protect health, safety and the environment that such regulations are based on objective and unbiased scientific and economic evaluation, and that the incremental risk reduction or other benefits will be likely to justify, and be reasonably related to, the incremental costs incurred by state, local, tribal governments, and the Federal government and other public and private entities.

7. To establish a certification process that no regulatory or nonregulatory alternative considered by the agency or proposed to the agency would be more likely to achieve a substantially equivalent reduction in risk in a more cost-effective manner.

8. To establish an independent and external peer review program of risk assessments used to formulate those regulations.

9. To clarify that judicial review of this legislation shall be pursuant to the Administrative Procedure Act.

10. To establish that for any risk assessment, risk characterization, cost benefit analysis, or peer review program prepared by, or on behalf of, any Federal agency that the head of each agency shall prioritize threats to human health, safety and the environment ac-

cording to seriousness of the risk and to achieve the greatest reduction in risk given the resources available to address those risks.

III LEGISLATIVE HISTORY AND COMMITTEE ACTION

Title III of H.R. 9 was referred to the Committee on Science and, in addition, to the Committees on Commerce and Government Reform and Oversight. Markup of Title III, Risk Assessment and Cost/Benefit Analysis for new regulations, was preceded by two hearings by the Full Committee on January 31, 1995 and February 3, 1995, respectively. During the first hearing the Committee received testimony from private sector witnesses, and the second hearing included witnesses from the Administration and environmental and other public policy entities.

The issue of risk assessment had been raised many times during the 103rd Congress. The Committee on Science, Space, and Technology was referred the bill, H.R. 4306. The bill was designed to establish a comprehensive risk assessment program within the Environmental Protection Agency (EPA). Within the Committee on Science, Space, and Technology, the bill was referred to the Subcommittee on Technology, Environment and Aviation (TEA). After reviewing testimony of witnesses during three hearings, the TEA Subcommittee marked up the bill on May 18, 1994. Following the Subcommittee markup, changes were made in an effort to enlist the support of EPA, environmental groups and industry groups. The Full Committee was convened to markup H.R. 4306 on July 20, 1994. After adoption of an amendment by Ranking Republican Member Robert S. Walker (R–PA) containing some of the principles now in Title III of H.R. 9, the Risk Assessment Improvement Act of 1994 was reported on October 7, 1994, to the House.

Other bills of the 103rd Congress, such as the Safe Drinking Water Act of 1994, the Superfund Reform Act of 1994, the Agriculture Reorganization Act of 1994, the Department of Environment Act of 1993 and the Environmental Research, and Development and Demonstration Act of 1993 included provisions for risk assessment or risk management.

FULL COMMITTEE MARKUP

On February 8, 1995, the Science Committee convened to markup Title III of H.R. 9. Chairman Walker offered an Amendment in the Nature of a Substitute. The substitute clarified that risk assessments and risk characterizations in Subtitle A are supplemental to, but do not supersede, any other provision of law designed to protect health, safety, or the environment; made clear the importance of characterizing and then communicating the nature of risks to decisionmakers and to the public in terms that are clear and understandable; elaborated on the concept of substitution risk (past regulatory action in trying to ameliorate one type of risk has often merely substituted another hazard); clarified that risk assessments and characterizations that are undertaken between the date of the enactment and the effective date of this legislation may be reviewed on the basis of risk assessment guidelines and any new information received, if such information would significantly alter results; clarified the cost/benefit analysis criteria; and assured that

the normal time-tested judicial review provisions of the Administrative Procedure Act apply.

Of the thirteen (13) amendments offered, nine (9) were adopted regarding Subtitle A:

Mr. Minge offered an amendment to Section 3001 which provides for a finding that there should be prompt relief from the burden of unnecessary and overly complex regulations. The amendment was adopted by voice vote.

Mr. Davis offered an amendment to Section 3104(a) to clarify the use of available scientific data. The amendment was adopted by a roll call vote: Yeas—36, Nays—9.

Mr. Davis offered a second amendment to Section 3104(b)(1) which adds for the provision of raw data, and requires that data acquired from animal experiments should be reviewed for its relevancy. The amendment was adopted by voice vote.

Mr. Barton offered an amendment to Section 3104(b) mandating that agencies cannot adopt the risk recommendations of a non-U.S. based entity without performing their own independent risk assessment. The amendment was adopted by a roll call vote: Yeas—36, Nays—11.

Mr. Olver offered an amendment in two parts to Section 3105(3). The first part of the amendment reinstated the words "human health, safety, or the environment" and was adopted by voice vote.

Mr. Roemer offered an amendment which adds a provision for Research and Training in Risk Assessment. The amendment was adopted by voice vote.

Mr. Roemer offered a second amendment which adds a provision to study Comparative Risk Analysis. The amendment was adopted by voice vote.

Mr. Bartlett offered an amendment which clarifies the definition of "significant risk assessment document." The amendment was adopted by voice vote.

Mr. Tanner offered an amendment which clarifies the role of the Defense Department by adding the phrase to Section 3103, "or to be necessary to maintain military readiness." The amendment was adopted by voice vote.

Two (2) of three (3) amendments offered to Subtitle B were adopted.

Mr. Davis offered an amendment to Section 3201(a). The amendment applies to major rules to protect human health, safety and the environment and requires the considering agency to identify reasonable alternatives which would achieve the identical benefits of the proposed rule including (1) no government action; (2) accommodation of geographic difference; (3) use of performance or market-based standards that provide flexibility to achieve identified benefits; (4) an assessment of the aggregate effects on small business, and (5) a cost/benefit analysis based on the net benefits to society. The amendment was adopted by voice vote.

Mr. Wamp offered an amendment to Section 3201(a)(3) requiring Departments or Agencies to meaningfully quantify, in a rule making, the cumulative burden on manufacturers or other affected parties, of multiple regulations by the same agency, as well as the cumulative effect by different agencies for the same product. The amendment was adopted by voice vote.

One (1) of the two (2) amendments offered under Subtitle C was adopted:

Mr. Boehlert, Mrs. Morella, and Mr. Ehlers offered an en bloc amendment which adds Section 3401 that would mandate the agencies to prioritize threats to human health and the environment; identify opportunities for the most significant risk reduction, to direct their resources accordingly in areas where they can do the most good for the American people and for the environment. This amendment was adopted by voice vote.

The Committee favorably reported the bill, as amended, by voice vote.

IV. SUMMARY OF HEARINGS

The Committee convened two days of hearings on Title III of H.R. 9, the "Job Creation and Wage Enhancement Act of 1995." Title III would create a system of risk assessment and cost-benefit analysis for all federal agencies which issue regulations designed to protect human health, safety, and environment. On January 31, 1995, the Committee heard testimony from private sector witnesses. On February 3, 1995, the Committee heard testimony from members of Congress, the Administration, and from public policy groups. In receiving the testimony from the witnesses, the following questions were explored by the Committee:

Does the current system of risk characterization properly convey to the American people the environmental, health or safety hazards they encounter in their daily lives?

Do current risk assessments identify real or imaginary risks?

Can risk assessments be used to achieve more efficient regulation by prioritizing which risks can be best addressed in the most cost-efficient manner?

What will the administrative burden be on the agencies implementing risk assessment?

a. Risk assessment and cost/benefit analysis, January 31, 1995

This hearing evaluated testimony from witnesses representing the private sector.

The witnesses were:

Dr. Jerry J. Jasinowski, President, National Association of Manufacturers (NAM), representing the Alliance for Reasonable Regulation;

Dr. John Graham, Professor of Policy and Decision Sciences, Harvard Center for Risk Analysis;

Mr. Gordon Garner, Executive Director, Louisville and Jefferson County Metropolitan Sewer District;

Mr. Sam Kazman, General Counsel, Competitive Enterprise Institute; and

Mr. Scott Holman, President/CEO, Bay Cast, Inc.

Mr. Jasinowski testified that federal agencies must develop a more rational, risk-based system to evaluate (and set priorities for the regulation of) risks to human health, safety, and the environment. Agencies must improve their risk assessment methodologies and the accuracy and relevance of the resulting risk estimates and characterizations. In order to ensure that risk-based decisions have a sound scientific and technical underpinning, any risk assessment

that may potentially serve as the basis for a major rule should be subjected to independent, external peer review. Opportunities for public participation in the hazard evaluation and risk assessment process should be increased—both prospectively and, in appropriate cases, retrospectively as well. The risk management decisionmaking process must be improved in a number of respects.

Dr. Graham testified that there is a need to mandate broad-based rankings of health, safety and environmental risks that cut across the jurisdictions of existing agencies. There is a need, he said, to make sure that the findings of benefit-cost analyses are actually used by federal agencies when making specific rulemaking decisions. The capacity of the Executive Office of the President to exercise leadership analysis needs to be strengthened by legislative authorization and resources. More thought needs to be given to whether the universities in this country are providing professional scientists with appropriate training in risk analysis to meet the demands likely to be generated by this legislation.

Mr. Garner testified that he believes the "Risk Assessment and Communication Act of 1995" provides a mechanism for better priority-setting consistent with efforts being made by state and local governments across the country and with efforts already being used by some federal agencies, but not required by law. The Act is just one piece of the solution to the puzzle; it requires that a baseline level of information be available when national legislation is being considered. It should be supported, and efforts to twist the intent and the effect of the legislation should be avoided. Risk assessment, he said, must be based on available resources and the best information the agencies can find, recognizing that there is an element of uncertainty in the risk assessment process. Risk assessments should not be inappropriately used to undervalue natural systems. Mr. Garner also expressed his concern that Title III of H.R. 9 not lead to extensive litigious burden.

Mr. Kazman testified that Title III of H.R. 9 would constitute a major advance of this issue, directing agencies to carefully consider a host of factors that are often neglected in government contexts. He supported retention of Title III's judicial review provision, section 3301(e), to ensure that all cost-benefit and risk assessment materials are available to the courts in cases challenging agency action. Peer review should be the responsibility of an entity whose institutional responsibility is to review and restrain agency action. H.R. 9 should do the opposite—it should modify these and other statutes to require that every regulatory action be shown to produce a net benefit.

Mr. Holman testified that small business strongly supports the effort to make risk-based decisionmaking a priority for the new Congress through passage of Title III of H.R. 9. The provisions of Title III would strengthen the use of risk and cost-benefit analysis and lead toward the development of higher-quality decisions by regulators. Title III would increase accountability of federal agencies.

b. Risk assessment and cost/benefit analysis, February 3, 1995

On February 3, 1995, the Committee on Science held a second day of hearings on Risk Assessment and Cost Benefit Analysis,

Title III of H.R. 9, Job Creation and Wage Enhancement Act of 1995. Panel One consisted of witnesses from the Executive Branch:

The Honorable Jack Gibbons, Director, Office of Science and Technology Policy, Executive Office of the President;

Dr. Lynn Goldman, Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances, U.S. Environmental Protection Agency;

Mr. Keith Collins, Acting Chief Economist, Department of Agriculture; and,

Mr. William Schultz, Deputy Commissioner for Policy, Food and Drug Administration.

Panel Two consisted of witnesses from academia and regulatory and public policy institutes:

Dr. Thomas A. Burke, Associate Professor of Health Policy and Management, Johns Hopkins University School of Hygiene and Public Health;

Dr. Paul R. Portney, Vice President, Resources for the Future;

Mr. Thomas O. McGarity, University of Texas School of Law;

Mr. Terry F. Yosie, Senior Vice President, E. Bruce Harrison Company;

The Honorable Don Ritter, Chairman, National Environmental Policy Institute; and,

Mr. Thorne Auchter, Former Assistant Secretary of Labor, Occupational Safety and Health Administration.

Prior to proceeding with testimony from witnesses on Panels One and Two, the Committee heard testimony from Congressman John Mica (R–FL) and Congressman Dick Zimmer (R–NJ).

Both Members testified in support of the legislation. Mr. Mica stressed that requiring federal agencies to provide "best estimates" of risk is critical, and that the language requiring an agency to place the risk in context by comparing the risk with three other risks that are familiar to the general public must be passed. Mr. Zimmer presented testimony regarding his support of risk assessment and addressed components of H.R. 690, the Risk Assessment Cost-Benefit Analysis Act of 1995, a bill which he has introduced.

Dr. Gibbons testified that the Administration actively supports the goal of bringing "greater scientific and economic rationality to the regulation of risks to our health, safety, and environment." He discussed the Executive Order on Regulatory Planning and Review (No. 12866) signed by the President September 30, 1993, which required agencies to propose or adopt regulations only after determining that their benefits justify their costs, and that the rules are developed according to sound regulatory principles. Dr. Gibbons expressed the Administration's opposition to the legislation, saying, that they have reviewed Title III of H.R. 9 carefully, and regretted that it is not fair, effective and affordable; nor does it live up to its own professed standards or regulatory efficiency and cost-effectiveness.

Dr. Goldman of EPA also expressed strong support for the "science of risk assessment and of its appropriate use along with cost benefit and other analyses." She reiterated Dr. Browner's previously stated support for legislation that says that risk assessment should provide both decision-makers and the public with a clear

and meaningful understanding of the risks that will be addressed. Dr. Goldman expressed the Administration's opposition to the legislation based on the concern that Title III of H.R. 9 would create new opportunities for litigation, resulting in delay of the rulemaking process, and that the cost-benefit requirements of the bill would conflict with statutory provisions currently administered by EPA.

Mr. Collins testified that USDA also supported the "use of risk assessment and cost-benefit analysis for the efficiency and effectiveness these analytical tools can bring to government programs." He objected, however, to provisions of Title III which he saw as having negative effects on the Department's ability to protect human health, safety, and the environment, and which would "create unnecessary red tape and bureaucracy." Mr. Collins noted that the Department is in the process of implementing legislation enacted last year which created an Office of Risk Assessment and Cost-Benefit Analysis. He expressed concern about the breadth of application of the legislation, particularly as it pertains to the nature of the USDA's work.

Mr. Schultz conveyed the FDA's opposition to Title III of H.R. 9. Nonetheless, he too called risk assessment a useful tool, which the agency has been using for more than 20 years. He opposed Title III, however, on the grounds that it adds "extensive new procedural and substantive requirements to the tens of thousands of decisions involving informal assessment of risk that the FDA performs annually." He cited additional burdens and costs to industry, delay of products reaching the marketplace, and delays in the agency's enforcement programs, adversely impacting the use of perishable products.

Dr. Burke also supports efforts to improve the risk assessment process, but he stated his concern that Title III of H.R. 9 relies on an "over-dependence upon risk assessment and cost-benefit analysis as the primary vehicles for shaping our national approach to managing and preventing public health and environmental risks."

Dr. Portney expressed support for cost-benefit analysis as a "powerful analytical tool that can play a very useful role in public policymaking. Benefit-cost analysis can help illuminate cases in which regulatory proposals have not been carefully thought through.

Mr. McGarity opposes Title III, on the grounds that it would effectively repeal certain statutes.

Mr. Yosie testified that H.R. 9 "represents an ambitious attempt to codify and restructure certain aspects of the risk assessment process. It reflects a frustration that many people have concerning the slow pace of improving risk assessment and altering regulatory policies." He believes that H.R. 9 would not substantially change the way risk assessments are currently conducted, would make the current process more inefficient and expensive. He expressed opposition to the peer review provision as especially burdensome.

Mr. Ritter expressed his strong support for Title III of H.R. 9, stating that the legislation "has the potential to help decision-makers and regulators know better where to put our energies, our talents, and our dollars."

Mr. Auchter expressed strong support for Title III of H.R. 9, and cited risk assessment as an "invaluable starting point for the consideration of regulatory issues, provided it is systematically employed through the adoption of common principles." He expressed support for a petition process that could be then appealed in court.

V. EXPLANATION OF THE BILL AS REPORTED: SECTION-BY-SECTION ANALYSIS AND COMMITTEE VIEWS

SEC. 3001. FINDINGS

The findings indicate that health, safety and environmental regulations have led to dramatic improvements in these areas. However, these regulations could be improved based upon a greater use of a realistic consideration of risk, risk reduction opportunities and costs. These objectives can be achieved by a greater reliance on risk assessments based on sound science.

The findings also recognize that resources to accomplish reductions in hazards to health, safety and the environment are not unlimited and should be allocated so that the greatest needs for corrective action should be addressed first.

The third finding recognizes that these goals can be accomplished by employing unbiased risk assessments, comparative risk analysis, and risk management choices that are grounded in cost-benefit principles.

The findings also state that despite the fact that risk assessment has been a useful analytical tool, further improvements need to be made in risk assessment methodology. Once a risk assessment has been formulated, however, it must be characterized in such a manner so that the nature of the assessment can be communicated to decision makers and the public in a clear and concise manner. Such transparent communication will allow the decision makers and the public to better understand the risks that are being addressed by health, environmental and safety regulations.

Finally, finding number six discusses the fact that risk assessment is only one analytical tool that needs to be employed to secure regulatory relief.

SUBTITLE A—RISK ASSESSMENT AND COMMUNICATION

SEC. 3101. SHORT TITLE: "RISK ASSESSMENT AND COMMUNICATION ACT OF 1995"

SEC. 3102. PURPOSES.

The purposes of this subtitle are 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; to provide for full consideration and discussion of relevant data and potential methodologies used in risk assessments and risk characterizations; to require explanation of significant choices in the risk assessment process which will allow for better peer review and public understanding; and to improve consistency within the executive branch in preparing risk assessments and risk characterizations.

SEC. 3103. EFFECTIVE DATA; APPLICABILITY; SAVINGS PROVISIONS.

The date upon which Subtitle A becomes effective is 18 months after the day of its enactment, except as otherwise specified.

This subtitle shall apply to all agencies of the Federal government who administer programs designed to protect human health, safety and the environment.

Each agency of the Federal government shall assure compliance with the guidelines required by this bill for all significant risk assessment and significant risk characterization documents used in each of the following:

1. Any major rule designed to protect human health, safety and the environment which annually increases costs to the Federal, state, local and tribal governments and individuals and the private sector of $25,000,000 or more;
2. Any proposed or final regulatory decision relating to decontamination or other clean-up plans for a facility;
3. Any report to Congress which assesses human health, safety, or environmental risks;
4. Placement of a substance or health effects value on the Integrated Risk Information System (IRIS) Database maintained by the Environmental Protection Agency;
5. Any regulatory action to place a substance on any official list of carcinogens, toxic or hazardous substances;
6. Any risk assessment document or risk characterization document, regardless of origin, provided by an agency to the public that is likely to result in an annual effect on the economy of at least $25,000,000; and
7. Any risk assessment or risk characterizations forming the basis of a final risk assessment protocol of general application.

Further, this section requires federal agencies to promulgate within 15 months of the date of enactment of this legislation a rule which lists other risk assessment and risk characterization documents deemed to be significant and sets forth criteria to be considered when making the rule.

Federal agencies establish policy on risk assessment and risk characterization through many different types of formal and informal guidance. Formal guidance usually is in the form of regulations. Informal guidance may come through policy statements, guidelines, action levels, protocols, speeches, congressional testimony, notices, and a wide variety of other similar documents. Whether formal or informal, this guidance constitutes the vast bulk of federal policy in the area of risk assessment and risk characterization.

Section 3103(b)(2) includes such guidance as a "significant risk assessment document" and "significant risk characterization document" where it establishes policy of general applicability, but not where it is product-specific. Thus, a guideline establishing general principles for testing a class of products, or for agency review and approval of a type of ingredient, is subject to subtitle A, but the application of that guideline to a specific ingredient or product is not. A regulation establishing new product labeling requirements is subject to subtitle A, but the application of those rules to individual labels is not. Action levels establishing enforcement policy are sub-

ject to subtitle A, but their application to specific products in individual compliance actions are not.

Finally, there can be no diminution of public health protection under this law. Section 3103(b)(3) explicitly exempts any situation that the head of an agency considers to be an emergency. This assures that immediate action can be taken wherever justified.

This section also provides that this subtitle does not apply to emergencies or situations necessary to maintain military readiness, screening analysis, or food, drug and product labels requiring federal approval prior to their use as well as any health, safety or environmental inspections or individual facility permitting actions. Military readiness should be interpreted to mean training procedures of military personnel required to provide for the national security

The Committee expects that the head of an agency shall determine an emergency situation based on ordinary notions of urgency. Such factors which may be considered are any condition, circumstance, or practice reasonably expected to cause death, serious illness, or severe injury to humans, or substantial endangerment to private property or the environment. Further, in determining whether an emergency exists, an agency head should be guided by applicable statutory definitions. However, the mere existence of the usual kind and level of risk which any statute subject to this title is designed to regulate does not constitute an emergency.

The Committee also notes that it has jurisdiction over the National Aeronautics and Space Administration (NASA). The Committee acknowledges that NASA currently performs stringent risk assessments to evaluate safety, mission-success probabilities, programmatic cost and scheduling issues. These risk assessments are integral to the accomplishment of NASA's statutory mandate to improve "the usefulness, performance, speed, safety, and efficiency of aeronautical and space vehicles" [42 U.S.C. 2451(d)(2)]. While the Committee does intend for the provisions of Title III of H.R. 9 to apply to NASA, the Committee does not believe or intend that these requirements impose any unjustifiable new costs or burdens on the agency. Since NASA is a leading fundamental science mission agency, the Committee expects compliance with scientifically objective, unbiased risk guidelines to be fully consistent with their mission. It should be noted, however, that Title III of H.R. 9 provides for a transitional plan and Congressional reporting process.

Within 180 days after the date of enactment of this title, Federal agencies, with guidance from the Office of Management and Budget, shall develop transition plans to assist the agencies, the public, and the regulated community in the implementation of this title, including any new requirements or procedures needed to supplement prior agency practices.

Federal agencies shall report to Congress annually as to whether their implementation of this title has created any significant regulatory or program management complication resulting from any differences between the certification provisions of this title and decisional criteria for rule making that otherwise would have been applicable under other statute.

This section also clarifies that the provisions of the subtitle do not modify, and are supplemental to, existing federal health, safety

and environmental standards. It further clarifies that nothing in the title requires disclosure of trade secrets or confidential information.

SEC. 3104. PRINCIPLES FOR RISK ASSESSMENT

To assure that risk assessments distinguish scientific findings from other considerations and present a complete, unbiased description of risk, this section sets forth the following principles for the preparation of significant risk assessment documents: (1) in documents discussing human health risks, a discussion of laboratory and epidemiological data, the correlation between health risks and potential toxins and activities, and an explanation of conflicts among the data; (2) in documents selecting significant assumptions, inferences or models, an explanation of alternative assumptions, an explanation of choices made between models, identification of policy or value judgments, a full description of models used and their underlying assumptions, and an indication of conflicts between models and empirical data; and (3) a prohibition against the automatic adoption or incorporation, without opportunity for notice and comment, of any recommendation or classification of the health effects value of a substance made by a non-United States-based entity. The Committee states that the term non-United States-based entity means: any foreign nation or government and its agencies; the United Nations or any of its subsidiary organizations; other international governmental bodies or standards-making organizations or any other organization or private entity without a place of business located in the United States or its territories.

Risk characterizations currently produced by Federal agencies frequently overstate risks and lack key information. The bill addresses this problem by requiring Federal agencies to assure that significant risk assessment documents and all of their components distinguish scientific findings from other considerations and are, to the maximum extent feasible, scientifically objective, unbiased, and inclusive of all relevant data, including animal data which shall be reviewed with regard to its relevancy to humans.

Subsection 3104(b) provides principles that describe a scientifically objective and unbiased risk assessment. These principles will make risk assessment processes more transparent, allowing risk managers and the public to understand the evaluation and selection of data, models, and assumptions in a risk assessment.

Federal agencies often use default options when real data exist. Default options allow risk assessors to make quantitative estimates of risk when available data are incomplete. Often agencies choose default options which, given the available scientific information, tend to overstate risks in the resulting risk estimate. One such default option is to simply base risk estimates on studies which find a positive correlation. Agencies often persist in using these defaults, even when chemical or situation-specific data are available. The bill addresses this problem by requiring significant risk assessments to include all relevant data. Subparagraph 3104(b)(2) will remove the current disincentive for organizations to develop data that will increase the accuracy of risk assessments.

SEC. 3105. PRINCIPLES FOR RISK CHARACTERIZATION AND COMMUNICATION

This section provides for a description in significant risk documents of the populations or natural resources subject to risk characterization; a best estimate and other risk estimates, and an explanation of attendant uncertainties in risk assumptions; an explanation of exposure scenarios, comparisons to routinely encountered risks that place the federally addressed risks in context; a statement of significant and clear substitution risks; and a summary of other risk estimates, to the extent feasible.

Federal agencies generally do not provide complete characterizations of risk, but rather provide only single-point, upper-bound estimates of risk. This forces risk managers to make decisions with incomplete information and misleads the public into believing that some risks are much greater than they are.

This section mandates that federal agencies provide, to the extent feasible, the best estimate or estimates for the given populations or natural resources, along with the reasonable range of scientific uncertainty. The agency may present plausible upper bound or conservative estimates in conjunction with plausible lower bound estimates. Indeed, the savings clause in Subtitle A makes clear that no calculation is precluded. Best estimates are defined to be a central estimate, which is the most statistically probable level of risk, as well as any other methodology designed to provide the most plausible level of risk, given the scientific information available to the head of the department of agency. Subtitle A does not opine on which combination of scientific assumptions or methodology are most appropriate and, thus, makes no pronouncement on the science itself. The decision should be made under the current standards of review. The standard presentation of best estimates, however, differs substantially from the current system at EPA of simply presenting different forms of upper-bound or conservative point estimates.

Best estimates will: (1) help provide a more realistic picture of the nature and magnitude of the risks; (2) make the impact of conservative assumptions in an upper-bound estimate clearer to decision makers and the public; (3) separate scientific findings from considerations affecting regulatory strategies; (4) provide for more realistic comparisons between risks; and (5) move scientific debate forward by requiring consideration of new, more plausible models and assumptions.

The provision prohibits agencies from simply ignoring more scientifically plausible assumptions and methodologies when they are available. The requirement does not require papering over legitimate scientific disagreements by averaging incompatible estimates. Nor would agencies need to perform new evaluations which are excessively burdensome. This is, however, a narrow exception and the agency would need to explain why a given approach is not ''feasible.'' Moreover, under the language ''to the extent feasible,'' agencies would be required to try to get as close to a best estimate as feasible. For example, it may be feasible to use the most plausible assumptions for some components of a best estimate calculation but not others. Finally, what is feasible will change over time. Cer-

tainly, where public comment provides a scientifically sound means of getting a risk estimate which is closer to a best estimate, the agency should utilize this approach. This specifically means that actual information should be used in lieu of default options where the actual information is more scientifically plausible than the information underlying the default assumption.

Where practical, agencies should provide probability distributions for risk estimates that reflect both variability and uncertainty. Presenting the full distribution of risk provides risk managers and the public with the most complete picture of what is and what is not known about risk.

Paragraph 3105(2) requires agencies to explain the exposure scenarios used and provides a statement of the size of the population and likelihood that an exposure will occur. This information will help assure that the public understands the precise basis of the given risk assessment. Moreover, the requirement will help separate more likely exposure scenarios from unlikely exposure scenarios, such as a child eating handfuls of dirt from a fenced-in industrial site.

Paragraph 3105(3) requires agencies to provide a statement placing the nature and magnitude of risks in context. Statements such as "there is a one in ten thousand additional lifetime risk of getting cancer," without context, may promote confusion and misapprehension. Additional information will assist the public in understanding how the risk affects them, and how it relates to other risks with which they are more familiar. This section acknowledges the difficulty in making useful and meaningful risk comparisons by including references to relevant distinctions among categories of risk and limitations to comparisons. However, simply for illustrative purposes, the following chart demonstrates the type of comparisons that provide a helpful context for evaluating the significance of a statistical risk.

APPROXIMATE DOSES OF NATURALLY-OCCURRING SUBSTANCES IN FOOD OR DRINK THAT PRODUCE AN UPPER-BOUND, LIFETIME RISK OF CANCER OF "1 IN 10,000" FOR A LIFETIME OF CONSUMPTION, USING EPA METHODOLOGY [1]

Substance	Dose
Ethyl Alcohol	One glass of wine every three years as an adult; or One bottle of beer every two years as an adult
Caffeic Acid	One head of lettuce every two years; or One apple a month; or Three stalks of celery a month; or Three carrots a month; or Five potatoes a month.
Caffeic Acid and 18 other rodent carcinogens	Three and one half cups of coffee a month as an adult.
8-Methoxypsoralen	Five parsnips a year.
Allyl Isothiocyanate	One 3-ounce jar of brown mustard a year.
Mixture of hydrazines	Four mushrooms a year.
Estragole	Four grams of dried basil a year.
d-Limonene	Two 6-ounce glasses of orange juice a month.
Aflatoxin	Three peanut butter sandwiches a month.

[1] Converted from data in "Rodent Carcinogens: Setting Priorities" by Lois Swirsky Gold, Thomas H. Sloane, Bonnie R. Stern, Neela B. Manley, Bruce N. Ames (Science, Vol. 258(9). October 1992) in a manner similar to current EPA risk assessment guidelines.

Note.—The risk posed by these foods could be as low as zero.

Paragraph 3105(4) requires that each significant risk assessment or significant risk characterization document referred to in section

3103(b) shall include a statement of any significant substitution risks to human health, where information on such risk is available to the agency. The term "substitution risk" is defined in section 3109 to mean any potential risk to human health, safety or the environment resulting from a regulatory option designed to decrease other risks. Current risk characterization and communication fail to provide adequate information about the "new" risks that the proposed action will pose. Because they are not currently assessed, those causal risks are often assumed to be zero. Many risk management actions pose their own intended and unintended risks.

This requirement applies to "significant" substitution risks. The Committee expects agencies to look to the substitution risk relative to the risk being addressed by the particular regulatory strategy. If a regulatory strategy is addressing minor risks, then a minor substitution risk may be significant. If the strategy is addressing major risks, then a minor substitution risk may not be significant by itself.

Paragraph 3105(5) requires agencies to present summaries of other risk estimates, if they meet certain requirements. Because risk assessments often require many subjective judgments, risk characterizations conducted by different organizations can vary greatly. Inclusion of other risk estimates, provided that they meet the standards set forth in the amendment, will provide a fuller characterization of risk.

SEC. 3106. GUIDELINES, PLAN FOR ASSESSING NEW INFORMATION, AND REPORT

This section requires the President to issue guidelines for Federal agencies within 15 months of the date of enactment of this legislation consistent with sections 3104 and 3105. 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; weighing of evidence with respect to extrapolating human health risks from sensitive species; evaluation of benign tumors, and evaluation of different human health endpoints.

This section also requires that within 18 months after the date of enactment of this legislation, each Federal agency which conducts risk assessments shall publish a plan to review and, where appropriate, revise any significant risk assessment document or risk characterization document which was issued before the effective date of this legislation. The head of the agency determines that the application of the principles set forth in sections 3104 and 3105 would likely significantly alter the results of the prior risk assessment or risk characterization; the plan shall provide procedures for receiving and considering new information and risk assessments from the public. The final plan shall set priorities for review, and, where appropriate, for revision of risk assessment documents and risk characterization documents based on the potential to more efficiently focus national economic resources within Federal programs designed to protect human health, safety, or the environment on the most important priorities and on such other factors as such Federal agency considers appropriate.

This section also requires agencies to evaluate policy and value judgments inherent in their risk assessments and report to Congress within 3 years after the date of the enactment of this legislation.

Further, this section requires the President to review and, where appropriate, revise the guidelines published under this section at least every 4 years. In this manner, advances in risk assessment and risk characterization science and methodology can be incorporated into each agency's program.

The guidelines, plan and report under this section are subject to public notice and comments.

SEC. 3107. RESEARCH AND TRAINING IN RISK ASSESSMENT

This section would require that each Federal agency regularly and systematically evaluate risk assessment research and training needs. Further, each agency head must develop a strategy schedule, and delegation of responsibility within the agency to meet those needs and report to Congress on the progress made to implement this section. Section 3106 would be applicable to only the following agencies: the Environmental Protection Agency, the Consumer Product Safety Commission, the Occupational Health and Safety Administration, the Department of Labor, the Department of Transportation, the Department of Energy, the Department of Agriculture, the Department of Interior, and the Food and Drug Administration.

SEC. 3108. STUDY OF COMPARATIVE RISK ANALYSIS

This section would require the Director of the Office of Science and Technology Policy to conduct or commission a study using comparative risk analysis to rank health and environmental risks, and to provide a common basis for evaluating strategies for reducing or preventing these risks. The purpose of this study is to improve and list comparative risk methodology.

This section further directs the Director of OSTP to enter into an agreement with the National Research Council to provide technical guidance on varying ways in which to prioritize environmental risks using comparative risk analysis.

Paragraph 3108(2)(e) requires the Director of OSTP to report to Congress on the findings of the study.

SEC. 3109. DEFINITIONS

This section defines certain terms. 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 "risk characterization document" means a document quantifying or describing the degree of toxicity, exposure, or other risk they pose for exposed individuals, populations, or resources. The term "best estimate" means an estimate which is based on one of the following: central estimates of risk using the most plausible assumptions; an approach which combines multiple estimates based on different scenarios and weighs the probability of each scenario; 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. The term "substitution risk" means a potential risk to human health, safety, or the environment from a regulatory option designed to decrease other risks. As used in this title, 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. The term "document" includes material stored in electronic or digital form. As used in this title, the term "prepare," when referring to risk assessment, risk characterizations, or analyses of risk reduction benefits and costs, includes both the preparation or use of such a document by an agency.

SUBTITLE B—ANALYSIS OF RISK REDUCTION BENEFITS AND COSTS

SEC. 3201. ANALYSIS OF RISK REDUCTION BENEFITS AND COSTS

This section directs the President to require federal agencies to prepare the following for major rules proposed or promulgated after the date of enactment and designed to protect human health, safety or the environment: an assessment of incremental costs and incremental benefits for each significant regulatory alternative; reasonable alternatives for the proposed rule including alternatives that require no government action, an assessment of the aggregate effect of the rule on small businesses with fewer than 100 employees; an analysis of whether the identified benefits of the proposed or promulgated rule are likely to exceed the identified costs of the proposed or promulgated rule, a comparison of any human health, safety, or environmental risks addressed by the regulatory alternatives to other greater or lesser risks chosen by the head of the agency, including at least three (3) other risks regulated by the agency and to at least three (3) other risks which the public is familiar; a quantitative assessment of the cumulative financial burden that persons producing products that are regulated by the rule will bear in order to comply with the rule and with existing standards that affect the product or other similar products produced by such persons; a statement placing the nature and magnitude of the risks in context; and for each final rule, an assessment of the costs and benefits of compliance with the rule. This section prohibits promulgation of any final rule subject to this title unless the cost-benefit assessment is based on an objective, unbiased scientific and economic information; incremental benefits are reasonably related to and justify the incremental costs; and no other proposed or considered options would be more likely to achieve a substantially equivalent risk reduction in a more flexible or cost-effective manner. This section provides that notwithstanding other provisions of law, the requirements of the bill supplement, and to the extent of any conflict, supersede, the decisional criteria of underlying statutes. It prohibits promulgation of any major rule unless the requirements of this section are met and supported by substantial evidence of the rulemaking record. For each major rule, it requires agencies to publish in the Federal Register or otherwise make available the information required to be prepared under this section. For the purposes of this subtitle, "costs" are defined to include

the direct and indirect costs of compliance to the federal government, state and local governments, and private entities; "benefits" are defined to include direct and indirect social and economic benefits; "major rule" is defined to mean any regulation, other than a regulation or other action to authorize or approve any individual substance or product, that is likely to result in an annual increase in costs of $25 million or more.

Emergencies as defined in subtitle A of this legislation are exempted from these requirements.

The provisions of 3201(c) make the provisions of this section applicable to new regulations promulgated under existing federal statutes. The decisional criteria supplement, and to the extent there is a conflict, supersede, the decisional criteria for rulemaking otherwise applicable under the statute pursuant to which rule is promulgated. In effect, agencies will continue to follow the instructions provided by Congress in past and future Federal legislation, but shall, in addition, follow the risk assessment principles and procedures, and apply as additional decisional criteria the cost-benefit and cost-effectiveness certification requirements of this section.

When there is a conflict with or explicit textual language in a federal statute prohibiting consideration of the criteria as set forth, the provisions of 3201(f) state that the decisional criteria in this section shall supersede those in the statute pursuant to which the rule is promulgated, but only to the extent there is a conflict. The decisional criteria otherwise applicable under other statutory authority will continue to apply to the extent not inconsistent with this section criteria. By this means, the language molds the ultimate decisional criteria for rulemaking applied under all such statutes to the requirements of this section with as little disruption as feasible to the otherwise applicable instructions of Congress.

An illustration chart on the manner in which this would be applied to certain existing federal statutes follows:

SUMMARY CHART

IMPACT OF SUBTITLE B ON VARIOUS STATUTES

Subtitle B includes provisions: (1) elaborating the principles for risk assessments, (2) determining when cost/benefit analyses must be considered, and (3) defining the circumstances under which independent peer review will be required. This chart presents, in summary form, the primary statutes affected by Subtitle B. The assessment of impact is based solely on those instances when Subtitle B applies. Thus, no excluded agency activities or analyses are affected. These exclusions include: health, safety, and environmental inspections; individual facility permitting; product/substance clearance; screening analyses; and emergency situations. In addition, scope limitations apply. Basically, the bill mandates risk assessment and cost/benefit analysis requirements for major rules with an economic impact of $25 million or more. For peer review, the threshold is $100 million or more. As an example, section 6 of the Toxic Substances Control Act establishes procedures and an unreasonable risk criteria under which the Environmental Protection Agency can place restrictions on products. The bill does not affect those procedures or criteria, except to the extent that it supple-

ments the existing risk assessment, cost/befit analysis, and peer review requirements.

As used in the following chart, the term "SUPPLEMENTS" means that the statute already contains a risk assessment, cost/benefit analysis or peer review requirement, and that the provisions in the bill will better or more explicitly define the agency's obligations. "ADDS" refers to statutes that are silent as to risk assessment, cost/benefit analyses, or peer review. In those cases, the bill adds a new requirement to the agency's process. The term "SUPERSEDES" is used when existing legislation does not permit risk assessment, cost/benefit analyses, or peer review. In these instances, Subtitle B would now require these principles or procedures to be implemented. The term "N/A" is used when the provisions of the bill are not applicable to particular agency action. This table is intended to be exemplary only and is not an exhaustive or detailed listing of the impact of Subtitle B.

Statute	Risk assessment	Cost benefit analysis	Peer review
Occupational Safety and Health Act	Supplements	Adds	Adds
Consumer Product Safety Act:			
Product recalls	N/A	N/A	N/A
Product safety standards	Supplements	Supplements	Adds
Products bans	Supplements	Supplements	N/A
Federal Hazardous Substances Act	Supplements	Supplements	Adds
Poison Prevention Packaging Act	Supplements	Supplements	Adds
Hazardous Materials Transportation Uniform Safety Act:			
Designating/defining hazardous materials	Supplements	Supplements	Adds
Packing, labeling, placarding	Adds	Adds	Adds
Shipping documentation	Adds	Adds	N/A
Unintended release notice	Adds	Adds	N/A
Package/container design	Adds	Adds	Adds
Clean Air Act	Supplements	Supersedes	Supplements
Resource Conservation and Recovery Act	Supplements	Supersedes	Supplements
Clean Water Act	Adds	Supplements	Supplements
Toxic Substances Control Act	Supplements	Supplements	Supplements
Comprehensive Environmental Response, Compensation, and Liability Act.	Supplements	Supersedes	Adds
Safe Drinking Water Act	Supplements	Supplements	Supplements
Federal Insecticide, Fungicide, and Rodenticide Act	Supplements	Supersedes	Supplements
Oil Pollution Act	Adds	Supplements	Adds
Emergency Planning and Community Right-to-Know Act	Adds	Adds	Adds
Endangered Species Act	Supplements	Supersedes	Supplements
Clean Water Act Section § 404 Wetlands Permit Program	Supplements	Supersedes	Adds
Federal Food, Drug, and Cosmetic Act	Supplements	Supersedes	Supplements
Federal Trade Commission Act	Adds	Adds	Adds
Federal Mine Safety and Health Act	Supplements	Adds	Adds

Subtitle B establishes a flexible decisionmaking framework for Federal agencies that reflects the straightforward, common-sense way in which real people make real decisions. It requires that every Federal agency answer two simple questions before a major rule ($25 million impact or more on the economy) is promulgated—is this action "worth it," and does this way of doing it maximize society's net benefits because the agency has chosen the most cost-effective and flexible of the alternatives considered by or proposed to it. Section 3201(a) uses neutral principles, and creates a level and open playing field for public policy decisionmaking, with no effort to skew the results up or down in advance. Where risks need to be regulated and regulation is justified by its benefits, regulation will go forward even if costly or inconvenient to some.

Section 3201(a) contains both procedural requirements that a regulatory impact analysis be conducted, and substantive decisional criteria. To be effective, the cost/benefit analysis provided for in Section 3201(a) must govern agency decisions. The "certifications" required by Section 3201(a) are substantive decisional criteria, as is made clear by the provisions of Sections 3201(f)(1) and (2). In making its rulemaking decision, each agency must certify that the incremental risk reduction or other benefits of any regulatory or non-regulatory option chosen will be likely to justify, and, in addition, be reasonably related to, the incremental costs to be incurred by the action, and that no regulatory or non-regulatory alternative considered by or proposed to the agency during or prior to the public comment period would be more likely to achieve a substantial equivalent reduction in risk in a more cost-effective manner or would be more likely to provide flexibility to the regulated entities in achieving the objectives of the regulation.

Section 3201(b) provides that the information required by Section 3201(a) must be placed in the administrative record, and is to be published in a clear and concise manner in the Notice of Proposed Rulemaking and the Federal Register notice for the final regulation.

The requirements of Section 3201(a) are also designed to ensure that risk assessments and risk comparisons based on good science will be provided to aid in reasoned decisionmaking. Quantification in cost/benefit analysis and risk assessments is required to the extent feasible, and other factors relevant to the decisionmaking may be qualitatively described. The methodology and level of detail for both risk assessments and cost/benefit analyses should be appropriate to the significance and complexity of reasoned decisionmaking on the matter at issue, considering any need for expedition.

In this regard, it is important to emphasize that both risk assessments and cost/benefit analyses can be "tiered"—that is, they can be tailor-made to fit the nature of the decisionmaking process and the decision confronting a particular agency, as long as the basic elements of reasoned decisionmaking and the logic of the cost/benefit and risk assessment methodology are respected. This legislation does not intend to place a "straitjacket" on agency decisionmaking, nor does it require a "cookbook" approach to risk assessment or cost/benefit analysis. Rather, it aims at ensuring the essential rationality of both the decisionmaking process and the ultimate decisions by Federal agencies, recognizing the wide variance in the types of decisions and types of situations faced by agency officials. The Committee anticipates that the cost/benefit analysis guidance to be developed by the Office of Management and Budget under Section 3201(e) will provide agencies with sufficient flexibility so that the basic principles of risk assessment and cost/benefit analysis can be made workable in the individual circumstances faced by each. Further, the legislation is intended to promote agency use of the best available science as it conducts its risk assessment.

In short, Section 3201(a) focuses on decisionmaking, not on simply multiplying procedural burdens. Its mandates are flexible and goal-oriented—not prescriptive. The risk and cost/benefit requirements can be molded to the nature of the decisionmaking faced by the agency in question. They do not require the impossible, but ju-

dicial review will hold government decisionmakers clearly accountable for doing the possible in good faith.

Section 3201(a) calls for an assessment of "incremental" costs and "incremental" risk reduction or other benefits associated with each significant regulatory alternative. It is essential, and this language considering "incremental" costs and benefits is intended to ensure, that the agencies recognize the role of diminishing returns in taking action toward any regulatory objective. In many cases, high levels of benefit may be obtained by relatively cheap and simple steps; it is the intent of the word "incremental" that the agencies must apply cost/benefit analysis so as to assess the utility of each further increment of control or action, as well as ensuring that the action level finally chosen has benefits that outweigh its costs.

The cost/benefit and the cost-effectiveness decisional criteria embodied in Section 3201(a) are made applicable by Section 3201(f) to actions under all other Federal legislation. The Section 3201(a) decisional criteria supplement, and to the extent there is a conflict, supersede the decisional criteria for rulemaking otherwise applicable under the statute pursuant to which a rule is promulgated. In effect, agencies will continue to follow the instructions provided by Congress in past and future Federal legislation, but shall, in addition, follow the elaborated risk assessment principles and procedures, and apply as additional decisional criteria the cost/benefit and cost-effectiveness certification requirements of Section 3201(a).

When there is a conflict between the decisional criteria in Section 3201(a) and those decisional criteria otherwise applicable under the statute pursuant to which the rule is promulgated, or where there is explicit textual language in any other Federal statute prohibiting the consideration of the criteria set out in Section 3201(a), Section 3201(f)(1) provides that the decisional criteria in Section 3201(a) shall be used in place of those in the statute pursuant to which the rule is promulgated. In either case, however, the decisional criteria otherwise applicable will continue to apply to the extent not inconsistent with the Section 3201(a) criteria. By this means, the Committee intends to mold the ultimate decisional criteria for rulemaking applied under all such statutes to the requirements of Section 3201(a) with as little disruption to the otherwise applicable instructions by Congress in that statute or statutory program as is feasible. The reports to Congress required by Section 3201(h) should delineate any difficulties created by the operation of Section 3201(f)(1), and allow this Committee to focus on any legislative changes necessary in existing statutes to allow reasoned decisionmaking to prevail more simply and easily in all of the Federal regulatory programs covered by this legislation.

SUBTITLE C—PEER REVIEW

SEC. 3301. PEER REVIEW PROGRAM.

This section requires each federal agency to develop a systematic peer review program for significant risk assessment documents and economic assessments for regulatory programs addressing human health, safety or the environment. The program shall provide for peer review panels of independent and external experts and shall

be broadly representative and balanced to the extent feasible; may provide for differing levels of peer review depending on the significance or complexity of the problems and the need for expeditiousness; shall not exclude peer reviewers merely because they represent entities with a potential interest in the outcome, provided that the interest is fully disclosed, but for regulatory decisions affecting a single entity no person representing that entity may be included on the panel; may provide specific and reasonable deadlines for peer review panels to submit reports; and shall provide adequate protection for confidential business information and trade secrets. It requires peer review for any significant risk assessment document or cost assessment prepared for any regulation likely to increase costs by $100 million or more annually (other than actions to approve individual substances or products). It requires covered federal agencies to respond in writing to significant peer review comments. It requires that all peer review comments and agency responses be made available to the public and part of the administrative record. It exempts from peer review data and analysis which has been previously peer reviewed. It requires the President to appoint peer review panels to annually review the risk and cost assessment practices of each covered federal agency and requires those panels to report annually to Congress.

SUBTITLE D—OTHER PROVISIONS

SEC. 3401. JUDICIAL REVIEW

This section clarifies that judicial review shall be limited to the provisions of the Administrative Procedure Act. The availability of effective judicial review of an agency's regulatory impact analysis under Section 3201(a) is important if that analysis is to be a genuine element of the agency's procedural and substantive decisional process. For purposes of efficiency, the judicial review of the risk assessment and cost/benefit analyses contained in the regulatory impact analysis required under Section 3201(a) should proceed, on the basis of the whole record of the rulemaking (which will include the actions taken under Section 3201(a)), in conjunction with review of the rule under the statute granting the agency authority to conduct the rulemaking.

The promulgation of rules by agencies, whether "major" rules under this legislation or not, are, of course, already subject to judicial review under the particular statute granting the agency authority to conduct the rulemaking. Section 3401 of Subtitle D clarifies that the procedures and decisional criteria 3201(a) shall be judicially reviewable, pursuant to the Administrative Procedure Act. This review should occur at the same time and in the same court that reviews agency findings under the statute granting the agency authority to conduct the rulemaking. Other than in the case of the "major rule" determination noted below, it is essential that judicial review be "channeled" so that the entire decision related to a rule, including both the procedures and decisional criteria under this legislation and the procedures and decisional criteria under the statute granting the agency the authority to conduct the rulemaking, be coordinated. For example, a "major" rule promulgated by EPA under the Clean Air Act would be subject to judicial review

under Section 3401 to determine whether the rule satisfied the decisional criteria of Section 3201(a), under Section 307(d)(9) of the Clean Air Act. Thus, the language of Section 3401 is intended to ensure time and effort are not wasted needlessly during judicial review because the proper coordination of that review was not established during passage of this legislation.

The conduct of judicial review should, of course, proceed under the traditional standards of review established by Congress in the Administrative Procedure Act, as interpreted by the courts. It is essential, however, that the courts apply those standards of review in the way Congress intended, without undue deference to agency determinations. When conducting judicial review, the reviewing court should use the normal standards of review, but apply them carefully, as we note below, to assure that undue deference is not given to agency decisions.

The reviewing court should affirm the agency's interpretation of the statute granting authority to promulgate the rule if, applying traditional principles of statutory construction, it finds that the interpretation is clearly the interpretation of the statute intended by Congress. If, applying traditional principles of statutory construction, the court finds that an interpretation other than the interpretation applied by the agency is clearly the interpretation of the statute intended by Congress, the reviewing court should find that the agency's interpretation is erroneous and contrary to law.

If a reviewing court, applying established principles of statutory construction, finds that the statute gives the agency discretion to choose from among a range of permissible statutory constructions, the reviewing court shall apply the normal "arbitrary and capricious" and "substantial evidence in the record" standards of review, as appropriate. But, under the provisions of Section 3201(f)(2), the certification required under Section 3201(a) must be supported by substantial evidence in the rulemaking record. Further, the reviewing court should affirm the agency's interpretation where the record on review establishes that (1) the agency has correctly identified the range of permissible statutory constructions, (2) the interpretation chosen is one that is within that range, and (3) the agency has engaged in reasonable decisonmaking in determining that the interpretation it has chosen, rather than other permissible constructions of the statute, is reasonable because it is the one that maximizes net benefits to society.

The importance of both the procedural and substantive requirements of Section 3201(a) is such that it is the intention of this Committee that a reviewing court shall set aside agency action that fails to satisfy those procedural requirements or decisional criteria.

For similar reasons, it is essential that courts guard vigilantly against agency attempts to evade the requirements of Section 3201(a) by the promulgation of guidelines, guidance, criteria or general statements of interpretation which are declared by the agency not to be binding, and thus not subject to Section 3201(a) and to notice and comment rulemaking and judicial review at the time they are made public. Where such guidelines, guidance, criteria, or general statement of interpretation are applied in fact by either the Federal agency or by the states in such a way that they constitute "de facto" rules because they are given substantive effect

in individual cases or other agency actions, whether they are said by the agency to be binding or not, they constitute "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy" under the definition of "rule" in Section 551(4) of the Administrative Procedure Act, and must be classified by courts as rules for all purposes. It is the intent of this Committee that agencies not be allowed to avoid the important Section 3201(a) requirements for reasoned decisionmaking by simple agency declarations that their guidelines, guidance, criteria or general statements of interpretation are not "binding."

SECTION 3402: PRIORITIZATION OF THREATS AND RESOURCES USE.

This section establishes a method of prioritizing risks to human health, safety, and the environment on the basis of the seriousness of the risks addressed and resources available to reduce such risks.

Cost of Implementation

Title III of H.R. 9 does not authorize any additional appropriations for agencies to implement the provisions of this bill. First, it should be noted, the bill would not require any additional risk assessments other than those required by current law. Additionally, the following comments by Dr. John Graham, Director of the Harvard Center for Risk Analysis, regarding a $220 million estimate for EPA implementation during the Science Committee's January 31 legislative hearing, are additionally instructive:

> $220 million. Let's start, for the sake of argument, and say that is absolutely correct. The Environmental Protection Agency, it's roughly a $5 billion agency in taxpayer costs, yet it imposes, on the private sector of the economy and the states and localities $150 billion per year. For every dollar of EPA taxpayer costs, that is $30 in external activity. Even if we were to inadvertently double the size of EPA, if we could reduce by 10% the $150 billion cost of EPA, it would save $15 billion and only cost an extra $5 billion. So, when you are talking in millions of dollars, you are in the noise level of this issue. This is a massive regulatory program on the states and localities and the economy of this country. We can afford to do a little risk analysis to figure out how to save some of that $150 billion . . . even if you take the worst case possibility, as the agencies might be inclined to do . . .
>
> ". . . I think the idea of getting the Congressional Budget Office for example to make some estimates of this is fine, but with the process of doing that I certainly hope they look at the possibility of actually rearranging some of the existing personnel in EPA, reducing, for example, the number of lawyers of the U.S. Environmental Protection Agency and having a few more of them invested in risk analysis, and maybe we can do this without a substantial increase in the overall size of the Environmental Protection Agency.

It should also be noted for the record that the Congressional Budget Office cost estimate for H.R. 4306, the Risk Assessment Improvement Act of 1994, reported by the House Science, Space, and Technology Committee just last October, estimated the cost to the Federal government at only $15 million total over five (5) years. That bill, while limited to EPA and otherwise less complete, would have required EPA to review existing guidelines with specified minimum contents for characterizing risks, and respond in the Federal Register to peer review comments. H.R. 4306 also included a study of comparative risk analysis.

The Committee believes this legislation easily passes any cost/benefit analysis.

VI. OVERSIGHT FINDINGS

Clause 2(l)(3)(A) of rule XI requires each committee report to contain oversight findings and recommendations required pursuant to clause 2(b)(1) of rule X. The Committee has no oversight findings.

VII. OVERSIGHT FINDINGS AND RECOMMENDATIONS OF THE COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

Clause 2(l)(3)(D) of rule XI requires each committee report to contain a summary of the oversight findings and recommendations made by the Government Reform and Oversight Committee pursuant to clause 4(c)(2) of rule X, whenever such findings have been timely submitted. The Committee on Science has received no such findings or recommendations from the Committee on Government Reform and Oversight.

VIII. BUDGET ANALYSIS AND PROJECTIONS

This Act provides for no new authorization or budget authority or tax expenditures. Consequently, the provisions of Section 308(a) of the Congressional Budget Act are not applicable.

IX. COST ESTIMATE AND CONGRESSIONAL BUDGET OFFICE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, February 15, 1995.

Hon. ROBERT S. WALKER,
Chairman, Committee on Science,
U.S. House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for Title III of H.R. 9, the Job Creation and Wage Enhancement Act of 1995.

Enactment of Title III of H.R. 9 could affect direct spending or receipts. Therefore, pay-as-you-go procedures would apply to the bill.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

JAMES L. BLUM,
(For Robert D. Reischauer).

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: Title III of H.R. 9.

2. Bill title: Job Creation and Wage Enhancement Act of 1995.

3. Bill status: As ordered reported by the House Committee on Science on February 8, 1995.

4. Bill purpose: This title applies to all federal agencies with regulatory programs designed to protect human health, safety, or the environment. The provisions of subtitle A would apply to any risk assessment or risk characterization document prepared in connection with a rule that is expected to have direct or indirect costs to the federal government, state or local government, or the private sector of at least $25 million annually. Subtitle B would apply to agency rules expected to have a direct or indirect cost at least $25 million annually, regardless of whether or not a risk assessment or characterization document is prepared.

Subtitle A would require all agencies to apply specified principles when preparing risk assessments in connection with their regulatory programs. The bill would establish a list of components that agencies must include in risk characterization documents. Within 15 months following enactment, the President is to issue guidelines to agencies that are consistent with the risk assessment and risk characterization principles described in the bill.

Subtitle B would require these agencies to assess the incremental costs and incremental risk reduction or other benefits associated with proposed or promulgated rules designed to protect human health, safety, or the environment. The bill also would require a review and analysis of other regulatory or nonregulatory options considered by the agency. In addition, this subtitle would prohibit the promulgation of any final rule unless the agency certifies that the incremental risk reduction or other benefits of the regulation will be likely to justify, and be reasonably related to, the incremental costs.

Subtitle C would require the specified agencies to establish peer review procedures for risk assessments and economic assessments associated with rules expected to have annual costs to the economy exceeding $100 million.

5. Estimated cost to the Federal Government: We estimate that enactment of this title would increase the cost of issuing and reviewing regulations by the major federal regulatory agencies by at least $250 million annually. The title may also lead to additional legal challenges of proposed federal regulatory activities; federal agencies and the courts would incur additional costs to defend and process these cases, but CBO is unable to estimate the increase in the number of legal proceedings or the amount of additional costs. Enacting Title III of H.R. 9 could lead to the delay or loss of federal receipts expected under current law; therefore, pay-as-you-go procedures would apply to the bill. CBO is working with federal agencies

to determine the amount of the loss in receipts but cannot now provide an estimate.

Few of the agencies that would be affected by this bill have had time to systematically study the additional costs that its implementation would impose. The risk analysis work, the cost/benefit comparisons, and the peer review provisions are similar to the work most agencies now conduct for some regulations expected to have an economic impact greater than $100 million annually. This estimate assumes that agencies will try to adhere to their current schedules for implementing new regulations and revising existing rules. This estimate does not include any costs for implementing research and training in risk assessment, as outlined in section 3107 of the bill. CBO has insufficient information at this time to estimate the cost impacts of this bill on all federal agencies, however we believe the major cost impacts would fall upon the agencies discussed below.

EPA currently spends about $120 million annually on risk assessment and cost/benefit assessments to support rule making efforts for regulations expected to have an economic impact greater than $100 million annually. Based on information from the agency, we estimate that the volume of work that would be added by Title III would double the agency's cost for these studies. Based on its current regulatory workload, the agency estimates that lowering the threshold for detailed risk assessments and cost/benefit analysis from regulations with economic impacts of $100 million annually to $25 million annually would triple the number of regulatory actions requiring detailed study. Because it is not clear how the provisions of the bill would be applied to the permits issued by the agency, this estimate does not include any additional costs for risk assessments and cost/benefit analysis of permits. The agency handles hundreds of permit applications and modifications each year.

The Department of Agriculture (USDA) currently prepares regulatory impact assessments, environmental impact statements, and risk analyses for all regulatory actions affecting human health, safety, or the environment that are expected to result in annual costs to the economy of more than $100 million. Based on information from USDA, we estimate that lowering the threshold for these analyses would increase the number of risk assessments and cost/benefit studies by about 200 each year. The additional costs associated with such assessments and studies range from less than $100,000 for a relatively routine rule to several million dollars for a major regulatory change. CBO estimates that most of the additional work would cost $150,000 to $250,000 per analysis, or an additional $30 million to $50 million annually for the department.

The cost to the Department of Transportation (DOT) of implementing Title III of H.R. 9 also could be large. The agency currently spends about $300 million annually on formal rule-making proceedings. We cannot estimate the additional costs the bill would impose on DOT because the agency is currently unclear about how to implement the legislation. The type of risk assessments and characterizations conducted by DOT are generally quite different from the type defined in Title III.

Based on information from the Food and Drug Administration (FDA), CBO estimates that the requirements in Title III of the bill

would add about $20 million annually to the agency's current spending on pre-market regulatory activities. The agency estimates that the additional analysis required by the bill would add an average of about $700,000 to an additional 25 rules each year.

The Department of Energy (DOE) also would incur additional costs to implement Title III of H.R. 9. CBO has been unable to quantify the impact, but we expect that the incremental cost of risk assessment on both the environment, safety, and health program and the environmental management program would be significant, perhaps hundreds of millions of dollars.

The Department of the Interior (DOI) currently spends about $50 million per year for regulatory analysis. This work is carried out primarily by the Office of Surface Mining, the Minerals Management Service, and the Bureau of Land Management as part of their overall regulatory enforcement activities. DOI estimates that lowering the threshold for regulatory analyses from $100 million to $25 million would significantly increase the number of analyses these agencies would have to prepare, resulting in additional annual costs of about $20 million.

Requirements in H.R. 9 also would increase costs for the Occupational Safety and Health Administration (OSHA), the Mine Safety and Health Administration (MSHA), and the Consumer Product Safety Commission (CPSC). Based on information from these agencies, CBO estimates that Title III would result in total additional costs of less than $20 million per year for these agencies.

6. Comparison with spending under current law: CBO estimates enactment of this title would add at least $250 million annually to the cost of issuing regulations.

7. Pay-as-you-go considerations: Section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985 sets up pay-as-you-go procedures for legislation affecting direct spending or receipts through 1998. Enactment of Title III of H.R. 9 could affect receipts; therefore pay-as-you-go procedures would apply to the bill.

It is possible, depending on how the provisions of Title III are interpreted and implemented, that enactment of this title could result in a loss of receipts to the federal government, such as those from commercial activities on public lands. CBO estimates that DOI and USDA collect about $1 billion annually from new sales of federal resources that could be affected by Title III. If the leasing and sale activities of these agencies were significantly delayed, some of these receipts would also be delayed.

If provisions of the title are interpreted to apply to agency actions governing the sale federal resources such as oil, gas, and timber, then additional time would be needed to prepare cost/benefit analyses and environmental impact statements associated with these activities. These additional tasks would probably delay some sales. it is also possible that the requirements of Title III could be the basis for lawsuits against an agency's leasing or sale program, thus delaying some sales and associated receipts to the federal Treasury. At this time, CBO cannot estimate the loss of receipts that could occur if these activities are delayed by enactment of this bill.

8. Estimated cost to state and local governments: How enactment of Title III would affect the budgets of state and local governments

is unclear. If regulations that would impose additional requirements on state and local governments are either delayed or precluded by the enactment of these provisions, then costs to these entities would be less. It is also possible, however, that some regulatory actions that would otherwise provide relief to state and local governments could be delayed or precluded, thereby increasing their costs for various activities. CBO has no basis for predicting the direction, magnitude, or timing of such impacts.

9. Estimate comparison: On February 15, 1995, CBO prepared a cost estimate for Title III of H.R. 9, as ordered reported by the House Committee on Commerce on February 8, 1995.

There are three major differences between the two versions of Title III. First, the Science Committee version would apply to all federal agencies that prepare risk assessment documents in connection with regulatory programs designed to protect human health, safety, or the environment; the Commerce Committee version would limit the application of Title III of the bill to 12 specified agencies. Second, the Science Committee version of the bill would not apply to permitting activities conducted by the EPA and DOI, while the Commerce Committee version would cover these activities. Finally, the Science Committee version does not include the petitioning process described in subtitle D of the Commerce Committee version of the bill. Under subtitle D of the Commerce version of Title III, individuals would be able to petition the covered agencies to address whether or not existing regulations comply with the principles of H.R. 9.

CBO was not able to estimate the costs of applying Title III of H.R. 9 to permits issued by EPA and DOI or implementing a petitioning process under subtitle D, as required by the Commerce Committee's version of the bill. Such additional costs could be significant, but they would not apply to the Science Committee's version of the bill.

By expanding the coverage of Title III of H.R. 9 beyond the 12 agencies covered in the Commerce Committee version to include all federal agencies, the Science Committee version of the bill would increase the cost to the federal government of implementing this title. CBO does not have sufficient information at this time to estimate the cost of including all federal agencies under the provisions of Title III; however, we believe that most of the costs for complying with Title III would be incurred by the 12 agencies specified in the Commerce Committee version.

10. Previous CBO estimate: None.

11. Estimate prepared by: Kim Cawley and Connie Takata.

12. Estimate approved by: Paul N. Van de Water, Assistant Director for Budget Analysis.

X. IMPACT ON INFLATION

In accordance with rule XI, clause 2(l)(4) of the Rules of the House of Representatives, this legislation is assumed to have no inflationary effect on prices and costs in the operation of the national economy.

XI. CHANGES IN EXISTING LAW

If enacted, this bill would make no change in existing law.

XII. COMMITTEE RECOMMENDATION

On February 8, 1995, a quorum being present, the Committee on Science favorably reported the bill, as amended, by a voice vote.

XIII. PROCEEDINGS FROM FULL COMMITTEE MARKUP OF TITLE III OF H.R. 9

COMMITTEE ON SCIENCE

FULL COMMITTEE MARKUP—FEBRUARY 8, 1995—AMENDMENT ROSTER

Title III—Risk assessment and cost benefit analysis for new regulations (H.R. 9, the Job Creation and Wage Enhancement Act of 1995)

Motion to adjourn the markup: Defeated: Y—22; N—25.

Motion to order the measure reported, as amended: Agreed to by voice vote.

Attendance Record.

No.	Sponsor	Description	Results
1	Mr. Walker	Amendment in the Nature of a Substitute for Title III (Original text to be used as the markup vehicle).	Adopted.
		SUBTITLE A	
2	Placeholder—Being drafted by LC.	Amendment will limit application of Title III to the Environmental Protection Agency.	Not offered.
3	Placeholder—Being drafted by LC.	Amendment will exclude USDA as one of the federal agencies covered by the bill.	Not offered.
4	Placeholder—Being drafted by LC.	Amendment will limit application of Title III to specified covered agencies, and a definition of covered agencies to include: Environmental Protection Agency, Occupational Safety and Health Administration, the Food and Drug Administration.	Not offered.
5	Ms. McCarthy	New Sec. 3002—Savings Clause	Withdrawn.
5a	Mr. Minge	Relief from the burden of unnecessary and overly complex regulations.	Unanimous consent to modify amendment was adopted. Modified amendment adopted by voice vote.
5b	Mr. Brown	Sec. 3002—Savings Clause	Defeated by a roll call vote: Y—15; N—18.
6		En bloc amendment page 36, line 11; page 45, line 16	Not offered.
6a	Mr. Brown	In section 3103(b)(1) (page 4, lines 12 and 13), strike ''in connection with Federal regulatory programs'' and insert ''in connection with major rules''.	Defeated by voice vote.
7		Amends Sec. 3103(b)—Applicability	Not offered.
8	Mr. Davis	Amends Sec. 3103(c)—Savings Provisions	Withdrawn.
9	Mr. Davis	Clarifying amendment—In section 3104(a), insert ''and rely, to the extent available and practicable, on scientific findings'' after ''inclusive of all relevant data''.	Adopted by a roll call vote: Y—36: N—9.
10	Mr. Davis	Add at the end of Sec. 3104(b) a new paragraph (3)	Withdrawn.
11	Mr. Davis	Amends Sec. 3104(b)(1)—Principles	Adopted by voice vote.
12	Mr. Barton	Mandates that agencies cannot adopt the risk recommendations of a non-U.S. based entity without performing their own independent risk assessment.	Substitute offered instead of amendment listed in the roster. Adopted by a roll call vote: Y—36; N—11.

No.	Sponsor	Description	Results
13	.....	Sound Science: Comparisons	Not offered.
13a	Mr. Olver	(Requested unanimous consent to break his amendment down into 2 separate amendments.). In section 3105(3) (page 11, line 13), insert ''‚ safety, or the environment'' after ''human health''	Adopted by voice vote.
13b	.....	Amends Sec. 3105(3)—Comparisons of Risk	Defeated by voice vote.
14	Mr. Barton	Establishes a petition process with reasonable deadlines for targeted review and revision of existing regulations to either comply with the provisions of Title III or consider new methodologies.	Withdrawn.
15	Mr. Roemer	Amends Sec. 3106—Guidelines, Plan for Assessing New Information, and Report—by adding a new subsection (f).	Withdrawn.
15a	Mr. Roemer	Amends Sec. 3107—Research and Training in Risk Assessment.	Adopted by voice vote.
16	.....	New Sec. 3107—Research and Training in Risk Assessment	Not offered.
17	.....	Amends Sec. 3107—Definitions	Not offered.
18	.....	New Sec. 3108—Study of Comparative Risk Analysis	Redrafted.
18a	Mr. Roemer	Amends Sec. 3107—Study of Comparative Risk Analysis	Adopted by voice vote.
19	.....	En bloc amendment ''Cost-Benefit/Certification: Substitute''	Not offered.
	Mr. Tanner	End of Title III, Subtitle A, Section 3103—Language with regard to the Department of Defense.	Withdrawn.
	Mr. Bartlett	Perfecting amendment	Adopted by voice vote.
	Mr. Olver	Strike pages 15, lines 9 through 21 and insert the following: (3) Best Estimates.	Unanimous consent to add 2 words to the text—''agreed to.'' Defeated by voice vote.
	Mr. Tanner	At the end of title III, subtitle A, section 3103, subsection b(3)(a)(i) (page 7, at the end of line 6, add the following phrase:) ''or to be necessary to maintain military readiness.''.	Adopted by voice vote.
	Mr. Minge	En bloc amendment—Exempts the U.S. Dept. of Agriculture	Defeated by voice vote.
	Ms. Lofgren	Risks to Particular Groups	Defeated by voice vote.
	Mr. Traficant	Amendment to define ''non-United States-based entity''	Withdrawn.
		SUBTITLE B	
20	Mr. Davis	In section 3201(a), insert after paragraph (1) the following new paragraphs (2) through (6) (and redesignate subsequent paragraphs accordingly).	Adopted by voice vote.
21	.....	At the end of Sec. 3201(a)(1), insert: ''In any situation in which benefits or costs cannot be quantified, qualitative measures should be provided''.	Not offered.
22	Mr. Wamp	Amends Sec. 3201(a)(3)	Adopted by voice vote.
23	Mr. Davis	En bloc amendment—Sec. 3201(b) and Sec. 3201(b) new subsection (c)—Limitation.	Withdrawn.
24	.....	Amends Sec. 3201 to request a ''Report to Congress''	Not offered.
25	.....	Page 48, line 11, strike ''and indirect''	Not offered.
26	Ms. McCarthy	En bloc amendment—page 48, 52	Not offered.
27	Mr. Barton	New Sec. 3202—Judicial Review Provides for judicial review of the cost-benefit analyses mandated by Title III. The courts would be able to declare any agency action unlawful if it does not comply with H.R. 9 and could grant injunctive relief.	Not offered.
	Ms. Jackson Lee	Further refinement of the definition of the words ''major rule.''.	Withdrawn.
	Mr. Olver	Strike paragraph (f)(1) of Sec. 3201	Defeated by a roll call vote; Y—12; N—31.
		SUBTITLE C	
28	Mr. Roemer	Amends Sec. 3301—Peer Review Program—(a) through (f) .	Substitute amendment offered instead of amendment listed in the roster—Withdrawn.
29	Mr. Doggett	Amends Sec. 3301—Peer Review Program	Defeated by a roll call vote; Y—16; N—26.

No.	Sponsor	Description	Results
	Mr. Boehlert	En bloc amendment—Establishes	
	Mrs. Morella	Prioritization of Hazard Reduction	Adopted by voice vote.
		SUBTITLE D	
30	Mr. Geren	New Subtitle D—Agency Priorities. Sec. 3401—Agency Program Goals.	Withdrawn.
31	Mr. Roemer	New Subtitle D—Agency Priorities. Sec. 3401—Agency Program Goals.	Not offered.
32	Mr. Tanner	New Subtitle D—Other provisions. Sec. 3401—National Security Waiver.	Not offered.
33		New Subtitle D—General Provisions. Sec. 3401—Judicial Review.	Not offered.
34	Mr. Doggett	New Subtitle IV—Sunset. Sec. 3401—Sunset. This title shall cease to be in effect on January 3, 2000.	Defeated by a roll call vote: Y—13; N—29.
	Mr. Roemer	Amends Sec. 3401—Judicial Review	Defeated by a roll call vote: Y—16; N—27.
	Mr. Barton	Subtitle D—Agency Priorities	Defeated by a division vote: Y—15; N-25.

ATTENDANCE RECORD COMMITTEE MARKUP OF H.R. 9, TITLE III

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
2369	52411	Mr. Walker, PA	X				
2300	56161	Mr. Brown, CA	X				
2332	55101	Mr. Sensenbrenner, WI	X				
2236	56673	Mr. Hall, TX	X				
2246	53665	Mr. Boehlert, NY	X				
2446	55261	Mr. Traficant, OH	X				
2159	53515	Mr. Fawell, IL	X				
2432	52031	Mr. Hayes, LA	X				
106	55341	Mrs. Morella, MD	X				
1127	54714	Mr. Tanner, TN	X				
2452	52011	Mr. Curt Weldon, PA	X				
2448	55071	Mr. Geren, TX	X				
2338	52415	Mr. Rohrabacher, CA	X				
407	53915	Mr. Roemer, IN	X				
2404	56316	Mr. Schiff, NM	X				
236	54801	Mr. Cramer, AL		X			
2264	52002	Mr. Barton, TX	X				
1410	58171	Mr. Barcia, MI	X				
1034	51986	Mr. Calvert, CA	X				
217	56411	Mr. McHale, PA	X				
1724	51880	Mr. Baker, CA	X				
325	58220	Ms. Harman, CA	X				
322	52721	Mr. Bartlett, MD	X				
1123	58885	Ms. Johnson, TX	X				
1717	53831	Mr. Ehlers, MI	X				
1415	52331	Mr. Minge, MN	X				
423	53271	Mr. Wamp, TN	X				
1027	55335	Mr. Olver, MA	X				
216	53671	Mr. Dave Weldon, FL	X				
1039	51313	Mr. Hastings, FL	X				
1429	55301	Mr. Graham, SC	X				
1116	56261	Ms. Rivers, MI	X				
115	52635	Mr. Salmon, AZ	X				
1232	54535	Ms. McCarthy, MO	X				
415	51492	Mr. Davis, VA	X				
1032	55401	Mr. Ward, KY	X				
417	56565	Mr. Stockman, TX	X				
118	53072	Ms. Lofgren, CA	X				
425	52472	Mr. Gutknecht, MN	X				
126	54865	Mr. Doggett, TX	X				
1216	53601	Mrs. Seastrand, CA	X				

ATTENDANCE RECORD COMMITTEE MARKUP OF H.R. 9, TITLE III—Continued

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
1218 ...	52135	Mr. Doyle, PA	X				
1319 ...	56216	Mr. Tiahrt, KS	X				
1520 ...	53816	Ms. Jackson=Lee, TX	X				
410	52211	Mr. Largent, OK	X				
1419 ...	52271	Mr. Luther, MN	X				
114	56831	Mr. Hilleary, TN	X				
1114 ...	52311	Mrs. Cubin, WY	X				
506	55792	Mr. Foley, FL	X				
509	51976	Mrs. Myrick, NC	X				
		Total	49	1			

MOTION TO ADJOURN BY MR. BROWN

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not voting
2369 ...	52411	Mr. Walker, PA				X	
2300 ...	56161	Mr. Brown, CA			X		
2332 ...	55101	Mr. Sensenbrenner, WI				X	
2236 ...	56673	Mr. Hall, TX			X		
2246 ...	53665	Mr. Boehlert, NY					
2446 ...	55261	Mr. Traficant, OH			X		
2159 ...	53515	Mr. Fawell, IL				X	
2432 ...	52031	Mr. Hayes, LA			X		
106	55341	Mrs. Morella, MD				X	
1127 ...	54714	Mr. Tanner, TN			X		
2452 ...	52011	Mr. Curt Weldon, PA				X	
2448 ...	55071	Mr. Geren, TX			X		
2338 ...	52415	Mr. Rohrabacher, CA				X	
407	53915	Mr. Roemer, IN			X		
2404 ...	56316	Mr. Schiff, NM				X	
236	54801	Mr. Cramer, AL					
2264 ...	52002	Mr. Barton, TX				X	
1410 ...	58171	Mr. Barcia, MI			X		
1034 ...	51986	Mr. Calvert, CA				X	
217	56411	Mr. McHale, PA			X		
1724 ...	51880	Mr. Baker, CA				X	
325	58220	Ms. Harman, CA			X		
322	52721	Mr. Bartlett, MD				X	
1123 ...	58885	Ms. Johnson, TX			X		
1717 ...	53831	Mr. Ehlers, MI					
1415 ...	52331	Mr. Minge, MN			X		
423	53271	Mr. Wamp, TN				X	
1027 ...	55335	Mr. Olver, MA			X		
216	53671	Mr. Dave Weldon, FL				X	
1039 ...	51313	Mr. Hastings, FL			X		
1429 ...	55301	Mr. Graham, SC				X	
1116 ...	56261	Ms. Rivers, MI			X		
115	52635	Mr. Salmon, AZ				X	
1232 ...	54535	Ms. McCarthy, MO			X		
415	51492	Mr. Davis, VA				X	
1032 ...	55401	Mr. Ward, KY			X		
417	56565	Mr. Stockman, TX				X	
118	53072	Ms. Lofgren, CA			X		
425	52472	Mr. Gutknecht, MN				X	
126	54865	Mr. Doggett, TX			X		
1216 ...	53601	Mrs. Seastrand, CA				X	
1218 ...	52135	Mr. Doyle, PA			X		
1319 ...	56216	Mr. Tiahrt, KS				X	
1520 ...	53816	Ms. Jackson-Lee, TX			X		
410	52211	Mr. Largent, OK				X	
1419 ...	52271	Mr. Luther, MN			X		

MOTION TO ADJOURN BY MR. BROWN—Continued

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not voting
114	56831	Mr. Hilleary, TN	.....	.....	.....	X	
1114 ...	52311	Mrs. Cubin, WY	.....	.....	.....	X	
506	55792	Mr. Foley, FL	.....	.....	.....	X	
509	51976	Mrs. Myrick, NC	.....	.....	.....	X	
		Total	.....	.....	22	25	

ORIGINAL MARKUP VEHICLE

[H.R. 9, The Job Creation and Wage Enhancement Act of 1995.—Title III, referred to the Committee on Science and, in addition, to the Committees on Commerce and Government Reform and Oversight—pages 33–52.]

TITLE III—RISK ASSESSMENT AND COST/BENEFIT ANALYSIS FOR NEW REGULATIONS

SEC. 3001. FINDINGS.

The Congress finds that:

(1) Environmental, health, and safety regulations have led to dramatic improvements in the environment and have significantly reduced human health risk; however, the Federal regulations that have led to these improvements have been more costly and less effective than they could have been; too often, regulatory priorities have not been based upon a realistic consideration of risk, risk reduction opportunities, and costs.

(2) The public and private resources available to address health, safety, and environmental concerns are not unlimited; those resources need to be allocated to address the greatest needs in the most cost-effective manner and so that the incremental costs of regulatory options are reasonably related to the incremental benefits.

(3) To provide more cost-effective and cost-reasonable protection to human health and the environment, regulatory priorities should be based upon realistic consideration of risk; the priority setting process must include scientifically sound, objective, and unbiased risk assessments, comparative risk analysis, and risk management choices that are grounded in cost-benefit principles.

(4) Risk assessment has proven to be a useful decision making tool; however, improvements are needed in both the quality of assessments and the characterization and communication of findings; scientific and other data must be better collected, organized, and evaluated; most importantly, the critical information resulting from a risk assessment must be effectively communicated in an objective and unbiased manner to decision makers, and from decision makers to the public.

(5) The public stake holders must be fully involved in the risk-decision making process. They have the right-to-know about the risks addressed by regulation, the amount of risk to be reduced, the quality of the science used to support decisions,

and the cost of implementing and complying with regulations. This knowledge will allow for public scrutiny and promote quality, integrity, and responsiveness of agency decisions.

Subtitle A—Risk Assessment and Communication

SEC. 3101. SHORT TITLE.

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

SEC. 3102. PURPOSES.

The purposes of this subtitle 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.

SEC. 3103. EFFECTIVE DATE; APPLICABILITY; SAVINGS PROVISIONS.

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

(b) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (2), this title applies to all risk assessments and risk characterizations prepared by, or on behalf of, any Federal agency in connection with Federal regulatory programs designed to protect human health, safety, or the environment.

(2) EXCEPTIONS.—(A) This title does not apply to risk assessments or risk characterizations performed with respect to either of the following:

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

(ii) A screening analysis, including a screening analysis for purposes of product regulation, product reregistration, or premanufacturing notices.

(B) No analysis shall be treated as a screening analysis for purposes of subparagraph (A) if the results of such analyses are used either—

(i) as the basis for imposing restrictions on substances or activities, or

(ii) to characterize a positive finding of risks from substances or activities in any final agency document made available to the general public.

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

(c) SAVINGS PROVISIONS.—Nothing in this subtitle shall be construed to modify any statutory standard or requirement designed to protect health, safety, or the environment. Nothing in this subtitle 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 title shall be construed to require the disclosure of any trade secret or other confidential information.

SEC. 3104. PRINCIPLES FOR RISK ASSESSMENT.

(a) IN GENERAL.—The head of each Federal agency shall apply the principles set forth in subsection (b) when preparing risk assessments in order to assure that such risk assessments and all of their components distinguish scientific findings from other considerations and are, to the maximum extent feasible, scientifically objective, unbiased, and inclusive of all relevant data. 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.

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

(1) When assessing human health risks, a risk assessment shall consider and discuss both laboratory and 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 assessment shall include discussion of possible reconciliation of conflicting information, and as appropriate, differences in study designs, comparative physiology, routes of exposure, bioavailability, pharmacokinetics, and any other relevant factor.

(2) Where a risk assessment involves selection of any significant assumption, inference, or model, the Federal agency preparing the assessment shall—

(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.

SEC. 3105. PRINCIPLES FOR RISK CHARACTERIZATION AND COMMUNICATION.

In characterizing risk in any risk assessment document, regulatory proposal or decision, report to Congress, or other document which is made available to the public, each Federal agency characterizing the risk shall comply with each of the following:

(1) ESTIMATES OF RISK.—The head of such agency 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 and scientifically appropriate, 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 department, agency, or instrumentality); and

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

In addition to such best estimate or estimates, the Federal agency may present plausible upper-bound or conservative estimates in conjunction with plausible lower bounds estimates. Where appropriate, the Federal agency may present, in lieu of a single best estimate, multiple estimates based on assumptions, inferences, or models which are equally plausible, given current scientific understanding. To the extent practical and appropriate, the Federal agency shall provide descriptions of the distribution and probability of risk estimates to reflect differences in exposure variability in populations and uncertainties.

(2) EXPOSURE SCENARIOS.—The Federal agency 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.—To the extent feasible, the Federal agency shall provide a statement that places the nature and magnitude of risks to human health in context. Such statement shall include appropriate comparisons with estimates of risks that are familiar to and routinely encountered by the general public as well as other risks. The statement shall identify relevant distinctions among categories of risk and limitations to comparisons.

(4) SUBSTITUTION RISKS.—When a Federal agency provides a risk assessment or risk characterization for a proposed or final regulatory action, such assessment or characterization shall include a statement of any significant substitution risks to human health, where information on such risks has been provided to the agency.

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

(A) a Federal agency provides a public comment period with respect to a risk assessment or regulation,

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

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

the agency shall present such summary in connection with the presentation of the agency's risk assessment or the regulation.

SEC. 3106. GUIDELINES, PLAN FOR ASSESSING NEW INFORMATION, AND REPORT.

(a) GUIDELINES.—Within 15 months after the date of enactment of this subtitle, the President shall issue guidelines for Federal agencies consistent with the risk assessment and characterization principles set forth in sections 3104 and 3105 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) PLAN.—Within 18 months after the date of enactment of this subtitle, each Federal agency shall publish a plan to review and revise any risk assessment published prior to the expiration of such 18-month period if the agency determines that significant new information or methodologies are available that could significantly alter the results of the prior risk assessment. The plan shall provide procedures for receiving and considering new information and risk assessments from the public. The plan may set priorities for review and revision of risk assessments based on factors such Federal agency considers appropriate.

(c) REPORT.—Within 3 years after the enactment of this subtitle, each Federal agency shall provide a report to the Congress evaluating the categories of policy and value judgments identified under subparagraph (C) of section 3104(b)(2).

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

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

SEC. 3107. DEFINITIONS.

For purposes of this subtitle:

(1) RISK ASSESSMENT.—The term "risk assessment" means the process of identifying hazards and quantifying or describing the degree of toxicity, exposure, or other risk they pose for exposed individuals, populations, or resources. Such term also refers to the document containing the explanation of how the assessment process has been applied to an individual substance, activity, or condition.

(2) RISK CHARACTERIZATION.—The term "risk characterization" means that element of a risk assessment that involves presentation of the degree of risk in any regulatory proposal or decision, report to Congress, or other document which is made available to the public. The term includes discussions of uncertainties, conflicting data, estimates, extrapolations, inferences, and opinions.

(3) BEST ESTIMATE.—The term "best estimate" means an estimate which, to the extent feasible and scientifically appropriate, is based on one of the following:

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

(B) An approach 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 increased risk to human health, safety, or the environment from a regulatory option designed to decrease other risks.

(5) 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.

Subtitle B—Analysis of Risk Reduction Benefits and Costs

SEC. 3201. ANALYSIS OF RISK REDUCTION BENEFITS AND COSTS.

(a) IN GENERAL.—Except as provided in subsection (b), the President shall require each executive branch agency to prepare the following for each major rule designed to protect human health, safety, or the environment that is proposed or promulgated by the agency after the date of enactment of this Act:

(1) For each such proposed or promulgated rule, an assessment of incremental costs and incremental risk reduction or other benefits associated with each significant regulatory alternative considered by the agency in connection with the rule or proposed rule.

(2) For each such proposed or promulgated rule, to the extent feasible, a comparison of any human health, safety, or environmental risks addressed by the regulatory alternatives to other risks chosen by the head of the agency, including at least 3 other risks regulated by the agency and to at least 3 other risks with which the public is familiar.

(3) For each such proposed or promulgated rule, a statement of other human health risks potentially posed by implementing or complying with the regulatory alternatives, including substitution risks.

(4) For each final rule, an assessment of the costs and risk reduction or other benefits associated with implementation of, and compliance with, the rule.

(5) For each final rule, a certification by the head of the agency of each of the following:

(A) A certification that the assessment under paragraph (4) is based on an objective and unbiased scientific and economic evaluation of all significant and relevant information provided to the agency by interested parties relating to the costs, risks, and risk reduction or other benefits addressed by the rule. Such information shall have been subjected to peer review to the extent required by section 3301.

(B) A certification that the rule will substantially advance the purpose of protecting human health or the envi-

ronment, as applicable, against the risk addressed by the rule.

(C) A certification that the rule will produce benefits to human health or the environment that will justify the costs incurred by local and State governments, the Federal Government, and other public and private entities as a result of implementation of and compliance with the rule, as determined under paragraph (1).

(D) A certification that there is no regulatory alternative that is allowed by the statute under which the regulation is promulgated that would achieve an equivalent reduction in risk in a more cost-effective manner, along with a brief explanation of why other regulatory alternatives that were considered by the head of the agency were found to be less cost-effective.

(b) PUBLICATION.—For each major rule referred to in subsection (a) the head of each agency shall publish in a clear and concise manner in the Federal Register along with the proposed or final regulation, or otherwise make publicly available, the information required to be prepared under subsection (a) of this section.

(c) DEFINITIONS.—For purposes of this section:

(1) COSTS.—The term "costs" includes the direct and indirect costs to the United States government, costs to State and local governments, and costs to the private sector, of implementing and complying with a regulatory action.

(2) MAJOR RULE.— The term "major rule" means any regulation that is likely to result in one or more of the following:

(A) An annual effect on the economy of $25,000,000 or more.

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

(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 or export markets.

Subtitle C—Peer Review

SEC. 3301. PEER REVIEW PROGRAM.

(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 and economic assessments used by the agency. Such program shall be applicable across the agency and—

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

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

(3) shall not exclude peer reviewers merely because they represent entities that may have a potential interest in the out-

come, provided that interest is fully disclosed to the agency; and

(4) shall provide open opportunity to become part of a peer review panel at a minimum by soliciting nominations through a Federal Register announcement.

(b) REQUIREMENT FOR PEER REVIEW.—Each Federal agency shall provide for peer review of scientific and economic information used for purposes of any evaluation under section 3201(a)(5)(A) or for purposes of any significant risk or cost assessment prepared in connection with a major rule. In addition, the Director of the Office of Management and Budget shall order that peer review be provided for any major risk assessment or cost assessment that may have a significant impact on public policy decisions.

(c) CONTENTS.—

(1) IN GENERAL.—Each peer review under this section shall include a report to the Federal agency concerned with respect to each of the following:

(A) An evaluation of the technical, scientific, and economic merit of the data and methods used for the assessment and analysis.

(B) A list of any considerations that were not taken into account in the assessment and analysis, but were considered appropriated by a majority of the members of the peer review panel.

(C) A discussion of the methodology used for the assessment and analysis.

(2) COMMENTS AND APPENDIX.—Each peer review report under this subsection shall include—

(A) all comments supported by a majority of the members of the peer review panel submitting the report; and

(B) an appendix which sets forth the dissenting opinions that any peer review panel member wants to express.

(3) SEPARATION OF ASSESSMENTS.—Peer review of human health, safety, environmental, and economic assessments may be separated for purpose of this subtitle.

(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 for purposes of judicial review of any final agency action.

(f) 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.

(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.

(h) MAJOR RULE DEFINED.—For purposes of this section, the term "major rule" has the same meaning as provided by section 3201(c) except that "$100,000,000" shall be substituted for "$25,000,000".

AMENDMENT IN THE NATURE OF A SUBSTITUTE FOR TITLE III OFFERED BY MR. WALKER

Page 33, strike line 6 and all that follows through page 52, line 13, and insert the following:

TITLE III—RISK ASSESSMENT AND COST/BENEFIT ANALYSIS FOR NEW REGULATIONS

SEC. 3001. FINDINGS.

The Congress finds that:

(1) Environmental, health, and safety regulations have led to dramatic improvements in the environment and have significantly reduced human health risk; however, the Federal regulations that have led to these improvements have been more costly and less effective than they could have been; too often, regulatory priorities have not been based upon a realistic consideration of risk, risk reduction opportunities, and costs.

(2) The public and private resources available to address health, safety, and environmental concerns are not unlimited; those resources need to be allocated to address the greatest needs in the most cost-effective manner and so that the incremental costs of regulatory options are reasonably related to the incremental benefits.

(3) To provide more cost-effective and costreasonable protection to human health and the environment, regulatory priorities should be based upon realistic consideration of risk; the priority setting process must include scientifically sound, objective, and unbiased risk assessments, comparative risk analysis, and risk management choices that are grounded in cost-benefit principles.

(4) Risk assessment has proven to be a useful decision making tool; however, improvements are needed in both the quality of assessments and the characterization and communication of findings; scientific and other data must be better collected, organized, and evaluated; most importantly, the critical information resulting from a risk assessment must be effectively communicated in an objective and unbiased manner to decision makers, and from decision makers to the public.

(5) The public stake holders must be fully involved in the risk-decision making process. They have the right-to-know about the risks addressed by regulation, the amount of risk to be reduced, the quality of the science used to support decisions, and the cost of implementing and complying with regulations. This knowledge will allow for public scrutiny and promote quality, integrity, and responsiveness of agency decisions.

Subtitle A—Risk Assessment and Communication

SEC. 3101. SHORT TITLE.

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

SEC. 3102. PURPOSES.

The purposes of this subtitle 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.

SEC. 3103. EFFECTIVE DATE; APPLICABILITY; SAVINGS PROVISIONS.

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

(b) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (3), this subtitle applies to all significant risk assessment documents and significant risk characterization documents prepared by, or on behalf of, or used by, any Federal agency in connection with Federal programs designed to protect human health, safety, and the environment.

(2) SIGNIFICANT RISK ASSESSMENT DOCUMENT OR SIGNIFICANT RISK CHARACTERIZATION DOCUMENT.—(A) As used in this subtitle, the terms "significant risk assessment document" and "significant risk characterization document" include, at a minimum, risk assessment documents or risk characterization documents included in, or in the administrative record for, each of the following:

(i) Any major rule, as defined in subtitle B, promulgated as part of any Federal regulatory program designed to protect human health, safety, or the environment.

(ii) Any proposed or final regulatory decision relating to decontamination or other clean-up plans for a facility.

(iii) Any report to Congress.

(iv) Placement of a substance or health effects value on the Integrated Risk Information System Database maintained by the Environmental Protection Agency.

(v) Any regulatory action to place a substance on any official list of carcinogens or toxic or hazardous substances.

Such terms also include any risk assessment or risk characterization that forms the basis of a final risk assessment or risk characterization guideline or protocol of general application.

(B) The terms "significant risk assessment document" and "significant risk characterization document" also include such

risk assessment and risk characterization documents of agency as—

(i) are provided by an agency to the public and are likely to result in an annual effect on the economy of $25,000,000 or more; or

(ii) the head of the agency may identify, in consultation with the Director of the Office of Management and Budget.

(C) Within 15 months after the date of the enactment of this Act, each agency administering programs 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 to be considered significant risk assessment documents or significant risk characterization documents for purposes of this subtitle. In establishing such categories, the head of the agency shall consider—

(i) the benefits of consistent compliance by documents in the categories concerned with the principles under sections 3104 and 3105;

(ii) the administrative burdens of including documents in various categories concerned with the principles under section 3104 and 3105;

(iii) the need to make expeditious administrative decisions regarding documents in various 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; and

(v) such other factors as may be appropriate.

(3) EXCEPTIONS.—(A) This subtitle does not apply to the following:

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

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

(iii) Any individual food, drug, or other product label or to any risk characterization appearing on any such label, if the individual product label is required by law to be approved by a Federal agency prior to use.

(iv) Any health, safety, or environmental inspections or individual facility permitting actions.

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

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

SEC. 3104. PRINCIPLES FOR RISK ASSESSMENT.

(a) IN GENERAL.—The head of each Federal agency shall apply the principles set forth in subsection (b) in order to assure that risk assessments and all of their components distinguish scientific findings from other considerations and are, to the maximum extent feasible, scientifically objective, unbiased, and inclusive of all relevant data. 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.

(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 laboratory and 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 include discussion of possible reconciliation of conflicting information, and as appropriate, differences in study designs, comparative physiology, routes of exposure, bioavailability, pharmacokinetics, and any other relevant factor.

(2) Where a significant risk assessment document involves selection of any significant assumption, inference, or model, a Federal agency shall—

(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.

SEC. 3105. PRINCIPLES FOR RISK CHARACTERIZATION AND COMMUNICATION.

In a significant risk assessment document, each Federal agency shall assure compliance with each of the following:

(1) ESTIMATES OF RISK.—The risk characterization shall describe the populations or natural resources which are the subject of the risk assessment. If a numerical estimate of risk is provided, the agency shall, to 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 department, agency, or instrumentality); and

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

In addition to such best estimate or estimates, the risk characterization may present plausible upper-bound or conservative estimates in conjunction with plausible lower bounds esti-

mates. Where appropriate, the risk characterization may present, in lieu of a single best estimate, multiple estimates based on assumptions, inferences, or models which are equally plausible, given current scientific understanding. To the extent practical and appropriate, the characterization shall provide descriptions of the distribution and probability of risk estimates to reflect differences in exposure variability or sensitivity in populations and uncertainties.

(2) EXPOSURE SCENARIOS.—Where relevant, the risk characterization 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 Federal agency shall provide a statement that places the nature and magnitude of risks to human health in context. Such statement shall include appropriate comparisons with estimates of greater and lesser risks that are familiar to and routinely encountered by the general public as well as other risks. The statement shall identify relevant distinctions among categories of risk and limitations to comparisons.

(4) SUBSTITUTION RISKS.—Each significant risk assessment or risk characterization document referred to in section 3103(b) shall include a statement of any significant substitution risks to human health, where information on such risks is available to the agency.

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

(A) a Federal agency provides a public comment period with respect to a significant risk assessment document, or

(B) a commenter provides a significant risk assessment document, and a summary of results of such risk assessment, and

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

the agency shall present such summary in connection with the presentation of the agency's risk assessment document, risk characterization document, or the regulation. 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.

SEC. 3106. GUIDELINES, PLAN FOR ASSESSING NEW INFORMATION, AND REPORT.

(a) GUIDELINES.—Within 15 months after the date of enactment of this subtitle, the President shall issue guidelines for Federal agencies consistent with the risk assessment and characterization principles set forth in sections 3104 and 3105 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) PLAN.—Within 18 months after the date of the enactment of this subtitle, each Federal agency shall publish a plan to review and, where appropriate, revise any significant risk assessment document or significant risk characterization document published prior to the expiration of such 18-month period if, based on information available at the time of such review, the head of the agency determines that the application of the principles set forth in sections 3104 and 3105 would be likely to significantly alter the results of the prior risk assessment or risk characterization. The plan shall provide procedures for receiving and considering new information and risk assessments from the public. The final plan shall set priorities for review, and where appropriate, revision of risk assessment documents and risk characterization documents based on the potential to more efficiently focus national economic resources within Federal programs designed to protect human health, safety, or the environment on the most important priorities and on such other factors as such Federal agency considers appropriate.

(c) REPORT.—Within 3 years after the enactment of this subtitle, each Federal agency shall provide a report to the Congress evaluating the categories of policy and value judgments identified under subparagraph (C) of section 3104(b)(2).

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

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

SEC. 3107. DEFINITIONS.

For purposes of this subtitle:

(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, or describing the degree of toxicity, exposure, or other risk they pose for exposed individuals, populations, or resources.

(2) RISK CHARACTERIZATION DOCUMENT.—The term "risk characterization document" means a document quantifying or describing the degree of toxicity, exposure, or other risk they pose for exposed individuals, populations, or resources.

(3) BEST ESTIMATE.—The term "best estimate" means an estimate which is based 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 option designed to decrease other risks.

(5) FEDERAL AGENCY.—As used in this title, 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.

(6) DOCUMENT.—The term "document" includes material stored in electronic or digital form.

(7) PREPARE.—As used in this title, the term "prepare", when referring to risk assessment, risk characterizations, or analyses of risk reduction benefits and costs, includes both the preparation or use of such a document by an agency.

Subtitle B—Analysis of Risk Reduction Benefits and Costs

SEC. 3201. ANALYSIS OF RISK REDUCTION BENEFITS AND COSTS.

(a) IN GENERAL.—Except as provided in section 3103(b)(3) and subsection (d), the President shall require each Federal agency to prepare the following for each major rule designed to protect human health, safety, or the environment that is proposed or promulgated by the agency after the date of enactment of this Act:

(1) For each such proposed or promulgated rule, an assessment of incremental costs and incremental risk reduction or other benefits associated with each significant regulatory alternative considered by the agency in connection with the rule or proposed rule. Costs and benefits shall be quantified to the extent feasible and appropriate and may otherwise be qualitatively described.

(2) For each such proposed or promulgated rule, to the extent feasible, a comparison of any human health, safety, or environmental risks addressed by the regulatory alternatives to other greater or lesser risks chosen by the head of the agency, including at least 3 other risks regulated by the agency and to at least 3 other risks with which the public is familiar.

(3) For each final rule, an assessment of the costs and risk reduction or other benefits associated with implementation of, and compliance with, the rule.

(4) For each final rule, a certification by the head of the agency of each of the following:

(A) A certification that the assessments under subtitle B are based on an objective and unbiased scientific and economic evaluation of all significant and relevant information and risk assessments provided to the agency by interested parties relating to the costs, risks, and risk reduction or other benefits addressed by the rule.

(B) A certification that incremental risk reduction or other benefits of any regulatory or non-regulatory option chosen will be likely to justify, and be reasonably related to, the incremental costs incurred by State, local, and tribal governments, the Federal Government, and other public and private entities.

(C) A certification that no regulatory or non-regulatory alternative considered by the agency or proposed to the agency during or prior to the public comment period would be more likely to achieve a substantially equivalent reduction in risk in a more cost-effective manner or would be more likely to provide flexibility to the regulated entities in achieving the objective of the regulation, along with a brief explanation of why other regulatory or non-regulatory alternatives that were considered by or proposed to the agency were found to be less cost-effective or less flexible.

(b) PUBLICATION.—For each major rule referred to in subsection (a) each agency shall publish in a clear and concise manner in the Federal Register along with the proposed and final regulation, or otherwise make publicly available, the information required to be prepared under subsection (a) of this section. The agency shall publish in the Federal Register, along with the final regulation, the certifications required by subsection (a).

(c) DEFINITIONS.—For purposes of this section:

(1) COSTS.—The term "costs" includes the direct and indirect costs to the United States Government, to State, local, and tribal governments, and to private-sector prices, wage earners, consumers, and the economy, of implementing and complying with a regulatory action.

(2) BENEFIT.—The term "benefit" means the social and economic benefits that are expected to result directly or indirectly from implementation of a rule or an alternative to a rule.

(3) MAJOR RULE.—The term "major rule" means any regulation that is likely to result in an annual increase in costs of $25,000,000 or more.

(d) SUBSTANCES AND PRODUCTS.—This section and section 3301 do not apply to any action authorizing or approving any individual substance or product. No government action shall be treated as authorizing or approving any individual substance or product for the purposes of this subsection if the results of such action are used as the basis of imposing bans, cancellations, suspensions, or revocations of any previously marketed or approved substance or product.

(e) COST/BENEFIT ANALYSIS GUIDANCE.—Within 15 months after the date of the enactment of this title, the Office of Management and Budget shall issue regulations for Federal agencies, consistent with this title, governing the development and preparation of analyses of risk reduction benefits and costs.

(f) APPLICABILITY.—

(1) IN GENERAL.—Notwithstanding any other provision of law, the requirements of this section shall supplement and, to the extent there is a conflict, supersede the decisional criteria for rulemaking otherwise applicable under the statute pursuant to which the rule is promulgated.

(2) SUBSTANTIAL EVIDENCE.—Notwithstanding any other provision of Federal law, no major rule shall be promulgated by any Federal agency pertaining to the protection of health, safety, or the environment unless the requirements of section 3201(a) are met and the certifications required therein are supported by substantial evidence of the rulemaking record.

(g) TRANSITIONAL PLAN.—Within 180 days after the date of the enactment of this title, Federal agencies, with guidance from the Office of Management and Budget, shall develop transition plans to assist the agencies, the public, and the regulated community in the implementation of this title, including any new requirements or procedures needed to supplement prior agency practice.

(h) REPORTS TO CONGRESS.—Federal agencies shall report to Congress annually whether their implementation of this title has created any significant regulatory or program management complications resulting from any differences between the certification provisions of this title and the decisional criteria for rulemaking that otherwise would have been applicable under other statute.

Subtitle C—Peer Review

SEC. 3301. PEER REVIEW PROGRAM.

(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 and economic assessments used by the agency. Such program shall be applicable across the agency and—

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

(2) may provide for differing levels of peer review 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.—Each Federal agency shall provide for peer review of any evaluation under section 3201(a)(5)(A) or for purposes of any significant risk or cost assessment prepared in connection with any regulation that is likely to result in an annual increase in costs of $100,000,000 or more (other than any regulation or other action taken by an agency to authorize or approve any individual substance or product). 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.—

(1) IN GENERAL.—Each peer review under this section shall include a report to the Federal agency concerned with respect to each of the following:

(A) An evaluation of the technical, scientific, and economic merit of the data and methods used for the assessment and analysis.

(B) A list of any considerations that were not taken into account in the assessment and analysis, but were considered appropriate by a majority of the members of the peer review panel.

(C) A discussion of the methodology used for the assessment and analysis.

(2) COMMENTS AND APPENDIX.—Each peer review report under this subsection shall include—

(A) all comments supported by a majority of the members of the peer review panel submitting the report; and

(B) an appendix which sets forth the dissenting opinions that any peer review panel member wants to express.

(3) SEPARATION OF ASSESSMENTS.—Peer review of human health, safety, environmental, and economic assessments may be separated for purpose of this subtitle.

(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 for purposes of judicial review of any final agency action.

(f) 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.

(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.

Subtitle D—Other Provisions

SEC. 3401. JUDICIAL REVIEW.

Compliance with the requirements of this title shall be reviewable pursuant to the Administrative Procedures Act.

AMENDMENT TO H.R. 9

[Placeholder: Text being drafted by Leg Counsel. Amendment will limit applications of Title III to the Environmental Protection Agency.]

AMENDMENT TO H.R. 9 OFFERED BY MR. MINGE

[Placeholder: Text being drafted by Legislative counsel. Amendment will exclude USDA as one of the federal agencies covered by the bill.]

[Placeholder: Text being drafted by Leg Counsel. Amendment will limit application of Title III to specified covered agencies, and a definition of covered agencies to include: Environmental Protection Agency, Occupational Safety and Health Administration, the Food and Drug Administration, perhaps others.]

AMENDMENT TO H.R. 9 OFFERED BY MS. MCCARTHY

SEC. 3002. SAVINGS CLAUSE.

Nothing in this title shall create an obligation or burden on any State or local government of change of affect any State law or regulatory requirement or otherwise impose any financial burden any State or local government.

AMENDMENT OFFERED BY MR. MINGE TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE FOR TITLE III OFFERED BY MR. WALKER

At the end of section 3001 (page 3, after line 4), add the following new paragraph:

(6) Although risk assessment is one important method to improve regulator decision-making, other approaches to secure prompt relief from the burden of unnecessary and overly complex regulations will also be necessary. [The productivity and competitiveness of American businesses will be enhanced by implementing a variety of measures to simplify Federal regulatory requirements and reduce transaction costs.]

AMENDMENT OFFERED BY MR. BROWN OF CALIFORNIA TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE FOR TITLE III OFFERED BY MR. WALKER

After section 3001 (page 3, after line 4), add the following new section:

SEC. 3002. SAVINGS CLAUSE.

Nothing in this title shall be construed to modify any statutory standard or requirement designed to protect health, safety, or the environment or to change the factors that an agency is authorized to consider in promulgating a regulation pursuant to any statute, or shall delay any action required to meet a deadline imposed by a statute or a court.

AMENDMENT OFFERED BY MR. BROWN SECTION 3002

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
2369	52411	Mr. Walker, PA				X	
2300	56161	Mr. Brown, CA			X		
2332	55101	Mr. Sensenbrenner, WI					
2236	56673	Mr. Hall, TX					
2246	53665	Mr. Boehlert, NY					
2446	55261	Mr. Traficant, OH			X		
2159	53515	Mr. Fawell, IL				X	
2432	52031	Mr. Hayes, LA					
106	55341	Mrs. Morella, MD				X	
1127	54714	Mr. Tanner, TN			X		
2452	52011	Mr. Curt Weldon, PA				X	
2448	55071	Mr. Geren, TX					
2338	52415	Mr. Rohrabacher, CA				X	
407	53915	Mr. Roemer, IN			X		

AMENDMENT OFFERED BY MR. BROWN SECTION 3002—Continued

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
2404	56316	Mr. Schiff, NM				X	
236	54801	Mr. Cramer, AL					
2264	52002	Mr. Barton, TX				X	
1410	58171	Mr. Barcia, MI					
1034	51986	Mr. Calvert, CA				X	
217	56411	Mr. McHale, PA			X		
1724	51880	Mr. Baker, CA				X	
325	58220	Ms. Harman, CA					
322	52721	Mr. Bartlett, MD				X	
1123	58885	Ms. Johnson, TX			X		
1717	53831	Mr. Ehlers, MI				X	
1415	52331	Mr. Minge, MN			X		
423	53271	Mr. Wamp, TN				X	
1027	55335	Mr. Olver, MA			X		
216	53671	Mr. Dave Weldon, FL				X	
1039	51313	Mr. Hastings, FL					
1429	55301	Mr. Graham, SC				X	
1116	56261	Ms. Rivers, MI			X		
115	52635	Mr. Salmon, AZ				X	
1232	54535	Ms. McCarthy, MO			X		
415	51492	Mr. Davis, VA				X	
1032	55401	Mr. Ward, KY					
417	56565	Mr. Stockman, TX					
118	53072	Ms. Lofgren, CA					
425	52472	Mr. Gutknecht, MN					
126	54865	Mr. Doggett, TX			X		
1216	53601	Mrs. Seastrand, CA					
1218	52135	Mr. Doyle, PA			X		
1319	56216	Mr. Tiahrt, KS				X	
1520	53816	Ms. Jackson-Lee, TX			X		
410	52211	Mr. Largent, OK				X	
1419	52271	Mr. Luther, MN			X		
114	56831	Mr. Hilleary, TN					
1114	52311	Mrs. Cubin, WY					
506	55792	Mr. Foley, FL					
509	51976	Mrs. Myrick, NC					
		Total			15	18	

AMENDMENT TO H.R. 9 OFFERED BY

Page 36, line 11, strike "in connection with Federal regulatory programs" and insert in lieu thereof "in connection with major rules."

Page 45, line 16, insert at the end of section 3107 the following new subsection:

> "(6) MAJOR RULE—The term "major rule" means any regulation that is likely to result in an annual effect on the economy of $100,000,000 or more."

AMENDMENT OFFERED BY MR. BROWN OF CALIFORNIA TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE OFFERED BY MR. WALKER

In section 3103(b)(1) (page 4, lines 12 and 13), strike "in connection with Federal regulatory programs" and insert "in connection with major rules".

AMENDMENT TO H.R. 9 OFFERED BY MR.

In section 3103(b)(2)(i), strike the period and insert ''or where the head of the agency determines that compliance with this subtitle could endanger human health, safety, or the environment,''.

AMENDMENT TO H.R. 9 OFFERED BY MR. DAVIS

In section 3103(c), strike ''Nothing in this subtitle shall be construed to modify any statutory standard or requirement designed to protect health, safety, or the environment.''.

AMENDMENT TO H.R. 9 OFFERED BY MR. DAVIS

In section 3104(a), insert ''and rely, to the extent available and practicable, on scientific findings'' after ''inclusive of all relevant data''.

AMENDMENT OFFERED BY MR. DAVIS TO SECTION 3104

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
2369	52411	Mr. Walker, PA			X		
2300	56161	Mr. Brown, CA				X	
2332	55101	Mr. Sensenbrenner, WI			X		
2236	56673	Mr. Hall, TX			X		
2246	53665	Mr. Boehlert, NY			X		
2446	55261	Mr. Traficant, OH			X		
2159	53515	Mr. Fawell, IL			X		
2432	52031	Mr. Hayes, LA			X		
106	55341	Mrs. Morella, MD			X		
1127	54714	Mr. Tanner, TN			X		
2452	52011	Mr. Curt Weldon, PA			X		
2448	55071	Mr. Geren, TX					
2338	52415	Mr. Rohrabacher, CA			X		
407	53915	Mr. Roemer, IN			X		
2404	56316	Mr. Schiff, NM			X		
236	54801	Mr. Cramer, AL					
2264	52002	Mr. Barton, TX			X		
1410	58171	Mr. Barcia, MI			X		
1034	51986	Mr. Calvert, CA					
217	56411	Mr. McHale, PA			X		
1724	51880	Mr. Baker, CA			X		
325	58220	Ms. Harman, CA			X		
322	52721	Mr. Bartlett, MD			X		
1123	58885	Ms. Johnson, TX				X	
1717	53831	Mr. Ehlers, MI			X		
1415	52331	Mr. Minge, MN			X		
423	53271	Mr. Wamp, TN			X		
1027	55335	Mr. Olver, MA				X	
216	53671	Mr. Dave Weldon, FL			X		
1039	51313	Mr. Hastings, FL				X	
1429	55301	Mr. Graham, SC			X		
1116	56261	Ms. Rivers, MI				X	
115	52635	Mr. Salmon, AZ			X		
1232	54535	Ms. McCarthy, MO				X	
415	51492	Mr. Davis, VA			X		
1032	55401	Mr. Ward, KY				X	
417	56565	Mr. Stockman, TX			X		
118	53072	Ms. Lofgren, CA			X		
425	52472	Mr. Gutknecht, MN			X		
126	54865	Mr. Doggett, TX				X	
1216	53601	Mrs. Seastrand, CA			X		
1218	52135	Mr. Doyle, PA					
1319	56216	Mr. Tiahrt, KS			X		

AMENDMENT OFFERED BY MR. DAVIS TO SECTION 3104—Continued

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
1520	53816	Ms. Jackson Lee, TX				X	
410	52211	Mr. Largent, OK			X		
1419	52271	Mr. Luther, MN			X		
114	56831	Mr. Hilleary, TN			X		
1114	52311	Mrs. Cubin, WY					
506	55792	Mr. Foley, FL			X		
509	51976	Mrs. Myrick, NC			X		
		Total			36	9	

AMENDMENT TO H.R. 9 OFFERED BY MR. DAVIS

Add at the end of section 3104(b) the following new paragraph:

(3) A risk assessment shall be prepared 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.

AMENDMENT TO H.R. 9 OFFERED BY MR. DAVIS

In section 3104(b)(1), insert after "any other relevant factor" the following:

, including the availability of raw data for review. Greatest emphasis shall be placed on data that indicate a biological basis of the resulting harm in humans. Animal data shall be reviewed with regard to its relevancy to humans.

AMENDMENT TO H.R. 9 OFFERED BY MR. BARTON OF TEXAS

Page 39, after line 11, (in section 3104(b), after paragraph (2)), insert the following:

(3) 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 subtitle.

AMENDMENT OFFERED BY MR. BARTON

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
2369	52411	Mr. Walker, PA			X		
2300	56161	Mr. Brown, CA				X	
2332	55101	Mr. Sensenbrenner, WI			X		
2236	56673	Mr. Hall, TX			X		
2246	53665	Mr. Boehlert, NY					
2446	55261	Mr. Traficant, OH			X		
2159	53515	Mr. Fawell, IL			X		
2432	52031	Mr. Hayes, LA			X		
106	55341	Mrs. Morella, MD			X		
1127	54714	Mr. Tanner, TN			X		
2452	52011	Mr. Curt Weldon, PA			X		
2448	55071	Mr. Geren, TX			X		
2338	52415	Mr. Rohrabacher, CA			X		

AMENDMENT OFFERED BY MR. BARTON—Continued

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
407	53915	Mr. Roemer, IN			X		
2404	56316	Mr. Schiff, NM			X		
236	54801	Mr. Cramer, AL					
2264	52002	Mr. Barton, TX			X		
1410	58171	Mr. Barcia, MI			X		
1034	51986	Mr. Calvert, CA			X		
217	56411	Mr. McHale, PA			D		
1724	51880	Mr. Baker, CA			X		
325	58220	Ms. Harman, CA			X		
322	52721	Mr. Bartlett, MD			X		
1123	58885	Ms. Johnson, TX				X	
1717	53831	Mr. Ehlers, MI			X		
1415	52331	Mr. Minge, MN			X		
423	53271	Mr. Wamp, TN			X		
1027	55335	Mr. Olver, MA				X	
216	53671	Mr. Dave Weldon, FL			X		
1039	51313	Mr. Hastings, FL				X	
1429	55301	Mr. Graham, SC			X		
1116	56261	Ms. Rivers, MI				X	
115	52635	Mr. Salmon, AZ			X		
1232	54535	Ms. McCarthy, MO				X	
415	51492	Mr. Davis, VA			X		
1032	55401	Mr. Ward, KY				X	
417	56565	Mr. Stockman, TX			X		
118	53072	Ms. Lofgren, CA				X	
425	52472	Mr. Gutknecht, MN			X		
126	54865	Mr. Doggett, TX				X	
1216	53601	Mrs. Seastrand, CA			X		
1218	52135	Mr. Doyle, PA			X		
1319	56216	Mr. Tiahrt, KS					
1520	53816	Ms. Jackson Lee, TX				X	
410	52211	Mr. Largent, OK			X		
1419	52271	Mr. Luther, MN				X	
114	56831	Mr. Hilleary, TN			X		
1114	52311	Mrs. Cubin, WY			X		
506	55792	Mr. Foley, FL			X		
509	51976	Mrs. Myrick, NC			X		
		Total			36	11	

AMENDMENT TO H.R. 9

III. (C) SOUND SCIENCE: COMPARISONS

On page 41, line 3 following the word "health" inset: "; safety, or the environment"

On page 41, line 4 strike the sentence beginning with, "Such statement" through the end of line 9 and insert:

"Where appropriate and meaningful, such a statement shall include a comparison of risks 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 and involuntary nature of risks, and the preventability and nonpreventability of risks)."

AMENDMENT OFFERED BY MR. OLVER TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE OFFERED BY MR. WALKER

13(a) In section 3105(3) (page 11, line 13), insert ", safety, or the environment" after "human health".

13(b) In section 3105(3) (page 11, lines 13 through 19), strike "Such statement" and all that follows through the end of the paragraph and insert the following:

Where appropriate and meaningful, such a statement shall include a comparison of risks 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 and involuntary nature of risks, and the preventability and nonpreventability of risks).

AMENDMENT TO H.R. 9 OFFERED BY MR. BARTON OF TEXAS

Page 42, strike line 23 and all that follows down through line 9 on page 43 and insert the following (and redesignate subsections (c), (d), and (e) on page 43 accordingly):

(b) IN GENERAL.—(1) Within 1 year after the date of enactment of this Act the agency head shall establish procedures for accepting and considering petitions for—

(A) reviewing and revising any health or environmental effects value, such as those values in the Integrated Risk Information System (IRIS) database or any other compilation of risk, hazard or health or environmental effects information prepared by the agency that is made commonly available or is used by any Federal department, agency, or instrumentality, the States or local governments as a scientific basis for regulatory action;

(B) reviewing a risk assessment and revising it to take into consideration new information or methodologies or to comply with the requirements of this subtitle;

(C) requiring that a risk assessment or other agency scientific or technical document supporting a regulatory action be peer reviewed; or

(D) reviewing any regulation promulgated prior to the effective date of this title and revising it to comply with the requirements of this title.

(2) Such procedures be consistent with each of the following:

(A) Any interested member of the public may petition.

(B) Such petitions shall include adequate supporting documentation, including, where appropriate, new studies or other relevant information that provide the basis for a proposed revision or modified health effects value and where appropriate a summary characterization of the risk complying with the requirements of section 3105 of this title.

(3) The agency head shall respond to the petition in the Federal Register within 90 days from receipt.

(4) The agency shall accept the petition if the new information or methodologies or the application of the provisions of this title would significantly alter the result of the existing risk assessment, health effects value or regulation. If the agency head rejects the pe-

tition, the agency head shall state the reasons for doing so. If the agency head accepts the petition, he shall publish a notice in the Federal Register for comment on the substantive issues raised in the petition. The agency head shall accept and consider any relevant data of sufficient quality submitted in response to the notice.

(c) FINAL AGENCY ACTION.—(1) Within 1 year following the submission of a petition under subsection (b), the agency head shall take final action either—

(A) initiating the action requested in the petition; or

(B) denying the petition by determining that the risk assessment, health effects value or regulation should not be changed, stating in the Federal Register the reasons therefore.

(2) Rejection or denial of a petition by an agency head shall constitute final agency action and be subject to review as provided in section 700 and following of title 5 of the United States Code (the Administrative Procedures Act).

AMENDMENT TO H.R. 9 OFFERED BY MR. ROEMER

At the end of section 3106, add the following new subsection:

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

AMENDMENT OFFERED BY MR. ROEMER TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE OFFERED BY MR. WALKER

Add after section 3106 the following new section 3107 (and redesignate subsequent sections accordingly):

SEC. 3107. RESEARCH AND TRAINING IN RISK ASSESSMENT.

(a) EVALUATION.—The head of each Federal agency shall regularly and systematically evaluate risk assessment research and training needs of the such agency, including the following needs:

(1) Research to reduce data gaps or redundancies, address modelling needs, and validation of default options, particularly those common to multiple risk assessments.

(2) 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.

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

(4) Emerging and future areas of research, including research on comparative risk analysis, exposure to multiple chemicals and other stressors, noncancer endpoints, biological markers, 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. An evaluation under this paragraph shall include an estimate of the resources needed to provide necessary training and recommendations on appropriate educational risk assessment curricula.

(b) DEVELOPMENT OF STRATEGY.—The head of each Federal agency shall develop a strategy, schedule, and delegation of responsibility for carrying out research and training to meet the needs identified in subsection (a).

(c) REPORT.—Not later than 120 days after the date of the enactment of this Act, the head of each Federal 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 Federal agency shall report to the Congress whenever the evaluations, strategy, and schedule are updated or modified.

AMENDMENT TO H.R. 9

VI. (A) RESEARCH AND TRAINING IN RISK ASSESSMENT

On page 43, line 24 insert the following new Section 3107 and renumber subsequent sections accordingly:

SEC. 3107. RESEARCH AND TRAINING IN RISK ASSESSMENT.

(1) EVALUATION.—The head of each covered agency shall regularly and systematically evaluate risk assessment research and training needs of the Environmental Protection Agency, including the following needs:

(A) Research to reduce data gaps or redundancies, address modelling needs, and validation of default options, particularly those common to multiple risk assessments.

(B) 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.

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

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

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

(2) DEVELOPMENT OF STRATEGY.—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 paragraph (1).

(3) REPORT.—Not later than 120 days 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 paragraph (1) and the strategy and schedule developed under paragraph (2). The Administrator shall report to the Congress whenever the evaluations, strategy, and schedule are updated or modified.

III. (B) SOUND SCIENCE: DEFINITIONS

On page 44, strike line 1 through line 16 and insert:

(1) RISK ASSESSMENT.—The term "risk assessment" means a systematic process or procedure for organizing and analyzing scientific knowledge identify, characterize, and to the extent practicable quantify the potential adverse health, safety, or ecological effects of exposure of individuals, populations, habitats or ecosystems and (their associated species) to hazardous pollutants, activities, or other stressors.[1]

(2) RISK CHARACTERIZATION.—The term "risk characterization" means the final component of a risk assessment. Risk characterization involves integration of information from the first three steps of a risk assessment to develop an estimate 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 the exposure. Risk characterization should also include a full discussion of the uncertainties associated with the estimate or risk.[2]

VI. (B) COMPARATIVE RISK ASSESSMENT STUDY

Insert a new Section 3108 and renumber subsequent sections as appropriate.

SEC. 3108. 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 using comparative risk analysis to rank health and/or 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 develop and rigorously test improved methods of comparative risk analysis.

Not later than 90 days after the date of enactment of this Act, the Director, in collaboration with appropriate federal agencies shall enter into a contract with the National Research Council to provide technical guidance on approaches to using comparative risk

[1] National Research Council, "Risk Assessment in the Federal Government: Managing the Process", 1983, and National Research Council, "Science and Judgment in Risk Assessment," 1994.

[2] National Research Council, "Science and Judgment in Risk Assessment, 1994; and Council on Environmental Quality, "Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks," 1989.

analysis and other considerations in setting 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 environmental risk reduction. The study shall compare and evaluate a range of diverse environmental risks, both as to risks to and within an environmental medium and risks across environmental media.

(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 Act 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 decisionmaking in appropriate federal agencies.

AMENDMENT TO WALKER AMENDMENT IN NATURE OF A SUBSTITUTE OFFERED BY MR. ROEMER

Insert after section 3106 (page 14, line) the following new section 3107 (and redesignate subsequent sections accordingly):

SEC. 3107. STUDY OF COMPARATIVE RISK ANALYSIS.

(a) IN GENERAL.—(1) The Director of the Office of Science and Technology Policy shall conduct, or provide for the conduct of, a study using comparative risk analysis to rank health 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 develop and rigorously test improved methods of comparative risk analysis.

(2) Not later than 90 days after the date of the enactment of this Act, 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 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 environmental risk reduction. The study shall compare and evaluate a range of diverse environmental risks, both as to risks to and within an environmental medium and risks across environmental media.

(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 nontech-

nical, 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 Act 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.

V. (C) COST-BENEFIT / CERTIFICATION: SUBSTITUTE

On page 45, line 22 insert the phrase "regulatory analysis" immediately after the word "following".

On page 46, strike line 1 through page 48 line 2 and insert the following:

(b) REGULATORY ANALYSIS.—The head of each Federal agency shall ensure that any regulatory analysis that is conducted under this section includes a risk assessment and cost-benefit analysis that is performed consistently and uses reasonably obtainable and sound scientific, technical, economic, and other data. Such an analysis shall be conducted with as much specificity as practicable, of—

(1) the risk, including the effect of the risk, to human health, human safety or the environment, and any combination thereof, addressed by the regulation, including, where applicable and practicable, the health and safety risks to persons who are disproportionately exposed or particularly sensitive;

(2) the costs, including the incremental costs, associated with implementation of, and compliance with, the regulation;

(3) 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

(4) the quantitative and qualitative benefits of the regulation, including the reduction of prevention of risk expected from the regulation.

Where such a regulatory analysis is not practicable because of compelling circumstances, the head of each Federal agency shall provide an explanation in lieu of conducting an analysis under this section.

(c) EVALUATION.—For each final rule, the regulatory analysis referred to in paragraph (b) should also contain a statement that the head of the Federal agency evaluated each of the following:

(1) whether the regulation will substantially advance the purpose of protecting against the risk referred to in paragraph (b)(1); and

(2) whether the regulation will produce benefits and reduce risks to human health, human safety, or the environment, and any combination thereof, in a cost-effective manner as a result of the implementation of and compliance with the regulation, by local, State, and Federal Government and other public and private entities, as estimated in paragraph (b)(2).

(2) MAJOR RULE.—As used in this section, the term "major rule" means any regulation that is likely to have an annual impact on the economy of the United States $100,000,000 in 1995 dollars.

AMENDMENT OFFERED BY MR. TANNER TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE OFFERED BY MR. WALKER

At the end of title III, subtitle A, section 3103, subsection (b)(3)(A) (Page 7, after line 18), add the following new clause:

(v) Any situation or circumstance where the Secretary of Defense or the Secretary of a military department determines that compliance is not consistent with national security interests and missions. The Secretary of Defense or the Secretary of a military department shall promptly notify Congress of any such determinations and the reasons for such determinations.

AMENDMENT OFFERED BY MR. BARLETT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE

Page 15, line 1, after "assessed" strike all through line 3 and insert"."

AMENDMENT OFFERED BY MR. OLIVER TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE OFFERED BY MR. WALKER

Strike page 15, lines 9 through 21 and insert the following:

(3) BEST ESTIMATE.—The term "best estimate" means an appropriate statistical representation of the full range of the estimate of risk, given the current scientific information available to the Federal agency concerned, including a discussion and analysis of uncertainties, limitations, and assumptions affecting the risk estimate.

AMENDMENT OFFERED BY MR. TANNER TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE OFFERED BY MR. WALKER

At the end of title III, subtitle A, section 3103, subsection (b)(3)(A) i (page 7, at the end of line 6, add the following phrase:

Or to be necessary to maintain military readiness.

AMENDMENT OFFERED BY MR. MINGE TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE FOR TITLE III OFFERED BY MR. WALKER

In section 3107(5) (page 16, line 6), add after the period the following: "Such term does not include the Department of Agriculture.".

At the end of section 3201(c) (page 19, after line 20), add the following new paragraph:

(4) EXECUTIVE BRANCH AGENCY.—The term "Federal agency" does not include the Department of Agriculture.

At the end of section 3301 (page 25, after line 5) add the following new subsection:

(h) FEDERAL AGENCY DEFINED.—For purposes of this section, the term "Federal agency" does not include the Department of Agriculture.

AMENDMENT OFFERED BY MS. LOFGREN TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE FOR TITLE III OFFERED BY MR. WALKER

Add at the end of section 3105 (page 12, after line 18) the following new paragraph 6:

(6) RISKS TO PARTICULAR GROUPS.—Notwithstanding any other provision of this title, risk assessments shall, to the extent feasible and scientifically appropriate, describe risks to particular groups (such as infants, children, the elderly, pregnant women, individuals with atypical diets, and individuals with preexisting illnesses) whose risk is higher than that of the rest of the studied population due to greater exposure or greater susceptibility to adverse effects.

AMENDMENT OFFERED BY MR. TRAFICANT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE OFFERED BY MR. WALKER

On page 16, following line 13, insert the following:

(8) NON-UNITED STATES-BASED ENTITY.—As used in this title, the term "non-United States-based entity" means (a) an entity which is not incorporated in the United States, does not have its principal place of business in the United States, and does not provide a benefit to the United States economy and (b) the United Nations or any of its divisions.

(9) UNITED STATES.—As used in this title, the term "United States" means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, the Commonwealth of the Northern Marianas Islands, and any other territory or possession of the United States.

AMENDMENT TO H.R. 9 OFFERED BY MR. DAVIS

In section 3201(a), insert after paragraph (1) the following new paragraphs (2) through (6) (and redesignate subsequent paragraphs accordingly):

(2) For each such proposed or promulgated rule, an identification (including an analysis of the costs and benefits) of reasonable alternative for achieving the identified benefits of the proposed or promulgated rule, including alternatives—

(A) that require no government action;

(B) that will accommodate differences among geographic regions and among persons with different levels of resources with which to comply; and

(C) that employ performance or other market-based standards that permit the greatest flexibility in achieving

the identified benefits of the proposed or promulgated rule and that comply with paragraph (3).

(3) An assessment of the feasibility of establishing a regulatory program that operates through the application of market-based mechanisms.

(4) An assessment of the aggregate effect of the rule on small businesses with fewer than 100 employees, including the effect of the net employment effect of the rule.

(5) An analysis of whether the identified benefits of the proposed or promulgated rule are likely to exceed the identified costs of the proposed or promulgated rule, and an analysis of whether the proposed or promulgated rule will provide greater net benefits to society than any of the alternatives to the proposed or promulgated rule, including alternatives identified in paragraph (2).

(6) At the time of the publication of the final major rule, a final cost-benefit analysis (to be published in the rulemaking record), including a summary of the analysis in a statement of basis and purpose.

AMENDMENT TO H.R. 9 OFFERED BY MR.

At the end of section 3201(a)(1), insert: "In any situation in which benefits or costs cannot be quantified, qualitative measures should be provided".

AMENDMENT TO H.R. 9 OFFERED BY MR. WAMP

In section 3201(a)(3), insert before the period the following: ", including, to the maximum extent practicable, a quantitative assessment of the cumulative financial burden that persons producing products that are regulated by the rule will bear in order to comply with the rule and with related existing standards that affect the product or other similar products produced by such persons".

AMENDMENT TO H.R. 9 OFFERED BY MR. DAVIS

In section 3201(b), strike "proposed or final regulation" and insert "proposed and final regulation".

In section 3201, insert after subsection (b) the following new subsection (c) (and redesignate subsequent subsections accordingly):

(c) LIMITATION.—Notwithstanding any other provision of Federal law, no major rule shall be promulgated by any Federal agency pertaining to the protection of health, safety, or the environment unless the requirements of subsections (a) and (b) are met and the certification required therein is supported by substantial evidence of the rulemaking record.

AMENDMENT TO H.R. 9 OFFERED BY MR.

Insert the following after section 3201(b) and redesignate section 3201 (c) as (d):

(c) REPORT TO CONGRESS.—Whenever an agency head is unable to make a certification required by subsection (a) with respect to one or more of the matters addressed in subsection (a)(b), the agency shall identify those matters for which certification cannot be

made, and shall include a statement of the reasons therefore in the Federal Register along with the rule. Not later than March 1 of each year, each agency head shall submit a report to Congress identifying those major rules promulgated during the previous calendar year for which complete certification was not made, and summarizing the reasons therefore.

Page 48, line 11, strike "and indirect".

AMENDMENT TO H.R. 9 OFFERED BY MS. MCCARTHY

Page 48, strike line 15 through page 49, line 3, and insert in lieu thereof the following:

"MAJOR RULE—The term "major rule" means any regulation that is likely to result in an annual effect on the economy of $100,000,000 or more."

Page 52, strike lines 10 through 13.

AMENDMENT TO H.R. 9 OFFERED BY MR. BARTON OF TEXAS

Page 49, after line 3 insert:

SEC. 3202. JUDICIAL REVIEW.

(a) IN GENERAL.—When a rule, order, or other agency action that is predicated in whole or in part on a risk assessment or risk characterization subject to subtitle A, or a major rule that is subject to the requirements of section 3201, is brought before a court for judicial review under any other provision of law, the risk assessment and risk characterization and any material prepared by the agency pursuant to section 3201 shall be made a part of the administrative record to be considered by the court. In addition to any other matters that the court may consider in deciding whether the agency's action was lawful, the court shall have the authority to hold unlawful and set aside the rule, order, or other agency action being reviewed if it finds that—

(1) in preparing the risk assessment or characterizing the risk, the agency did not apply or comply with the risk assessment principles of section 3104 or the risk characterization principles of section 3105;

(2) the agency did not comply with the requirements of section 3201; or

(3) a certification required to be made under section 3201 was arbitrary, capricious, an abuse of discretion, or unsupported by substantial evidence.

(b) CIVIL ACTIONS.—(1) Any person who is adversely affected by a risk assessment or risk characterization that is prepared by an agency and made available to the public independently of a rule or other agency action that is subject to judicial review may commence a civil action against the agency where it is alleged that in preparing the risk assessment or risk characterization, the agency did not apply or comply with the applicable risk assessment or risk characterization principles of sections 3104 and 3105.

(2) The district courts shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to hold the risk assessment or risk characterization unlawful and grant appropriate injunctive relief in such an action if the court finds that the agency failed to apply or comply with the applicable risk as-

sessment or risk characterization principles of sections 3104 and 3105, without limiting the court's discretion, appropriate relief may include issuance of an order—

(A) requiring the agency to prepare and make publicly available a revised risk assessment and/or risk characterization that applies or complies with the risk assessment or risk characterization principles of sections 3104 and 3105;

(B) requiring the agency to provide the appropriate notice to the public that the challenged risk assessment and/or risk characterization has been found to be unlawful;

(C) prohibiting the agency from relying on or otherwise using the challenged risk assessment and/or risk characterization as a basis for taking regulatory action; and

(D) providing for any other injunctive relief that the court finds to be appropriate.

AMENDMENT OFFERED BY REP. JACKSON LEE TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE OFFERED BY MR. WALKER.

''On page 19, line 20, after the period add the following sentence: ''Such term does not include any regulation that the head of any Federal agency in connection with Federal programs determines is an immediate life threatening situation.'''

AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE OF H.R. 9, TITLE III OFFERED BY MR. OLIVER

Strike Paragraph (f) (1) of SECTION 3201 and renumber the following paragraph as paragraph (f) (1).

AMENDMENT OFFERED BY OLVER

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
2369	52411	Mr. Walker, PA			X		
2300	56161	Mr. Brown, CA					
2332	55101	Mr. Sensenbrenner, WI			X		
2236	56673	Mr. Hall, TX			X		
2246	53665	Mr. Boehlert, NY		X			
2446	55261	Mr. Traficant, OH			X		
2159	53515	Mr. Fawell, IL			X		
2432	52031	Mr. Hayes, LA					
106	55341	Mrs. Morella, MD		X			
1127	54714	Mr. Tanner, TN					
2452	52011	Mr. Curt Weldon, PA			X		
2448	55071	Mr. Geren, TX			X		
2338	52415	Mr. Rohrabacher, CA			X		
407	53915	Mr. Roemer, IN			X		
2404	56316	Mr. Schiff, NM			X		
236	54801	Mr. Cramer, AL					
2264	52002	Mr. Barton, TX			X		
1410	58171	Mr. Barcia, MI		X			
1034	51986	Mr. Calvert, CA			X		
217	56411	Mr. McHale, PA		X			
1724	51880	Mr. Baker, CA			X		
325	58220	Ms. Harman, CA					
322	52721	Mr. Bartlett, MD			X		
1123	58885	Ms. Johnson, TX		X			
1717	53831	Mr. Ehlers, MI			X		
1415	52331	Mr. Minge, MN			X		
423	53271	Mr. Wamp, TN			X		

AMENDMENT OFFERED BY OLVER—Continued

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
1027	55335	Mr. Olver, MA		X			
216	53671	Mr. Dave Weldon, FL			X		
1039	51313	Mr. Hastings, FL					
1429	55301	Mr. Graham, SC			X		
1116	56261	Ms. Rivers, MI		X			
115	52635	Mr. Salmon, AZ			X		
1232	54535	Ms. McCarthy, MO					
415	51492	Mr. Davis, VA			X		
1032	55401	Mr. Ward, KY		X			
417	56565	Mr. Stockman, TX			X		
118	53072	Ms. Lofgren, CA		X			
425	52472	Mr. Gutknecht, MN			X		
126	54865	Mr. Doggett, TX		X			
1216	53601	Mrs. Seastrand, CA			X		
1218	52135	Mr. Doyle, PA			X		
1319	56216	Mr. Tiahrt, KS			X		
1520	53816	Ms. Jackson-Lee, TX		X			
410	52211	Mr. Largent, OK			X		
1419	52271	Mr. Luther, MN		X			
114	56831	Mr. Hilleary, TN			X		
1114	52311	Mrs. Cubin, WY			X		
506	55792	Mr. Foley, FL				X	
509	51976	Mrs. Myrick, NC				X	
		Total			12	31	

AMENDMENT OFFERED MR. ROEMER TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE OFFERED BY MR. WALKER

In section 3301(a)(3) (page 22, beginning on line 10), strike ''and in the case of'' to the end of the paragraph and insert the following: ''and the peer reviewers do not have a financial or other interest that will, or may reasonably be expected to, create a bias in favor of obtaining an outcome that is consistent with such financial or other interest;''.

Strike section 3301(a)(4) (page 22, line 14 through line 16) and insert the following:

> (4) 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;

Page 22, line 20, strike the period and insert ''; and''.

At the end of section 3301(a) (page 22, after line 20), insert the following new paragraph:

> (6) may provide specific and reasonable deadlines for peer review panels to submit reports under subsection (c).

In section 3301(b) (page 23, lines 1 through 7), strike ''(other than any regulation'' and all that follows through ''policy decision.'' and insert the following: ''. The Director of the Office of Management and Budget may order that peer review be provided for any significant risk assessment or cost assessment if the agency has failed to do so itself.''.

At the end of section 3301(b) (page 23, line 7), add the following: ''Where such a peer review is not practicable because of compelling circumstances, the head of each Federal agency shall provide an

explanation in lieu of conducting a peer review under this subtitle.''.

After section 3301(g) (page 25, after line 5) insert the following:

(h) DEFINITIONS.—For purposes of this subtitle:

(1) INDEPENDENT EXPERTS.—The term ''independent experts'' means individuals who have not participated in the design, conduct, or analysis of the experiment or data in question.

(2) EXTERNAL EXPERTS.—The term ''external experts'' means experts who are not direct employees of the Federal Government, as well as Federal Government employees who are external to the program which produced the risk assessment or economic assessment being peer reviewed and who did not participate, in a significant way, in the preparation of such assessment or in the key data upon which the assessment depends.

(3) MAJOR RULE.—The term ''major rule'' means any rule (as such 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.

AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE OFFERED BY MR. WALKER OFFERED BY MR. DOGGETT

Page 22, line 6 through 13. Strike paragraph (3) and insert the following:

Shall exclude peer reviewers who have a potential interest in the outcome:

AMENDMENT OFFERED BY MR. DOGGETT

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
2369	52411	Mr. Walker, PA				X	
2300	56161	Mr. Brown, CA					
2332	55101	Mr. Sensenbrenner, WI				X	
2236	56673	Mr. Hall, TX			X		
2246	53665	Mr. Boehlert, NY				X	
2446	55261	Mr. Traficant, OH			X		
2159	53515	Mr. Fawell, IL				X	
2432	52031	Mr. Hayes, LA					
106	55341	Mrs. Morella, MD				X	
1127	54714	Mr. Tanner, TN					
2452	52011	Mr. Curt Weldon, PA				X	
2448	55071	Mr. Geren, TX			X		
2338	52415	Mr. Rohrabacher, CA				X	
407	53915	Mr. Roemer, IN			X		
2404	56316	Mr. Schiff, NM				X	
236	54801	Mr. Cramer, AL					
2264	52002	Mr. Barton, TX					
1410	58171	Mr. Barcia, MI			X		
1034	51986	Mr. Calvert, CA				X	
217	56411	Mr. McHale, PA			X		
1724	51880	Mr. Baker, CA				X	
325	58220	Ms. Harman, CA					
322	52721	Mr. Bartlett, MD				X	
1123	58885	Ms. Johnson, TX			X		
1717	53831	Mr. Ehlers, MI				X	
1415	52331	Mr. Minge, MN			X		
423	53271	Mr. Wamp, TN				X	
1027	55335	Mr. Olver, MA			X		
216	53671	Mr. Dave Weldon, FL				X	
1039	51313	Mr. Hastings, FL					

AMENDMENT OFFERED BY MR. DOGGETT—Continued

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
1429	55301	Mr. Graham, SC				X	
1116	56261	Ms. Rivers, MI			X		
115	52635	Mr. Salmon, AZ				X	
1232	54535	Ms. McCarthy, MO					
415	51492	Mr. Davis, VA				X	
1032	55401	Mr. Ward, KY			X		
417	56565	Mr. Stockman, TX				X	
118	53072	Ms. Lofgren, CA			X		
425	52472	Mr. Gutknecht, MN				X	
126	54865	Mr. Doggett, TX			X		
1216	53601	Mrs. Seastrand, CA				X	
1218	52135	Mr. Doyle, PA			X		
1319	56216	Mr. Tiahrt, KS				X	
1520	53816	Ms. Jackson-Lee, TX			X		
410	52211	Mr. Largent, OK				X	
1419	52271	Mr. Luther, MN			X		
114	56831	Mr. Hilleary, TN				X	
1114	52311	Mrs. Cubin, WY				X	
506	55792	Mr. Foley, FL				X	
509	51976	Mrs. Myrick, NC				X	
		Total			16	26	

AMENDMENT OFFERED BY MRS. MORELLA, MR. BOEHLERT, OR MR. EHLERS TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE OFFERED BY MR. WALKER

In section 3301(a) (page 21, line 20), insert "independent and external" after "program for".

In section 3301(a)(1) (page 21, line 24), strike "independent and external".

In section 3301(a)(1) (page 22, line 2), strike "to the extent feasible" and insert the following:

and to the extent feasible and appropriate, include representatives of industry, universities, agriculture, labor, consumers, conservation organizations, and other public interest groups and organizations.

At the end of the title, add the following:

SEC. 3402. PRIORITIZATION OF THREATS AND RESOURCE USE.

For any risk assessment, risk characterization, cost-benefit analysis, or peer review program prepared by, or on behalf of, any Federal agency under this title, the head of the Federal agency shall—

(1) prioritize threats to human health, safety, and the environment according to—

(A) the seriousness of the risk they pose; and

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

(2) prioritize the use of resources available to the agency under those laws to reduce those risks in accordance with the priorities established under paragraph (1), including applying the priorities to the budget, strategic planning, and research activities of the agency.

SEC. 3403. RESEARCH AND TRAINING IN RISK ASSESSMENT.

(a) EVALUATION.—The head of each covered agency shall regularly evaluate risk assessment research and training needs of the agency, including the following:

(1) Research to improve model sensitivity and otherwise reduce generic data gaps, particularly those common to multiple risk assessments.

(2) Research leading to improvement of methods to quantify and communicate uncertainty and variability throughout risk assessment.

(3) Emerging and future areas of research, including research on comparative risk analysis, exposure to multiple chemicals, noncancer endpoints, biological makers of exposure and effect, mechanisms of action in both mammalian and nonmammalian species, ecosystem exposures, and prediction of ecosystem-level response.

(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 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).

(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.

(d) COVERED AGENCY DEFINED.—For purposes of this section, the term "covered agency" means each of the following:

(1) The Environmental Protection Agency.
(2) The Consumer Product Safety Commission.
(3) The Occupational Health and Safety Administration.
(4) The Department of Labor.
(5) The Department of Transportation.
(6) The Department of Energy.
(7) The Department of Agriculture.
(8) The Department of the Interior.
(9) The Food and Drug Administration.

AMENDMENT TO H.R. 9 OFFERED BY MR. GREEN OF TEXAS

At the end of title III add the following new subtitle:

Subtitle D—Agency Priorities

SEC. 3401. AGENCY PROGRAM GOALS.

(a) PRIORITIZING ACTIVITIES.—In exercising authority under the Federal laws to protect human health, safety, and the environment

within the agency's jurisdiction, the head of each Federal agency shall—

(1) prioritize threats to human health, safety, and the environment according to—

(A) the seriousness of the risk they pose; and

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

(2) prioritize the use of resources available to the agency under those laws to reduce those threats in accordance with the priorities established under paragraph (1), including applying the priorities to the agency's budget, strategic planning, and research activities.

(b) REPORTS TO CONGRESS.—The head of each Federal agency shall annually submit to Congress—

(1) a budget analysis describing—

(A) the results of the agency's prioritization under subsection (a)(1);

(B) the basis for that prioritization; and

(C) explicitly how the funds requested by the agency will be used to address those risks; and

(2) in March of each year, an analysis of any statutory, regulatory or administrative obstacles to allocating agency resources in accordance with the priorities established under subsection (a)(1) with recommendations—

(A) for repealing or modifying existing laws to reduce, eliminate or enhance programs or mandates relating to human health, safety and the environment; and

(B) for modifying statutorily or judicially mandated deadlines that would better enable the agency to prioritize its activities to address the threats to human health, safety, and the environment consistent with the priorities established under subsection (a)(1).

SEC. 3402. COMPARATIVE RISK ANALYSIS.

(a) REQUIREMENT.—Within 3 months after the date of the enactment of this title, the Director of the Office of Management and Budget shall enter into a contract with an appropriately qualified organization to conduct a comparative risk analysis. The analysis shall compare and rank, to the extent feasible, human health, safety, and environmental risks potentially regulated across the existing Federal programs to protect human health, safety and the environment.

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

(1) the analysis is conducted with sufficient specificity and scope to provide guidance to the President and the heads of Federal agencies in allocating budgetary resources across agencies and among programs to achieve the greatest degree of reduction in risk for the public and private resources expended;

(2) the analyses is conducted, to the extent feasible and practicable, in a manner consistent with the risk assessment and risk characterization criteria contained in subtitle A of this title;

(3) the analysis is conducted by individuals with relevant expertise in areas such as toxicology, biology, medicine, industrial hygiene, engineering, and environmental effects;

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

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

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

(c) REPORT.—Not later than 3 years after the date of the enactment of this Act, the Director shall complete the comparative risk analysis referred to in subsection (a) and submit to the President and Congress a report that reviews the comparative risk analysis. The Director shall review and revise the comparative risk analysis every 5 years thereafter for a minimum of 15 years following the completion of the first analysis. The Director shall arrange for such review and revision in the same manner as provided in subsections (a) and (b).

AMENDMENT TO H.R. 9 OFFERED BY MR. ROEMER

At the end of title III add the following new subtitle:

Subtitle D—Agency Priorities

SEC. 3401. AGENCY PROGRAM GOALS.

(a) PRIORITIZING ACTIVITIES.—In exercising authority under the Federal laws to protect human health, safety, and the environment within the agency's jurisdiction, the head of each Federal agency shall—

(1) prioritize threats to human health, safety, and the environment according to—

(A) the seriousness of the risk they pose; and

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

(2) prioritize the use of resources available to the agency under those laws to reduce those threats in accordance with the priorities established under paragraph (1), including applying the priorities to the agency's budget, strategic planning, and research activities.

(b) REPORTS TO CONGRESS.—The head of each Federal agency shall annually submit to Congress—

(1) a budget analysis describing—

(A) the results of the agency's prioritization under subsection (a)(1);

(B) the basis for that prioritization; and

(C) explicitly how the funds requested by the agency will be used to address those risks; and

(2) in March of each year, an analysis of any statutory, regulatory or administrative obstacles to allocating agency re-

sources in accordance with the priorities established under subsection (a)(1) with recommendations—

(A) for repealing or modifying existing laws to reduce, eliminate or enhance programs or mandates relating to human health, safety and the environment; and

(B) for modifying statutorily or judicially mandated deadlines that would better enable the agency to prioritize its activities to address the threats to human health, safety, and the environment consistent with the priorities established under subsection (a)(1).

SEC. 3402. COMPARATIVE RISK ANALYSIS.

(a) REQUIREMENT.—Within 3 months after the date of the enactment of this title, the Director of the Office of Management and Budget shall enter into a contract with an appropriately qualified organization to conduct a comparative risk analysis. The analysis shall compare and rank, to the extent feasible, human health, safety, and environmental risks potentially regulated across the existing Federal programs to protect human health, safety and the environment.

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

(1) the analysis is conducted with sufficient specificity and scope to provide guidance to the President and the heads of Federal agencies in allocating budgetary resources across agencies and among programs to achieve the greatest degree of reduction in risk for the public and private resources expended;

(2) the analysis is conducted, to the extent feasible and practicable, in a manner consistent with the risk assessment and risk characterization criteria contained in subtitle A of this title;

(3) the analysis is conducted by individuals with relevant expertise in areas such as toxicology, biology, medicine, industrial hygiene, engineering, and environmental effects;

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

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

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

(c) REPORT.—Not later than 3 years after the date of the enactment of this title, the Director shall complete the comparative risk analysis referred to in subsection (a) and submit to the President and Congress a report that reviews the comparative risk analysis. The Director shall review and revise the comparative risk analysis every 5 years thereafter for a minimum of 15 years following the completion of the first analysis. The Director shall arrange for such review and revision in the same manner as provided in subsections (a) and (b).

AMENDMENT TO H.R. 9 OFFERED BY MR. TANNER

At the end of title III (page 52, after line 13), add the following new subtitle:

Subtitle D—Other Provisions

SEC. 3401. NATIONAL SECURITY WAIVER.

The Secretary of Defense or the Secretary of a military department may waive a provision of this title with respect to the Department of Defense or the military department if the Secretary concerned—

(1) determines that such a waiver is necessary in the national security interests of the United States; and

(2) promptly notifies Congress of the waiver and the reasons for the waiver.

AMENDMENT TO H.R. 9 OFFERED BY MR.

At the end of subtitle C insert:

Subtitle D—General Provisions

SEC. 3401. JUDICIAL REVIEW.

Nothing in this title creates any right to judicial or administrative review, nor creates any right or benefit, substantive or procedural, enforceable at law of 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 certification or other document prepared pursuant to this title, and any alleged failure to comply with this title, may not be used as grounds for affecting or invalidating such agency action, but statements and information prepared pursuant to this title, including statements contained in the certification or document 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.

AMENDMENT TO H.R. 9. OFFERED BY MR. DOGGETT

Add at the end of title III the following new subtitle:

Subtitle IV—Sunset

SEC. 3401. SUNSET.

This title shall cease to be in effect on January 3, 2000.

AMENDMENT OFFERED BY MR. DOGGETT

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
2369	52411	Mr. Walker, PA				X	
2300	56161	Mr. Brown, CA					
2332	55101	Mr. Sensenbrenner, WI				X	
2236	56673	Mr. Hall, TX			X		

AMENDMENT OFFERED BY MR. DOGGETT—Continued

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
2246	53665	Mr. Boehlert, NY				X	
2446	55261	Mr. Traficant, OH			X		
2159	53515	Mr. Fawell, IL				X	
2432	52031	Mr. Hayes, LA					
106	55341	Mrs. Morella, MD				X	
1127	54714	Mr. Tanner, TN					
2452	52011	Mr. Curt Weldon, PA				X	
2448	55071	Mr. Geren, TX				X	
2338	52415	Mr. Rohrabacher, CA				X	
407	53915	Mr. Roemer, IN				X	
2404	56316	Mr. Schiff, NM				X	
236	54801	Mr. Cramer, AL					
2264	52002	Mr. Barton, TX					
1410	58171	Mr. Barcia, MI				X	
1034	51986	Mr. Calvert, CA				X	
217	56411	Mr. McHale, PA			X		
1724	51880	Mr. Baker, CA				X	
325	58220	Ms. Harman, CA					
322	52721	Mr. Bartlett, MD				X	
1123	58885	Ms. Johnson, TX			X		
1717	53831	Mr. Ehlers, MI				X	
1415	52331	Mr. Minge, MN			X		
423	53271	Mr. Wamp, TN				X	
1027	55335	Mr. Olver, MA			X		
216	53671	Mr. Dave Weldon, FL				X	
1039	51313	Mr. Hastings, FL					
1429	55301	Mr. Graham, SC				X	
1116	56261	Ms. Rivers, MI			X		
115	52635	Mr. Salmon, AZ				X	
1232	54535	Ms. McCarthy, MO					
415	51492	Mr. Davis, VA				X	
1032	55401	Mr. Ward, KY			X		
417	56565	Mr. Stockman, TX				X	
118	53072	Ms. Lofgren, CA			X		
425	52472	Mr. Gutknecht, MN				X	
126	54865	Mr. Doggett, TX			X		
1216	53601	Mrs. Seastrand, CA				X	
1218	52135	Mr. Doyle, PA			X		
1319	56216	Mr. Tiahrt, KS				X	
1520	53816	Ms. Jackson-Lee, TX			X		
410	52211	Mr. Largent, OK				X	
1419	52271	Mr. Luther, MN			X		
114	56831	Mr. Hilleary, TN				X	
1114	52311	Mrs. Cubin, WY				X	
506	55792	Mr. Foley, FL				X	
509	51976	Mrs. Myrick, NC				X	
		Total			13	29	

AMENDMENT OFFERED BY MR. ROEMER TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE FOR TITLE III OFFERED BY MR. WALKER

Strike section 3401 (page 25, lines 7 through 10) and insert the following:

SEC. 3401. JUDICIAL REVIEW.

Nothing in this title 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 ad-

ministrative review under any other provision of law, the adequacy of any certification or other document prepared pursuant to this title, and any alleged failure to comply with this title, may not be used as grounds for affecting or invalidating such agency action, but statements and information prepared pursuant to this title, including statements contained in the certification of document 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.

AMENDMENT OFFERED BY MR. ROEMER

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
2369	52411	Mr. Walker, PA				X	
2300	56161	Mr. Brown, CA					
2332	55101	Mr. Sensenbrenner, WI				X	
2236	56673	Mr. Hall, TX			X		
2246	53665	Mr. Boehlert, NY			X		
2446	55261	Mr. Traficant, OH			X		
2159	53515	Mr. Fawell, IL				X	
2432	52031	Mr. Hayes, LA					
106	55341	Mrs. Morella, MD			X		
1127	54714	Mr. Tanner, TN					
2452	52011	Mr. Curt Weldon, PA				X	
2448	55071	Mr. Geren, TX			X		
2338	52415	Mr. Rohrabacher, CA				X	
407	53915	Mr. Roemer, IN			X		
2404	56316	Mr. Schiff, NM				X	
236	54801	Mr. Cramer, AL					
2264	52002	Mr. Barton, TX				X	
1410	58171	Mr. Barcia, MI			X		
1034	51986	Mr. Calvert, CA				X	
217	56411	Mr. McHale, PA			X		
1724	51880	Mr. Baker, CA				X	
325	58220	Ms. Harman, CA					
322	52721	Mr. Bartlett, MD				X	
1123	58885	Ms. Johnson, TX				X	
1717	53831	Mr. Ehlers, MI				X	
1415	52331	Mr. Minge, MN			X		
423	53271	Mr. Wamp, TN				X	
1027	55335	Mr. Olver, MA			X		
216	53671	Mr. Dave Weldon, FL				X	
1039	51313	Mr. Hastings, FL					
1429	55301	Mr. Graham, SC				X	
1116	56261	Ms. Rivers, MI			X		
115	52635	Mr. Salmon, AZ				X	
1232	54535	Ms. McCarthy, MO					
415	51492	Mr. Davis, VA				X	
1032	55401	Mr. Ward, KY			X		
417	56565	Mr. Stockman, TX				X	
118	53072	Ms. Lofgren, CA			X		
425	52472	Mr. Gutknecht, MN				X	
126	54865	Mr. Doggett, TX			X		
1216	53601	Mrs. Seastrand, CA				X	
1218	52135	Mr. Doyle, PA			X		
1319	56216	Mr. Tiahrt, KS				X	
1520	53816	Ms. Jackson Lee, TX				X	
410	52211	Mr. Largent, OK				X	
1419	52271	Mr. Luther, MN			X		
114	56831	Mr. Hilleary, TN				X	
1114	52311	Mrs. Cubin, WY				X	
506	55792	Mr. Foley, FL				X	

AMENDMENT OFFERED BY MR. ROEMER—Continued

Rm.	Phone	Name	Present	Absent	Yea	Nay	Not Voting
509	51976	Mrs. Myrick, NC	.....	.....	.....	X	
		Total	.....	.....	16	27	

H.R. 9 AMENDMENT OFFERED BY MR. BARTON OF TEXAS

After subtitle C, insert the following new subtitle and make the necessary conforming changes:

Subtitle D—Agency Priorities

SEC. 3401. PETITION PROCESS.

(a) IN GENERAL.—(1) Within 1 year after the date of enactment of this Act the head of each covered agency shall establish procedures for accepting and considering petitions for—

(A) reviewing and revising any health or environmental effects value, such as those values in the Integrated Risk Information System (IRIS) database or any other compilation of risk, hazard or health or environmental effects information prepared by the agency that is made commonly available or is used by any Federal department, agency, or instrumentality, the States or local governments as a scientific basis for regulatory action;

(B) reviewing a risk assessment that supports a major rule, as defined in section 3201(c)(2), and revising it to take into consideration new information or methodologies or to comply with the requirements of subtitle A;

(C) requiring that a risk assessment that supports a major rule, as defined in section 3201(c)(2), or other agency scientific or technical document supporting a regulatory action be peer reviewed; or

(D) reviewing any major rule, as defined in section 3201(c)(2), promulgated prior to the effective date of this title and revising it to comply with the requirements of this title.

(2) Such procedures be consistent with each of the following:

(A) Any persons with a direct financial interest may petition.

(B) Such petitions shall include adequate supporting documentation, including, where appropriate, new studies or other relevant information that provide the basis for a proposed revision or modified health effects value and where appropriate a summary characterization of the risk complying with the requirements of section 3105 of this title.

(3) The agency head shall respond to the petition in the Federal Register within 90 days from receipt.

(4) The agency shall accept the petition if the new information or methodologies or the application of the provisions of this title would significantly alter the result of the existing risk assessment, health effects value or regulation. If the agency head rejects the petition, the agency head shall state the reasons for doing so. If the agency head accepts the petition, he shall publish a notice in the Federal Register for comment on the substantive issues raised in

the petition. The agency head shall accept and consider any relevant data of sufficient quality submitted in response to the notice.

(b) FINAL AGENCY ACTION.—(1) Within 1 year following the submission of a petition under subsection (a), the agency head shall take final action either—

(A) initiating the action requested in the petition; or

(B) denying the petition by determining that the risk assessment, health effects value or regulation should not be changed, stating in the Federal Register the reasons therefore.

(2) Rejection or denial of a petition by an agency head shall constitute final agency action and be subject to review as provided in section 700 and following of title 5 of the United States Code (the Administrative Procedures Act). Any person whose petition was rejected or denied and who can establish that—

(A) he or she had a direct financial interest in subject of the petition,

(B) the petition included adequate supporting evidence, and

(C) the agency failed or refused to comply with this section may bring an action in the appropriate United State district court for judicial review of such rejection or denial.

MARK UP ON OVERSIGHT AGENDA CONSIDERATION OF TITLE III RISK ASSESSMENT AND COST/BENEFIT ANALYSIS FOR NEW REGULATIONS OF H.R. 9 THE JOB CREATION AND WAGE ENHANCEMENT ACT OF 1995

WEDNESDAY, FEBRUARY 8, 1995

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE,
Washington, DC.

The Committee met at 10:12 a.m., in Room 2318 of the Rayburn House Office Building, the Honorable Robert S. Walker, Chairman of the Committee, presiding.

The CHAIRMAN. The Committee will come to order.

Today, the Committee is convened to conduct several items of important business: to adopt its Oversight Agenda, as required by the rules of the House; to mark up Risk Assessment; and the hydrogen research legislation.

Although these may on the surface appear to be disparate issues, they do have one thing in common—they are focused on the future of this Committee and on the future of the country.

The Oversight Agenda is this Committee's plan of action over the next two years. It sets out a blueprint for comprehensive examination of the issues under the jurisdiction of the Science Committee.

The Risk Assessment bill, at long last, puts the Federal Government role in determining and communicating risk into perspective. For too long, the burden of regulation has fallen squarely on the backs of the regulated. And ultimately, on consumers.

Title III of H.R. 9 finally puts some balance back into the system by requiring regulators to assume the responsibility of assuring that the regulations are drafted on the basis of sound science.

In my view, the most important section of this legislation is the risk characterization and communications sections. It is important that not only decision-makers understand the real hazards that are encountered in our daily lives, but that the members of the public-at-large also understand the risks which face us.

In the final analysis, each one of us in a free society are our own ultimate risk-assessors.

Finally, the Hydrogen Future Act of 1995 is about doing research now on a fuel of the future. Surely, we are better off spending scarce dollars in developing a clean, renewable fuel than on funding a complex regulatory process.

I would now yield to the Ranking Minority Member of the Committee, Mr. Brown.

Mr. BROWN. Thank you very much, Mr. Chairman.

I commend you for moving ahead on these important items. I think that we are in substantial agreement on the Oversight program which has been proposed, and we certainly would like to be cooperative in instigating a vigorous oversight program.

We have shared your concern over hydrogen in the past and I think, with a little cooperation, we can work out a suitable hydrogen bill. And I offer my full cooperation in attempting to do this with the Chairman.

On the risk bill, Mr. Chairman, I have very, very substantial reservations. I ask you if you can engage in a flight of fancy. To imagine that we were back in the good old days of the last Congress and you were presented with a piece of important legislation and told that we had to get that through in a time certain.

You hadn't yet seen the bill. You ask for a postponement in order to review it. You did not receive acceptance of that.

You ask for an opportunity to see the bill at the earliest possible date and you still haven't seen the bill.

What tactics would you use at that point to demonstrate that you, as an important member of the Minority, were not going to be run over roughshod by an uncaring Majority which was bent on ramming through a piece of legislation which had not even seen the light of day yet?

That may be difficult for you to do, but I know that you have the ability to do it. I know you can envision precisely what tactics you would use. And I would ask you if it would not be better if you were to allow the Minority, in this particular case, based upon your own previous position on minority rights, to have an opportunity to study the bill, to cooperate with the Minority in achieving some acceptable amendments, and to postpone further efforts to mark this bill up for some reasonable period of time.

Maybe a week. Maybe even 24 hours.

I know the gentleman is under compulsion to move this bill and I ask you to consider very carefully the point that you may not be able to keep every bill that you want to keep on schedule, on schedule. And that at some point, you're going to have to accept the inevitable and ask for an opportunity in your own leadership to do a good job, instead of a haphazard job and take another few weeks, another month, in order to accomplish some of the things that need to be done.

I ask that with full respect for all the pressures that are on you, Mr. Chairman. But the current situation with regard to the Risk bill is utterly impossible, from my standpoint, and I think most members of the Minority share that view.

We have not even seen a draft of your en bloc amendments until this morning. You have consistently said that you expected to receive at least 24 hours' notice, and I presume you meant to say that you would give 24 hours' notice of what the text of a bill was, or other important action.

That has not been done in this case and we're not very happy with it.

Now I can elaborate on that. But rather than do so, I'll conclude my remarks and ask that I be permitted to extend them in the record.

The CHAIRMAN. Without objection.

OPENING STATEMENT REPRESENTATIVE GEORGE E. BROWN, JR.

Mr. Chairman, I realize that this is the first mark-up that you have presided over in this Congress. I hope that the process that we have followed in consideration of this bill is not representative of the way that we will proceed in the future.

Mr. Chairman, this is an important bill. It proposes serious changes in the way that we have passed regulations over the last twenty years to protect the environment, consumers, and workers. It deserves thoughtful scrutiny and honest and open debate. Unfortunately, that has not happened. Although we were assured that this legislation was going to be thoroughly examined before we proceeded to mark-up, the fact is that this bill is being rushed through the Committee without a serious opportunity to consider it or to negotiate our differences.

Let me point out that the hearing record on this bill is still open, and we have not even had time to receive responses to my requests for information from more than half of the agencies who will be required to implement this legislation. I don't think that any of us can truthfully say that we fully understand the implications of this legislation. While it is true that we had hearings in prior Congresses, this bill—and the Walker amendment—go far beyond anything the Committee has previously considered. Further, about half of this Committee is new to this Congress and have not had the benefit of our past debates.

Indeed, this bill has far more to do with economic and financial analyses than with scientific ones. I am particularly disappointed by the latter characterization. I have always thought of science as a tool to be used to educate and inform us and to improve our quality of life. In this bill, science is relegated to the role of a deregulatory handmaiden.

I will again state my sincere belief that we should work to improve the regulatory process. I believe that scientific and economic information, and analyses such as risk assessment and cost-benefit analyses are useful tools that can assist us in designing a regulatory system that is cheaper, better, and faster. I regret that we have not had an opportunity during the development of this bill to pursue this important goal.

The minority have never been consulted about this bill, despite our assurances of willingness to work together. The Administration has never been consulted about this bill, despite its willingness, expressed at last Friday's hearing, to work with you in developing a legislative vehicle. We were anticipated the receipt of a copy of the mark-up vehicle and amendments to be offered by Majority members on Monday evening. However, our staff did not see "draft" amendments until 6 p.m. last night; other amendments we have seen for the first time this morning. It is disappointing that the Walker amendments introduce at the very last hour major changes, including wholesale revisions of definitions, back-door repeals of

laws that have been written by Congress over the last 20 years to protect consumers, workers, and the environment, and fundamental changes in the standards under which courts review agency actions.

We expect to be here for quite a while this afternoon because we have a great number of questions about the amendments. The cursory examination of the amendments that time permitted me, left me wondering where in the hearing record are the bases for these proposals? I hope that we will be able to clarify the intent of these suggested changes as we move along today.

I realize that many of the majority Members promised to complete the Contract legislation within the first 100 days of this Congress. I made no such promise, nor would I have. If this bill is enacted in close to its present form, I doubt our constituents will be consoled by the fact that we did not use any additional time to produce it. It is easy enough to make mistakes even when legislation is well thought out and fully debated, as many have pointed out in regard to our regulatory statutes. A fast-track process such as we have experienced with this bill is certain to result in more unintended than intended consequences.

By treating Committee business in such cavalier fashion Members are abdicating their legislative responsibilities. Hearings and mark-ups at the subcommittee and full committee levels all serve as important points at which we gather information, hear views of those who will be impacted by the legislation under consideration. They provide an opportunity for all Members to exchange their thoughts and perspectives with each other so that areas of common concern and consensus for action can be identified. We lose much more than time when we do not take advantage of the opportunities that Committee activities provide.

The past operating procedure of the Committee was that the Minority received the bill the night before. My understanding is that it was delivered to your staff yesterday at 6:00, and that this is exactly the same pattern that we operated under in the past, and that we will proceed ahead with this.

We are, in fact, because we showed it to you early and understood that you would object to the handling of the en block amendments, we are in the process of redrafting into a substitute to satisfy the concern of the Minority.

We will recess the Committee at an appropriate time here in order to give members an opportunity to look at the substitute. It would in fact incorporate the en bloc amendments, which have been available since last night.

So we are going to try to give people an opportunity to digest this. But we are proceeding in exactly the same manner that the previous majority proceeded on these kinds of issues.

With that——

Mr. BROWN. Would the gentleman allow me just a brief rebuttal?

The CHAIRMAN. Sure. I'd be happy to.

Mr. BROWN. We could quibble over whether we received the documents last night at 6 o'clock. I don't think the Legislative Council finished drafting them until midnight.

But, nevertheless, what the gentleman proposed to do was to offer about 50 amendments in the form of en bloc amendments covering 16 pages, in violation of the rules of the Committee.

We indicated that we would object to this, and now the gentleman proposes to redraft them in a proper form and submit them to us. Obviously, we haven't seen the redraft. We assume that it will include what he has in the en block amendments.

But let me say that there have been so many changes in the en bloc amendments, I can't accept anything as being for sure until I actually see the document in proper form.

The CHAIRMAN. Well, I thank the gentleman for that. It is the indication of the Chair to assure members that what was in the en bloc amendments is in fact what is being redrafted into the bill.

But because of the gentleman's suspicion and his unwillingness to accept the Chair's word on that, we are in fact, as I say, going to redraft the bill and make it available so that members can assure themselves that that is precisely what the Committee intends to do.

I don't want to have anybody feel as though they don't have an opportunity to see the legislation. And so that is the way in which we proceed.

As to the gentleman's point that we never submitted to the wishes of leadership when the other majority was in place, I remember well debating issues like proxy voting, where the gentleman would assure me over and over again that he was in fact in favor of getting rid of proxy voting, but his leadership simply wouldn't let the Committee move in that direction.

In my case, the leadership has a schedule that they wish to keep and it is important to us to maintain that schedule.

I think that we have an obligation, as the Majority here, to do that, and are prepared to move head.

We obviously would like to have the cooperation of all members in moving forward because I think that these are important issues to address. But it is our intention to move ahead and to move forward.

With that, I would proceed on to adoption of the Oversight Agenda, which is before the Committee. Members have before them the proposed Oversight Agenda for the 104th Congress.

This is the first time that we have done this kind of setting of an Oversight Agenda. It reflects the rules change that was made to highlight the importance of the Committee's oversight activities.

We have solicited input for this agenda from all members on both sides and have incorporated, I think, virtually all the suggestions that were given to us by members in a timely manner into the document.

This will be submitted to the Committees on House Oversight and Government Reform as an indication of the ways in which we intend to proceed.

The agenda is a plan for reviewing those programs under the Committee's jurisdiction. The oversight will be conducted in a number of ways. And I want the members to understand this point.

It will include, but will not be limited to, hearings, briefings, correspondence, and information requests. This Oversight Agenda is not just a schedule for hearings that will be held by the Committee.

There are a number of different ways in which the Committee pursues its Oversight Agenda, and this document indicates the topics that will be a part of the overall oversight work of the Committee.

This is not all-inclusive, nor is it final. Additional crisis-oriented or emerging topics will be identified as they are appropriate to this Committee's work.

I would yield to Mr. Brown for further discussion, and then to any other members that might wish to be recognized.

Mr. BROWN. Mr. Chairman. I understand that there has been staff cooperation in the compiling of this list and that the items that we thought could be added were not objectionable to the people, the staff members on your side.

I know that there's no particular magic in listing these items. They can either be pursued aggressively or not aggressively, as we have the opportunity and the motivation.

But I would like to offer the amendments to the Oversight Agenda which I understand were discussed and agreed to on your side.

The CHAIRMAN. Well, I would say to the gentleman, I've opened the matter for discussion at the present time on kind of the overall issue.

We will move to the amendment process in a timely manner. At that point, I will certainly be glad to consider the amendments, and those that we've agreed to, we would certainly be willing to consider en bloc.

Mr. BROWN. Let me just in brief say that we concur with your desire to proceed with an aggressive oversight plan. We will do everything we can to assist. And we look forward to the strong cooperation between both sides on this aggressive agenda.

The CHAIRMAN. I thank the gentleman for that.

Mr. Sensenbrenner.

Mr. BARTON. Mr. Chairman.

The CHAIRMAN. Mr. Barton.

Mr. BARTON. I'd just like to commend you for putting this agenda together. I'm the subcommittee chairman on oversight and investigation on the Energy and Commerce Committee and I can tell you it's a different task to try to determine the schedule and the subjects that should be reviewed.

I think you and your staff, in conjunction with the Minority staff, have done an outstanding job of clarifying and codifying what this Committee's oversight role is going to be. And I just want to commend you on that.

The CHAIRMAN. I thank the gentleman.

Mr. Traficant.

Mr. TRAFICANT. From what I understand, there's no contentious points on any of these amendments, save for one that I have brought. And mine deals with the fruits of American research trickling down to American firms. And I understand the Chair has a concern about the definition of what those U.S. firms really are.

It is not my intention to exclude those corporations that do business in America and hire Americans. And I am open to accommodate those types of changes to the thrust.

But I'd just like to say before we get into this matter, this may be the only contentious matter. And my concern is that we pay an awful lot of money through federal research for our gains in tech-

nology. And much of that then trickles down to the benefit of foreign companies and foreign nations that enjoy great surpluses with us.

The thrust of my language is simply to try and focus as much as possible for that trickle-down to benefit American firms.

So I am not opposed to those corporations, foreign firms that are doing business in America and hiring American workers. And I would be willing to consider those changes.

But I just wanted to make that point and I wanted to say, Mr. Chairman, that, overall, I wanted to commend you, as Mr. Barton did, for your position here on oversight and hope that there can be some medium of approveability to that concern that I have.

The CHAIRMAN. Well, I thank the gentleman. He does help clarify the matter.

The Chair would ask for just as a purpose, that when we give members an opportunity to work with us in advance, that it would be helpful to have these issues come before us so that we can have these kinds of discussions and resolve these kinds of questions.

If the gentleman is assuring me that there is no attempt here to try back us out of participation in the global marketplace, that it's simply an assurance that our R&D is in fact benefiting firms that do business in this country, I see no particular problem with that in this sense.

I do want to make certain that those things that we do recognize that research and development, as well as business these days, is in fact a global enterprise and that science always has been something which the data has been generally shared across the world and has not been nationalized.

And so, I just want to make certain that anything that we're doing here does not get in the way of kind of long-standing traditions, and certainly the opening of the global economy.

Mr. TRAFICANT. Would the Chairman yield?

The CHAIRMAN. Sure. I'd be happy to yield.

Mr. TRAFICANT. Certainly, no intention to the contrary to anything that you've spoken. But I would like to say that we come up with billions of dollars of research and many times that technology is used against us, and we're at a major trade deficit in this world economy.

And I would just like to see some emphasis being placed on a reasonable approach to having some of that research investment trickle down to the benefit of America and our ability to compete in that global marketplace.

So it is a bona fide intention not to obstruct, and I would welcome any supportive language that you could fashion and would welcome it.

The CHAIRMAN. I would say to the gentleman, all we're doing is adopting an Oversight Agenda here, and with his assurance that that Oversight Agenda is in fact a broad one on this topic.

Obviously, the work of this Committee is aimed at assuring that the science that we develop in this country is used insofar as possible to the benefit of this country. And that is the overall mission of the Committee.

It sound to me as though the gentleman's language fits in with that very well, and so we can probably include that as a part of the en bloc.

Mr. HAYES. Would the gentleman yield?

The CHAIRMAN. Sure, I'll be happy to yield to the gentleman from Louisiana.

Mr. HAYES. Mr. Walker, is it not correct that with your approval as Chair, that if Mr. Barton and Mr. Traficant were to get together on the subject nature of a hearing on this, that you could in fact approve that with or without its inclusion today in the Oversight Agenda, as the substance of a hearing to be chaired by Mr. Barton?

Would you not have that authority?

The CHAIRMAN. I think Mr. Barton is making the point that he in fact has jurisdiction on some of these matters at the Commerce Committee, rather than here.

But the fact is, as I stated earlier, that this is not an inclusive list. This is strictly a list of items that we are committing ourselves to at this point.

But just because some item is not on this list doesn't mean that the Committee may not have an opportunity to deal with it in the future.

Ms. Harman.

Ms. HARMAN. Mr. Chairman, I would like to state my enthusiasm for this Oversight Agenda. I'm sure Mr. Brown's additions will be good, too.

But this line of approach I think finally fulfills much of the promise of this Committee. Our legislative jurisdiction is not vast, but our oversight jurisdiction and our ability to discuss these critical issues that will be central in the 21st century, which is only five years off, is vast.

And so, I commend you for putting this together this way and I hope that we will proceed in this direction.

The CHAIRMAN. I thank the gentlelady.

Mr. Weldon.

Mr. WELDON of Pennsylvania. Thank you, Mr. Chairman.

I too want to applaud you for this agenda. It's aggressive, but I think it's certainly timely and fitting for the jurisdictional responsibilities of this Committee.

I just want to note for the record that as the current chairman of the Research and Technology Subcommittee of the National Security Committee, that I have offered—and I understand that we have at least some general agreement on conducting joint hearings on areas where the jurisdiction of this Committee overlaps, or in fact interconnects with the jurisdiction of the Research and Technology Subcommittee of the National Security Committee.

So, hopefully, we can have that joint effort throughout the next two years on issues that in fact are under the DoD budget, but certainly have science and technology implications.

The CHAIRMAN. I thank the gentleman for his remarks.

If there is no further general discussion, the Chair would open the Oversight Agenda to amendment at this point, and would welcome the Ranking Minority Member taking those items that he wishes to and putting them en bloc, and then, again, we can have discussion on the various items, if that's the will of the Committee.

I would recognize the gentleman from California.

Mr. BROWN. The distinguished Chairman is not trying to trap me into offering a long series of complicated amendments en bloc in order to set a precedent for what he's trying to do on another bill.

The CHAIRMAN. The gentleman is entirely too suspicious. [Laughter.]

Mr. BROWN. Mr. Chairman, I offer the four items listed on the package in front of you as additional items for oversight by the Committee.

The CHAIRMAN. Is there any discussion on the amendment en bloc offered by the gentleman from California?

[No response.]

Hearing none, I would entertain a unanimous consent request that the amendment en bloc be approved.

Mr. TRAFICANT. Mr. Chairman, I ask unanimous consent the amendment en bloc be approved.

The CHAIRMAN. Without objection—well, let me ask whether or not we have any other amendments to the oversight——

Mr. BROWN. I was just going to say that I understand one of our members may have an additional item.

Ms. JACKSON. Mr. Chairman, I wanted to inquire whether or not we could have by unanimous consent to add to those utilization of women and minorities in science-related businesses.

The CHAIRMAN. Well, we have just approved the women and minorities in science amendment as a part of the en bloc amendment.

Ms. JACKSON. And that's why I was adding in science-related businesses.

The CHAIRMAN. Understanding that this is a general oversight agenda, that particular item would certainly be included under Amendment No. 4 listed on the roster.

Ms. JACKSON. That's all I would ask, is that you'd have your commitment that we could look at those issues.

The CHAIRMAN. Sure.

Ms. JACKSON. Thank you.

The CHAIRMAN. That would be included in that overall.

Ms. JACKSON. Thank you.

The CHAIRMAN. Are there any other amendments to the oversight agenda to come before the Committee?

[No response.]

If not, I would turn to the gentleman from California for a motion.

Mr. BROWN. Mr. Chairman, I move that the Oversight Agenda for the Committee on Science for the 104th Congress be adopted as amended, that the staff be instructed to make the necessary technical and conforming changes, and that the agenda be forwarded to the Committees on House Oversight and Government Reform in accordance with House Rule X2D1.

The CHAIRMAN. The motion has been heard. All of those in favor, say aye.

[A chorus of ayes.]

Those opposed, no.

[No response.]

The ayes have it. A quorum being present, the Oversight Agenda is approved.

I am informed by staff that the Legislative Council is in the process of delivering the substitute amendment on Risk Assessment at the present time.

It is the intention of the Chair to recess the Committee for a period of time so that members do have an opportunity to look at that particular amendment and have time to digest it.

So, therefore, we hope to have that in hand and hope to have it reviewed by 11:00 o'clock. It is the Chair's intention to give members then two hours to have an opportunity to review it before we go into a marathon session to consider other amendments that may come before the body.

And so——

Mr. BROWN. Mr. Chairman.

The CHAIRMAN. I yield to the gentleman from California.

Mr. BROWN. Mr. Chairman, I hope that the Chair understands, and I want the members to understand, that our request for time to review this is not something that is engaged in or put forward for the purpose of creating delay or obfuscating the basic situation that we're in.

The fact is that it is very difficult to amend the en bloc amendment, and that's why the rules require unanimous consent to do that.

We have a series of what we think are constructive amendments on our side. They can be offered much more readily to the substitute, and that's what we propose to do.

But we need now to redraft our amendments to conform to the language of the substitute which we have not yet seen. So we need an opportunity to review it and then to redraft our amendments.

That is the purpose lying behind our request for an adequate amount of time.

Now, we do not know at this point whether a delay which may or may not be up to as much as two hours will allow us to go through this fairly complicated process. Our amendments are drafted, but they all have to be conformed to the new language.

We would prefer 24 hours. As you know, the Committee on Commerce delayed their mark-up from Tuesday until today because of similar reasons.

But if you feel that two hours is the most you can give, I want it fully understood that we may not be able to do the kind of workmanlike job that we think ought to be done on this bill.

And I'm putting that to you for your consideration.

The CHAIRMAN. Well, the reason why the Chair decided to go the en bloc route was so that we could share all of these items with the Minority in advance.

I understand that that does require unanimous consent and that you were well within your rights to suggest that that was not something that you were willing to proceed with.

That is the reason why the Chair has gone back and drafted a substitute.

I repeat again that the substitute will reflect that which was in the en bloc amendments, so the subject matter should be familiar with you from last night's discussion, last night's material.

With regard to the business of making certain that the page numbers and line numbers are right, the Chair is not going to be

picayune about those kinds of questions. It is subject matters and we'll see to it that they're plugged in at the right point. And if we have to have corrections made as the amendments are being distributed to members to put the right page numbers and so on in, we are certainly going to permit that to take place.

So that I would hope that in a timely manner, we can proceed ahead.

But it is the Chair's intention to proceed ahead with the markup on the bill. We have attempted to accommodate the Minority with regard to hearings. We did schedule an extra set of hearings at your request. I think it was a valuable addition. We learned a lot and we've incorporated some of that into the substitute.

So we will continue to try to cooperate insofar as we can, but we do have obligations that we have to meet and it is the Chair's intention to meet those obligations.

I'd be happy to yield to the gentleman.

Mr. BROWN. The gentleman knows the high regard I have for him and his sense of fairness, and we will try and observe that at all times.

I would point out to the gentleman that we pointed out the difficulties to him on Friday of this process and asked and informed him that we would ask him to abide by the rules in this matter. And we still didn't get the fruits. We didn't get, for example, an affirmation that you would follow the route which the rules require until right today, as a matter of fact.

The Chair was of course correct in stating that we received an additional day of hearings. I might point out that that, too, is required by the rules.

What I'm saying to the gentleman is he's been meticulous in making sure that we got what the rules require we get, but not one iota more.

Now he may think that that is an example of outreach and cooperation. We think that it is good judgment on his part to observe the rules.

The CHAIRMAN. I thank the gentleman for that and I assure him that we have in fact followed the rules and will continue to do so, so that all members, both Majority and Minority, are appropriately protected.

Mr. ROHRBACHER. Mr. Chairman?

The CHAIRMAN. I'd be happy to yield to the gentleman from California.

Mr. ROHRBACHER. I think it's important for us to note at this time and juncture of the discussion that the Chairman is, number one, being very scrupulous in his going by the rules and making sure all the rules are being met.

But also, he's being very diligent in making sure we move forward this piece of legislation.

As the Minority, as well as the Majority, realizes, we have set a deadline in this first 100 days of accomplishing certain things in Congress. And after this 100 days, when we have accomplished that legislative agenda, I'm sure that the Chairman will be much more inclined towards giving the Minority even more time than is legally required for them to get.

But in this case, the Chairman is absolutely right, that the Majority has to be diligent. We have made an agreement with the people. We said this during the last election, we would accomplish certain legislative items within a certain period of time.

The Chair is abiding by the rules, but being very diligent and moving the legislation along is appreciated.

Mr. BROWN. Would the gentleman yield briefly?

Mr. ROHRBACHER. I yield to my former chairman, Mr. Brown, sure.

Mr. BROWN. I understand what the gentleman has stated. And while I think that's wrong, I'm not anxious to delay this. I'm offering to cooperate in every way possible.

Our effort would be to have as good a product for you as possible. And I'll tell you very frankly, that in many cases, in strategy debates within the Democratic side, we have debated whether or not we ought to screw you up by letting you go ahead and do what you're doing. [Laughter.]

But the point that I would like to make with regard to your comment that at the end of the 100 days you're going to give us more time, at the end of the 100 days, you're going to rest.

this is the biblical way. [Laughter.]

The CHAIRMAN. I would only say to that, I hope so. [Laughter.]

But let me also comment to the gentleman that the problem, of course, that we face is that the rules also require things after the process finishes here.

We are going to be meticulous in giving everyone their chance for three days on the report and a number of other items, which means that even after the bill leaves the Committee, there are about ten days before you can possibly bring it to the floor.

On the schedule that we are proceeding under, that does compress our time fairly substantially and means that we do have to accomplish some of these things in a timely manner, so that we can be assured that we can be on the floor at the time that we have been assigned by the leadership.

Let me go to Mr. Roemer, and then come back to a couple of other members.

Mr. ROEMER. Mr. Chairman, let me just preface my remarks by saying that I certainly recognize your timeframe and the need to move in a quick fashion, given what the Contract for America says.

Let me also preface my remarks by saying, I come from a position on both these bills as strong supporters of both Risk Assessment and the Hydrogen bill.

Risk Assessment—many of us on this side fought rules put together by our own party last year because they did not consider the opportunity for us to attach Risk Assessment to the elevation of EPA as a new Cabinet-level agency.

We believe strongly in this legislation.

But that does not, I would hope, preclude us from the possibility of reading the legislation and amending it. I am not suggesting any kind of dilatory tactics here.

Much was made last year by people on both sides of the aisle about crime bills that would come to us with six hours of preparation on the floor of the House and we couldn't read it, we couldn't amend it. We'd have to vote on it a couple of hours later.

A similar fashion I think might be repeated today if we only get the legislation a few hours before we are seriously supposed to consider it, intellectually amend it, improve it, modify, it. And again, I am coming at this as a supporter, as somebody that will probably vote for final passage of both bills.

We just had hearings on both these bills in the last couple of weeks. For instance, on Hydrogen, I intend to offer a couple of amendments based upon the hearings and suggestions in the hearings last week. I'm hopeful that you will agree to those amendments, and they won't even be controversial.

But on Risk Assessment, I think that we can work together to improve it as well.

And I think that Mr. Brown is not saying we want to wait two weeks. I think we just want to have time to read it.

Maybe a suggestion would be that we bring up Hydrogen first and get to Risk Assessment later today or first thing in the morning.

But in no way am I trying to delay either your first 100 days or this legislation. I am just trying to make the point that I think that there are some bipartisan things that we can do in a committee process to try to improve both bills.

The CHAIRMAN. Well, I thank the gentleman for his statement. I don't think the Chair has indicated in any way that he believes that anybody is engaging in dilatory tactics here.

I am not reviewing the amendments that the Minority has put forward. I agree with some of them. I don't agree with others of them.

I think we need to have that debate.

But in all cases, the amendments that I have seen thus far have been valuable additions to the debate and I think will help us better understand the bill.

I don't see any need based upon the fact that the Minority has been able to put together a series of what I think are fairly substantive amendments, to delay the consideration and the debate on those amendments because, in most instances, these are exactly the same issues that we debated in the last Congress before we reported legislation. There may be difference in detail in some elements of the bill, but, again, that's the reason why we want members to have some time to understand it here, and we are prepared to give you a couple of hours to do that.

But there is obviously a good enough understanding that some very reasonable amendments and valuable amendments have been put together.

As I say, I may not agree with all of those, but the fact is I think they are going to inspire very useful debate about the nature and content of this bill.

I don't see any particular reason to delay moving forward with that debate.

Mr. BAKER. Mr. Chairman.

Mr. Baker of California.

Mr. BAKER. Is it the Chairman's intention, then, to reconvene in two hours and accept the Minority's amendments as written for debate, without renumbering, repaging, all of the tedious work that needs to be done?

The CHAIRMAN. Yes. It's the Chair's view that the Minority amendments in fact go to the policy within the bill that the substitute is going to have those policies.

And I would urge the members of the Majority not to get into any kind of technicality debate here on whether or not it's properly numbered.

In other words, to facilitate the debate, I'm going to allow the numbers and so on to be changed in terms of page numbers and that sort of thing without engaging in some argument over technicalities.

Mr. BAKER. All right. And as the Chair who worked with the former chairman on these two bills last year, both of which, I believe, got on the floor and out of this Committee, would it be your intention to review the status as we go along to see if there's any areas of misunderstanding that need more time?

The CHAIRMAN. Well, I think we've tried to do that. That's the reason why we did try to get the information to the Minority last evening.

In all honesty, I did not have a chance to go over some of the negotiations that have taken place with the Commerce Committee until about 5:00 o'clock last evening myself.

Mr. BAKER. Right. But since this issue——

The CHAIRMAN. And soon, as soon after that, that I got my chance to review the final nature of the language, that it was shared with the Minority as well.

Mr. BAKER. But since this issue has been before us for two years, some members notwithstanding, and the details are pretty well beaten out, it's your intention to start the debate and see how we go as we move along.

Is that right?

The CHAIRMAN. That is my intention. And my intention is to go today until we have completed action on the bill.

Mr. Barton.

Mr. BARTON. Mr. Chairman, I want to make all the members aware of something that they may already be aware of. But the identical bill with almost identical amendments in many sections is being marked up today in the Energy and Commerce Committee, and apparently is going to be done simultaneously, since we're going to take this break.

Now I have two questions. Number one, what would happen if for some reason we didn't finish our mark-up? Would we go with—assuming that the other committee finishes their mark-up, is that the document that goes to the Rules Committee?

And number two, if we do intend to finish it, do you intend to finish it today, even if we're here until midnight?

The CHAIRMAN. Well, I would say to the gentleman that it is my intention of finishing the bill today.

We are the primary committee of jurisdiction on this legislation. If we report a bill, our bill will be the primary bill taken before the Rules Committee. The Commerce Committee's bill will be a part of that consideration as well.

If in fact we did not report a bill from this Committee, we would lose our jurisdiction, our primary jurisdiction, and at that point, the Commerce Committee's bill would become the operative bill.

Mr. BARTON. So it is important that we have a work product.

The CHAIRMAN. Well, insofar as we want to be the lead committee on the floor with the bill, it seems to me that we do want to complete our work and move it forward, yes.

Mr. BARTON. Thank you.

Mr. BROWN. Would the gentleman yield briefly to me?

The CHAIRMAN. Certainly, I'd be glad to yield to the gentleman.

Mr. BROWN. I understand the parliamentary situation to be that no bill can go forward unless we report a bill or we are discharged from the consideration of that bill.

I agree completely with the gentleman that it's in our best interest to move forward with a bill, even though it may be substantially equivalent to the Commerce Committee bill.

I understand also the difficulties in the liaison between the two committees. I will say that my understanding is that the Commerce Committee members had the substance of the substitute that the gentleman is proposing last Friday and, nevertheless, postponed their Tuesday mark-up until today.

We sense that there is a certain confusion here. We do not blame anybody for it. We would like to help alleviate it, as a matter of fact, and go forward with a good bill from our Committee that can be the vehicle for action on the floor.

I have at no time assumed that the Chairman was deliberately trying to obfuscate this process. I have too much respect for him to think that. Just as he recognizes that we have made a good-faith effort to draft sound amendments to the bill.

But, nevertheless, it has been a rather hectic process and we would like to see that improve.

It is not quite correct to say that we have substantially addressed the substance of this bill in prior Congresses. For one thing, a third of the members of this Committee are new and have never had an opportunity to address this bill. For another thing, two-thirds of the provisions of Title III are new and do not include what we discussed, which is Part A of Title III, in the last Congress.

But despite that, there are large overlaps. The subject matter has not only been addressed in the last session, but occasionally, over the last 15 years, and has been controversial during all that period of time.

I think it's only fair to point out that new members and those who never really understood the issue before really ought to have a little time, if it can be arranged within the constraints of the schedule that the Chairman is compelled to follow.

Mr. BARTON. Would the gentleman from California yield on that point?

Mr. BROWN. The Chairman has the time.

The CHAIRMAN. Well, let me just point out to the gentleman, and then I will come to the gentleman from Texas, that I believe that we have followed exactly the same process that the Commerce Committee followed on this matter. The Commerce Committee, though, had a day earlier schedule.

The fact is that there were briefings of LAs and so on the end of last week on the mark-up vehicle that was going to be before this Committee.

That has been changed somewhat. It is my understanding that the Commerce Committee was shared a draft of the amendments or the substitute two days ago. But since that was revised again, it was then given to them last night at the same time that this Committee got it.

Now, we did not do the intermediate step of the Monday situation because we believe that we did not have a final vehicle in hand at that point.

But a soon as we had a final draft, that is when we shared it with the Minority. And that was the draft as of last night, and it's my understanding that the Commerce Committee got it the same time that we did as of last night.

So we are trying to proceed along the same grounds, and they are marking up on the same schedule that we are, given the nature of the drafting process that went forward.

I am in fact trying to provide the members with some time that would then provide similar time as to what is available to the Commerce Committee to review the bill before we move forward.

The gentleman from Texas?

Mr. BARTON. Mr. Chairman, I think I have a solution. I believe I'm the only member of either party that are on both committees.

If we could ask unanimous consent to let me just take control of the entire bill, I'll go to John Dingell and Tom Bliley and get their unanimous consent and everybody else can take the rest of the day off, and I guarantee you we'll have a bill out of here by 2:00 o'clock this afternoon [Laughter.]

The CHAIRMAN. Yes. I think you've got objection from our side on that. [Laughter.]

The gentleman from Tennessee?

Mr. TANNER. I don't want to belabor the point, Mr. Chairman, but I want to echo that Mr. Roemer said.

We have some ideas and we'd like to participate. I know when you all were in the Minority, you wanted the same consideration.

But the position we sometimes see or feel ourselves in today is now, not only are we rushing against an arbitrary 100-day deadline, now we're in the position of racing other committees within the House.

We just want to ask that we be given consideration to participate fully, thoughtfully, and in a constructive way. And when we're placed in the position of not only racing against a deadline of 100 days, but now racing against another committee to the floor, this is not the best approach, Mr. Chairman.

The CHAIRMAN. Well, I would say to the genetleman——

Mr. TANNER. And we're for the legislation.

The CHAIRMAN. I don't think there's any race with the Commerce Committee with regard to this. It doesn't matter whether we report it our first or not.

There's no race involved on it. It's simply a matter that in both cases, the committees are bound by the rules of the House which require certain period of lay-over and so on before we can go to the Rules Committee and before we can report it to the floor.

And given our schedule, and we, while I understand that there may be some in the Minority who feel that the 100-day mandate is in fact an arbitrary mandate, I assure you that on our side of

the aisle, we do not regard it as arbitrary. We regard it as a true mandate upon us to move ahead, and we do intend to stick to that schedule.

So the arbitrary nature of that is, I think, in the eyes of the beholder.

We are in fact, though, intent upon doing our work at this Committee and hopefully including all members who wish to participate.

Mr. ROHRBACHER. Mr. Chairman?

The CHAIRMAN. It is the Chair's intention to allow any member that has something to contribute to the process, to make that contribution in the course of this, and depending on how many members want to make their contribution along the line, we could be here quite a long time doing that.

But we will do so.

Mr. ROHRBACHER. Mr. Chairman, we've been discussing this about a half-hour now. Those folks could have been reading the bill and doing their work all this half-hour.

The CHAIRMAN. Well, I'm kind of watching the time. I was told it would probably be available about 11:00. So I was perfectly willing to have a discussion here until the time that I knew it would be available.

My staff tells me it's now available, so we've done our work very well here. It's been very efficient use of the time.

We do in fact have this available for members to review.

The Chair would declare a recess until 1:00.

[Whereupon, at 11:00 a.m., the Committee recessed, to reconvene at 1:00 p.m. of the same day.]

The CHAIRMAN. The Committee will come to order.

It is the intention of the Chair to proceed at this time with the markup of Title III of H.R. 9 which is the Risk Assessment and Cost/Benefit Analysis For New Regulations.

It is further the intent of the Chair to put on the table for amendment, a substitute that has grown out of the hearings that were held last week.

In my view, those hearings brought to light a number of issues which demanded some clarification and, it seemed to me, demanded some changes in the original text of H.R. 9.

There is now before the members a copy of the Substitute. What the Substitute does is incorporates the en bloc amendments that were developed over the last couple of days and were made available last night.

As I said earlier, I assured the Committee that what is included in this Substitute is the same as what was in those en bloc amendments, so that there has been a period of review.

Let me clarify just what we have here so that you'll understand the nature of the changes that were made.

Under the Substitute, only regulations of major import, which are based upon risk assessment and risk characterizations, are included within the scope of the Substitute.

These include any regulatory effect on the economy of $25 million or more, any proposed final regulatory decision to decontaminate or clean up facilities, any report to Congress, placement of a substance or health effects value on the Integrated Risk Information

System Database, any regulatory action to place a substance on any official list of carcinogens or toxic or hazardous substances, and any risk assessment or risk characterization guideline or protocol of general application.

In consideration of the ministerial functions of the Government on which we receive testimony, the Substitute also exempts certain categories of Government activities, such as emergencies, screening analyses, food, drug or other product labels, health and safety or environmental inspection or individual facility permitting action.

The Substitute would give direction to agencies to establish additional risk assessment and characterization criteria.

These include consistence compliance throughout the Federal Government, administrative burden, impact on Federal, State and local governments.

The Substitute also clarifies that risk assessments and risk characterizations are supplemental to, but do not supersede, any other provision of law designed to protect health, safety, or the environment.

The Substitute also makes clear the importance of characterizing and then communicating the nature of risks to decisionmakers and to the public in terms that are clear and understandable.

The characterization shall include a description of the impact of risks on specific and sensitive populations or natural resources.

The Substitute further elaborates on the concept of substitution risk, past regulatory action in trying to ameliorate one type of risk has often merely substituted another hazard.

The Substitute clarifies that risk assessments and characterizations that are undertaken between the date of enactment and the effective date of this legislation may be reviewed on the basis of risk assessment guidelines and any new information received, if such information would significantly alter the results.

Subtitle B of the Bill deals with the analysis of risk reduction benefits and costs. Amendments to the Subtitle attempt to put into perspective the benefits as well as the costs of the Environmental Health and Safety Regulations.

The amendments ask for certification from the affected agency that benefits will justify the cost of Federal, State, and local governments and private entities, and that there will be no regulatory or non-regulatory alternative more likely to achieve substantially equivalent reduction in risk in a more cost effective manner.

The Substitute also clarifies that the cost benefit analysis shall supplement existing law. However, to the extent that there is a conflict with existing law, the criteria for rulemaking for rulemaking the criteria in this section shall supersede existing law.

However, to ameliorate those conflicts of law, the Office of Management and Budget shall develop transition plans to meet the new criteria.

Further, so that the Congress may consider changing these laws in conflict, the Federal agency shall report any differences between the certification provisions of this Title and the decisional criteria for rulemaking that would have otherwise been applicable under other statute.

Subtitle C of the Bill is a section which formalizes a peer review process amongst agencies. My amendment to this section attempts

to resolve concerns expressed at the hearing about the potential conflict of interest of the reviewers by proposing that no peer reviewer may be excluded because the reviewer represents an interest that may have a potential stake in the outcome, provided that interest is fully disclosed.

In the case of a regulatory decision affecting a single entity, no peer reviewer representing such an entity may be included on the panel.

To exclude an individual with requisite knowledge base in a given field would be impractical. My language, however, would assure that full disclosure of the reviewer's interests is made.

Now that covers the major items that are included in the Substitute that were not in the original Bill. And the Chair is of course prepared to discuss a variety.

There's one thing that I also want to point out to the Committee. That under this provision, we also do retain judicial review, and that's largely to ensure that agencies do what we tell them to do in the Bill.

However, there's been concern expressed that we need to make certain that there are appropriate limitations on that judicial review, and that we don't end up with every scientific decision going to court.

So what we've done, under the Substitute, is to assure that the normal time-tested judicial review provisions of the Administrative Procedures Act apply.

So that we have done as a typical process under the Administrative Procedures Act is going to apply in this case.

Under our judicial review provision, a risk assessment, cost benefit certification, or peer review requirement could only be subject to judicial review when associated with a final agency action, like a rule, because they would be a part of the administrative record.

Mr. BROWN. Would the gentleman yield to me on that point?

The CHAIRMAN. I'd be happy to.

Mr. BROWN. I haven't had the benefit of discussion this with counsel but its my off-the-cuff opinion that this clarification of the judicial review is helpful and desirable.

We were deeply concerned that there would be an indefinite number of opportunities for judicial review before, and this makes that much more clear.

I am constrained to point out, however, that this was added between 6:00 o'clock last night and this morning, when we got this final text, along with several other, some minor, some not so minor changes, and this illustrates to me, and I hope to you, the need for the opportunity to review these points.

Now some of our amendments were aimed at this judicial review provision. They are no longer necessary. They may be necessary, I'm advised.

But in any event—you can never depend on counsel to back you up in this game, you know. [Laughter.]

Mr. BROWN. In any event, this is a constructive move forward, and we would hope that we could have some additional movement of a similar nature.

The CHAIRMAN. Well, thank you.

And I think the nature of the amendment process is going to be that we probably will be able to proceed in a constructive way.

The gentleman is correct that this is an addition. It was done primarily at the instruction of the Chairman who had an evening to think about what he had heard about the Bill yesterday, and decided that I did want to clarify what I've always believed the intent of the Bill was, and asked staff to do that this morning. And so——

Mr. HASTINGS. Would the Chairman yield?

The CHAIRMAN. That is a different position. That is virtually the only thing in the substitute which is a change from what the amendments en bloc that was provided last evening.

The gentleman from Florida.

Mr. HASTINGS. I thank the Chair, and I'd like to put a question to the Chairman.

I'm not completely clear that this is going to minimize the opportunities for persons to litigate. And I'm curious as to how it works.

If it's applicable, if the law itself is applicable to the Administrative Procedures Act, then I assume that all things that the Act allows for will allow for an individual to litigate it appropriately.

So how is it that some so-called judicial limitation is going to stop folk from litigating matters of consequence that appear in the Bill itself?

The CHAIRMAN. Well, as I explained earlier in my comments, the Administrative Procedures Act is applicable to those things which are involved in the regulatory process.

And so this would limit judicial review to those things that become a part of the administrative record. And it would mean then that every little instance out there where there's regulatory action being taken would not necessarily be subject to judicial review. It would mean that the major rulemaking authority that is in the agencies, subject to the other exemptions, would be the things that would be brought under judicial review.

Mr. HASTINGS. I thank the Chair.

Mr. ROEMER. Mr. Chairman, just a simple statement.

I have an amendment on judicial review that I would still like to offer and discuss.

The CHAIRMAN. Nothing in the substitute precludes anybody from offering any amendments.

In fact, you know, we now have a vote on the floor. You know, it is my intention to come back, open the floor to discussion on the Bill and on the Substitute. And then proceed into the amendment process.

What we're trying to do in this Substitute is handle some of the questions that have arisen, but it is not meant in any way to preclude any member from offering amendments that they think help clarify or help improve the Bill.

Mr. ROEMER. And that's where I would like to work with the Chairman on this clarification, moving from being silent on this issue of judicial review to clarifying where we want to go.

The CHAIRMAN. Well, I would say to the gentleman that my concern was that the Bill was silent on the issue. I don't believe that the language that I have developed changes the Bill in any substantive way. However, I thought it was important to have lan-

guage in the Bill that clarified directly what it was we intended to have be the process for judicial review.

If the gentleman wants to further clarify that, we'll certainly consider his amendments. I'm not positive that I am prepared to take amendments that go further than this particular provision, but we certainly want to have those kinds of discussions.

Mr. ROEMER. I like your direction, Mr. Chairman, and just want to provide further clarification.

The CHAIRMAN. I thank the gentleman.

Mr. ROEMER. Thank you, Mr. Chairman.

The CHAIRMAN. With that, the Committee will recess to go vote, and then we'll proceed immediately following the vote.

[Recess.]

The CHAIRMAN. The Chair would call the Committee to order.

The Chair has explained the Substitute that has been laid before the Committee, would now open the Committee for purposes of general discussion of the measure, of the Substitute, before actually laying the Substitute before the Committee for amendment.

And so the Chair would recognize those members who wish to engage in discussion of the Substitute and the Bill.

Mr. BROWN. Mr. Chairman?

The CHAIRMAN. The gentleman from California?

Mr. BROWN. I think the Chair, himself, has gone through an done a reasonably good job in explaining the main thrust, but sometimes the devil is in the details.

And I wonder if the counsel could provide for the members of the Committee a brief discussion, starting with any differences that may exist between the version that we received this morning and the version that we had a couple days ago.

Now staff on our side has gone through and identified possibly a couple dozen relatively minor changes, plus the addition of the judicial review provision.

And I would just like to have Committee counsel confirm those changes that have been made, if he's had a chance to review it in sufficient detail.

The CHAIRMAN. Would counsel specify those areas where there have been changes between the measure put before the members last evening as a draft and the version of the Substitute that is now before us?

Mr. BROWN. I might say that we recognize that the process of improving language goes on continuously, particularly with the legislative counsel, and we're not objecting to this. We just want to make sure we've identified all the changes.

Mr. BERINGER. Mr. Brown, the major changes you've already pointed our was in the addition of the judicial review section. It was our intention that the rest of the changes, for instance, there were several misspellings, just the word "likely" would be merely clarifying or technical changes.

I know of no others that are of substance other than the judicial review section.

Mr. BROWN. May I call the counsel's attention to a couple of instances here.

For example, on page 10 of the version that was presented to us this afternoon, and this is more or less picked at random, it says

"In a significant risk assessment document . . ." whereas the earlier version had "In a significant risk characterization document."

Is that intended to represent a difference or a clarification or what?

Mr. BERINGER. It's supposed to read "characterization" being in that Title.

Mr. BROWN. It is supposed to read "characterization" which is the way it originally was?

Mr. BERINGER. That's my understanding.

The CHAIRMAN. It is my understanding that that, that it is as it was presented last night.

Mr. BROWN. Yes, but the document before us says risk assessment.

[Pause.]

Mr. BERINGER. The bill's supposed to read "characterization."

[Pause.]

The CHAIRMAN. It is my understanding that the way the language is now drafted indicates that a risk characterization is in fact a portion of a risk assessment, and it is the same as was presented, the language, as was presented in the amendment provided last night.

Now this is different from language that was given to you three days ago. And that is in fact changed. It's one of the series of changes that we went though before finalizing some of this last night.

But this language that you have before you is the language that was provided to the Committee last evening.

Mr. BROWN. Well, I'm not sure that I understand the significance of the difference between assessment and characterization.

I think the Committee wants to know what is the language that is currently before us and how it differs from any previous language that was offered.

The CHAIRMAN. And the language before you indicates that in a significant risk assessment document.

Mr. BROWN. Yes.

The CHAIRMAN. And we are talking about the risk assessment document and we are talking about—later on we are talking about risk characterizations being a part of that risk assessment document.

And so what we have in the language——

[Pause.]

Mr. BROWN. We found about 20 instances of this kind of minor changes, and I'm not at all attempting to sow confusion in your ranks here, but——

The CHAIRMAN. Well, there is no confusion in our ranks. The fact is that risk characterization is a part of a risk assessment document, and that is exactly what the legislation now says. So there is no confusion about this in any way, shape, or form.

I'm sorry that it's confusing people otherwise, but I don't believe that we feel that there's any confusion at all, and that the language now conforms with what legislative counsel has told us is the appropriate way to make certain that we are addressing those things that we wanted to get addressed.

Mr. BROWN. All right. You're sure then that what you want is risk assessment, not risk characterization, in the language on line 3?

The CHAIRMAN. Line 3 simply refers to the fact that as you see, we are talking about principles for risk characterization and communication, so we are defining where that would take place. It would take place in a risk assessment document, risk characterization being a part of risk assessment.

And so we have placed language in the law that assures that we are characterizing risk in the appropriate documents.

Mr. BROWN. Well, you recognize that you have in the Bill provisions for both risk assessment documents and risk characterization documents?

The CHAIRMAN. I understand that, and they are—we are trying to assure that we have clarified exactly what it is we want at particular points in the Bill. That's what we thought we were doing.

Mr. BROWN. Well, I'm happy if the gentleman feels that it's clarified. I'm not at all clear as to what it means and I'm worried about some poor bureaucrat reading this and wondering what the risk assessment document means in a paragraph on principles of risk characterization, and what the different uses of the different documents are intended to be.

The CHAIRMAN. Well, if the gentleman would go back to the original language that was before the Committee in H.R. 9, we said there, "in characterizing risk in any risk assessment document." We have changed that to "in a significant risk assessment document."

So what we have attempted to do is be more clear than what you had before. We have attempted to say, first of all, that this is not in any risk assessment document, it's in a significant risk assessment document and that in fact, since we are defining characterization anyhow, we didn't think we had to use the word, characterizing, in the earlier language.

Now I realize that all of this gets very confusing but, you know, I don't think we're confused at all about what it is we accomplished.

Mr. BROWN. You made the decision last night then to change the document which said "risk characterization document."

The CHAIRMAN. No. No. We did not make the decision last night. It was handed to you last night in this form.

Mr. BROWN. It was handed to us in the form of a risk characterization document last night, and then changed this morning to a risk assessment document.

The CHAIRMAN. Everything that we have before, I mean, I have the documents here that were handed to you last night.

Mr. MINGE. Mr. Chairman, perhaps I could shed some light on this?

If you would look at pages 4, lines 17, 18, 19, and 20, the two phrases are used interchangeably.

Mr. BROWN. Page 4.

Mr. MINGE. And I think the confusion may arise from the fact that we have two phrases that are very similar and the question is, are these phrases used in different contexts in different places in the Bill, and what is the significance of the difference?

Because the provision on page 4 between lines 15 through some place in the middle of page 5, well, through the end of that page and on to page 5, that is new language in this draft of the Bill.

So what I think has happened—I wonder if this isn't tied to the judicial review provision because there's an attempt to talk about final agency action or decisions and so on at this point.

And I would just ask if the counsel for the Committee could explain why we have two different parallel phrases and the function of this new section or this new language in the Bill so that we know how it relates to other language in the Bill.

Mr. BERINGER. The risk assessment documents are the—first of all the document part attempts to define what is the scope of the coverage of the Bill. Only significant documents that are in the purview of the Bill.

The characterization section goes to the way in which risk is described to the decisionmakers and the general public.

And so there is a difference between risk assessment and risk characterization. However, risk characterization comes as a result of the risk assessment.

Mr. MINGE. Would we minimize confusion if we used the same phrase consistently in the Bill, rather than having two separate phrases?

Mr. BERINGER. Well, no, because they are two separate concepts. The characterization is the way in which the scientist or the people conducting the risk assessment so indicate what they think the risk is. For instance, what is the exposure of certain populations to a certain risk. Sometimes it's determined in qualitative form, sometimes it's in quantitative form.

For instance, we heard discussion the other day about the population exposure of ten to the minus sixth. That would mean one extra cancer risk for every millionth person. That's a risk characterization.

So there is a difference.

Mr. MINGE. Is there a place in the Bill where those two phrases are defined?

Mr. BERINGER. Yes. Yes, they are.

Mr. MINGE. At what point are they defined?

[Pause.]

Mr. BROWN. Mr. Chairman, may I continue with another question or two?

The CHAIRMAN. Certainly.

Mr. BERINGER. Page 14 and 15.

[Pause.]

Mr. MINGE. If I may say?

Mr. BERINGER. Yes, sir?

Mr. MINGE. I think those of us here that have worked with administrative agencies find this a fairly illusive distinction, and I'm afraid that those in the public trying to deal with it, or even those in the agencies will find some confusion.

And I'm wondering if there's any way that we could clarify that to minimize the confusion that's apt to arise?

The CHAIRMAN. Well, the gentlemen is certainly able to offer an amendment at the appropriate time if he thinks other clarification is necessary.

Mr. BERIGNER. The assessment is the basic science. The characterization is the way in which that science is interpreted.

[Pause.]

The CHAIRMAN. The gentleman from California.

Mr. BROWN. Mr. Chairman, I note that on page 16, line 6. specific reference is made to the Office of Technology Assessment.

I would like to inquire of counsel if an OTA report requested by Congress on hazardous waste, for example, be a risk assessment document under the definition of risk assessment document contained in this Bill, and thus trigger the kinds of procedural activities that are required here?

Mr. BERINGER. That would be the way that would be interpreted.

What we're trying to get at, Mr. Brown, seven though that's, as you point out, is a mandate on the Congress itself, but it's a certain area of the Congress, the OTA, that rather than putting out, if you will, a free floating assessment without any review, that they have to undertake some of the other things that people are required to do under the Act.

Mr. BROWN. Well, I'm inclined to feel that this is inappropriate in this sense. That OTA does not make risk assessments per se. It does technology assessments and these are peer reviewed by stakeholders throughout the country and agreed to through a consensus process by those stakeholders.

It would seem to me highly undesirable and inappropriate to consider these to be formal risk assessments in the sense that the legislation is intended to address, and may stem from a misunderstanding of what the role of OTA is.

May I ask if that factor was considered in including the OTA in this language?

Mr. BERINGER. What was considered, Mr. Brown, was the fact that they do hazard evaluation and we felt that it should be under the same stringencies as the other agencies of the Government.

I understand the point you're making, but it was considered.

Mr. BROWN. Well, the point is this entire legislation is aimed at reducing the impact of Federal regulations based upon a better form of risk assessment.

The OTA engages in no regulation, has in no way any impact upon the public except in the fact that they can read the reports.

Mr. BERINGER. Well, I'd also say that since they are not rulemaking that by and large they would not have to undertake this. But there might be some cases where they put out a warning, so to speak, about some hazard that may not be sufficiently reviewed.

The CHAIRMAN. Let me ask counsel, doesn't it also—isn't it also further limited because it would fall under page 4, Section (b)(1) in which it would have to be anything relating to protection of human health, safety and environment.

And so that that limitation means that it's not all reports at OTA. It is simply those in that narrow category included as coverage in the Bill.

Is that not correct?

Mr. BERINGER. That's correct, Mr. Chairman.

Mr. BROWN. But the language of the Bill on page 5, line 4, says "Any report to Congress."

and I've just asked if that included the OTA report, and in fact it specifically says OTA reports.

The CHAIRMAN. But it's also limited, if you will look further up under "Applicability," it's limited by the fact that any Federal agency in connection with Federal programs designed to protect human health, safety, and the environment.

So you've got to look at the totality of it, not just individual lines along the way.

And in totality, once again, there is no confusion. It says specifically what we mean.

Mr. BROWN. Mr. Chairman, if you will allow me, the OTA does not engage in any of the things that you have mentioned here. It does not have any programs that in any way, shape or form, are designed to protect human health, safety, and the environment, which is the thrust of the Bill.

Now why do you even include OTA there?

The CHAIRMAN., As counsel has explained, they have in fact issued reports, from time to time, hat do deal with hazards of one kind or another that in fact may have the impact.

It was felt that the nature of those reports to Congress could in fact influence regulatory authority and so, therefore, should include a risk analysis. But they are only in that very narrow category.

Mr. BROWN. Mr. Chairman, I appreciate the effort that you have made to reassure me.

May I assure you that I'm not reassured, that I think that this was a mischaracterization in the Bill, and that it should never have been included.

I will agree with you that it might have trivial impact because most people with common sense, understanding that OTA does not engage in any regulatory activity, are not going to worry about it too much. But I don't think this is good legislative draftsmanship.

The CHAIRMAN. Well, I thank the gentleman. He speaks as a true member of the Board of OTA.

Mr. BROWN. One who was trying to recruit you, as a matter of fact.

Mr. CHAIRMAN. Yes, Ms. McCarthy?

Mr. MCCARTHY. Thank you, Mr. Chairman.

would like some clarification, while we're on general discussion, on the standard for major rules.

I understand there are three different triggers in Section A, B, and C.

Could you review those for me and then give some explanation of why the amounts differ?

The CHAIRMAN. Counsel?

Mr. BERINGER. The standards in Subtitle A are $25 million, and in Subtitle B also $25 million, and in Subtitle C $100 million.

The reason is trying to limit the burden on agencies for a full-blown review process.

We were trying to get at regulations or economic impacts of $100 million, which was approximately 4 to 8 percent of rules that are issued on health, safety and the environment by the agencies, according to our analyses from CRS.

Twenty-five million was designed to try to capture a greater percentage of the rules and make them subject to the requirements of this Act.

Ms. MCCARTHY. How do you get a risk assessment without a peer review?

Mr. BERINGER. This doesn't preclude doing a risk assessment without peer review for the higher level. It just merely—this merely says that for those risk assessments in the $100 million category, you shall peer review.

As we heard in testimony, many times the agencies do peer reviews on many risk assessments, even ones that would be considered minor. The second panel on the second day testified to that.

Ms. MCCARTHY. Would you look with me on page 5, lines 1, 2, and 3 at the top. It's a subheading (ii).

Mr. BERINGER. Yes, ma'am.

Ms. MCCARTHY. On line 3, what type of facility are we talking about here? Is it a state or a Federal facility?

Mr. BERINGER. It would be any facility that would come under the purview of Federal law.

Ms. MCCARTHY. So it we're doing a $75 million rule with regard to this, does that trigger risk assessment or peer review?

Mr. BERINGER. Yes, ma'am.

Ms. MCCARTHY. One or both?

Mr. BERINGER. It would trigger risk assessment and characterization, but it would not, not not, if I may use a double negative, bring in peer review.

In other words, they could do a peer review and they probably would, but we were trying to limit the scope on mandatory peer review to the $100 million category.

Ms. MCCARTHY. Even if it's a RCRA facility, you think there's complete discretion there on whether to do the peer review or not at $75 million?

Mr. BERINGER. Yes.

Ms. MCCARTHY. By lowering from 100 to 25 the risk assessment in cost benefit levels, contrary to the witnesses, every witness that we heard, how many more risk assessments will we be doing?

Mr. BERINGER. I asked CRS for figures on that, and they did not have them. So there is no definitive answer.

Ms. MCCARTHY. The $100 million threshold which was first used in the Ford Administration for regulatory review, and has also been used in the Reagan, Bush, and Clinton Executive Orders, those figures are available. OMB estimated those figures.

Do you happen to have those for the Committee?

Mr. BERINGER. We provided them for the record in the Committee the other day.

Ms. MCCARTHY. Do you recall what those were?

Mr. BERINGER. If you would allow me to refer to the document, we could give that to you.

Ms. MCCARTHY. I would appreciate that.

While he's doing that, Mr. Chairman, I would like to ask you a question, because in my earlier questioning of witnesses I raised my concern about what this measure is going to cost the American taxpayers.

And my concern is that the standards that we've set for the major rule are going to trigger additional costs. In fact, EPA estimates a considerable amount of costs for its department in preparing these new, following these new guidelines.

So I would like staff to address the costs as well because I think that's something that needs to be considered as we review these different standards, especially in light of the fact that every witness that came before us recommended a threshold higher than $25 million.

Mr. Jasonowski, on January 31st, at your very own questioning, Mr. Chairman, said to you, "the coalition we are testifying on behalf of, Mr. Chairman, suggests and recommends $50 million."

And there was no other witnesses that came forward that recommended the 25, so I'd like an explanation as to why the 25 is in the final version that's before us, a sense of the costs to the American public?

The CHAIRMAN. Well, further review of Mr. Jasonowski's remarks indicated that he may have been speaking for a lot of his people in big business, but there were a lot of people in small business that did not agree with that higher threshold.

And it was our belief that perhaps small businessmen and individuals ought to be taken into account, as well as the big corporate entities.

And so that was the main reason why we retained the figure.

I would say to the gentlelady, with regard to the numbers here, the Congressional Research Service says that there were 82 rules issued at the $100 million level in 1990.

It's interesting to note that in the six months beginning October 1st of 1993, the Administration issued 67 rules of such magnitude, putting it on tract to issue over 130 rules in 1993–94, an increase over 60 percent in rules with an impact of $100 million.

So, indeed, to some extent, this will be a case of how much rulemaking the Administration wants to do.

Now, in my view, one of the ways that you can mitigate the expense of this is to do less rulemaking. In all honesty, one of the things that many of us think is probably worthwhile is to have the Federal Government doing less rulemaking and higher quality rulemaking. And that this process will in fact lead not to additional expense but to less expense because we won't have as many rules that we have to comply with.

Ms. MCCARTHY. Well, Mr. Chairman, I appreciate that particular point of view, and certainly those of us that have labored out in the states under Federal rulemaking appreciate it as well.

But I think when you're speaking to the American public, and particularly on some of the issues with regard to the environment, there is a genuine concern that it is the responsibility of the Federal Government to step up to the plate and address these issues.

And that's why I was concerned about the language on page 5, and about the differing amounts and the burden that might be placed on anyone trying to assess the standard and comply with it.

May I go back to staff, please, for an answer to my question that was addressed to you?

Mr. BERINGER. First of all, we're getting the document for you right at this moment.

But the main concern was that $25 million would indeed capture a large segment of the small business community that has been adversely impacted by regulations; for instance, the dry cleaning industry, the local gas stations, people such as that.

So there is an expression of concern to us that the threshold not be raised so high that these people aren't included in the analysis of risk and benefit.

The CHAIRMAN. The Chair is attempting to be generous with time here, so that there can be an explanation of the things that the members are concerned with.

I will say to the membership, however, that it is the intention of the Chair to complete this Bill today or tonight or tomorrow morning or wherever it happens to come down.

And so, you know, while we want to be generous with the time in terms of asking questions and so on, I have not held people to the five-minute rule, but it is our intention to proceed.

Ms. MCCARTHY. Thank you, Mr. Chairman.

The CHAIRMAN. The gentleman from Florida, Mr. Weldon.

Mr. DAVE WELDON. In an effort to expedite the operation, I'll withhold my question, Mr. Chairman.

The CHAIRMAN. I thank the gentleman.

Mr. BARTLETT. Mr. Chairman.

The CHAIRMAN. Mr. Bartlett.

Mr. BARTLETT. Thank you very much, Mr. Chairman.

I'd like to return, for just a moment, to a question that was raised by Mr. Brown and by Mr. Minge, and that is the definition of risk assessment and risk characterization.

And if you could turn to page 15, I think that we might do a relatively simple thing that would help clarify this.

Let me first read, on page 14, what a risk assessment document is, the first part of that definition.

"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 . . ."

And I think that that's pretty much what you said it was.

If you'll now look at the language that follows that, after the "or", lines 1, 2, and 3, you will find that that is exactly identical language with lines 6, 7, and 8, beginning with the word "describing."

And obviously you can't describe two documents which are different using exactly the same language to describe them.

And I would wonder if we couldn't just strike the "or" and everything after it on lines 1, 2, and 3, so as it would now make the risk assessment document different than the risk characterization document.

The CHAIRMAN. Let me say to the gentleman, as I said to Mr. Minge, if in fact the gentleman has a clarifying amendment that he wishes to offer at the appropriate place in the process, we would certainly be willing to consider it at that time.

Mr. BARTLETT. We will do that sir, and thank you very much.

Mr. MINGE. I've marked mine in the identical fashion. I'll join with Mr. Bartlett.

Mr. BARTON. Mr. Chairman?

The CHAIRMAN. The gentleman from Texas.

Mr. BARTON. I just have a parliamentary inquiry.

Have you offered your en bloc amendment for discussion yet?

The CHAIRMAN. Well, we are in fact discussing both the Substitute and kind of the general subject at the present time. As soon

as members have had a chance to do this, it is my intention at that point to offer the Substitute and open it for amendment.

Mr. BARTON. And following up on that, when amendments are in order to be offered, are you going to go in the sequence in which they've been printed in you agenda, or are you going to allow that members that have multiple duties on the same bill in two different places to perhaps go out of order?

The CHAIRMAN. Well, it is my intention to go in the order in which they were on the agenda, and then, as we complete each Subtitle, to close the Subtitle so that if there are amendments that are not reflected on the agenda to that particular Subtitle, they would have to be offered at the end of the Subtitle before we closed out that Subtitle.

Mr. BARTON. Thank you.

Mr. BROWN. Mr. Chairman?

The CHAIRMAN. Mr. Brown?

Mr. BROWN. Just to kind of pick up a couple of loose ends.

First of all, the amendment process is going to have to be fairly flexible because our original amendment, which is the basis of the agenda, were addressed to the earlier version of your legislation, not to the text that we have before us at the present time.

And with a little leniency on you part, I think we can adapt to that.

The CHAIRMAN. The Chair has already indicated that as long as we are addressing the same subject matters that are there, that we are going to attempt to deal with any kind of technicalities in a very flexible way to assure the amendment is properly in order.

Mr. BROWN. Now, in connection with the previous discussion of the $25 million designation for a significant risk assessment document, there was some parts of the discussion, and in fact you contributed to this by indicating that you wanted to cover small businesses—this figure has nothing to do with the size of the business, it has to do with the national economic impact.

Now that could occur as the impact on one very large corporation or on a thousand very small corporations. And we need to look at that with a factual understanding of what that limit means.

And the implication that you gave, and perhaps unintentionally, was that you wanted to include a lot more small businesses. I don't think this has any relevance to including additional small businesses.

The CHAIRMAN. Well, it's sector specific and insofar as it deals with a sector of the economy, we want to make certain that that sector of the economy is in fact a $25 million impact.

When you begin to raise that overall limitation, you eliminate certain sectors of the economy, most of them involving small business. So it is small businesses who are most concerned about maintaining that figure because it broadens the applicability to sectors of the economy.

The fact is that big businesses are more likely to have a broader impact, and so anything which affects them is likely to have broader impacts of $50 million is perfectly appropriate for them. Fifty million dollars isn't much to General Motors. It's quite a bit to the dry cleaning industry.

Mr. BROWN. Mr. Chairman, may I respond briefly?

And I don't want to belabor this point at all.

First of all, I would like, since you indicated you made a command decision in order to protect small business to leave the figure at $25 million, would you be able to point to anything in the record or any documentation that small business in any way supported this, or that it would make a difference in the way it impacts them?

And secondly, could we make it clear that this has nothing to do with the size of the business but it relates to the impact of say an air regulation, and this is particularly true in Southern California.

It impacts dry cleaners, paint shops, all kinds of small business, and has a cumulative effect of $100 million or more, and it's irrelevant to the size of the business.

And most of the big businesses, as a matter of fact, have already made the necessary corrections. The major power plants, for example, the big industries probably wouldn't be concerned, but you're going to distort this thing, it seems to me, in a fashion that will probably achieve your goal of reducing the amount of regulation, just because you're now going to require when it has an impact nationally on any sector of $25 million.

If that's your goal to preclude additional regulation, you will well achieve it by this.

The CHAIRMAN. Well, I thank the gentleman.

I can only say that the feedback that we got from testimony before the Committee from groups such as the Chamber of Commerce, indicated that they were not satisfied with the $50 million figure, that they were in fact looking at the $25 million figure, which was the figure I believe that was in the original Bill as being important.

We are going to have amendments offered here to lower that figure even further. It is the Chair's intention not to be in favor of those particular amendments despite the fact I understand the legitimacy of what they're doing.

Those are being primarily offered at the behest of small businesses who believe that the impact is as I've described it. And, you know, I do believe that there are people who view this in different ways, depending upon the size of their impact on the totality of the economy.

And we are simply trying to assure that people who may have interests in this particular legislation feel as though we have treated a number of sectors of the economy, including the biggest sectors, in a fair and equitable way.

Ms. JACKSON-LEE. Mr. Chairman.

The CHAIRMAN. Ms. Jackson-Lee.

Ms. JACKSON-LEE. Thank you very much, Mr. Chairman.

I wanted to pursue a line of questioning with staff just to further understand the definition as used on the major rule.

And I note that the new section on page 4, and I guess in section (a) then refers to the definition of major rule. On page 19 section (b), and I think the line of questioning preceding mine follows the same line of thought.

I noted in the testimony that we had, there was some comment, and I don't have an exact recollection, but there was some comment

as to decisions made under the Reagan Administration about lead content in gasoline.

And that there was a determination that it was such an important issue that they would move forward as quickly as they possibly could.

My question is, is there anywhere in here in reading the issue or reading the definition of major rule, that gives some further refinement if the matter is life-threatening?

I use lead in gasoline, but then I can also refer to lead paint as it impacted children in inner cities, and whether or not there is a way that we would be able to further refine that that if it is a life-threatening matter, that this definition of a major rule would be further refined by putting some exceptions or some breaks, if you will, as to whether we need to do this because of the life-threatening situation.

Mr. BERINGER. The Bill throughout has exemptions for emergencies but that doesn't exactly answer the question of the gentlelady.

There could be further refinements and language that would make that clear. However, the overall thrust of the Bill would try to do risk assessments in all these general areas because in the case, for instance, of life-threatening asbestos in schools, it was later discovered that the one threat of removal was probably greater than the threat of having them remain in the school.

So there is a balancing test. It's up to the members of the Committee to determine what that test should be.

Ms. JACKSON-LEE. And I appreciate that the give and take will be amongst the Committees, recognizing that those of us who've come from communities outside of Washington, we've certainly heard the debate on risk assessment and its overall impact.

I would say to you that, and staff, that I'd like to suggest and be able to work, Mr. Chairman, with further refinement as it relates to the life-threatening issues. I find that distinctive, and you cite the asbestos problem in our schools throughout the nation and in fact in old buildings.

And there have been situations where it was an emergency to do it, and other situations where it was the wise thing to leave it alone.

But I think we can further refine this language to narrowly capture what all of us could agree to would be life-threatening situations where you would not want to be inhibited by what was interpreted here, and further refine the words "major rule."

The CHAIRMAN. I thank you.

All right. With that, the Chair will put before the Committee the Substitute of the Chair, and open the Substitute to amendment.

The first amendment listed is the en bloc amendment which is no longer needed because of the Substitute. There is an amendment that would limit application of Title III to the Environmental Protection Agency that's listed next that was a placeholder amendment.

Is that being offered?

Mr. BROWN. No, that's not being offered, Mr. Chairman.

The CHAIRMAN. The next amendment would exclude USDA as a placeholder amendment.

Is that going to be offered?

Mr. BROWN. I'm informed that that amendment will be offered but it's at a different location in the Bill, Mr. Chairman.

The CHAIRMAN. Fine. We'll get to it at the appropriate place then.

There is an amendment to limit application of Title III to specifically covered agencies.

Is that going to be offered?

Mr. BROWN. That will not be offered, Mr. Chairman.

The CHAIRMAN. All right, then.

Ms. McCarthy would have an amendment, a new Section 3002.

Mr. BROWN. Mr. Chairman, if I may be permitted, I have a savings clause amendment which occurs at Section 3002, which we would like to—

The CHAIRMAN. Is this in lieu of Ms. McCarthy's amendment?

Mr. BROWN. No, this is a different amendment.

The CHAIRMAN. What I'd hoped to do, and I mean, I'm subject to change on this, but what I'd hoped to do is go down through the ones that we had put on the schedule and then come back and pick up any others in that particular section, in Section A.

Mr. BROWN. Mr. Chairman, I appreciate the need for an orderly procedure, which the Chair can keep on top of, and you are doing a reasonable thing.

The CHAIRMAN. Okay, very good.

So I will recognize Ms. McCarthy.

Ms. MCCARTHY. Thank you, Mr. Chairman.

My amendment that I offer would be inserted on page 3, after line 4. And it addresses the nature of unfunded mandates.

"Nothing in this title shall create an obligation or burden on any state or local government or change or affect any state law or regulatory requirement or otherwise impose any financial burden on any state or local government."

My concern, and I raised this during the testifying of the witnesses and during general discussion, is that I have a genuine concern about the costs, and particularly with regard to permitting which is done in many ways by the states. The states administer much of this nation's health and safety programs and often they face demands for cleanup of Federal environmental facilities.

I don't want them to have to undertake risk assessment, Mr. Chairman, and so I offer this amendment genuinely to make sure we are carrying through with our intent in this Congress, which is to not further unfunded mandates onto any state or local government.

Mr. BROWN. Would the gentlelady yield briefly to me?

Ms. MCCARTHY. Absolutely.

Mr. BROWN. I merely want to ascertain that each member has the current draft of the gentlelady's amendment before them. I understood that there was an original and then a revised draft.

Mr. MCCARTHY. Excuse me, gentlemen.

I was under the impression the Committee would print up and distribute the amendments. I did turn it in in a timely fashion as per the request of the Chairman.

Due to the nature of a new draft this morning, the title—the actual directions would have to change, not the language itself, which

would be a new section, Section 3002, a Savings Clause, but it would have to be inserted after Section 3001 now on page 3, not page 35, and after line 4.

And I'm not sure if the Committee has received the new amendment, gentlemen, because that I left to the Committee's staff.

[Pause.]

Mr. BROWN. Well, I have the gentlelady's revised version. I just wanted to make sure that the other members of the Committee did.

The CHAIRMAN. It is my understanding that what the members have before them is what was in the package. If the gentlelady has changed the amendment since the package was put together, then we do need to have distributed to the members the full text of her amendment.

Ms. MCCARTHY. I appreciate that, Mr. Chairman.

The only thing that has changed is because we received a substitute late this morning, the page number has changed. If you would prefer that I withdraw it and offer it at another time, I would——

The CHAIRMAN. I'm not worried about page numbers, but if there has been change in the language in any way——

Ms. MCCARTHY. No, Mr. Chairman, there has not.

The CHAIRMAN. So the language then that is being offered by the gentlelady reads. "Nothing in this Title shall create an obligation or burden on any state or local government or change or affect any state law or regulatory requirement or otherwise impose any financial burden on any state or local government."

Is that correct?

Ms. MCCARTHY. That's correct, Mr. Chairman.

The CHAIRMAN. That's fine.

Is there discussion?

Mr. Baker.

Mr. BAKER. The purpose as stated on page 1 of this draft that states that Federal funds are not unending and that when we regulate, we have to carefully target out regulations so that they're effective against the highest and worst risks.

That's generally called risk assessment, and it's going to take a few dollars and a few minutes for the agencies to step back and review the regulations to see are we indeed going after something worth going after.

And obviously if this amendment passes, we won't include risk assessment, we'll just include regulations.

But don't forget the regulations impose a tremendous burden on the private sector without regard to risk assessment.

So what we're saying is don't curtail big Government, don't inconvenience them by looking before they leap, just go out and do it.

An example would be the EPA. In California, we license under strict licensure, the automobile emissions, and private sector checks the automobiles, regulated by the State of California.

EPA went out and said the heck with all that. The State should set up a system of licensure and checking of automobiles, period, putting all of those companies out of business.

No one looked at that. No risk assessment, no mandates, no problem, just wipe out an industry in California, and substitute for

it a big, bureaucratic Government agency to which, like in Washington, D.C., you can spend four hours in line with you auto running polluting the air and wait a half a day and lose that pay, and then get up and pay the Government instead of some of you friendly neighbors at a gas station or a licensed clinic the fee.

So all we're saying here is look before you leap. It's obviously going to cost a few cents more, but perhaps we could save billions on the private sector by determining that was not a very smart thing to do.

This morning in Transportation Committee, the Assistant Director of CalTrans was there bemoaning the fact that EPA tried to mandate this on the State of California, and they're going to try and undo that in the 1st legislation.

Mr. DOGGETT. Will the gentleman yield?

Mr. BAKER. Yes, I certainly will.

Mr. DOGGETT. I can't tell if you're for or against the amendment.

Mr. BAKER. I'm against the amendment because it is a none-too-subtle way of trying to kill the process of risk assessment.

Mr. DOGGETT. So how do you see this Bill intersecting with the unfunded mandates legislation? Is it your desire to—

Mr. BAKER. I think what you're going to end up with is a lot less regulation and a lot less cost in the private sector.

Mr. DOGGETT. But you're opposed to the idea of this not being an unfunded mandates requirement?

Mr. BAKER. If I had my way, there'd be half as much regulation and a lot less Government expense. I see the cute point to this trick, and I'm happy to joust with you, but I think the cost of the regulation is far worse than the risk assessment being added to the regulation.

Ms. MCCARTHY. Would the gentleman yield?

Mr. Chairman, I'm having difficulty understanding the thrust of the gentleman's point in order to respond.

Mr. BAKER. Even if they had to type one sheet, there'd be a cost. Even if they had to type up a sheet saying there's no major risk and therefore no assessment is needed, there would be a cost.

The CHAIRMAN. I think what the gentleman is saying is that the amendment is so broad that virtually any expense incurred by state or local government, even to respond that they have no liability in this, would in fact be covered under the gentlelady's amendment and would make it impossible for agencies to even determine the appropriate nature of potential risk assessment.

Ms. MCCARTHY. Mr. Chairman, I appreciate that clarification. I thought that's why we put thresholds in the Bill and we'd had a lengthy discussion on the nature of those lower thresholds at $25 million just moments ago, a discussion which I instigated.

The CHAIRMAN. But your amendment contains no thresholds. Your amendment is in a Section of the Bill long before the thresholds, and so therefore says that absolutely no costs can be incurred, even if it's 32 cents for a stamp.

Ms. MCCARTHY. Mr. Chairman, putting it in the context of the bill, there would be no rule made, correct, at those particular threshold levels until we reached them? That was, I thought, the reason to have them.

The CHAIRMAN. Well, the gentlelady I think misunderstands. The threshold level is $25 million of impact on the totality of the economy. That might have a fairly minimal impact on any state and local government, but if the agency writes them and asks them whether or not there's any minimal impact, and they write back and say no, there is no impact, they have in fact expended money at that point for 32 cents for a stamp, and that would be in violation of the gentlelady's amendment.

Ms. MCCARTHY. Well, that is not the intent of the amendment. It is to work hand in hand with the unfunded mandates law which this House has spoken to and then quite strongly.

The CHAIRMAN. Well, I'm sure that that is the intent, but the practical applicability of the amendment is such that it means that they could not expend any money in any way. And we have passed an Unfunded Mandates Bill that will certainly be directly related to this because this applies only to Federal agencies.

It doesn't apply to imposing costs on state and local governments anyhow. If you'll look at the language in the bill, it applies to the work being done by Federal agencies. And if Federal agencies are in fact incurring costs for state and local governments, then the unfunded mandate legislation, assuming that it becomes law, would in fact be applicable.

Mr. MINGE. Would the gentlelady yield for a moment?

Ms. MCCARTHY. Yes, certainly.

Mr. MINGE. I doubt we're working at cross purposes here. I don't think that your intent is to essentially repeal this legislation by inserting a provision that's inconsistent with the rest of it, but instead to try to avoid this legislation having an unexpected effect on state and local governments.

And with the leave of the Committee Chair, I would suggest that perhaps withdrawing the amendment at this time, with the understanding that you could submit it later in the day with any corrective language, would be a way to achieve your intent without running afoul of the unintended consequence that's being identified by some of the other members of the Committee.

The CHAIRMAN. Well, we will certainly be willing to consider it again as a part of Section A if a redrafted amendment is brought forward.

Mr. MINGE. Would that be a way to achieve your goal, which I think is really one that almost everybody in this Committee would support?

Ms. MCCARTHY. Yes. I thank you gentlemen, and as you were drawing those conclusions, I was thinking that this should be redrawn to make it parallel the unfunded mandates provisions that have passed this House so that we are not contrary to the purposes of the House.

So, Mr. Chairman, with the understanding it could be reoffered if redrafted properly, I would like to withdraw the amendment at this time.

The CHAIRMAN. So long as we are in Section A. Once we close out Section A of the Bill,——

Ms. MCCARTHY. Well, I believe I'm the only amendment in this section.

Mr. MINGE. Well, I have one that I'll offer.

Ms. MCCARTHY. Oh, good. Thank you.

The CHAIRMAN. Okay, we know of two others. So as long as we are in this Section of the Bill, I would certainly entertain the amendments, but I don't think that we can start a process where everybody, once they find out they've got a problem, comes back later on and does amendments.

So we're going to accept the amendments and hope that they're in good form at the beginning, but since this is the first one, we will attempt to accommodate the gentlelady.

Mr. MINGE. Mr. Chairman?

The CHAIRMAN. This amendment, having been withdrawn by unanimous consent, if I hear no objection?

[No response.]

The CHAIRMAN. And none is heard.

The next amendment on my list is an en bloc amendment on page 36.

Do you have an amendment before we get to Section A, Mr. Minge?

Mr. MINGE. Yes, I have an amendment to Section 3001 and I believe that this amendment has been presented to the Chair, and it hold be with the counsel for the Committee.

The CHAIRMAN. We would ask that the amendment be distributed.

Mr. BERINGER. We don't have copies of it and have not seen the amendment.

[Pause.]

Mr. MINGE. Mr. Chairman, just so I use the Committee's time while you're waiting, I don't expect this amendment would be controversial. It is designed to complement the purpose of the Bill and to emphasize that while we recognize that there are new regulatory measures that are being considered by agencies and rules that are being or will be promulgated in the future, we have a grave need in American industry, commerce and industry, for relief from regulations which are currently unnecessary or overly complex. And that, at the same time that we're pursuing this goal of relief from unnecessary regulation or overly burdensome regulation in the future, we should be looking at ways to deal with the bulk of the regulatory framework that burdens American commerce and industry.

And it's simply a statement to that effect. It does not impose any requirement on Congress or any other agency to take any steps, it's simply a recognition.

The CHAIRMAN. Well, I thank the gentleman.

I don't have any problem with the statement, but I would ask counsel whether or not this has in any way a broadening effect to the Bill that might cause us jurisdictional problems?

Mr. BERINGER. Mr. Chairman, that is my opinion that it might be beyond the scope of this particular Bill, and we may be getting into the Judiciary Committee's territory here.

The CHAIRMAN. That would be my one concern is that it has the effect of broadening the scope and moves us outside our particular jurisdiction as the gentleman would understand.

I mean, we've had to draft very carefully to stay within what is the jurisdiction of this particular Committee. and while I am sensitive to the need to look at a host of other things, and we're going

to do that in a series of hearings in this Committee, when we actually go to legislating, we do have some restrictions on our ability.

It seems to me that if the gentleman would eliminate the final sentence, that we probably then don't have a problem. If he simply makes the statement that there are other ways, there are other overly complex regulations that are necessary, but doesn't get into the questions of productivity and competitiveness and simplifying and a lot of that, we probably don't have a particular problem with it.

Would the gentleman be willing to modify it?

Mr. MINGE. I'm willing to withdraw the final sentence of the amendment as offered in order to avoid the problems that the Chair is concerned about.

The CHAIRMAN. If that's, without objection, the amendment——

Mr. HASTINGS. Reserving the right to object, Mr. Chairman, and I would not object. but I would like to ask counsel how it is that this puts us outside the scope, since you assert that it does.

I have difficulty understanding how that last sentence—as a matter of fact, Mr. Chairman, what I have proposed would be to take the first sentence out and leave the last sentence.

How is it that it does something outside the scope of the jurisdiction of this Committee?

And I thank the Chair, and I will not object.

Mr. BERINGER. Congressman, I think it has to do more with the word "implementing" probably than anything else. Because that's implementing regulatory decisions, and there are a number of things that are being considered by the Judiciary Committee which would deal with that right now.

So that's my opinion without actually having conferred with the Judiciary Committee.

The CHAIRMAN. Well, if the gentleman, by unanimous consent—if there is no objection to the gentleman modifying his amendment, the Chair is prepared to accept the amendment as modified.

Mr. MINGE. Well, to begin with, I would agree with my colleague from Florida that this amendment should not impinge on the jurisdiction of the Judiciary Committee. However, I do not wish to make an issue of the language of the amendment.

The amendment is simply something that allows our Committee to recognize that with our limited jurisdiction, we're trying to do what we can. But we, as a Committee know, and we want the rest of the world to know that we're aware that many other things need to be done.

That's the long and short of it.

The CHAIRMAN. The gentleman, with his modified amendment, has helped us make that point. I appreciate it.

Gentlelady Ms. Rivers?

Ms. RIVERS. Thank you, Mr. Chairman.

That raises a question for me as we're talking about implementing in this Bill. In another section, and I didn't get a chance to ask this earlier, but it falls right into this.

On page 18, there's new language put in that creates two new concepts, and one of the concepts that's put into place is the idea that the agency involved must examine non-regulatory as well as regulatory alternatives.

And since we're talking about jurisdiction, what jurisdiction do agencies have to implement non-regulatory alternatives?

Mr. BERINGER. This would propose an examination of those.

Ms. RIVERS. And then?

Mr. BERINGER. They don't have the—unless Congress gives them specific jurisdiction, they don't have the authority to implement them.

Ms. RIVERS. So if they have no authority, why are we asking them to consider them?

Mr. BERINGER. We are asking them to—well, Congress may have given them the authority, so we are—it's another one of the examinations that we feel should go forward in the Bill.

Ms. RIVERS. What would it look like? What is an example of a non-regulatory alternative that a regulatory agency would be putting in place?

The CHAIRMAN. Well, we don't want to go into it at this point, but for instance, the adoption of hydrogen fuel would allow us to get rid of a bunch of regulations that now affect other kinds of fuels.

So I mean there are in fact ways of developing new ideas and new things.

Tax policy that would encourage people to do things might be used in place of mandates, command and control mandates, that force people to do things.

I mean, there are a variety of non-regulatory approaches that we might want to have examined toward possible legislation in the future.

Ms. RIVERS. But those would be normally the ones you are pointing to would be Congressional initiatives as opposed to agency initiatives, and these appear to be an obligation that the agency incurs as a part of this whole process.

The CHAIRMAN. I would love to have some agencies to recommend to us some non-regulatory approaches.

Mr. TRAFICANT. Mr. Chairman.

The CHAIRMAN. Mr. Traficiant.

Mr. TRAFICANT. I'm not going to make an issue of the amendment that was offered by Mr. Minge.

But I do want to make an issue for the sake of precedent because I do not believe, as the gentleman from Florida, that that last sentence would throw this into a consequential referral.

The language did not say that productivity and competitiveness of American businesses will be enhanced by implementing the following measures. It is a vague, general statement that just basically says that productivity and competitiveness in American businesses would be enhanced by implementing a variety of measures of which we do not mandate, of which we do not cover here with any legislative authority.

So I'm not going to make a further issue over this, but I think that if we're going to do this, and if we're going to be constantly worried about consequential referral, I think that's going to have to come over specific issues that may in fact violate or push us into a referral to another committee.

I'm not so sure this one did.

The CHAIRMAN. Well, I thank the gentleman for his point, and of course it would have been easier to evaluate this had we had the amendment further in advance. And I understand that there are a variety of reasons why that couldn't be done.

I just want to make certain that we don't have the problems. The gentleman has agreed to modify his amendment. I think it still makes his statement, and without objection, the amendment is adopted.

Is there objection?

[No response.]

The CHAIRMAN. The Chair hears none. The amendment's adopted.

We will not go on to—do we have another amendment to the findings?

Does anybody else have an amendment to findings?

Mr. BROWN. Mr. Chairman, I have an amendment that goes to the findings. It's amendment I have labeled number two.

The CHAIRMAN. Do we have that before us?

Mr. BROWN. Which I would like to have the Clerk distribute.

The CHAIRMAN. The Clerk will distribute the amendment.

Mr. BROWN. And it adds Section 3002 on page 3 after line 4.

[The amendment is distributed.]

[Pause]

The CHAIRMAN. The gentleman is recognized to describe his amendment.

Mr. BROWN. Mr. Chairman, this is essentially the same kind of savings clause language that already exists in the Bill on page 8, but only applying to that Subtitle.

What my amendment seeks to do is to apply this same savings clause language to the entire Title.

There may be some good reason why the Chair, in his wisdom, was willing to put a savings clause in with respect to the Subtitle, and I'm sure he'll explain that, but not willing to put it in for the entire Title.

Now, one of the things that has aroused considerable anxiety on the part of many people around the country is that this Bill is really intended to override existing law on a large scale.

That it is intended in effect to negate a lot of the environmental, health, and safety and other laws, perhaps the Safe Drinking Water Act, the Clean Air Act, and they would be much more reassured and willing to accept the thrust of this, which is improving the regulatory process, if they were reassured by an amendment of the sort that I'm offering, which, as I've said, merely repeats language that applies to one portion of this Title and applies it to the entire Title, and makes it clear that this is not designed to modify any statutory standard or requirement that currently exists or delay any action required to meet a deadline imposed by a statute or a court.

I think it would be an amendment which would make this Bill far more acceptable, and it would garner much support for it from the public and other Members of Congress.

The CHAIRMAN. Well, I thank the gentleman.

I think that the Chair is concerned about some of the language in this particular section and applying it to the whole Title, be-

cause when you state that nothing in the Title shall change the factors that the agency is authorized to consider in promulgating a regulation pursuant to any statute, that means that not only present statutes but statutes in the future, no agency would be able to change the factors that it's authorized to consider.

This whole Bill is aimed at attempting to change some of the factors that they use in promulgating regulations, and so the gentleman, in this particular finding, has essentially gutted what we are attempting to achieve in the whole risk assessment process.

And so that particular language, I think, would cause the Chair to have some considerable degree of problem with the proposal.

Mr. TRAFICANT. Mr. Chairman.

The CHAIRMAN. The gentleman from Ohio.

Mr. TRAFICANT. I'm not so sure that I share the same anxieties you have with this language. I think that your language in the Bill, in your Substitute, certainly speaks to salient points that are also covered by this amendment and in tandem might even clarify the long range issues that the amendment portends to address.

And as I see it, on page 8, all of that of the substitute from line 1 through line 9, I think that it amplifies upon, and even strengthens, the language that the Chairman has in his substitute.

The CHAIRMAN. Mr. Weldon.

Mr. DAVE WELDON. Well, I would disagree with the gentleman and I would assert that the language in this amendment would seriously go to weaken the provisions in the Bill as proposed, and the intent of the legislation is to make the regulatory process a more difficult one for Federal agencies and to provide some regulatory relief to industry—and acknowledging the fact that the American marketplace is being overly regulated by the Federal Government.

Also, I believe this legislation is intended to bring some sanity to the regulatory process. And this amendment would seriously undermine the intent of the legislation.

And I would oppose this amendment.

The CHAIRMAN. I thank the gentleman.

The Chair will put the question on the amendment.

Those in favor of the amendment say aye?

[Chorus of ayes.]

Mrs. MORELLA. Mr. Chairman.

The CHAIRMAN. Mrs. Morella.

Mr. MORELLA. Thank you, Mr. Chairman.

I want to ask you how this amendment that's being offered correlates or connects with, on page 20, the applicability which deals with the fact that no major rule shall be promulgated by any Federal agency, number 2, and then number 1 also.

I mean, does it——

The CHAIRMAN. That was the point that the Chair made a few minutes ago. It conflicts with that particular section.

Mrs. MORELLA. Yes. I think it does conflict with it.

The CHAIRMAN. Yes. Yes. And that's one of the Chair's problems with the language, that this offers a conflicting standard.

Mr. TRAFICANT. Mr. Chairman, rather than have a vote on this, I think that the members are not quite sure on this thing.

The CHAIRMAN. Well, we're going to find out.

Mr. TRAFICANT. If it be the will of the membership here, maybe we should wait until we get back. We've got a vote underway on the floor.

The CHAIRMAN. I appreciate the gentleman, but the facts is the Committee has not recessed, and the Chair intends to put the question, and does put the question, on the amendment. Those in favor, say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed, no.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair, the noes have it.

Mr. BROWN. Mr Chairman, I'd like to request a roll call vote on this.

The CHAIRMAN. The Clerk will call the roll.

The CLERK. Mr. Walker?

The CHAIRMAN. No.

The CLERK. Mr. Walker, no.

Mr. Brown?

Mr. BROWN. Aye.

The CLERK. Mr. Brown, aye.

Mr. Sensenbrenner?

[No response.]

The CLERK. Mr. Hall?

[No response.]

The CLERK. Mr. Boehlert?

[No response.]

The CLERK. Mr. Traficant?

Mr. TRAFICANT. Aye.

The CLERK. Mr. Traficant, aye.

Mr. Fawell?

Mr. FAWELL. No.

The CLERK. Mr. Fawell, no.

Mr. Hayes?

[No response.]

The CLERK. Mrs. Morella?

Mrs. MORELLA. Mrs. Morella passes.

The CLERK. Mr. Tanner?

Mr. TANNER. Aye.

The CLERK. Mr. Tanner votes aye.

Mr. Weldon of Pennsylvania?

[No response.]

The CLERK. Mr. Geren?

[No response.]

The CLERK. Mr. Rohrabacher?

Mr. ROHRABACHER. No.

The CLERK. Mr. Rohrabacher votes no.

Mr. Roemer?

Mr. ROEMER. Aye.

The CLERK. Mr. Roemer votes aye.

Mr. Schiff?

Mr. SCHIFF. No.

The CLERK. Mr. Schiff votes no.

Mr. Cramer?

[No response.]

The CLERK. Mr. Barton?
Mr. BARTON. No.
The CLERK. Mr. Barton votes no.
Mr. Barcia?
[No response.]
The CLERK. Mr. Calvert?
Mr. CALVERT. No.
The CLERK. Mr. Calvert votes no.
Mr. McHale?
[No response.]
The CLERK. Mr. Baker?
Mr. BAKER. No.
The CLERK. Mr. Baker votes no.
Ms. Harman?
[No response.]
The CLERK. Mr. Bartlett?
Mr. BARTLETT. No.
The CLERK. Mr. Bartlett votes no.
Ms. Johnson?
Ms. JOHNSON. Aye.
The CLERK. Ms. Johnson votes aye.
Mr. Ehlers?
Mr. EHLERS. No.
The CLERK. Mr. Ehlers votes no.
Mr. Minge?
Mr. MINGE. Aye.
The CLERK. Mr. Minge votes aye.
Mr. Wamp?
Mr. WAMP. No.
The CLERK. Mr. Wamp votes no.
Mr. Olver?
Mr. OLVER. Yes.
The CLERK. Mr. Olver votes aye.
Mr. Weldon of Florida?
Mr. DAVE WELDON. No.
The CLERK. Mr. Weldon votes no.
Mr. Hastings?
[No response.]
The CLERK. Mr. Graham?
Mr. GRAHAM. No.
The CLERK. Mr. Graham votes no.
Ms. Rivers?
Ms. RIVERS. Aye.
The CLERK. Ms. Rivers votes aye.
Mr. Salmon?
Mr. SALMON. No.
The CLERK. Mr. Salmon votes no.
Ms. McCarthy?
Ms. MCCARTHY. Aye.
The CLERK. Ms. McCarthy votes aye.
Mr. Davis?
Mr. DAVIS. No.
The CLERK. Mr. Davis votes no.
Mr. Ward?

[No response.]
The CLERK. Mr. Stockman?
[No response.]
The CLERK. Ms. Lofgren?
[No response.]
The CLERK. Mr. Gutknecht?
[No response.]
The CLERK. Mr. Doggett?
Mr. DOGGETT. Aye.
The CLERK. Mr. Doggett votes aye.
Mrs. Seastrand?
[No response.]
The CLERK. Mr. Doyle?
Mr. DOYLE. Aye.
The CLERK. Mr. Doyle votes aye.
Mr. Tiahrt?
Mr. TIAHRT. No.
The CLERK. Mr. Tiahrt votes no.
Ms. Jackson-Lee?
Ms. JACKSON-LEE. Aye.
The CLERK. Ms. Jackson-Lee votes aye.
Mr. Largent?
Mr. LARGENT. No.
The CLERK. Mr. Largent votes no.
Mr. Luther?
Mr. LUTHER. Aye.
The CLERK. Mr. Luther votes aye.
Mr. Hilleary?
[No response.]
The CLERK. Mrs. Cubin?
[No response.]
The CLERK. Mr. Foley?
[No response.]
The CLERK. Mrs. Myrick?
[No response.]
The CHAIRMAN. The Clerk will report.
How is Mr. McHale recorded?
The CLERK. Mr. McHale is not recorded.
Mr. MCHALE. I'd like to be recorded as aye.
The CLERK. Mr. McHale votes aye.
The CHAIRMAN. Mr. Weldon of Pennsylvania?
The CLERK. Mr. Weldon of Pennsylvania is not recorded.
Mr. CURT WELDON. No.
The CLERK. Mr. Weldon votes no.
The CHAIRMAN. The Clerk will report.
Mrs. Morella, how is she recorded?
Mrs. MORELLA. Mrs. Morella is going to change the pass to no on the basis of what the Chairman has said about the fact that it is not parallel with the other sections.
The CHAIRMAN. Mrs. Morella votes no.
The CLERK. Mrs. Morella votes no.
Mr. Chairman, I have 15 yeas, 18 nays.
The CHAIRMAN. The amendment is defeated. The Committee stands in recess to go vote.

[Recess.]

The CHAIRMAN. The Committee will come to order.

Mr. HASTINGS. Mr. Chairman, I have a point of parliamentary inquiry.

The CHAIRMAN. The gentleman will state it.

Mr. HASTINGS. Mr. Chairman, is it proper for the Chair to call a roll call vote at the same time that a record vote is called? And I cite for you the background on what just transpired.

My understanding is that the bell had gone off. Several members, including myself, left to go and vote on a recorded vote, and you called a roll call vote.

I understand the ruling from the House, from the Speaker, but I'm curious as to how you're going to operate this Committee and how it is that I'm supposed to be able to vote here and there at the same time?

The CHAIRMAN. Well, I thank the gentleman for his inquiry. The recorded vote was requested. The Committee had not gone into recess at that point. While the Committee is meeting there is a potential for recorded votes, and members need to be advised of that.

I am aware that for some members, it's created a hardship that they were at other Committees and so on. That is one of the difficulties that we have under a system where we're trying to do a lot of business very fast, and I wish that all members could have been here for the vote.

On both sides of the aisle, there were members who missed the vote because of other obligations.

But I will say I don't believe that there was anybody who was in the room who participated in the recorded vote who missed the vote in the House. I think virtually everybody was able to get to the House in time to make the vote.

Mr. HASTINGS. Will the Chair yield?

The CHAIRMAN. And so, you know, it was the discretion of the Chair of course that when a recorded vote as asked for, to move ahead with the recorded vote with the members who were in the room at that time. And at the time that the vote was over, we did declare a recess so that members could go and vote.

Mr. HASTINGS. All right. I'll take the matter up with the Chair, but I'd have you to understand that all of us may not have the physical wherewithal. I had heart surgery last year, and the doctor told me when the bill rings, leave. And I've learned to do that, and somehow or another my life means a little more to me than the recorded vote, but I'll take it up with you, Mr. Chairman.

Ms. LOFGREN. Mr. Chairman, I would like to, if I may, concur in Mr. Hastings' comments. I think that I'm a new member, but I've never, in my years in local government and observing here seen something like this happen. I think it's highly discourteous to the members, and I don't think when the bells ring and members go over to fulfill their obligations on the floor that it is reasonable to call a recorded vote in this Committee, and I would like to register my objection in defense.

The CHAIRMAN. Well, it seems to me that the Chair has a duty to respond to the member who's asking for a recorded vote. It is in fact the right of every member to ask for a recorded vote on their amendment, and that was in fact what the Chair did, and so that

the Chair was responding to the request of the member for a recorded vote.

The Chair would prefer that we could avoid recorded votes, but that is the circumstance that does arise.

I would say—the gentleman from Wisconsin?

Mr. SENSENBRENNER. Mr. Chairman, I would point out that the House Rules specifically state that the Chair does not have the power to declare a recess once the Chair puts the question on a voice vote, and after the Chair announces his decision on which side had it, should a member ask for a recorded vote, the Chair is obligated to direct the Clerk to call the roll and does not have the power, under House Rules, to declare a recess.

So what the Chair did was entirely within the scope of House rules. I was one who missed the vote because I heard the bell ring and I went over to vote. I guess that's the breaks of the game.

The CHAIRMAN. I thank the gentleman, because I think that is a reflection of the rules.

Mr. FOLEY. Mr. Chairman?

The CHAIRMAN. The gentleman from Florida.

Mr. FOLEY. Yes Mr. Chairman. I don't want to belabor the point, but there would be an opportunity to at least inform our fellow colleagues if one of the members will be demanding a recorded vote in that interim. I was here in the room when the bells went off and did in fact go to the floor to vote.

So I think in fairness, our colleagues should at least alert us if you are going to call a vote or ask the Chair to call a vote.

The CHAIRMAN. The Chair would indicate that he thinks that that would be desirable. On the other hand, most members don't know whether or not they're going to get a recorded vote until they see how the voice votes come out or how a division vote comes out, so it's kind of hard for them at times to inform the members.

But the Chair would appreciate also knowing. It would in fact help us to assure members of their status.

Mr. DOGGETT. Mr. Chairman, for the parliamentary inquiry on that subject then, do I understand that under the Rules of the House then, once a matter is put to a voice vote, that you cannot declare a recess for a vote of the House thereafter?

The CHAIRMAN. After the vote has begun and is underway, at that point it is not open to the discretion of the Chair to halt that process.

Mr. DOGGETT. Was not the last vote of this Committee initiated after the bell had rung?

The CHAIRMAN. That's correct.

Mr. DOGGETT. And do the Rules of the House contemplate casting votes in Committee after the bell has rung?

The CHAIRMAN. Well, the Rules of the House are such that as long as members can get there within the 15 minute time, that only until the Committee has declared a recess are the members free to leave.

Mr. DOGGETT. Would a rule of this Committee that prohibited the taking of votes during the time, during the 15-minute period, be out of order or inconsistent with the Rules of the House?

The CHAIRMAN. They are not a part of the Rules of the Committee.

Mr. DOGGETT. Would such a rule, if it were adopted, be a part—would be in conflict?

The CHAIRMAN. It would be in conflict with the House if in fact the recess would occur in the midst of attempting to deal with a matter before the Committee that has been put to a vote.

Mr. DOGGETT. The recess requirement wouldn't apply if the vote weren't put during the 15-minute period?

The CHAIRMAN. Well, again, I mean—

Mr. DOGGETT. Are our Committee rules subject to—is it proper under the Rules of the Committee to advance further amendments to the rules after they've been adopted during the course of this session in Congress?

The CHAIRMAN. Well, that would be an unusual circumstance and I would say to the gentleman that my guess is that that would have to be something to be taken up at a separate session of the Committee.

Mr. DOGGETT. Thank you.

Mr. HASTINGS. Mr. Chairman, I have a request. And my request is, had I been present at the last roll call vote that was called during a recorded vote, then I would have voted yes.

The CHAIRMAN. The gentleman's statement will be recorded.

Ms. LOFGREN. Mr. Chairman, I have a unanimous consent request to the same effect as Mr. Hastings. I would have voted yes.

The CHAIRMAN. The gentlelady's vote mentioned will be recorded.

The gentleman from Wisconsin?

UNKNOWN MEMBER. Mr. Chairman, I make the same request. Had I been present, I would have voted yes to the amendment.

The CHAIRMAN. The gentleman from Florida?

Mr. DAVE WELDON. The same request for a recorded yes vote.

UNKNOWN MEMBER. The same request for a no vote.

The CHAIRMAN. The gentleman from Texas.

The CHAIRMAN. The gentleman from Florida wishes to be record as?

Mr. FOLEY. No vote.

The CHAIRMAN. No, okay.

These will not be reflected, you understand, in the vote itself. They will simply be reflected in the record.

Ms. CUBIN. Mr. Chairman, the same request with a recorded no vote.

The CHAIRMAN. The gentlewoman's will be noted.

The gentlewoman from North Carolina? The same request for a no vote.

Mr. TANNER. The same request, Mr. Chairman, for a no vote.

The CHAIRMAN. No vote, OK.

Mr. HAYES. Mr. Chairman, I would make the same request for a yes vote.

The CHAIRMAN. The gentleman from Louisiana makes the same request for a yes vote.

All right. We will proceed onward now to the next amendment listed on the markup amendment roster as Amendment Number 6, en bloc amendment to page 36 and page 45 that raises the dollar limit.

Who will be offering this amendment? We don't have a—

Mr. BROWN. Mr. Chairman, I'm informed that I have this amendment but that I have to offer a substitute for the one that's listed in your record, and that I would need to ask the Clerk to distribute the substitute.

The CHAIRMAN. The Clerk will distribute the substitute.

[The substitute is distributed.]

Mr. BROWN. I assume that the content is the same—Because of the numbering problem, sequencing.

Mr. Chairman, while the Clerk is distributing this, it's a very simple amendment, and if you will turn to your substitute, Mr. Walker's substitute on page 4, line 12, there would be a substitution of about four or five words there.

The word "in connection with Federal programs" would be stricken, and instead it would insert "in connection with major rules."

Now, this is intended to reflect an emphasis in this Bill on the rulemaking procedure, not on a function of trying to change Federal law with regard to programs.

This entire thrust of this Bill has to do with the regulatory process, as implemented through the rulemaking procedures, and we are suggesting that this would be better reflected if we would just substitute actually the two words "major rules" for "Federal programs."

And I would ask support for this modest change, which I think better reflects what the thrust of the legislation should be.

Ms. LOFGREN. Mr. Brown? Mr. Brown, would you yield for a question?

Mr. BROWN. I'd be happy to yield to the lady.

Ms. LOFGREN. Some of the questions that I have gotten over on the floor from Judiciary Committee members are in the nature of whether this Bill would in fact cover the Bureau of Prisons, the FBI, law enforcement agencies who are charged with the protection of the safety of people.

And there are a number of lawyers on that Committee who feel that this Bill would in fact cover rulemaking in the Bureau of Prisons and elsewhere which, from the hearings and the discussion here, I don't think was really what most members had in mind as needing reform, unless I'm misunderstanding the nature of the testimony I heard.

Would your amendment cure that defect, do you think? My sense is it would not, but I'm anxious to address that.

Mr. BROWN. Without intending to be facetious, I doubt if any simple amendment will cure the defects in this Bill, but the fact is that it moves the Bill in the direction of restricting it to an area which is more sensible and more proper in terms of approving the risk assessment process.

Now the way the Bill is currently drafted, it is extremely broad in scope, and I think some of the Chairman's amendments have served to narrow that scope somewhat. But it still has overly broad language in a number of areas.

For example, just at the bottom of that same page, page 4, "any major," it refers to significant documents and says, "any major rule as defined in subtitle B, promulgated as part of any Federal regulatory program designed to protect human health, safety, or the environment."

That would include Federal prisons, for example, or other Federal agencies which definitely enact rules that are aimed at protecting human health, safety and the environment, but which I think should not be within the scope of this Bill which intended to apply to a different category of problems than would be included in the Federal prisons.

Ms. LOFGREN. Thank you.

The CHAIRMAN. Is there further discussion on the amendment?

[No response.]

The CHAIRMAN. If there's no further discussion, the Chair would indicate that the gentleman from California's described his amendment correctly. It is an amendment which has very, very severe limits in it.

By characterizing only major rules, rather than regulatory programs, it means only the regulations would be covered under the Act.

this would mean that potentially this would not cover the clean-up and decontamination of facilities, it would not cover things such as anything that an agency or OMB identifies as a potential problem, it would not cover reports to the Congress, it would not cover documents with over a $25 million effect.

Let me give you one thing that it would not have covered that I think most of us agree is a problem. The Alar controversy where an agency literally almost ruined an entire food product industry in this country would not be covered under this kind of provision.

It is exactly that kind of problem that we seek to resolve with this legislation. And so this would have an extremely detrimental effect on solving some of the problems that we believe are very real in this society.

I don't want to approve a piece of legislation that would not have covered the Alar controversy. In this particular case, this amendment would cause that problem.

Mrs. MORELLA. Mr. Chairman?

The CHAIRMAN. The gentlelady from Maryland.

Mrs. MORELLA. Thank you.

Just an inquiry. I'm just wondering if this Bill and the amendment being offered would cover the Centers for Disease Control?

The CHAIRMAN. Does counsel wish to comment?

Mr. BERINGER. In certain cases, it probably would. However, most of the things that the Centers for Disease Control do are responding to emergencies or sometimes in response to health, safety, or environmental types of—even though they don't do the inspections themselves, they promote those inspections, so I think those two things taken together could be fairly represented to exempt that agency.

Mrs. MORELLA. So your feeling is that by and large it is excluded by virtue of the fact that, although it doesn't say, emergency when they do preventive programs, they are geared toward disease prevention?

Mr. BERINGER. Right.

The CHAIRMAN. Thank the gentleman.

Mr. Bartlett?

Mr. BARTLETT. Mr. Chairman, do we have a problem with being concerned that the cure not be worse than the disease no matter where it occurs in our society?

The CHAIRMAN. I think that that's one of the things we're trying to deal with.

I thank the gentleman.

If there's no further comment, the Chair will put the question on the amendment.

All those in favor of the amendment by Mr. Brown will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say no.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair, the noes have it.

The next amendment will be Amendment Number 7 on the list.

Mr. BROWN. I understand we're withdrawing that amendment.

The CHAIRMAN. It's my understanding that that amendment then is withdrawn.

Next on the list was an amendment by Mr. Davis, Number 8, which he is not going to offer, but he is going to offer his Amendment Number 9.

The gentleman will describe the amendment.

Mr. DAVIS. This simply adds, if you can look at the appropriate section, 3104(a), the amendment adds, "and rely, to the extent available and practicable, on scientific findings."

I think it's a clarifying amendment, and I would offer it for that reason.

The CHAIRMAN. This is an amendment that is in the packet, and I would say to the gentleman that this is an amendment that the Chair did have an opportunity to examine, and is prepared to accept.

I don't know if there's additional comment on the amendment or not?

Anybody else have additional comment?

Mr. BROWN. Mr. Chairman? I'm having difficulty in understanding the amendment.

Although it appears to be fairly simple, it uses the term "to the extent available and practicable on scientific findings."

I wonder if the author would be able to indicate what his intentions were in connection with this amendment?

Mr. DAVIS. I think it's clarifying. It comes out of the Senate Bill which parallels this. It makes them read congruent. It's congruent to that, and I think it speaks for itself.

Mr. BROWN. Well, the gentleman may feel that it does, but I can assure him that it doesn't speak to me. [Laughter.]

Mr. DAVIS. I don't think much of these do.

Mr. BROWN. And I have not found it always practicable to rely on Senate language in the past.

Now there's some of the amendment that we were intending to pose that would incorporate Senate language, but I had a feeling that that was not sufficient to justify us offering the amendments, and we haven't done so.

Mr. DAVIS. Well, the purpose here is that when the head of an agency will apply the principles that are set forth in subsection B when preparing risk assessments, in order to assure that the risk

assessment and all the other components distinguished scientific findings from other considerations are to the maximum extent feasible scientifically objective, unbiased and inclusive of all relevant data.

This reinforces the idea that the focus, when preparing a risk, should be on scientific findings.

The CHAIRMAN. And the Chair, when he examined this amendment, felt that also it adds a little bit of additional discretion for the head of the agency as well because it does use the language "to the extent available practicable," it does give a little——

Mr. DAVIS. A little wiggle room.

The CHAIRMAN [continuing]. Additional room for the agency heads to deal with the matter.

Mr. DAVIS. Does that clarify the gentleman's concern or?

Okay.

The CHAIRMAN. Well, is there any further discussion on the amendment?

[No response.]

The CHAIRMAN. All those in favor of the amendment will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those oppose will say no.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair, the ayes have it. The amendment is approved.

Mr. HAYES. Mr. Chairman, on that I ask for a vote, since I missed some, I'm going to get some back. [Laughter.]

The CHAIRMAN. The gentleman from Louisiana has requested a recorded vote.

Those in favor will be recorded as aye, those opposed will be no.

The Clerk will call the roll.

The CLERK. Mr. Walker?

The CHAIRMAN. Aye.

The CLERK. Mr. Walker votes aye.

Mr. Brown?

Mr. BROWN. No.

The CLERK. Mr. Brown votes no.

Mr. Sensenbrenner?

Mr. SENSENBRENNER. Aye.

The CLERK. Mr. Sensenbrenner votes aye.

Mr. Hall?

Mr. HALL. Pass.

The CLERK. Mr. Hall votes present.

Mr. Bochlert?

Mr. BOEHLERT. Aye.

The CLERK. Mr. Boehlert votes Aye.

Mr. Traficant?

Mr. TRAFICANT. Aye.

The CLERK. Mr. Traficant votes aye.

Mr. Fawell?

Mr. FAWELL. Aye.

The CLERK. Mr. Fawell votes aye.

Mr. Hayes?

Mr. HAYES. Aye.

The CLERK. Mr. Hayes votes aye.

Mrs. Morella?
Mrs. MORELLA. Aye.
The CLERK. Mrs. Morella votes aye.
Mr. Tanner?
Mr. TANNER. Aye.
The CLERK. Mr. Tanner votes aye.
Mr. Weldon of Pennsylvania?
Mr. CURT WELDON. Aye.
The CLERK. Mr. Weldon votes aye.
Mr. Geren?
[No response.]
The CLERK. Mr. Rohrabacher?
Mr. ROHRABACHER. I give an aye.
The CLERK. Mr. Rohrabacher votes aye.
Mr. Roemer?
[No response.]
The CLERK. Mr. Schiff?
Mr. SCHIFF. Aye.
The CLERK. Mr. Schiff votes aye.
Mr. Cramer?
[No response.]
The CLERK. Mr. Barton?
Mr. BARTON. Yes.
The CLERK. Mr. Barton votes aye.
Mr. Barcia?
Mr. BARCIA. Aye.
The CLERK. Mr. Barcia votes aye.
Mr. Calvert?
[No response.]
The CLERK. Mr. McHale?
Mr. MCHALE. Aye.
The CLERK. Mr. McHale votes aye.
Mr. Baker?
Mr. BAKER. Aye.
The CLERK. Mr. Baker votes aye.
Ms. Harman?
Ms. HARMAN. Aye.
The CLERK. Ms. Harman votes aye.
Mr. Bartlett?
Mr. BARTLETT. Aye.
The CLERK. Mr. Bartlett votes aye.
Ms. Johnson?
Ms. JOHNSON. No.
The CLERK. Ms. Johnson votes no.
Mr. Ehlers?
Mr. EHLERS. Aye.
The CLERK. Mr. Ehlers votes aye.
Mr. Minge?
Mr. MINGE. Aye.
The CLERK. Mr. Minge votes aye.
Mr. Wamp?
Mr. WAMP. Aye.
The CLERK. Mr. Wamp votes aye.
Mr. Olver?

Mr. OLVER. No.
The CLERK. Mr. Olver votes no.
Mr. Weldon of Florida?
Mr. DAVE WELDON. Aye.
The CLERK. Mr. Weldon votes aye.
Mr. Hastings?
Mr. HASTINGS. Nay.
The CLERK. Mr. Hastings votes nay.
Mr. Graham?
Mr. GRAHAM. Aye.
The CLERK. Mr. Graham votes aye.
Ms. Rivers?
Ms. RIVERS. No.
The CLERK. Ms. Rivers votes no.
Mr. Salmon?
Mr. SALMON. Aye.
The CLERK. Mr. Salmon votes aye.
Ms. McCarthy?
Ms. MCCARTHY. No.
The CLERK. Ms. McCarthy votes no.
Mr. Davis?
Mr. DAVIS. Aye.
The CLERK. Mr. Davis votes aye.
Mr. Ward?
Mr. WARD. No.
The CLERK. Mr. Ward votes no.
Mr. Stockman?
Mr. STOCKMAN. Yes.
The CLERK. Mr. Stockman votes Aye.
Ms. Lofgren?
Ms. LOFGREN. Aye.
The CLERK. Ms. Lofgren votes aye.
Mr. Gutknecht?
Mr. GUTKNECHT. Aye.
The CLERK. Mr. Gutknecht votes aye.
Mr. Doggett?
Mr. DOGGETT. Nay.
The CLERK. Mr. Doggett votes no.
Mrs. Seastrand?
Mrs. SEASTRAND. Aye.
The CLERK. Mrs. Seastrand votes aye.
Mr. Doyle?
[No response.]
The CLERK. Mr. Tiahrt?
Mr. TIAHRT. Aye.
The CLERK. Mr. Tiahrt votes aye.
Ms. Jackson-Lee?
Ms. JACKSON-LEE. No.
The CLERK. Ms. Jackson-Lee votes no.
Mr. Largent?
Mr. LARGENT. Aye.
The CLERK. Mr. Largent votes aye.
Mr. Luther?
Mr. LUTHER. Aye.

The CLERK. Mr. Luther votes aye.
Mr. Hilleary?
Mr. HILLEARY. Aye.
The CLERK. Mr. Hilleary votes aye
Mrs. Cubin?
[No response.]
The CLERK. Mr. Foley?
Mr. FOLEY. Aye.
The CLERK. Mr. Foley votes aye.
Mrs. Myrick?
Ms. MYRICK. Aye.
The CLERK. Mrs. Myrick votes aye.
Mr. ROEMER. Mr. Chairman, how am I recorded?
The CHAIRMAN. The gentleman from Indiana, how is he recorded?
The CLERK. Mr. Roemer is not recorded.
Mr. ROEMER. Aye.
The CLERK. Mr. Roemer votes aye.
Mr. HALL. Mr. Chairman, how am I recorded?
The CHAIRMAN. How is Mr. Hall recorded?
The CLERK. Mr. Hall is not recorded.
Mr. HALL. I vote aye.
The CLERK. Mr. Hall votes aye.
The CHAIRMAN. Mr. Hall votes aye.
Is there anybody else in the room that is not certain how they've been recorded?
[No response.]
The CHAIRMAN. Then all members have been recorded.
The Clerk will report.
The CLERK. Mr. Chairman, I count 36 yeas, 9 nays.
The CHAIRMAN. Thirty-six yeas, 9 nays, the amendment is agreed to.
The next amendment on the list is also an amendment by Mr. Davis of Virginia.
Mr. DAVIS. This is Amendment 11. We're not going to offer 10 but Amendment 11.
This Section 3104(b) deals with risk assessment of human health risks. It addresses the types of data one should consider and discuss when conducting a risk assessment. The base document includes laboratory and epidemiological data and other relevant data.
This amendment adds raw data, such as may be acquired from animal experiments, to the data to be considered.
When reviewing this, the amendment asks that one consider the effects on human health and so on. The inclusion of raw data is important and may provide vital and necessary information, and under this amendment is specified as opposed to raw data being classified as any other relevant data.
I think this clarifies again, and once again I've shared this with the staff, and I hope the Chairman's in agreement.
The CHAIRMAN. Well, the Chair has reviewed this amendment and is prepared to accept the amendment.
Is there any further discussion?
[No response.]

Mr. BROWN. Mr. Chairman, I have reviewed this language myself and, as with the last amendment, I find that it does not convey to me any really significant indication of what it means.

It sounds innocuous enough, but I am afraid that the ordinary person, including the ordinary bureaucrat who will be called upon to carry out the intent of this law, is not going to be able to discern exactly what the authors intended.

Now I will admit that this is a personal opinion, but it comes from reading a lot of law with regard to what scientists should do, and I am not convinced at all that it provides any constructive guidance.

The CHAIRMAN. Is there any further discussion?

Mr. OLVER. Mr. Chairman.

The CHAIRMAN. The gentleman from Massachusetts.

Mr. OLVER. Mr. Chairman, the last sentence here on "animal data should be reviewed with regard to its relevancy to humans," that at least is already addressed in this section—I think. I am having difficulty, I must say. It takes awhile to find.

Mr. Chairman, I always thought this process was on the level, and I never realized that we did this to you when we were in the majority. [Laughter.]

Mr. OLVER. But I am having a difficult time reading through, once a whole lot more words in this area have been added, what the meaning can possibly be—which I think is about the same problem that the Ranking Member is having.

Could the Member, the colleague offering this amendment, please explain to me again why this is needed, in addition to the language that is already there?

Mr. DAVIS. The language that is there is so general, this calls specifically the attention of raw data for review, and then goes on to note that "the greatest emphasis would be placed on data that indicated a biological basis of the resulting harm in humans."

I think it is clarification when you say—right now it says "any other relevant data"; the "raw data" could be a key ingredient. I think it gives the "bureaucrats," as Mr. Brown describes them, the flexibility to go back after—and look at the raw data, the underlying—it may not be a published study, but the raw data itself, and use that as a basis. So I think it gives them flexibility.

Mr. OLVER. Well, the very last sentence, which says that "Animal data shall be reviewed with regard to its relevancy to humans," above, in the very same section, there is the language "where animal data is used as a basis, the document shall include discussion of the possible reconciliation of conflicting information."

I don't know what, then, the language that is in the amendment does to clarify or add to what is already there.

Mr. DAVIS. What it adds is the raw data. It emphasizes raw data as opposed to the current language that just says "any other relevant data." It just gives that flexibility, should there be any hesitancy on the part of someone putting out the rule or regulation.

I don't think it does—I think it is a clarification. It just gives the flexibility to the rulemaker.

The CHAIRMAN. The Chair would say to the gentleman from Massachusetts I think he raises a relevant point. The fact is that, while the language is duplicative, in one case it refers to conflicts, and

in the other cases it is definitional to the raw data and therefore the repeating of the language does not seem to do any harm, and certainly does not contradict that which was there earlier in the section.

Is there any further discussion on the amendment?

[No response.]

The CHAIRMAN. If not, those in favor of the amendment will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed, no.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair the ayes have it. The ayes have it, and the amendment is agreed to.

The next amendment is listed on the sheet as No. 12, Mr. Barton's amendment.

The gentleman is recognized.

Mr. BARTON. Thank you, Mr. Chairman.

[The bells ring.]

Mr. BARTON. Is the Committee in recess?

[Several Members shout "aye."] [Laughter.]

Mr. BARTON. Mr. Chairman, I would ask unanimous consent that my amendment be considered and adopted by voice vote immediately. [Laughter.]

The CHAIRMAN. The gentleman may be a bit hasty. In light of the bells ringing and the past controversy, the Chair would call an immediate recess and we will take up Mr. Barton's amendment when we come back.

[Brief recess.]

The CHAIRMAN. The Committee will come to order.

The next amendment is an amendment offered by Mr. Barton. The gentleman is recognized.

Mr. BARTON. I thank you, Mr. Chairman.

Let me give a report from the other Committee that is marking the bill up simultaneously. We are ahead. We are on Amendment 12. They are on Amendment No. 3. So I don't know if that's good or bad, but we are moving more expeditiously.

Mr. Chairman, I have two versions of the same amendment at the desk and I would like to offer the second version, which is marked "Barton 004".

The CHAIRMAN. Has the amendment been distributed?

Mr. BARTON. The amendment is in the process of being distributed.

The CHAIRMAN. The amendment needs to be distributed.

Mr. HAYES. Mr. Chairman, I ask that the amendment be read.

Mr. BARTON. Do you want me to read it, or the Clerk to read it?

The CHAIRMAN. The Clerk will report the amendment.

The CLERK. Amendment offered by Mr. Barton of Texas:

"Page 39, after line 11, (in section 3104(b)), after paragraph (2), insert the following:

(3) 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 adopt-

ed by a covered Federal agency on the basis of such a recommendation or classification shall comply with the provisions of this subtitle.''

Mr. BARTON. Mr. Chairman, what this amendment does is eliminate a past practice of some Federal agencies that have accepted verbatim regulations that were proposed and promulgated overseas and not studied in any independent way by a Federal agency in this country.

The amendment would say a Federal agency could take under advisement a regulation that has been adopted overseas, but before it could actually accept it it would have to conduct an independent assessment of that regulation.

Ms. RIVERS. Mr. Chairman.

The CHAIRMAN. Is there discussion?

Ms. Rivers.

Ms. RIVERS. Thank you, Mr. Chair.

I have a couple of questions. I was a little confused when I saw this because my recollection was, when we had hearings last week, people roundly criticized the FDA for not using data that were developed in other parts of the world. And that was shown as a flaw in the FDA's procedures.

So I am surprised now that we are seeing this.

But, more importantly, I am confused as to how this would work. If, for example, we have evidence in other countries that certain kinds of drugs are indeed injurious to the health of citizens in that country, are we required under this procedure to have Americans die or become ill in order to demonstrate that the data from the other country is acceptable?

There is no specificity as to what makes data acceptable under this provision.

Mr. BARTON. It is my understanding that the Act that is before us specifically excludes the Food and Drug Administration, so that question wouldn't be germane.

Ms. RIVERS. Well, in any other situation——

The CHAIRMAN. That is not true.

Ms. RIVERS. Yes. It's not true.

The CHAIRMAN. The gentleman has been misinformed. The Drug Administration is included.

Mr. BARTON. Well, if the FDA is included in this, the general point that the gentlelady was making, the purpose of this amendment, it doesn't preclude the acceptance of a regulation that's formulated overseas; it simply says, before it's actually adopted there has to be an independent risk assessment of that regulation.

Ms. RIVERS. And that's what I am asking is what that looks like. Does that mean we have to wait for independent evidence in this country? I mean, what does that mean? Are we essentially saying you can't——

Mr. BARTON. It does not mean that you have to go back and reinvent the wheel. It does mean that someone in a Federal agency in the United States Government has to do a study of the documentation and the risk assessment of the regulation that was promulgated overseas.

It doesn't mean that it has to be—the entire data trail has to be recreated. It simply means there has to be a study by a Federal agency of the studies that led to that regulation.

Ms. RIVERS. So would in effect this be an endorsement of the procedures that the FDA is now employing in their approval of drugs in this country?

Mr. BARTON. No, it's not an endorsement, nor is it a condemnation. It simply says that you have to conduct, at the Federal agency level in this country, an independent assessment of any regulation before it's also adopted.

So in some cases that could be fairly quick. In other cases it might take some time.

Ms. RIVERS. Thank you.

Mrs. MORELLA. Mr. Chairman.

Ms. LOFGREN. Mr. Chairman.

Mr. BROWN. Mr. Chairman.

Mrs. Morella. Mr. Chairman.

The CHAIRMAN. Mrs. Morella.

Mrs. MORELLA. Thank you, very much. Thank you, Mr. Chairman.

I wanted to ask the gentleman who offered the amendment, Mr. Barton, whether or not this would include international agreements like the Montreal Protocol which deals with the environment, and a number of others that we have on ocean dumping, and whatever, where nations have come together and have signed a treaty but you may not have individual experimentation or certification, or whatever, in your amendment for it.

So I just wondered if it would apply to those?

Mr. BARTON. If the gentlelady would yield?

Mrs. MORELLA. Yes.

Mr. BARTON. This deals with risk assessments and simply requires that there be a verification by Federal agency of the regulation before it's adopted in this Nation.

The key word is in the first sentence where it says: "No covered Federal agency shall automatically incorporate"—"automatically incorporate".

Mrs. MORELLA. Well, if it—would they automatically incorporate? What would be an instance where they would automatically incorporate?

Mr. BARTON. Well, there have been cases in the past where—and the one that is the most current is with the chemical compound styrene where a regulation was adopted in Europe and was automatically adopted in this country without any kind of independent review by the review by the Federal agency at all.

Mrs. MORELLA. Okay. Thank you.

Ms. LOFGREN. Mr. Chairman.

The CHAIRMAN. The gentlelady from California.

Ms. LOFGREN. I think I understand what the gentleman's goals are in offering the amendment, but I am concerned that the impact might invoke the law of unintended consequences.

I am thinking about, and I mentioned during the hearing, Clozapine, which is a very successful medication utilized with schizophrenics, for some section of schizophrenics that affects almost a miraculous recovery.

It was used successfully in Europe with thousands of schizophrenics for over ten years, and the impacts were well known beyond any trial that could possibly have been engaged in the United States.

The concern I have is I don't understand how this might or might not preclude utilizing not trails but an entire continent of people taking this medication to good effect, and incorporating that.

Another example that's currently being studied, and I frankly don't understand why, is an herbal tea in China that has been found to be effective in the treatment of alcoholism that has been used by 3 billion Chinese, and that we would have to study it here in the United States.

I am not sure how much additional study would be required, and I wondered if the gentleman could give us an idea in terms of months or years.

And the second question has to do——

The CHAIRMAN. If the gentlelady would yield to me——

Ms. LOFGREN. Certainly.

The CHAIRMAN. I think what you need to do is read the gentleman's amendment in light of the other provisions of the bill.

Ms. LOFGREN. Yes.

The CHAIRMAN. If you go to the Exceptions section, you will see that those things exempt from the bill include "A screening analysis, where appropriately labeled as such, including a screening analysis for purposes of product regulation, or premanufacturing notices."

Then if you go down to subsection (B)—I am on page 7:

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

Ms. LOFGREN. Okay, so——

The CHAIRMAN. So in other words, if what we are doing—this would not apply where we are trying to get approval of things that had been approved in other countries.

However, if we were using data from other countries to stop approval in this country, that would be covered by the gentleman's amendment. So the kinds of things you are citing, FDA could go ahead and approve based upon foreign data, but they could not stop an approval based upon foreign data under the gentleman's amendment.

Ms. LOFGREN. So if the foreign data says we will approve use of a substance and we're going to accept the foreign data, but if it's going to preclude use, if there's an alleged danger, we won't accept the data?

The CHAIRMAN. Then at that point you have to apply the guidelines specified in the gentleman's amendment. It doesn't mean that it couldn't happen. It simply means that at that point you would have to go out for notice and comment and do the things which are covered by the gentleman's amendment.

Ms. LOFGREN. Now would this include pesticides? I know a lot of pesticide companies, including some that are not owned wholly by U.S. interests, test in Latin America because of the reversal of seasons.

If they did their testing in the Southern Hemisphere in the growing season, would we be able or unable to use their results under this amendment?

The CHAIRMAN. Well again, if you look it is by non-United States-based entity.

Ms. LOFGREN. Right.

The CHAIRMAN. If it is our companies doing the testing, they are a U.S.-based entity.

Ms. LOFGREN. But my hypothetical is a multinational that could not be fairly ranked as a U.S.-based company—or is "U.S.-based company" defined in this Act?

Mr. BARTON. We are not doing risk assessment for private individuals or private organizations. This is for rules and regulations that, under the scope of the bill, this simply says that we can't automatically adopt something that has been adopted overseas without at least an opportunity for a comment period and a risk assessment study in this Nation.

It is actually pretty straight-forward.

Ms. LOFGREN. Well if I could, further, it says "non-U.S.-based entity". It doesn't say "private entity". It doesn't say "governmental entity"; it just says—it could be a university. It could be a company—or is that defined somewhere and I've missed it?

The CHAIRMAN. No, you have to read up—it's "no covered Federal agency shall automatically incorporate" and then you—

Ms. LOFGREN. I am looking on line 3, though, is the question I had.

The CHAIRMAN. But that refers back to the first line. This regulation is applying to "the Federal agency" not to "the U.S.-based entity".

Mr. BARTON. Right. We are simply giving an opportunity before a—if a Federal agency under its jurisdiction—we're not changing jurisdictions—if a Federal agency is contemplating adoption of a rule or regulation that has been adopted overseas, it can't automatically adopt it without giving an opportunity for public comment and notice, and review of any of the pertinent risk assessment documentation that was used overseas.

I mean, there is no Machiavellian intent in this amendment. It is simply to give our Federal agencies, which we have granted by Act of Congress, the right to issue rules and regulations for the public health and safety the requirement that they don't automatically adopt something that's been adopted overseas.

I mean, I've said that ten times, but that is the intent, Mr. Chairman.

Ms. LOFGREN. I am not trying to say there is a Machiavellian intent, and I hope the gentleman would understand that. I do think, though, it is drafted in such a way that it is subject to significant misinterpretation.

Mr. BARCIA. Mr. Chairman.

The CHAIRMAN. Mr. Barcia.

Mr. BARCIA. Mr. Chairman, I want to lend my support to Mr. Barton's amendment for the simple reasons, the concepts of sound science and greater accountability are compromised by the continued use of non-U.S.-based risk assessments. These assessments,

however beneficial as a source of information, should be used as just that: background information.

In fact I urge the use of such outside entities for background research, and I don't believe any of my colleagues would want available information suppressed when determining appropriate levels of regulation.

However, I don't believe nonregulatory agencies like the International Agency for Research on Cancer, even if the U.S. funds a major part of their operation, should be relied on for one-third of the input when determining OSHA's Hazardous Communications standard, or EPA's Toxic Release Inventory.

What is important to note is the degree to which IARC is relied on, not the fact that IARC assessment was used. Mr. Barton's amendment does not simply replace nongovernment entities like IARC with some other singular agency, but asks that Federal action not base itself solely on the recommendation of a singular non-U.S.-based entity.

Moreover, no agency action shall take such recommendations as gospel and automatically adopt them in their regulatory process. Ultimately this amendment simply encourages the use of non-U.S. recommendations as support for agency risk assessments rather than sole determinants of risk.

Mr. Chairman, it is my view that the mediocrity and complacency go hand in hand. If we become complacent with selective sources of information, we are subverting the very intention of this bill: to use sound science and the most reasonable data to best estimate risk.

Thanks.

The CHAIRMAN. I thank the gentleman.

Mr. Traficant.

Mr. TRAFICANT. Mr. Chairman, I support the amendment. I think it is straightforward and it is a good safeguard that serves this section of the bill very well. I think Mr. Barton has explained it very thoroughly and it is quite evident, if you read it, that the safeguards are also evident.

I yield back my time.

Mr. BROWN. Mr. Chairman.

The CHAIRMAN. Thank you. Mr. Brown, Mr. Olver was seeking recognition.

Mr. BROWN. Go ahead.

Mr. OLVER. Thank you, Mr. Chairman.

I would just like to comment that there is a great volume of very solid science and research that is available from other places, and I really do not understand why, if—and there are good organizations doing good risk analysis in some of our partners around the world, and I don't understand why there would be any need for this kind of language if the definitions of "risk analysis" are followed in the process of such evaluation in those other places.

What I am particularly concerned about here is that what this language does is put in a closed procedure. I am really puzzled by the language, the "No covered Federal agency shall automatically incorporate", but they could incorporate without automatically incorporating without this opportunity for notice and comment, and

so forth, and following the procedures of the legislation on risk assessment.

In essence we are in a situation when very good scientific input could come from places that are working on this, on developing a cure for AIDS, or whatever, and find that, because of this language, we had to go through some question of what were the scientific findings with all of the raw data by previous amendments that have been offered, along with independent studies and risk assessments and so forth, all because this language says one has to go through this, even though we have excellent evidence that there is good scientific research done in other places with good risk analyses being done.

I think that this really puts a straightjacket around an area where we should be looking for ways of using the most effective data available in competent places elsewhere to help us get around this sort of thing.

I find this very problematical language.

Mr. BARTON. If the gentleman would yield? If the gentleman would yield to the author of the amendment?

Mr. OLVER. I am happy to yield.

Mr. BARTON. The point is, it is not the intent of this amendment to preclude regulations that have been scientifically adopted and validated overseas in this country. That is not the intent at all.

The fact of the matter is that the standard are different overseas. Not all regulatory agencies overseas have the same criteria that we have in this country, and this amendment simply says that before we automatically adopt without even a public comment period, we at least have a public comment period and let those that have an interest comment on the proposed regulation.

It does not require that there be an actual reconstitution of the data base. It does say that there needs to be an assessment of the data base that was used to promulgate the regulation overseas.

In the cases that the gentleman has just referred to in a hypothetical sense, if in fact the regulation actually is based on sound scientific evidence and it has been properly research and developed, it will in all probability be adopted after a very cursory public comment period.

But it can't be done automatically. That is the intent of the regulation—of the amendment, excuse me.

I yield back to the distinguished gentleman.

Mr. BROWN. Mr. Chairman.

The CHAIRMAN. Mr. Brown.

Mr. BROWN. Mr. Chairman, I frankly am not on top, frankly, of what the impact of this amendment would be. In such situations I am inclined to want to go slowly with regard to something of this sort.

I know of nothing in the record of the hearings that dealt with this particular subject. I know of no testimony or requests from any of the Federal agencies for any of this. If the author of the amendment can make reference to the testimony of any witness or a request from any source for this language, I would certainly appreciate it. It would help me to evaluate it.

I am just—I am not an expert in this subject, either—recalling examples of Federal regulatory action over the past generation or

two, I can recall when, for example, when the European manufacturer, or even the American manufacturer of a product called Thalidomide sought to get it adopted in the United States, and it was initially offered in Europe.

The FDA was extremely leery about doing that, including accepting the data from the European company, and apparently that is what the gentleman is recommending in this amendment, that we be leery of such non-U.S.-based entities' claims with regard to something.

If what he is suggesting is what we are already doing, then I question why we need to repeat it in this legislation.

I would also point out that an increasing amount of health effects' studies in every area from pharmaceuticals to chemicals, to large-scale things like evaluating the impact of global warming, is being done on an international basis today and is being done under the auspices of international organizations.

While I don't believe that we should give any more credibility to this because of its international sponsorship, I certainly don't want to include a presumption that they are not engaged in the development of assessments and other documentation that is inferior to the United States, and this might tend to give that impression.

I am unclear as to what would happen, for example, when the global warming program decides that there is a risk associated with the use of freon and that we ought to withdraw that from the market.

Would this require that we not accept the finding?

Or would it in someway prejudice our ability to act to remove the threat of global warming?

I say this without knowing the answer, and hoping that the gentleman can enlighten me on some of these things so that I can be absolutely clear that this is the great piece of legislation that I know the proponent thinks it is.

Mr. BARTON. Well, I have the—if the distinguished former chairman would yield, I will be happy to attempt a probably nonsatisfactory response to his eloquent statement and question.

I guess I should have titled this "The All-America Review Amendment," taking a page out of Mr. Traficant's book. All we are attempting to do is give the appropriate Federal agency in this Nation the opportunity to review, and those in this country that are concerned about overseas' regulations, a public comment period.

In the cases that the work has been done satisfactorily according to standards that we find acceptable, this will not be a dilatory process.

In those cases where perhaps the work was not done satisfactorily, it might be a decision made to conduct some independent studies of our own before we adopt them.

I guess an analogy would be what's happening right now, today. We've got this bill being marked up simultaneously in two separate committees.

If you use this amendment as an analogy, it simply says we want the Science Committee to have an opportunity to take a look at what the Commerce Committee does before we accept it.

Now that is what we are attempting to do here. There is not anything other than that involved. I can assure the distinguished

former chairman that if he will vote with me on this, he will someday come and pat me on the back and say, Congressman Barton, I'm glad that I accepted your analysis and went with you, because it will not backfire on you; I assure you.

Mr. BROWN. Would the gentleman yield?

Mr. BARTON. It is your time, so I yield back to the distinguished gentleman.

Mr. BROWN. I really would very much like to have the gentleman pat me on the back and say that I had done something right for a change.

Mr. BARTON. Well the gentleman has done many things right. So this wouldn't be the first occasion.

Mr. BROWN. But I still would like a response to the first part of my question.

Can the gentleman refer to any request, any testimony, any indication of where the impetus for this amendment can from, other than the inspiration that he draws from on High?

Mr. BARTON. Well, actually the inspiration didn't come from on High, it came from several organizations that did not testify in the public comment period but had a concern based on, primarily on practices of the EPA in the past of adopting certain regulations without a comment period here in this country. But it was not a part of the record developed in the testimony before this Committee.

Mr. BROWN. Well that certainly clarified the genesis of the amendment and I appreciate it very much.

Mr. CHAIRMAN. Is there further discussion on the amendment?

Mr. TRAFICANT. Mr. Chairman, I've got an amendment to this amendment.

The CHAIRMAN. An amendment to this amendment would be a third-degree amendment, which would not be in order.

Mr. TRAFICANT. I ask unanimous consent that I be allowed to offer an amendment to this amendment that was heretofore ruled not in order for the sake of defining what a "U.S.-based company" is.

Mr. SENSENBRENNER. Reserving the right to object, I think we would like to see the amendment before waiving our rights.

Mr. BARTON. It doesn't say—if the gentleman from Ohio would yield—my amendment says non——

Mr. CHAIRMAN. The gentleman from Wisconsin controls the time under a reservation.

Mr. SENSENBRENNER. I would just like to see what the amendment is.

Mr. TRAFICANT. I believe the amendment is at the desk. Could they distribute the amendment?

The CHAIRMAN. Does the Clerk have the amendment?

The CLERK. No.

The CHAIRMAN. There is no amendment at the desk.

Mr. SENSENBRENNER. Well, Mr. Chairman, I object.

The CHAIRMAN. Objection is heard from the gentleman from Wisconsin.

Mr. BARTON. Mr. Chairman, if there is no further debate on my amendment, I would respectfully move the previous question. I

don't want to limit debate on it, but if there are no other Members wishing——

The CHAIRMAN. Is there further debate on the amendment?

[No response.]

The CHAIRMAN. If not, the Chair will put the question.

All those in favor of the amendment of the gentleman from Texas will say, aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say, no.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair, the ayes have it. The ayes have it, the amendment is adopted.

Ms. LOFGREN. Are we having a roll call vote? I would like a roll call vote.

The CHAIRMAN. The gentlewoman from California requests a roll call vote. The Clerk will call the roll.

The CLERK. Mr. Walker?

The CHAIRMAN. Aye.

The CLERK. Mr. Walker votes aye.

Mr. Brown?

[No response.]

The CLERK. Mr. Sensenbrenner?

Mr. SENSENBRENNER. Aye.

The CLERK. Mr. Sensenbrenner votes aye.

Mr. Hall?

Mr. HALL. Aye.

The CLERK. Mr. Hall votes aye.

Mr. Boehlert?

[No response.]

The CLERK. Mr. Traficant?

Mr. TRAFICANT. Aye.

The CLERK. Mr. Traficant votes aye.

Mr. Fawell?

Mr. FAWELL. Aye.

The CLERK. Mr. Fawell votes aye.

Mr. Hayes?

Mr. HAYES. Aye.

The CLERK. Mr. Hayes votes aye.

Mrs. Morella?

Ms. MORELLA. Aye.

The CLERK. Mrs. Morella votes aye.

Mr. Tanner?

Mr. TANNER. Aye.

The CLERK. Mr. Tanner votes aye.

Mr. Weldon of Pennsylvania?

Mr. CURT WELDON. Aye.

The CLERK. Mr. Weldon votes aye.

Mr. Geren?

Mr. GEREN. Aye.

The CLERK. Mr. Geren votes aye.

Mr. Rohrabacher?

Mr. ROHRABACHER. Aye.

The CLERK. Mr. Rohrabacher votes aye.

Mr. Roemer?

Mr. ROEMER. Aye.
The CLERK. Mr. Roemer votes aye.
Mr. Schiff?
Mr. SCHIFF. Aye.
The CLERK. Mr. Schiff votes aye.
Mr. Cramer?
[No response.]
The CLERK. Mr. Barton?
Mr. BARTON. Aye.
The CLERK. Mr. Barton votes aye.
Mr. Barcia?
Mr. BARCIA. Aye.
The CLERK. Mr. Barcia votes aye.
Mr. Calvert?
Mr. CALVERT. Aye.
The CLERK. Mr. Calvert votes aye.
Mr. McHale?
Mr. MCHALE. Aye.
The CLERK. Mr. McHale votes aye.
Mr. Baker?
Mr. BAKER. Aye.
The CLERK. Mr. Baker votes aye.
Ms. Harman?
Ms. HARMAN. Aye.
The CLERK. Ms. Harman votes aye.
Mr. Bartlett?
Mr. BARTLETT. Aye.
The CLERK. Mr. Bartlett votes aye.
Ms. Johnson?
Ms. JOHNSON. Aye.
The CLERK. Ms. Johnson votes aye.
Mr. Ehlers?
Mr. EHLERS. Aye.
The CLERK. Mr. Ehlers votes aye.
Mr. Minge?
Mr. MINGE. Aye.
The CLERK. Mr. Minge votes aye.
Mr. Wamp?
Mr. WAMP. Aye.
The CLERK. Mr. Wamp votes aye.
Mr. Olver?
Mr. OLVER. No.
The CLERK. Mr. Olver votes no.
Mr. Weldon of Florida?
Mr. DAVE WELDON. Aye.
The CLERK. Mr. Weldon votes aye.
Mr. Hastings?
Mr. HASTINGS. No.
The CLERK. Mr. Hastings votes no.
Mr. Graham?
Mr. GRAHAM. Aye.
The CLERK. Mr. Graham votes aye.
Ms. Rivers?
Ms. RIVERS. No.

The CLERK. Ms. Rivers votes no.
Mr. Salmon?
Mr. SALMON. Aye.
The CLERK. Mr. Salmon votes aye.
Ms. McCarthy?
Ms. MCCARTHY. No.
The CLERK. Ms. McCarthy votes no.
Mr. Davis?
Mr. DAVIS. Aye.
The CLERK. Mr. Davis votes aye.
Mr. Ward?
Mr. WARD. No.
The CLERK. Mr. Ward votes no.
Mr. Stockman?
Mr. STOCKMAN. Yes.
The CLERK. Mr. Stockman votes aye.
Ms. Lofgren?
Ms. LOFGREN. No.
The CLERK. Ms. Lofgren votes no.
Mr. Gutknecht?
Mr. GUTKNECHT. Aye.
The CLERK. Mr. Gutknecht votes aye.
Mr. Doggett?
Mr. DOGGETT. No.
The CLERK. Mr. Doggett votes no.
Mrs. Seastrand?
Mrs. SEASTRAND. Aye.
The CLERK. Mrs. Seastrand votes aye.
Mr. Doyle?
Mr. DOYLE. Aye.
The CLERK. Mr. Doyle votes aye.
Mr. Tiahrt?
[No response.]
The CLERK. Ms. Jackson-Lee?
Ms. JACKSON-LEE. No.
The CLERK. Ms. Jackson-Lee votes no.
Mr. Largent?
Mr. LARGENT. Aye.
The CLERK. Mr. Largent votes aye.
Mr. Luther?
Mr. LUTHER. No.
The CLERK. Mr. Luther votes no.
Mr. Hilleary?
Mr. HILLEARY. Aye.
The CLERK. Mr. Hilleary votes aye.
Mrs. Cubin?
Mrs. CUBIN. Aye.
The CLERK. Mrs. Cubin votes aye.
Mr. Foley?
Mr. FOLEY. Aye.
The CLERK. Mr. Foley votes aye.
Mrs. Myrick?
Mrs. MYRICK. Aye.
The CLERK. Mrs. Myrick votes aye.

Mr. BROWN. Mr. Chairman, how am I recorded?

The CHAIRMAN. How is Mr. Brown recorded?

The CLERK. Mr. Brown is not recorded.

Mr. BROWN. Mr. Brown votes no.

The CLERK. Mr. Brown votes no.

The CHAIRMAN. Any further—Ms. Johnson?

Ms. JOHNSON. How am I recorded?

The CLERK. Ms. Johnson is recorded "aye."

Ms. JOHNSON. I would like to change that to no.

The CLERK. Ms. Johnson votes no.

The CHAIRMAN. Anyone else in the room who has not been recorded?

[No response.]

The CHAIRMAN. If not, the Clerk will report.

The CLERK. Mr. Chairman, I count 36 yeas, 11 nays.

The CHAIRMAN. 36 yeas, 11 nays; the amendment is adopted.

The next amendment is by Mr. Olver. It is number 13 on the sheet that deals with comparability—"comparison," I should say.

Mr. OLVER. Mr. Chairman, are we—point of parliamentary inquiry here. Are we obliged to follow the order on the list? I mean, we are not moving into Section 3105, and I had two amendments in 3105, one earlier than the one that is listed as No. 13.

What is my obligation in this?

The CHAIRMAN. Well, the Chair intends to move through the amendments as reflected on the roster before the Members, and then any additional amendments to the particular section we will take up after we have completed those items on the roster, in the subtitle, I should say.

Mr. OLVER. Thank you very much for the clarification, Mr. Chairman.

I have an amendment which I think then has been circulated. It is an amendment in two parts.

The CHAIRMAN. This amendment we understand has not been circulated. If the Clerk has the amendment, would the Clerk distribute the amendment?

Is it amendment 13, which is in the package——

Mr. OLVER. Yes.

The CHAIRMAN. Or a different version?

Mr. OLVER. Yes, it is amendment 13 as it is in the package.

The CHAIRMAN. We are being told by counsel on both sides that that is not the case; that it has been changed since the package was prepared.

[Pause.]

Mr. OLVER. Mr. Chairman, if in fact the amendment is different from what was circulated, then I should wait until the Clerk has circulated the amendment.

The CHAIRMAN. The Clerk will distribute the amendment.

[The amendment is distributed.]

The CHAIRMAN. As I understand it, this is Amendment No. 8 in the supplementary minority package.

Mr. OLVER. That, I believe, is correct.

Mr. BARTON. Mr. Chairman?

The CHAIRMAN. Who seeks recognition? The gentleman from Texas.

Mr. BARTON. Mr. Chairman, I am the next amendment, Amendment No. 14, and I would be willing to go ahead with that amendment while we are clarifying this amendment, if that would be helpful. I am not trying to——

The CHAIRMAN. I think we now have it to distribute, so I thank the gentleman for his attempt to cooperate here, but I think we now have it coming around.

I recognize the gentleman from Massachusetts to discuss his amendment.

Mr. OLVER. Thank you, Mr. Chairman.

This amendment is in two parts. It reads in Section 3105(3) the addition of the words ", safety, or the environment" after the words "human health".

And, if I may, I would like to separate the two parts and deal with them separately.

The CHAIRMAN. The gentleman can do as he wishes. We will take up, then, his amendment to page 11, line 13 first. Is that——

Mr. OLVER. That's correct.

The CHAIRMAN. The gentleman is recognized.

Mr. OLVER. I would note that in the language as it came out, the words ", safety, or the environment" were removed there from an earlier version. And I would just call the attention of the Members of the Committee that the first finding on page 1 of the bill has to do with "environmental health and safety regulations have led to dramatic improvements in the environment and have significantly reduced human health risk," and point out that on page 4 we, in our applicability section on page 4, under Applicability, Part B, that the words "designed to protect human health, safety, and the environment" are what is involved there.

So that I would urge the adoption of the reinstatement of the words "human health, safety, or the environment" in context in the point that we're discussing.

The CHAIRMAN. Well the language had been removed in order to make this a less cumbersome kind of burden, but the Chair has no particular problems with including that language and would be willing to accept the amendment.

Mr. OLVER. If there is no discussion, then I would call for a vote on that.

The CHAIRMAN. The gentleman moves the previous question.

Those in favor of the amendment will say, aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say, no.

[No response.]

The CHAIRMAN. The ayes have it. The amendment is adopted.

Mr. OLVER. Thank you, Mr. Chairman.

If I may then go on to the second, which now—since that was simple, people may have had a chance to look at the second one which I've obviously prejudiced myself, I suppose, by allowing that time; but in the second instance, the rest of that statement has to do with comparisons of risks that should be considered under the risk assessment program.

The purpose of the amendment, as I have offered it, is to make certain that we are comparing risks that are of a similar nature and, in order to preclude the possibility that we will be dealing

with risks that relate to cancer and a variety, say, of cancer researches that have been done and the risk assessments that may have been done there, from a comparison with something that may be a driving risk, or a risk of falling on the ice outside today.

Because we have had a good deal of evidence from people before this Committee. Several of the people testifying have indicated that this kind of comparison ought to be made among similar kinds of risks for reasons, for instance, that if you look at voluntary and involuntary risks, or natural and technological risks, that people value those in quite different kinds of ways.

And if you take a voluntary risk that might come from something like a skiing accident, say, that to compare it, while the number that you might come up with, or the range of numbers might be somewhat similar, it is a very different thing in people's understanding from what might come from the risks of a natural earthquake, or some things which are Acts of God or something that might be from a technological act of man, the addition of additives to foods, or whatever.

The point here is that in order to be meaningful, that risk comparisons really should be done within what would be an appropriate decision making sphere. The contexts of the risks as they are considered ought to be in the same mode as has been indicated by a number of people who have testified in scientific evidence given to us, and the position taken by even groups like the National Research Council.

The CHAIRMAN. I thank the gentleman for his explanation.

Mr. Bartlett.

Mr. BARTLETT. Mr. Chairman, I think that limiting these comparisons to activities that are regulated by that Federal agency or other Federal agency denies the opportunity to provide really appropriate comparisons.

For instance, some risks may be no greater than the risk of being struck by lightning. If that in fact is the risk, I think the people have a right to understand that that is the level of the risk.

Comparing it with some arcane language in another government regulation may convey nothing relative to the real risk that the population is exposed to.

The CHAIRMAN. Any other discussion?

Mr. OLVER. If I may respond to that, I think the whole purpose of the risk assessment program is to help us as decision-makers, and to help the public understand the nature of the comparisons and of the risks that are involved and put them in a context that is an appropriate context.

And the gentleman who just spoke himself used the language that the comparisons ought to be appropriate comparisons, which is the very point of this; that the comparisons, if one crosses lines among in a general way those kinds of topics that I mentioned of voluntary and involuntary risks and natural or technological ones, that you have really crossed the boundaries of appropriate comparison for helping to educate and clarify for people the nature of the risks involved.

The CHAIRMAN. Is there further discussion on the amendment?

Mr. HASTINGS. Mr. Chairman.

The CHAIRMAN. The gentleman from Florida.

Mr. HASTINGS. I thank the Chair.

Following the discussion—and I strongly support the amendment—I would like to know what constitutes an "appropriate comparison" for placing the nature and the magnitude of risks to human health in context.

I am new to this Committee, and all of this is in some respects a bit confusing. In the base bill, there is a statement regarding categories of risk.

Well, what are the "categories of risk"?

And if I am reading the base bill, how do I know that? And what constitutes a "relevant distinction among categories of risk"?

It is very confusing. If counsel or someone can help me to understand that, I would appreciate it.

The CHAIRMAN. Counsel.

Mr. BERINGER. Excuse me, Mr. Hastings, were you referring to the amendment, or to the——

Mr. HASTINGS. The amendment and the base bill. Okay

Mr. BERINGER. Okay.

Mr. HASTINGS. The language as put forward in the bill is: "The statement shall identify relevant distinctions among categories of risk and limitations to comparisons".

If I read that, you know, I am a lawyer, and if that ain't gobbledygook, grits ain't groceries. [Laughter.]

I have a serious problem understanding how anybody will understand that other than agency types and people who deal with this on a regular basis.

The CHAIRMAN. The Chair is having trouble understanding where the gentleman is in the bill. We are on page 11 under the Comparison section. The amendment goes to that particular section.

Mr. HASTINGS. Exactly.

The CHAIRMAN. And the gentleman is quoting from a section of the bill that is not there.

Mr. HASTINGS. I am on page 11, Mr. Chairman, under "Comparisons". Page 11, Mr. Chairman, lines 16 through 19.

The CHAIRMAN. Oh, so the gentleman is referring to the statement "shall identify relevant distinctions among categories of risks and limitations to comparisons"? Is that the language?

Mr. HASTINGS. Yes, sir. And I don't mean to be facetious, Mr. Chairman, but I don't know what the "categories or risk" are, if I read this. I think that we need to be very clear in this regard.

And I certainly have some serious questions as to what an "appropriate comparison" is, as I've indicated earlier.

The CHAIRMAN. I thank the gentleman.

The gentleman from Pennsylvania, Mr. Weldon.

Mr. CURT WELDON. Mr. Chairman, I worked in the insurance industry for ten years, and worked in risk management, and we used to simply characterize it as "frequency" and "severity."

When you look at the potential for loss, they are the two basic characteristics you are looking at. What is the frequency of the incident that would occur? And what is the potential severity? Then, to assess it based on those two factors.

I think that is what we are talking about here, if I am not mistaken.

Mr. HASTINGS. Is that counsel's assessment of this?

The CHAIRMAN. The Chair would recognize the counsel.

Mr. BERINGER. Thank you, Mr. Chairman.

Mr. Weldon is correct. What the amendment is trying also to get at is say relevant distinctions among different categories of risks.

In other words, trying to compare risks that are relevant to each other by trying to categorize them in a meaningful way to the general public in ways in which they'll understand.

That is the relevancy test that I believe this is trying to get to.

Mr. HASTINGS. Well I thank the Chair, and I have no further questions, Mr. Chairman, but I urge you to be mindful that what we are doing here is likely to cause a very litigious society to become even more litigious, and it is akin to the kinds of things that we've tried to avoid.

I suggest to you that we are creating a legal morass.

The CHAIRMAN. Again I thank the gentleman.

Is there further discussion on the amendment?

Mr. OLVER. Mr. Chairman, may I make one last comment here? The language in the first sentence of the comparison section reads "placing the magnitude of risks in context".

The whole purpose of my amendment is to establish that "context" as risks which are comparable in their nature of people's consideration of them so that this is a section which helps us to clarify the way we are assessing these risks and to help to educate the public.

The CHAIRMAN. The Chair again thanks the gentleman.

The Chair feels as though this amendment does strike some very important language in the bill. One of the things that we have attempted to do in doing comparisons is to give the public some idea of what a standard is that is a greater risk, and then a lesser risk to that which is being proposed.

The gentleman strikes that section and instead has us rely upon the same kind of information now being developed by regulators which tends to be Federal gobbledygook that nobody can understand.

It is the Chair's understanding that that is the way Federal regulators and many who approve of these regulations want to keep the situation so that there is plenty of gobbledygook out there that gives a lot of latitude to lawyers.

We are hoping that, because the public would have some better understanding of the relative degree of risks compared to things that they understand in their everyday lives, that that would in fact reduce the amount of litigation that would be needed to move forward.

So the language in the original bill is in fact aimed at giving the public a more in depth understanding, thereby reducing the need for litigation, rather than having mounds and mounds of Federal agency gobbledygook that no one understands.

So the Chair would oppose this particular amendment.

Is there further discussion?

[No response.]

The CHAIRMAN. If not, the Chair calls the question.

Those in favor of the amendment will say, aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say, no.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair the noes have it. The noes have it, the amendment is not agreed to.

Mr. BROWN. Mr. Chairman?

The CHAIRMAN. Mr. Brown.

Mr. BROWN. May I raise a procedural question? The Chair has announced that he intends to move forward with this bill until it is completed.

I have sought to ascertain whether or not that is a practical goal, and I am informed that there may be as many as 25 or 30 additional amendments to yet come before us, which at the rate we are going would keep us here until about midnight.

Does the Chair have anything more optimistic to conclude about our procedures for the rest of the evening?

The CHAIRMAN. Well, the Chair would say to the gentleman that insofar as people want to breed bills, or breed amendments, that will in fact lengthen the amount of time that the Committee will have to meet.

But it is my intention to move ahead. And we would hope that we could get done before midnight, but if midnight is the goal then we would have to do that.

Mr. BROWN. Mr. Chairman, if I might comment further, this matter of "breeding amendments," which has a slightly derogatory tone to it, is something that Members of this Committee have learned from long experience on this Committee from a master who is sitting in the Chair now.

[Several voices: Amen.] [Laughter.]

Mr. BROWN. I do not wish to be contentious about this matter, but I do have a feeling that most of the Members might like to consider the possibility of having dinner this evening, perhaps seeing their families—since we are in a "family-friendly" atmosphere—[Laughter.]

Mr. BROWN. And, Mr. Chairman, I would like to move that we adjourn at this point.

The CHAIRMAN. The motion is in order. The gentleman from California moves that the Committee do now adjourn. The question is on the motion.

Those in favor will say, aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say, no.

[Chorus of nays.]

The CHAIRMAN. THE NOES HAVE IT.

Mr. BROWN. Mr. Chairman, I ask for a roll call.

The CHAIRMAN. The Clerk will call the roll.

The CLERK. Mr. Walker?

The CHAIRMAN. No.

The CLERK. Mr. Walker votes no.

Mr. Brown?

Mr. BROWN. Aye.

The CLERK. Mr. Brown votes aye.

Mr. Sensenbrenner?

Mr. SENSENBRENNER. No.

The CLERK. Mr. Sensenbrenner votes no.
Mr. Hall?
[No response.]
The CLERK. Mr. Boehlert?
[No response.]
The CLERK. Mr. Traficant?
Mr. TRAFICANT. Aye.
The CLERK. Mr. Traficant votes aye.
Mr. Fawell?
Mr. FAWELL. No.
The CLERK. Mr. Fawell votes no.
Mr. Hayes?
Mr. HAYES. Aye.
The CLERK. Mr. Hayes votes aye.
Mrs. Morella?
Ms. MORELLA. No.
The CLERK. Mrs. Morella votes no.
Mr. Tanner?
Mr. TANNER. Aye.
The CLERK. Mr. Tanner votes aye.
Mr. Weldon of Pennsylvania?
Mr. CURT WELDON. No.
The CLERK. Mr. Weldon votes no.
Mr. Geren?
Mr. GEREN. Mr. Chairman, my wife inquired whether or not she'd have a chance to vote on this one. [Laughter.]
I vote aye.
The CLERK. Mr. Geren votes aye.
Mr. Rohrabacher?
Mr. ROHRABACHER. No.
The CLERK. Mr. Rohrabacher votes no.
Mr. Roemer?
Mr. ROEMER. Aye.
The CLERK. Mr. Roemer votes aye.
Mr. Schiff?
Mr. SCHIFF. No.
The CLERK. Mr. Schiff votes no.
Mr. Cramer?
[No response.]
The CLERK. Mr. Barton?
Mr. BARTON. No.
The CLERK. Mr. Barton votes no.
Mr. Barcia?
Mr. BARCIA. Yes.
The CLERK. Mr. Barcia votes yes.
Mr. Calvert?
Mr. CALVERT. No.
The CLERK. Mr. Calvert votes no.
Mr. McHale?
Mr. MCHALE. Aye.
The CLERK. Mr. McHale votes aye.
Mr. Baker?
Mr. BAKER. No.
The CLERK. Mr. Baker votes no.

Ms. Harman?
Ms. HARMAN. Aye.
The CLERK. Ms. Harman votes aye.
Mr. Bartlett?
Mr. BARTLETT. No.
The CLERK. Mr. Bartlett votes no.
Ms. Johnson?
Ms. JOHNSON. Aye.
The CLERK. Ms. Johnson votes aye.
Mr. Ehlers?
[No response.]
The CLERK. Mr. Minge?
Mr. MINGE. Aye.
The CLERK. Mr. Minge votes aye.
Mr. Wamp?
Mr. WAMP. Not.
The CLERK. Mr. Wamp votes no.
Mr. Olver?
Mr. OLVER. Yes.
The CLERK. Mr. Olver votes aye.
Mr. Weldon of Florida?
Mr. DAVE WELDON. No.
The CLERK. Mr. Weldon votes no.
Mr. Hastings?
Mr. HASTINGS. Yes.
The CLERK. Mr. Hastings votes aye.
Mr. Graham?
Mr. GRAHAM. No.
The CLERK. Mr. Graham votes aye.
Ms. Rivers?
Ms. RIVERS. Aye.
The CLERK. Ms. Rivers votes aye.
Mr. Salmon?
Mr. SALMON. The spirit is willing—I vote no.
The CLERK. Mr. Salmon votes no.
Ms. McCarthy?
Ms. MCCARTHY. Aye.
The CLERK. Ms. McCarthy votes aye.
Mr. Davis?
Mr. DAVIS. No.
The CLERK. Mr. Davis votes no.
Mr. Ward?
Mr. WARD. Aye.
The CLERK. Mr. Ward votes aye.
Mr. Stockman?
Mr. STOCKMAN. No.
The CLERK. Mr. Stockman votes no.
Ms. Lofgren?
Ms. LOFGREN. Yes.
The CLERK. Ms. Lofgren votes aye.
Mr. Gutknecht?
Mr. GUTKNECHT. No.
The CLERK. Mr. Gutknecht votes no.
Mr. Doggett?

Mr. DOGGETT. Aye.
The CLERK. Mr. Doggett votes aye.
Mrs. Seastrand?
Ms. SEASTRAND. No.
The CLERK. Mrs. Seastrand votes no.
Mr. Doyle?
Mr. DOYLE. Aye.
The CLERK. Mr. Doyle votes aye.
Mr. Tiahrt?
Mr. TIAHRT. No.
The CLERK. Mr. Tiahrt votes no.
Ms. Jackson Lee?
Ms. JACKSON LEE. Aye.
The CLERK. Ms. Jackson Lee votes aye.
Mr. Largent?
Mr. LARGENT. No.
The CLERK. Mr. Largent votes no.
Mr. Luther?
Mr. LUTHER. Aye.
The CLERK. Mr. Luther votes aye.
Mr. Hilleary?
Mr. HILLEARY. No.
The CLERK. Mr. Hilleary votes no.
Mrs. Cubin?
Mrs. CUBIN. No.
The CLERK. Mrs. Cubin votes no.
Mr. Foley?
Mr. FOLEY. No.
The CLERK. Mr. Foley votes no.
Mrs. Myrick?
Ms. MYRICK. No.
The CLERK. Mrs. Myrick votes no.
Mr. BROWN. Mr. Chairman, Mr. Hall wants to know how he is recorded.
Mr. HALL. Yes, I do.
The CLERK. Mr. Hall is not recorded.
Mr. HALL. I vote aye.
The CLERK. Mr. Hall votes aye.
The CHAIRMAN. The Clerk will report.
The CLERK. Mr. Chairman, I count 22 yeas, 25 nays.
The CHAIRMAN. The motion is not agreed to.
The Chair appreciates those Members who indicated by their vote that they are willing to have the Committee continue to meet and do its business.
It is disappointing that, despite the fact that the House will be in until at least 8:30 tonight, that other Members did not care to continue with Committee business; but I do thank those Members that want to proceed ahead.
We will move ahead now with Amendment No. 14.
Mr. BARTON. Mr. Chairman, I have an amendment at the desk.
The CHAIRMAN. Mr. Barton.
Mr. BARTON. Mr. Chairman, I would ask unanimous consent that the amendment be considered as read.

The CHAIRMAN. Has the amendment been distributed to the Members?

Mr. BARTON. Yes, sir—it's certainly been at the desk and been available to all Members with the notification that we had to have it in by I think noon yesterday.

The CHAIRMAN. It is in the packet, so the gentleman may proceed.

Mr. BARTON. I thank the Chairman.

I think that this is one of the, at least it is the most important amendment that I will offer to the pending bill.

We want the Clerk to utilize the new amendment. I didn't realize there were differences. I only thought I had one, but apparently there are——

Ms. LOFGREN. Do we have——

The CHAIRMAN. The gentleman has provided assurance to the Members that that was the one in their pack.

Mr. BARTON. Yes, sir.

The CHAIRMAN. Is that not the case?

If so, the amendment must be distributed before we can proceed.

Mr. BARTON. It was my understanding it was the amendment that was in the packet. I am not—but my staff seems to think maybe it is not.

The CLERK. It is not. I don't have it.

Mr. BARTON. Mr. Chairman, the so-called "new amendment" has been narrowed in scope as to who has jurisdiction to petition. The original amendment said any person could petition.

The new amendment indicates that they have to have a direct financial interest in order to petition.

I believe that is the substantive change.

So the so-called "new amendment" is actually a more narrowly drawn amendment.

That is the difference. The one in the packet is a broader amendment, apparently. I am offering the more narrowly—and I can't say that—narrow amendment.

Let me explain the amendment and then if we need to read it, I'll be happy to have the change read, because it——

Mr. MINGE. Mr. Chairman, could we defer this until we have the amendment?

The CHAIRMAN. Can the gentleman tell us whether or not the amendment has been distributed to the Members in the form in which he wishes to offer it?

If not, it is not fair to all the Members.

Mr. BARTON. In all honesty—I understand, and I didn't know that it had not been——

Mr. BERINGER. It is being distributed now, Mr. Chairman.

Mr. BARTON. I would defer until it has been distributed.

I can explain it as it is being distributed, if that is the will of the Chairman.

The CHAIRMAN. Let's get it down to the Members, first.

[The amendment is distributed.]

The CHAIRMAN. This amendment would not be in order at this point.

The gentleman has now redrafted his bill as a new subtitle at the end of the bill. We are only considering those items in Subtitle

A, so I would ask the gentleman to withdraw his amendment at this point because it would not be in order to be considered at this juncture.

Mr. BARTON. I would ask unanimous consent to do that.

The CHAIRMAN. I thank the gentleman.

As I understand it, Amendment No. 15 by Mr. Roemer has been withdrawn, or is going to be withdrawn?

Mr. ROEMER. No, Mr. Chairman.

The CHAIRMAN. The gentleman wishes to offer that amendment?

Mr. ROEMER. The amendment on research and training and risk assessment? Is that the one you were referring to?

The CHAIRMAN. No, it is No. 15 on your sheet, the Guideline Plan for Assessing New Information.

Mr. ROEMER. No. 15 has been withdrawn; that's correct, Mr. Chairman.

The CHAIRMAN. It has been.

And the gentleman now wishes to offer a new Section 3107 on Research and Training and Risk Assessment?

Mr. ROEMER. That's correct.

The CHAIRMAN. The gentleman is recognized.

Mr. ROEMER. Thank you, Mr. Chairman.

Mr. Chairman, my amendment is a very simple and straightforward one.

As a strong proponent——

The CHAIRMAN. Is the amendment in the package? Let me ask the gentleman.

Mr. Roemer. Yes, it is.

The CHAIRMAN. I thank the gentleman.

Mr. ROEMER. As a strong supporter and proponent of this legislation on risk assessment, I come at this particular amendment, Mr. Chairman—and having heard the witnesses and attended the hearings on risk assessment, one thing that has been very, very much in agreement has been that we have needed to make sure that we reduce the uncertainty in estimating the risk.

In addition, the need for more people trained in the art of risk assessment was clearly identified. Yet the bill before us has no research and training requirements.

As you recall, the Office of Technology Assessment and the National Academy of Sciences both testified that this was indeed an important part for us to consider and for the bill to include.

This amendment simply establishes research and training activity in each Federal agency that is asked to conduct a risk assessment under this Act.

The CHAIRMAN. If the gentleman would withhold, we understand that there is new language that is now being submitted to the Members, the same thing I had a problem with Mr. Barton on.

These amendments are being drafted, and this is not the language that was in the package.

So if the gentleman would withhold for a moment until we have an opportunity to look at the language, the Chair would be appreciative.

Mr. ROEMER. I would be happy to stop and wait.

Mr. Chairman, all this does, this section is almost identical to a similar, very noncontroversial section that was contained in H.R.

4306, the risk assessment bill that was moved by this same Committee in the last Congress.

If we are going to increase our reliance on risk assessment as a keystone in the regulatory decisionmaking process, then it seems only reasonable that we support needed development in this field.

This amendment supports efficiency, better knowledge and true science in terms of developing better research and training in risk assessment.

Just as our businesses are so good at providing training in terms of total quality management, all this amendment says is our Federal agency should get up to speed as quickly as possible and provide the needed skills and requisite requirements for these people to perform these tasks, their tasks in the different agencies that will be performing this much-needed goal in terms of the legislation.

I would urge the Chairman to support the legislation.

The CHAIRMAN. Would the gentleman yield to the Chairman for a moment?

Mr. ROEMER. I would be happy to yield.

The CHAIRMAN. Did I understand the gentleman to say that the language he proposes is exactly the same as the language that was in H.R. 4306 that passed out of the Committee last year?

Mr. ROEMER. That's correct.

The CHAIRMAN. I thank the gentleman.

That being the case, the Chair is prepared to accept this amendment. I think it does add to the bill, and I am prepared to be supportive of the amendment.

Mr. ROEMER. I thank the Chairman.

Mr. ROHRABACHER. Mr. Chairman, is there a budgetary effect of this amendment? What do we expect this is going to cost?

The CHAIRMAN. Does the gentleman from Indiana have an answer to the gentleman from California?

Mr. ROEMER. We do not see any type of budgetary effect from this amendment. As the gentleman knows, they already have these kinds of training and evaluation teams at the Federal agencies.

They would just be taking on a different skill to train their employees, and we see that this will have negligible, if not neutral, budgetary effect.

Mr. ROHRABACKER. So the purpose of this amendment is not to——

Mr. ROEMER. It is not to set up a new office.

It is not to set up new personnel or new bureaucrats.

In fact, the purpose of the legislation, as the gentleman from California knows, is intended to draw down on precisely those things.

Mr. ROHRABACHER. I just wanted to make sure that was in the record, and thank you very much, Mr. Chairman.

The CHAIRMAN. I thank the gentleman from California.

Is there any further discussion on the amendment by the gentleman from Indiana?

[No response.]

The CHAIRMAN. If not, the Chair will put the question. Those in favor of the amendment will say, aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed, will say no.

[Chorus of nays.]

The CHAIRMAN. The ayes have it. The amendment is adopted.

Mr. ROEMER. I thank the Chairman.

The CHAIRMAN. Amendment No. 17 on the roster would be next.

[Pause.]

Has that one been withdrawn? Okay. It has been withdrawn.

We go now to Amendment No. 18 on the roster.

[Pause.]

The Chair would appreciate knowing who was going to offer Amendment No. 18, if indeed it is going to be offered.

Mr. ROEMER. Mr. Chairman, I am going to offer that amendment.

The CHAIRMAN. Mr. Roemer is offering the amendment.

Is the amendment available to be distributed?

Mr. ROEMER. It is available, and I would ask for its immediate distribution.

It is in the packet.

[The amendment is distributed.]

Mr. ROEMER. Mr. Chairman, it is listed as No. 18 in the packet.

The CHAIRMAN. The amendment that is being distributed on behalf of the gentleman is different from the amendment that is in the packet.

Now which one are we to——

Mr. ROEMER. All we have done is conform it to your substitute.

The CHAIRMAN. That's fine. All right. Then the gentleman is recognized.

Mr. ROEMER. Mr. Chairman, just as the last amendment in terms of training the personnel to perform risk assessment was noncontroversial, this amendment is also noncontroversial.

It was endorsed in testimony by the Western Center for Comparative Risk Analysis and by the Northeastern Center for Comparative Risk Analysis.

One of the clear messages from the hearings this year, and even last year, is that comparative risk analysis is a tool that is still developing and, while that can be used today, more should not be expected of it than it can provide.

In addition, efforts to improve the tool are needed.

What this amendment does is calls upon the Director of OSTP to create a study of comparative risk assessment with the goal of providing recommendations regarding the use of comparative risk analysis and ways to improve the use of comparative risk analysis for decision making.

This section is almost identical to a similar section, a very noncontroversial section that was contained again in H.R. 4306 last year, the risk assessment bill moved by this Committee.

If we are going to increase our reliance on comparative risk analysis to enhance the efficiency and cost effectiveness of the regulatory decisionmaking process, then it only seems reasonable that we invest in advancing the development of the tool.

If we are going to invest in the people, we need to also invest in the analysis and the tool, and I would encourage the Chairman to support this amendment, as well.

Mr. BROWN. Regular order.

The CHAIRMAN. Any other discussion on the gentleman's amendment?

[No response.]

The CHAIRMAN. The Chair has examined the amendment. The gentleman has proposed an amendment that the Chair sees no problem with and is prepared to accept it.

Mr. ROEMER. I thank the Chair.

The CHAIRMAN. With that, the Chair will put the question.

All those in favor of the amendment will say, aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say, no.

[No response.]

The CHAIRMAN. The ayes have it. The amendment is agreed to.

We have now completed everything that was in the original roster with regard to Subtitle A.

Mr. LUTHER. Mr. Chairman?

The CHAIRMAN. I am now prepared to accept additional amendments—excuse me.

The gentleman, Mr. Luther, had wanted to raise a couple of questions with regard to Section 3106. Let me recognize him to do that before we go to additional amendments that were not reflected on the roster.

The gentleman is recognized.

Mr. LUTHER. Thank you very much, Mr. Chairman.

The questions that I have with respect to Section A would be on page 13.

It would be beginning with Line 10, "(b) PLAN." As I understand it—and I would address the question to either the Chairman or to staff so that I could get a little better handle on what is being proposed here, but as I understand this section, this is the section that would require the agencies to go back and look at what has happened in the past.

The period covered presumably would be 18 months. The point in time would be 18 months after the effective date of this, and then beginning at that point in the future then everything that has been promulgated in the past would presumably be covered by this section, as I understand it, if I am reading it correctly.

My question—I guess my first question here is: How many documents would be involved in this kind of an assessment? Because as you know, my concern here is that we not get all kinds of bureaucracy involved in spending a lot of taxpayers' money on things that do not need to be reviewed.

So I guess my first question would be: What are we talking about here? What is the scope of this? What would have to be reviewed if we would enact this in the form that it is in?

The CHAIRMAN. The Chair recognizes counsel to respond to the gentleman.

Mr. BERINGER. Thank you.

The primary emphasis, Mr. Luther, is that within the 18-month period between the time of enactment and the time of the effective date of the Act, why there may be a number of risk assessments that are done that have not been done under the guidelines which would be promulgated under this particular Act.

The primary emphasis is on those risk assessments that are done in the interim period.

However, on past risk assessments, those that would be significantly altered by the guidelines would also be reviewable, espe-

cially on the basis of new information that came in that would change or significantly alter the previous risk assessment.

To answer your last question: There is no quantification that we have to know how many this would entail.

Mr. LUTHER. Then, Mr. Chairman, if I understand your response, the intention here is to only cover the 18 months beginning on the date of passage of the Act, rather than to go back prior to today, for example?

The way I read it, the plain language would seem to indicate that you would go back prior to today, and perhaps some clarification in the language would be needed.

I am looking at the language now on lines 14 and 15 of page 13. That says every "document published prior to the expiration of" the "18-month period".

Now that would seem to go back prior to today, for example.

Mr. BERINGER. No, I actually believe that is the intent to go back to prior risk assessments.

As I say, the main emphasis is on the ones that are here within the interim period.

Mr. LUTHER. Well, Mr. Chairman, perhaps I could understand your intent here, as well. Because I would think we would be talking about literally thousands and thousands of documents.

What concerned me in particular is, if this plan of review would only include final decisions, then I can see it being perhaps somewhat more of a finite number of items that would have to be in the plan of review.

But if literally every agency would be required to put together a plan of review that would cover every document that would fit in this category, I am wondering if that is really what is being proposed here.

And, if not, if we could just clarify this to try to focus on some kind of a process that would be more workable?

The CHAIRMAN. Well, I think the gentleman needs to look further down. If you look further down, it says "The final plan shall set priorities for review, and where appropriate, revision of risk assessment documents and risk characterization documents based on the potential to more efficiently focus national economic resources within Federal programs designed to protect", and so on.

In other words, the "where appropriate" certainly gives latitude on this.

I would also say to the gentleman, all that is being required here is an update of the science, where appropriate.

We are attempting to update the science that is involved in all of this.

I don't think we are creating a massive invasion here, because the final plan simply sets priorities, where appropriate.

Mr. LUTHER. Well, Mr. Chairman, I think that clarification is helpful.

What you are then saying is that when you refer to "plan to review" on line 12, you are not suggesting that each agency would go back and be required to conduct, or even plan to conduct a review of every documents that would fit in this category since the inception of the agency? Because that is what one could easily read into this.

The CHAIRMAN. Only if it "significantly alters the result of the prior risk assessment". If it is likely to do that.

That is the only—that is the standard.

Mr. LUTHER. Mr. Chairman, how would an agency make that determination? How would they determine if something would be "significantly altered"?

The CHAIRMAN. We are asking the agency for a plan to specifically do that; and that the final plan should set priorities for the review.

Mr. LUTHER. Well, Mr. Chairman, if I understand it, you're not suggesting that an agency would have to look at every document that fits in this category that they've produced?

The CHAIRMAN. They would be the judgment of whether or not it is likely to significantly alter the results. So, the answer to the gentleman's question is: No, it would not require review, but it would require them to come forward with a plan that fits with the criteria as specified here, and the criteria are on significantly altering the results.

Mr. LUTHER. And, Mr. Chairman, if I can follow up on that, you are suggesting that the way they would do that is by looking at current science and where in their judgment, the agency's judgment, they felt that current science would significantly alter the result of some prior document, that then their review would be limited to those documents?

The CHAIRMAN. Well, it also relates back to the principles set forth in Sections 3104 and 3105.

So I mean they would have to reference the principles in those sections.

Mr. LUTHER. Yes.

But it would be that approach that agencies would use?

The CHAIRMAN. That is my understanding.

Mr. LUTHER. Okay. That's helpful.

The CHAIRMAN. I thank the gentleman.

We have now completed the work in Subtitle A with regard to the amendments that were prepared in advance in the roster, the process by which, I would say to the Committee, that the gentleman from Pennsylvania most often followed when he was in a similar position, was preparing the amendments in advance so that it was there; but I do understand we now have a number of other amendments and I would recognize the people who want to offer those.

Mr. TANNER. Mr. Chairman?

The CHAIRMAN. The gentleman from Tennessee.

Mr. TANNER. Thank you, Mr. Chairman.

I want to make a parliamentary inquiry before I offer this amendment on Subtitle A.

I have an amendment that is listed that would come at the end of the evening's proceedings that would encompass, I think, the amendment that I feel compelled to offer now that would be a national security waiver for the Department of Defense.

Just by way of parliamentary inquiry, if we could adopt out of order the waiver at the end, I don't know that we need this one that I would otherwise attempt to offer now.

But if you want to go ahead and do this——

The CHAIRMAN. Well, I think we out to go ahead.

I mean, I don't want to skip down to the end of the bill.

We have a series of other people that would like to do the same thing. So I think we ought to go ahead with what the gentleman has prepared.

Mr. TANNER. All right, sir. Thank you, Mr. Chairman.

Mr. Chairman, has our amendment been circulated?

[The amendment is distributed.]

Mr. TANNER. It is listed as No. 6 in some package of paper I have. When we can't see over the paper, maybe we can adjourn.

The CHAIRMAN. The gentleman is recognized.

Mr. TANNER. Thank you, Mr. Chairman.

Mr. Chairman, at the end of Title III, Subtitle A, Section 3103, I would propose that we add the language that has been circulated here with regard to the Defense Department.

After a thorough reading of the bill, this will just wreck absolute havoc with the ongoing BRAC process, with procurement reform, the prior amendment last year; there is even some question of what it would do with National Guard Summer Camp across the country; military aircraft; even routine training flights might be subject to this; not to mention what happens wit the peer review.

So this amendment that I offer would just say that when the Secretary of Defense or a Secretary of the Army, Navy, Air Force, determines that it is not consistent with national security interests or missions to comply, they will notify us of that determination and the reasons for same.

I would urge its adoption.

Mr. DOGGETT. Mr. Chairman, will the gentleman yield?

Mr. TANNER. Yes.

Mr. DOGGETT. Naturally I am concerned that the Chair would offer an amendment that could wreck absolute havoc with all of those programs, to use your words, and I am wondering if the proposal will wreck absolute havoc with any other parts of the government like the Bureau of Prisons.

We were asked earlier about the Center for Disease Control.

Should any of these other programs also be included in this what appears to be a very necessary exemption?

Mr. TANNER. Well, I don't know how you voted on some of these other matters, but insofar as this amendment is concerned——

Mr. DOGGETT. I don't suppose that makes any difference. If this one has merit, I would want to vote for it, and I would want to exclude from absolute havoc any of the other vital agencies important to our national security such as certainly securing our neighborhoods from criminals at the Bureau of Prisons and things like the Center for Disease Control, and I am just wondering if the gentleman has considered the kind of havoc—as concerned as I am about not disrupting our important function of the National Guard—there may be other things that are equally important to our safety and that we would not want to wreck havoc, to use your words, there either.

Mr. TANNER. Well, Mr. Doggett, may I simply say, my amendment deals with the Department of Defense. We can take up your concerns on the other matters in a different amendment.

Mr. DOGGETT. I thank the gentleman.

The CHAIRMAN. Is there discussion on the amendment?

Ms. HARMAN. Mr. Chairman?

The CHAIRMAN. The gentlelady from California.

Ms. HARMAN. I would like to speak for the amendment, as a Member of the Committee on National Security, which was the reason I missed the vote earlier today. I feel very strongly that we do not want to interfere, especially now, with the work of the Department of Defense.

I think this is a valid amendment. I know that another one will be offered later in the process, and I intend or hope to add NASA to that.

I think we need to be very careful with the technical implications of this bill. The thrust is right. Risk assessment is a good idea. But there are some—or I believe there will be some unintended or maybe intended consequences here which we must guard against, and I strongly support the amendment.

The CHAIRMAN. Mr. Ehlers.

Mr. EHLERS. Thank you, Mr. Chairman.

Let me register a little concern about this in view of the history of the Department of Defense with regard to environmental compliance. This dates back many years back when I lived in California.

I recall very serious pollution problems in the Bay Area created by a very careless use of fuel and so forth. And in every case the claim was this was a concern of national security, and we had to have these—they simply could not put the money into containing a fuel, the fuel depots and things of that sort.

We all are aware of that. We've spent billions of dollars trying to clean up some of these sites, and we are still far behind where the private sector is in many cases.

I am a little concerned about giving carte blanche to any department without some sort of oversight. Without this, this just basically says they can do it, and all they have to do is let us know.

I would like to see some independent review of it if we are going to do something like this.

Thank you.

The CHAIRMAN. I thank the gentleman.

Mr. TANNER. May I respond, Mr. Chairman?

The Department of Defense already has probably as stringent or possibly more so stringent requirements on them on their environmental cleanup.

Just when I have been looking at this matter, this bill is supplemental to and in addition to all of the environmental cleanups that are ongoing now at the Department of Defense.

I am told that the peer review requirements just for the environmental cleanup in the DOD would amount to a delay of at least six months and cost anywhere from $35– to $70 million a year at a time when we are cutting defense; at a time when we need every dollar we can have for readiness; and at a time when the Department of Defense's environmental regulations that you refer to are as strong as they are anywhere in the government. That seems to me to add another layer of bureaucracy and risk assessment supplemental to and in addition to what the Department of Defense already has on it and is questionable.

Mr. TANNER. Mr. Chairman, would the gentleman yield?

The CHAIRMAN. Well, the gentleman from Michigan had the time. The gentleman from Tennessee was explaining—

Mr. EHLERS. Thank you, Mr. Chairman.

I just would like to respond. I guess you could use the same argument for putting these regulations on business, or any other sector and say, well, you can argue why should we put a $75 million or a $100 million expense on a business.

The point is, once you start making assumptions for any reason, then you have really created a situation where it is hard to defend applying it to the others who still are subject to the regulations.

I am not necessarily opposed to this, but I am certainly raising a question about it, whether or not this is necessary; and, if it is necessary for them, then why isn't it necessary for a great many others?

The CHAIRMAN. I thank the gentleman.

Mr. Weldon.

Mr. CURT WELDON. Thank you, Mr. Chairman.

I understand the concerns of my good friend, Mr. Tanner, and my understanding is that the legislation currently provides for an emergency process. Because I share the concerns relative to the military. I would not want to see us get in a position where you have to do a risk assessment every time you want to do a fly-over or a military exercise.

My understanding, Mr. Chairman, is that you have taken care of that. Is that correct?

The CHAIRMAN. The gentleman is correct that there are emergency procedures that would certainly deal with national security interests in the bill as drafted.

The Chair's concern is that the amendment goes much further than that and suggests missions. One of the missions of the military is the Corps of Engineers. The Corps of Engineers does the work that has dramatic impact on the public, and certainly should be subjected to the kind of processes that are within this particular bill.

To exempt the Corps of Engineers I think would create a major environmental loophole in the bill and would certainly be the case under the gentleman's amendment.

So the Chair has a very strong concern that that exemption goes much too far. Some of the national defense facilities that are in the process of being cleaned up may have an impact on the public at large around those. They should certainly be subjected to some of this review, as well, particularly those that we intend to do in the future.

So the Chair is concerned that this amendment does have some implications beyond simply the national security mission.

Mr. TANNER. Will the gentleman yield?

Mr. CURT WELDON. Sure.

Mr. TANNER. Mr. Chairman, if you read the language, we limit this to "consistent with national security interests and missions."

Now I hardly think the Corps of Engineers is engaged in matters that affect national security interests. I respect the gentleman's opinion, but that is not at all the intent of the legislation offered.

The CHAIRMAN. But certainly the Corps of Engineers, which is one of the largest parts of the United States Army, is a "mission,"

and it is something that would obviously be covered under this amendment.

I would simply say to the gentleman that that is a major loophole that we would be opening with this amendment.

Mr. BROWN. Mr. Chairman?

The CHAIRMAN. The gentleman from California.

Mr. BROWN. Mr. Chairman, I am going to support the amendment here, although I recognize the validity of the points that are made. I particularly applaud Mr. Ehler's principles in not wanting to exempt a major activity of this sort.

But I would like to point out that probably if you calculate all of the money being spent on environmental remediation anywhere in the United States, the Department of Defense is probably spending most of it—more than half of it—and it amounts to quite a few billions of dollars.

I will say that, since it is a department of the government, it is doing so under the direct direction of the President and his staff, and they are doing it in accordance with very high standards which have been promulgated by the Defense Department over the years.

I have had to deal with some of the military departments in connection with cleanup activities, and I will say that they have generally been above and beyond the call of duty. They have accepted their responsibilities and are carrying it out with great diligence.

Now it was my original bias in connection with this that the efforts being made by the author of this bill are spreading too wide a net. The bill here being considered is being compared to last year's bill, and I think we all know that last years' bill was focused very narrowly at the activities of the EPA in terms of environmental cleanup.

This seeks to go to every department of the government to encompass activities never before considered in connection with this.

And while I applaud the effort to develop standards for risk assessment that are applicable on a broader basis, I think that in including national defense agencies, national security agencies, that we are biting off far more than we are likely to be able to chew in connection with this bill.

I know that there is no Member here who would like to feel that this legislation in any way, shape, or form hampered the military in carrying out their security mission or required resources, as Mr. Tanner has pointed out, that are badly needed to meet the readiness needs of the services.

So for these various reasons, I am going to urge that this amendment be supported and I hope that it will be supported.

Mr. DOGGETT. Would you be willing to yield on that, Mr. Brown, for a question?

Mr. BROWN. Yes.

Mr. DOGGETT. Because I am sure that Mr. Tanner's objective in covering the amendment, now that I have read it, it would include the Defense Intelligence Agency, which I would think we would certainly want to exempt, but I do not believe the amendment includes the Central Intelligence Agency.

What impact might the kind of wholesale change in the law here have on our national security interest as it relates to the Central Intelligence Agency?

Mr. BROWN. The gentleman raises a good question, and I don't know whether the author intended to include that agency or not.

Mr. TANNER. None other than I think the focal point of the discussion here is that this bill as drafted is supplemental to and in addition to other laws relating to risk assessment particularly with regard to the Corps of Engineers who have—we certainly want to bring them in, but in order—and I did not mean to give them some sort of blanket exemption.

What we are talking about is national security interests and the fact that this is supplemental and in addition to all of the other rules and regulations that the Department of Defense undertakes.

This amendment relates to the Secretary of Defense and the Secretaries of the Services only. So in that regard, I doubt that the Central Intelligence Agency is included at all.

Mr. HASTINGS. Mr. Chairman.

The CHAIRMAN. Mr. Hastings.

Mr. HASTINGS. May I ask the author of the amendment if there is some way that language can be added that would demonstrate what would happen upon notification by a military department?

My point that I raise to my good friend from Tennessee is that it does not say that anything will happen. Let me give you a "for example."

The Secretary of the Army determines the day before an event that may very well require compliance with the base bill, makes a determination and notifies Congress that day. Well, what is Congress to do?

Fine?

Thank you very much for the notification?

Goodbye?

Assume for the moment that some harm does occur. There is no way that we are dealing with that. Or, is there oversight somewhere else in the government that would cover it? And if that is satisfactory, then I have no hesitancy in supporting it.

Do you understand what I am saying?

Mr. TANNER. The gentleman makes a good point. I don't know how you can craft language to that effect. I mean, if you have a surprise raid on Khadafi again, I don't know how you do a risk assessment on something of that nature. Maybe you can; I don't know how you do a peer review on some of the weapons that we are developing here.

I mean, are we going to ask the Russians if they think these are a good idea?

What I am saying is, there are rules and regulations. As our Ranking Member, Mr. Brown, said, this is a very, very broad bill. It is supplemental and in addition to all other laws.

I just think the Committee ought to realize and know what we are doing, particularly as it affects some of the activities that are carried on on the part of Defense to which this just does not make common sense.

Mr. HASTINGS. Reclaiming my time, the gentleman makes the point that I wish to make. Not only is it broad, it is over-reaching and it is vague. And that is going to cause additional problems—not just our amendment, but the base bill.

Your amendment is definitely vague on its face. In that sense, I don't think it accomplishes all that we should as sound legislators.

However, I would be very hesitant to not support something that was going to give added favor to national security interests and missions, but your amendment is flawed.

The CHAIRMAN. I thank the gentleman.

The debate on the Minority side has eaten into the time to get over to vote, so we don't want to continue any further.

The Committee will stand in recess.

[Recess.]

The CHAIRMAN. The Committee will come to order.

Mr. TANNER. Mr. Chairman?

The CHAIRMAN. The Committee will come to order.

The gentleman from Tennessee.

Mr. TANNER. Thank you, Mr. Chairman.

I think I want to withdraw this amendment, but before I do, Mr. Chairman, I am going to have another one at the end of the proceedings here this evening dealing only with military readiness that I hope everybody can support.

But I want to ask the counsel, if I may, what is the effect on nonemergency situations arising in the Department of Defense with respect to some of the matters they have to undertake in terms of training and readiness?

The CHAIRMAN. Counsel?

Mr. BERINGER. Yes, Mr. Tanner, first of all the bill is limited to health, safety, and environmental concerns. So first of all, that would be the first parameter.

But second of all, yes, they do do risk assessments. For instance, in their environmental cleanup efforts, decontamination, Mr. Williamson advises me that they do this for ocean dumping and things of that nature.

I think some of the things that were mentioned earlier such as military readiness would come under the emergency exemption. But by and large, they are already required to do, by their own regulations, a great deal of risk assessment and characterization, and this would be fairly much in line with what they already do.

So I don't think it would add that much of an administrative burden to them.

Ms. LOFGREN. Mr. Tanner?

Mr. TANNER. Well may I say, I think you make the point that this common sense would dictate that there ought to be some waiver on what is happening with military readiness. I just hope that when we get to the end of the evening we could reach an agreement on that.

The CHAIRMAN. If the gentleman would yield to the Chairman, it seems to me that the gentleman has raised a valuable and interesting point. The only interpretation that would make this at all a matter of concern is if you get a broad interpretation of the words "safety" that would include "national security" matters.

The way, it seems to me, of dealing with this matter is to simply say that the term "safety" would not relate to national security and military readiness types of matters.

That would assure, then, that the environmental issues that I raised with regard to the Corps of Engineers and so on could continue to be covered, which I—you know, when——

Mr. TANNER. I have no problem with that. That was not the intent.

The CHAIRMAN. I understand that. So what I am suggesting to the gentleman is that we can either deal with it in report language in a way that assures that it is clear that the word ''safety'' does not include military readiness or national security matters; or, if the gentleman feels that you want to do an amendment in that nature, it seems to me that that is one way of allowing us to assure that that does not.

But I looked at the gentleman's amendment in the nature of a substitute coming at the end of the bill and that still does not get us to the question, because the Secretary could still under that waiver perhaps exempt Corps of Engineers' activity. I do not thank that is the gentleman's intent, but it is my concern that the language is broad enough that it could do that.

I would be willing to accept an amendment that says that ''safety'' as defined in the bill does not include matters relating to national security or military readiness.

We would clarify that in report language. At the end of the bill, if the gentleman wants to offer such an amendment, I would be prepared to accept an amendment that assures that safety is not interpreted in that way.

Mr. TANNER. We will work on it during the evening.

The CHAIRMAN. I thank the gentleman.

Mr. CURT WELDON. Mr. Chairman.

Ms. LOFGREN. Mr. Chairman.

The CHAIRMAN. The gentleman from Pennsylvania.

Mr. CURT WELDON. I thank the Chairman.

I want to applaud our colleague from Tennessee who takes a back seat to no one in support of our military. I agree with the tone of the conversation that just occurred.

Let me say that I think in the end this legislation may help us, John, face what has become the largest single increasing cost in the defense budget, which is basically environmental cleanup.

For those of you who serve, as we do, on the National Security Committee, we know that we are spending $13 billion this year on cleaning up sites which on one day are okay for our military families to live on and kids to play at, and the next day when they are closed they all of a sudden become major environmental sites that we have to spend billions of dollars on.

Perhaps this risk assessment process, John, will in the end help us control some of those costs and have a positive impact on defense spending.

Mrs. MORELLA. Mr. Chairman.

Ms. LOFGREN. Mr. Chairman.

The CHAIRMAN. The gentlewoman from California—

Mrs. HARMAN. I just have a question in connection with what you have just suggested, which I strongly support. Maybe this would save us time.

As you know, later I will be offering an amendment about NASA which also engages in safety and related exercises, and which I think might be unfortunately swept up in overbroad coverage here.

I just wonder if you are considering some language to exempt functions that were not intended to be covered, whether NASA and its safety and mission success functions might be considered as well?

The CHAIRMAN. Well——

Ms. LOFGREN. Mr. Chairman.

The CHAIRMAN [continuing]. I have not fully considered that issue, but insofar as it related to national security certainly that would be covered under the language that I have suggested that we draft up in that regard.

The gentlelady from California.

Ms. LOFGREN. Mr. Chairman, along those same lines I wonder if there is language that is going to be put in the report, or added into the bill later, whether we should not also include law enforcement?

I think the issue about the FBI, the Bureau of Alcohol, Tobacco, and Firearms, potentially even the FBI, I mean those are important law enforcement functions that I don't think are really the object of the authors of this bill, but could be swept up into it and ought to be addressed.

The CHAIRMAN. Well, once again I think we may want to look at whether or not appropriate report language is a way of defining some of those kinds of things, but I don't think that we want to complete exempt Department of Justice activities and some of those kinds of things that may be involved.

So I think we need to be a little careful here just how far we extend that issue. But we will certainly consider matters as they are appropriate to be brought before the Committee.

Did Mr. Tanner withdraw his amendment? Is that my understanding?

By unanimous consent the amendment is withdrawn.

Any other amendments to Section A, Subtitle A?

Mr. BARTLETT. Mr. Chairman, I have an amendment at the table.

The CHAIRMAN. Mr. Bartlett.

The amendment of the gentleman needs to be distributed.

[The amendment is distributed.]

The CHAIRMAN. Okay. The amendment is being distributed. The gentleman will explain his amendment.

Mr. BARTLETT. Thank you very much.

Mr. Chairman, this is a very simple perfecting amendment. If you will turn to page 14 of the amendment in the nature of a substitute where we have definitions, there are two definitions there.

One of them is "risk assessment document" and the second one, found on page 15, is the "risk characterization document."

The definition of the risk assessment document has alternative definitions. The first one I think was the general intent of what the risk assessment document should be:

The term "risk assessment document" means a document containing the explanation of how hazards associated with a sub-

stance, activity, or condition have been identified, quantified, and assessed".

If you now look at the rest of the language there starting with line 1 and going through line 3, you will see that this is the alternative definition, "or describing the degree of toxicity" and so forth.

You will see that that is identical with the language that describes the risk characterization document. I would think that it would be clarifying if we simply, as my amendment indicates, strike from "assessed" on and just left the definition of the "risk assessment document" with the first of those two alternative definitions.

It is difficult to have two documents which are supposed to be different and have them defined with precisely the same language.

The CHAIRMAN. The gentleman I think has made a contribution to the Committee. I am told that there was mistaken language included here. The gentleman has discovered that and provides the correction that I think is a very valuable addition, and the Chair is prepared to accept the amendment.

Is there further discussion on the amendment?

[No response.]

The CHAIRMAN. If not, all those in favor of the amendment will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say no.

[No response.]

The CHAIRMAN. The ayes have it. The amendment is adopted.

Any other amendments to Subtitle A?

Mr. OLVER. Mr. Chairman.

The CHAIRMAN. Mr. Oliver.

Mr. OLVER. Thank you, Mr. Chairman.

I think I have discovered something very important. I too have a very simple perfecting amendment. It is in Section 3107 under the definition of "best estimate" that I think needs to be distributed.

The CHAIRMAN. Has the amendment of the gentleman been distributed?

Mr. OLVER. I have two that are being distributed, I believe.

The CHAIRMAN. Is this an amendment on page 10, or page 15?

Mr. OLVER. Page 15.

The CHAIRMAN. Page 15.

Mr. OLVER. In Section 3107 under the definition section under "best estimate."

[The amendment is distributed.]

Mr. OLVER. I would ask unanimous consent to add two words to this. In line 5 of the amendment after the word "discussion" to add the words "and analysis of uncertainties, limitations, and assumptions affecting the risk estimate".

The CHAIRMAN. Without objection.

Mr. OLVER. Thank you, Mr. Chairman.

This amendment has to do with the definition of the "best estimate" here. The problem that I see in the definition is that the bill calls for basically best estimates and puts emphasis on "central estimates", "central estimates" being estimates which place the emphasis on the center of a distribution; whereas, in proper risk anal-

ysis we have in almost any population, we have people or segments of that population which are at particular risk.

The CHAIRMAN. If the gentleman would suspend, it seems to me what we ought to do is allow the gentleman to make his explanation at a time when Members are not kind of trying to move out of the room to go vote.

Why don't we go vote and we'll come back and I will immediately recognize the gentleman for an explanation of his amendment.

Mr. OLVER. Thank you.

The CHAIRMAN. The Committee stands in recess for voting.

[Recess.]

The CHAIRMAN. The Committee will come to order.

When the Committee recessed we were in the process of considering an amendment from the gentleman from Massachusetts, Mr. Olver, numbered 13 on "best estimate." The gentleman was in the process of explaining his amendment when I suspended the hearing.

I want to go back to the gentleman to allow him to explain his amendment and move forward from there.

The gentleman is recognized.

Mr. OLVER. Thank you, Mr. Chairman, for your recognition.

I was a young man when I started explaining this amendment. [Laughter.]

This amendment is short. To me it represents a single and comprehensive and encompassing statement of what a best estimate for risk analysis ought to be.

To the degree that it is possible these days in science, it is probably something that could be an encompassing amendment and statement of what best estimate ought to be some years from now as well as just now, and as such it seems to me to get away from a couple of serious problems with the language that is in legislation in the Substitute that is the markup document.

Namely the two items that are the problem here is this language of mine avoids the use of a point estimate, a single point estimate. That is to say, a central estimate. Which is, whether it is upper bound central or lower bound, that kind of a point estimate is inconsistent with the recommendations of the National Research Council and the Risk Assessment and Risk Management Commission who attest that those kinds of point estimates are just not very reliable or very defensible.

Secondly, that the amendment in its same point, really avoids the central estimate of risk where a central estimate of risk ends up being a single estimate in the body of all possible persons, say, who might be involved in a hazardous situation, whereas it does not then properly reflect what is the experience for persons who may be at special risk; the individuals who are not average in some ways due to differences in genetics, susceptibility, or whatever, or susceptibility to disease, really are not likely to be covered by that central average estimate over the whole population, but allows then for an avoidance for the use of that central estimate and allows one to put emphasis on those who are really at risk and endangered under whatever is the problem, environmentally, or public safety, or public health.

So I think it avoids several considerable problems with the language and is a better living definition, and one that one could expect to stand some test of time at least.

The CHAIRMAN. I appreciate the gentleman's explanation. The Chair would simply say that the concept of central estimates is a definition which is a hallmark of this bill. We don't limit ourself to any issue of best estimates to only central estimates, but it is something which we think needs to be an option.

Central estimates in this case means the most likely probability based upon the science. We think that that is one measurement that ought to be available to the agencies.

But if you will look at the language in the substitute, we also give two other options. One is an approach which combined multiple estimates based upon different scenarios and weighted the probability of each scenario.

And we also give another option, which is any other methodology designed to provide the most unbiased representation and the most plausible level of risk given the current scientific information available to the Federal agency concerned.

So there are options available under this, but the idea that you can use at some point an estimate that comes to the most likely probability is fundamental to what we are trying to achieve in the bill. So, therefore, I would say that the gentleman's amendment goes to the heart of what we are attempting to accomplish here and is unacceptable to the Chair.

Mr. OLVER. Without wanting to extend this discussion a great deal, I would like to just merely respond to that. Every one of the alternatives is designed around a central estimate and really in the process of doing so it eliminates the proper evaluation of risk for those people who are the most seriously and severely at risk from an activity and a regulation process in any of the areas that we are trying to provide some benefit to people at risk.

I think that that is the central problem with the language of the best estimate definition.

The CHAIRMAN. I would simply say to the gentleman that the Chair does not agree with that characterization, when Part C says "any other methodology designed to provide the most unbiased representation of the most plausible level of risk."

That opens the door to virtually any other methodology, whether it involves central risk or not, or central estimates or not.

So it is far from being as the gentleman has characterized it, but we think what we have put in the bill is important.

Is there any other discussion on the amendment?

[No response.]

The CHAIRMAN. If not, the Chair will put the question. Those in favor of the amendment will respond by saying aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say no.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair the noes have it. The noes have it. The amendment is not agreed to.

The gentleman had—are there any other amendment to—I had said I would recognize the gentleman, Mr. Tanner, next.

Mr. TANNER. Thank you, Mr. Chairman.

I had an old professor in law school who said that anything that could be said could be said better in a few words.

Our amendment now reads "or to be necessary to maintain military readiness".

The CHAIRMAN. It is an excellent amendment which the Chair is prepared to take.

Mr. TANNER. Thank you, sir.

Unidentified Member: Move its adoption.

The CHAIRMAN. Is there any other discussion on the amendment?

[No response.]

The CHAIRMAN. If not, the Chair will put the question.

[Chorus of ayes.]

The CHAIRMAN. We should have had the amendment distributed. That is the fault of the Chair. But let me read it.

The gentleman has characterized it. What he says is: We add another item to the exceptions already in the bill to say "or be necessary to maintain military readiness".

So that it does provide an exception for the Secretary for purposes of military readiness. We believe that this is something which does no harm to the bill at all and further defines the exceptions clause.

With that, I would put the—the gentleman from Minnesota, or Michigan, I'm sorry.

Mr. EHLERS. I may be West, but not that far.

The CHAIRMAN. Yes.

Mr. EHLERS. I just——

The CHAIRMAN. They are all "Ms" up there to me. [Laughter.]

Mr. EHLERS. Do we still have a notification from them? The previous amendment said that for any such variation they would notify Congress of such determinations and the reasons for such determinations.

Is that still going to be part of it?

The CHAIRMAN. Well, we intend to define "military readiness" in the amendment, or in the report language in a way that would assure that these are items that are done in terms of training and true readiness procedures.

Since we do not deal with the environment and some of the other things in this particular language, we believe that there the Corps of Engineers and a lot of other things would still be covered.

But it was not the intent, as I read the language of the bill and participated in drafting the bill, to have military readiness impacted by what we were doing here. This simply clarifies that language.

Mr. EHLERS. Well, Mr. Chairman, I still register my concern and just point out that one great issue with the American public which we just resolved was exempting Congress from the laws which we pass. I am very concerned about exempting any branch of the Federal Government.

The CHAIRMAN. We are not exempting the Defense Department in any way, shape, or form here. We are simply exempting those activities in the Defense Department that are clearly questions of military readiness.

The Defense Department will still have to comply with the bill. We are not exempting the Defense Department with this language.

Mr. EHLERS. All right, I will conclude with one statement.

I think at some point in the future I will offer an amendment on another bill exempting Members of Congress who are worried about their political readiness. [Laughter.]

So thank you very much.

The CHAIRMAN. I thank the gentleman.

The Chair will now put the question. All those in favor of the amendment will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say no.

[Chorus of nays.]

The CHAIRMAN. The ayes appear to have it. The amendment is agreed to.

Are there any other amendments to Section A, or Subtitle A?

Mr. MINGE. Mr. Chairman?

The CHAIRMAN. The gentleman from Minnesota.

Mr. MINGE. I have an amendment that is at the table and I believe that it is also in the package you may have listed as No. 14.

The CHAIRMAN. The Clerk will distribute the amendment.

[The amendment is distributed.]

Mr. MINGE. To save time, I could quickly state what it is.

The CHAIRMAN. The gentleman is recognized.

Mr. MINGE. This amendment builds on the experience that we had in 1994 in the 103rd Congress when we decided that the United States Department of Agriculture, as a part of its reorganization, should be subject to a mandate to engage in risk assessment.

The purpose of this amendment is to exclude the U.S. Department of Agriculture from the bill that is under consideration.

The reason for this is that we should allow the U.S. Department of Agriculture to proceed with the risk assessment procedures that it currently is constructing and use that as a basis for determining whether the policy that we established in that legislation works better than the policy that we are establishing in this.

It is somewhat like saying that we have 50 States. It is an opportunity to experiment. We have within our Federal agencies a vast array of departments and operations. This is a chance for us to experiment.

I also believe that it is awkward for us to in one session of Congress establish a mandate for an agency or a department, and then in the next session of Congress we pull their—we jerk their chain and say, all right, start all over again, we're going to do it a different way. That is essentially what we are doing with USDA with respect to risk assessment.

The CHAIRMAN. Well, I thank the gentleman for his explanation.

We did have in mind some of the problems that were related to us that USDA would have in coming up with some of the exceptions that are on page 7, including food labeling, health and safety environmental inspections, and so on.

I think that we have attempted to deal with the problems that—in terms of the operation of the department.

The gentleman makes a legitimate point about the questions of the laws that were just passed recently and now would be subject to this change. It is a legitimate point.

However, the Chair would be reluctant to begin exempting whole departments from the coverage of this bill. It seems to me that we open the door to virtually everyone else coming up with some reason why they ought to be an exception on the bill.

In my view we have adopted much of what has previously been done on risk assessment in this particular approach, and I don't believe it should place an undue burden on the department. For that reason, I would oppose the amendment.

Are there other statements on this particular——

Mr. SCHIFF. Would the Chair yield to a question?

The CHAIRMAN. I certainly would.

Mr. SCHIFF. Very briefly, Mr. Chairman, I guess we just last year passed a similar bill for the Department of Agriculture. I wondered, did we do that for any other agency that could make the same argument that this Chair knows of for an exception?

The CHAIRMAN. I would say to the gentleman that there was nothing that cleared the Congress. We did in fact adopt some similar language with regard to the Green Technologies bill on the Floor, but that of course did not make it through the Senate.

So that is the case. But I would also say to the gentleman that I am not so certain that we want a host of different types of risk assessment going on around the Government.

If in fact what we are trying to do is establish a set of principles here, it seems to me that the set of principles ought to be standard.

I do not believe the Department of Agriculture is that far into their application of this that the new principles could not be applied to what they do.

Mr. SCHIFF. I thank the Chairman.

Mr. MINGE. The only other comment I would make on that is that the bill last time was adopted, I'm not sure if it was by a voice vote, but it was an overwhelming bipartisan vote, and that the process set up in that bill allows the agency a little more discretion in designing its risk assessment procedure.

I think that there is a real benefit in experimentation within our Federal system to try to develop the most effective risk assessment process, and this allows for some of that experimentation.

The CHAIRMAN. If there is no further discussion, the Chair will put the question.

Those in favor of the amendment will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say no.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair the noes have it. The noes have it, and the amendment is not agreed to.

Any other amendments to Subtitle A?

Ms. LOFGREN. Mr. Chairman?

The CHAIRMAN. The gentlewoman from California.

Ms. LOFGREN. I have an amendment at the desk, I think.

The CHAIRMAN. The Chair does not have a copy of this amendment, so the Chair would want to have it distributed before we move forward.

[The amendment is distributed.]

The CHAIRMAN. The gentlewoman is recognized to describe her amendment.

Ms. LOFGREN. Thank you, Mr. Chairman.

The proposed amendment specifies that where feasible and scientifically appropriate a risk assessment will identify risk to highly exposed groups.

The bill calls for risk assessments that use best estimates, as we discussed just a few minutes ago, using most plausible assumption and unbiased information.

I think these terms could be interpreted as excluding consideration for subsets of the population such as children who may be more highly exposed or more vulnerable than average adults because these subgroups have exposure and susceptibility patterns that are different from most members of the population.

Whereas I think arguable those estimates under Section B could in fact touch those groups. They are not required to assess the risk for those groups, and I think it is important that, in addition to the language that is currently in the bill, that we direct that highly sensitive groups such as children also be identified, and that that information be provided.

One example of the reason for the necessity for this would be lead. As we know, exposure of lead to children is much different than the exposure of lead to adults. Lead absorption in the stomach, from the stomach to blood in children is about 50 percent, whereas it is about 15 percent for adults, and clearly behavior of children—I have two—when they are little, in terms of ingesting dust and dirt, is considerably different than most adults.

So I think that this is well in order and will help in the assessment of actual risk to those who are most important to the future of our country, our children.

Thank you.

The CHAIRMAN. I appreciate the gentlewoman's explanation.

If the Chair can turn the Member's attention to pages 10 and 11 of the Substitute, you will find there that we say in the Substitute: "To the extent practical and appropriate" and the bottom of page 10, and then going onto page 11, "the characterization shall provide descriptions of the distribution probability of risk estimates to reflect differences in exposure variability or sensitivity in populations and uncertainties.

That is a very broad way of saying much the same thing that the gentlewoman is saying in her amendment, and I think it gives broader coverage to assure that there is sensitivity to population groups.

The reason why I would say that that is important is, I look at the gentlewoman's amendment and one group that I do not see covered under her amendment is, for instance, HIV-positive persons in the population.

It seems to me that in some instances we would want to have that as a particular population that we are concerned about.

She excludes that from her amendment. Under the language which is in the bill, that would in fact be included. So——

Ms. LOFGREN. If I may, reclaiming my time, Mr. Chairman, in the amendment——

The CHAIRMAN. The time of the gentlewoman had expired.

Ms. LOFGREN. Oh? Had it expired? Pardon me.

The CHAIRMAN. I would be happy to yield to the gentlewoman.

Ms. LOFGREN. I appreciate that very much.

The parentheses is not meant to be an exhaustive list. I am sure we can note the "such as infants". It is meant to be examples, but not to be an exhaustive list of all those who might be vulnerable, if I could just clarify that.

The CHAIRMAN. I thank the gentlewoman, but by singling out groups in her particular language, that is in fact a preference group that she is singling out.

What I am suggesting is that in the language that is in the substitute, we allow judgments to be made about particular groups that we may not know about at the present time.

This may be a situation where we would have particular groups that we want to have a particular sensitivity to at some time in the future that we don't even know how to describe at the present time.

So therefore it seems to me that the language that is in the bill right now gives broader applicability to sensitive groups than singling them out in this particular amendment.

Ms. LOFGREN. Mr. Chairman, I wonder if we could, just looking at the language that you have pointed out, "sensitivity in populations and subpopulations" might achieve what you and I are both talking about more directly.

The CHAIRMAN. Well, I am told by counsel that that is not necessarily needed here; that the sensitivity in populations is in fact a subpopulation as well. I mean, that that is a description that again simply narrows it and takes away from the discretion of the agency to do the kinds of things that I think the gentlewoman is seeking to do.

Ms. LOFGREN. Well, I don't want to go on at too great a length. I don't agree. Going back to when I took statistics, and Mr. Olver's earlier comments, I think that clearly the way the bill is drafted—and I am not disagreeing that we ought to look at what is the impact on most people in the center of it—but I think using that statistical analysis we will miss some groups. Which is why I have proposed this.

But I think there is disagreement, so perhaps we can just vote.

Mr. OLVER. Mr. Chairman?

The CHAIRMAN. The gentleman from Massachusetts.

Mr. OLVER. Mr. Chairman, on this amendment could counsel—maybe it is just late at night, but I really don't understand what "uncertainties" are and what their relationship are to the "variability or sensitivity in populations".

The CHAIRMAN. Counsel would reply.

Mr. BERINGER. The Chairman is quite correct. When this was drafted it was intending to be an all-encompassing amendment which would include many of the things that the gentlelady was referring to earlier.

The uncertainty part is one of the words that were used in this drafting to try to explain that, as has been stated many times throughout the day, that this is not necessarily pure science, but there are variables, and there are things that we are not certain about.

So what this is trying to do is give to the risk characterizes the broadest discretion possible to try to include, but yet at the same time note that everything may not be covered.

Mr. OLVER. If I may reclaim my time, the structure of that sentence leads one to think of "populations and uncertainties" being something that ought to be related to each other.

I wonder, is the "uncertainties" meant to be something somewhere else in this paragraph? It seems to be hanging in the wrong place.

Should it be reading "Should provide descriptions of distributions and probabilities and uncertainties of risk estimates to reflect differences in exposure, variability, or sensitivity in populations"?

Mr. BERINGER. Mr. Williamson is pointing out to me that to further refine what I had previously said, uncertainty means the quantifiable and unquantifiable potential error in the estimation of risk that is caused by the quality or absence of data or the assumptions used in risk estimation.

So it is, as I said, it is meant to be a qualifier. Perhaps it is not in the right place, but that is what it means.

The CHAIRMAN. We can in fact at a time, if in fact counsel agrees with the gentleman from Massachusetts, we can in fact in technical corrections work the sentence, and so on. But it is——

Mr. CURT WELDON. Would the Chairman yield? Mr. Chairman?

The CHAIRMAN. The gentleman from Pennsylvania.

Mr. CURT WELDON. Mr. Chairman, I thank you for yielding.

Can't we take care of much of this in report language?

The CHAIRMAN. Precisely.

Mr. CURT WELDON. I mean, working it out—not that I am trying to downplay the importance of these things, but I think we are getting into technical details which really could be worked out in report language to the satisfaction of both sides.

The CHAIRMAN. The gentleman is correct. I thank the gentleman.

The vote occurs on the amendment of the gentlewoman from California. Those in favor will say, aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed, no.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair, the noes have it. The noes have it, the amendment is not agreed to.

Are there any other amendments in Subtitle A?

Mr. TRAFICANT Mr. Chairman, I have an amendment.

The CHAIRMAN. The gentleman—has the amendment been distributed?

Mr. TRAFICANT. I believe that——

The CHAIRMAN. The Clerk will distribute the amendment.

[The amendment is distributed.]

Mr. TRAFICANT. While they are distributing it, it was brought up during the Barton amendment where it was alluded to, a "non-United States-based entity". I believe that the Barton amendment as passed is rather shallow without a definition.

This is an attempt to define "non-United States-based entity."

While you are reading, I will just briefly say: Under my definition an entity which is not incorporated in the United States, does not have as its principal place of business the United States, does

not provide a benefit to the United States economy, and the United Nations or any of its divisions.

It further clarifies, as it does in paragraph 9 there, that which is considered to be the United States. Now there has been a lot of discussion on this.

I think that the Barton amendment that I have supported is strengthened and it clarifies what in fact a non-United States-based entity is.

I would ask that the Committee, in lieu of this, support the amendment. I believe it makes sense, and it at least sets the legislative history that could at some point become important in the analysis of any of the fine line of the Barton amendment or any other aspect of the bill, alluding to such non-United States-based entity.

The CHAIRMAN. Would the gentleman——

Mr. TRAFICANT. I yield to the Chairman.

The CHAIRMAN. I thank the gentleman for his explanation.

Has the gentleman, since this does modify Mr. Barton's amendment, has the gentleman checked with Mr. Barton?

Mr. TRAFICANT. I have not been able to talk with Mr. Barton on that, but I do not see, after looking at Mr. Barton's, why there should be a tremendous rush to oppose this amendment.

I believe, if anything, the Barton amendment leaves open certain areas that could be questioned and perhaps reduce the effectiveness of the language that has been passed.

The CHAIRMAN. Well the gentleman makes a point, and there was in fact no definition in the Barton amendment.

As I explained to the gentleman earlier, I am not certain that I am wise enough off the cuff to be able to draft something that defines a "non-United States-based entity" in a way that meets all the various tests that the gentleman and Mr. Barton might have in mind, or that the lawyers might find as being acceptable.

What I would prefer to do, I would say to the gentleman, I think he has pointed out something that should be done. I would prefer to handle this in the report, as well. I think it would make more sense to define what we mean as a part of the report language.

If that is not satisfactory to the gentleman as we define it in the report, and if the report language is something that he wants to enter into the bill, then it seems to me that on the floor we might be able to take an amendment at that point, if that is still needed.

But at this point, I would be reluctant to adopt language that I am not certain that I know the full implications of, and I am not certain that we have had enough legal advice from both outside and inside this institution to know whether or not this is an appropriate definition for a non-United States-based entity.

Mr. TRAFICANT. In furtherance of my time, what would be the legal status of that report language and its impact on the Barton amendment and any other language in the bill?

The CHAIRMAN. Well, I would say to the gentleman that report language is in fact definitional of the things which are done by the Committee.

So insofar as the gentleman is concerned that we have not appropriately defined language in the bill, we can do that as a part of the report language.

My point to the gentleman is, if at the point we go to the Floor the gentleman does not think that that is strong enough, I would certainly support his right to offer an amendment on the Floor that takes the report language and puts it into the bill.

But I am just reluctant to say that I know that what has been drafted here is in fact the appropriate description of a "non-United States-based entity" at the present time.

Mr. TRAFICANT. With that, Mr. Chairman, I would like to ask a question of counsel, then.

Would the Barton amendment, as it stands, what would be the status of some shell structure under an umbrella of the United Nations that could in fact operate within the scope of that amendment that is located in the United States?

The CHAIRMAN. Counsel is recognized.

Mr. BERINGER It is my understanding, Mr. Traficant, that the United Nations entities within the United States territorially are not really part of the United States. But this just points out the difficulty of this is an off-the-cuff opinion, and this just points out the difficulty of trying to do this right at the moment.

Mr. TRAFICANT. I am not going to belabor this, but they are an entity that operates in this country and there is the potential for abuse and a shell game could come about, which is a concern that everybody has with that amendment.

So without belaboring it any longer, I want to yield to my chairman here, Chairman Hall.

Mr. HALL. I thank the gentleman for yielding.

I have of course looked at this, and the language appears enforceable and seems to enhance the bill, and I think it is supportive of the Barton amendment.

Actually, as Chairman Walker has suggested, also I think the gentleman from Ohio has the best of all worlds because we do have the word means an entity, and that's what report language is for, and shows what it does provide and what it does not provide, and it might be enlarged with report language.

But I think it enhances the bill. As a co-author of the bill, I intend to vote for it, if a vote is called.

Mr. SCHIFF. Mr. Chairman?

The CHAIRMAN. Who is seeking recognition? Mr. Schiff.

Mr. SCHIFF. Mr. Chairman, I sympathize with where the gentleman from Ohio is trying to go, but as I read this I am not entirely clear whether a non-United States entity under this language means an entity in which all three of these things exist.

In other words, an entity which is not incorporated in the United States; does not have its principal place of business; and does not provide a benefit to the United States' economy.

According to this, if one of the provisions does not exist, would this be a United States entity or not?

In other words, suppose that a business were incorporated in another country. Its principal place of business were in another country. But it provides a benefit to the United States economy such as having a branch in the United States that employs Americans.

Would that be a United States entity, or would that not be a United States' entity.

I would offer to yield to the gentleman from Ohio.

Mr. TRAFICANT. Yes. It would not be U.S.-based. They would not be based in America, even though it provides a benefit that accrues to our economy.

Mr. SCHIFF. So the gentleman is saying that is or is not a United States' entity in the example I gave?

Mr. TRAFICANT. If it is not based in here, no.

Mr. SCHIFF. What if it has a factory in the United States?

Mr. TRAFICANT. Then if that factory is incorporated as a subsidiary and it meets the other requirements, it would be considered as a United States' entity.

Mr. SCHIFF. Well, in other words——

Mr. TRAFICANT. Let me further say this. I am not going to belabor this tonight—and I want to say this to the Chair—before I offer a unanimous consent to withdraw, I want to work with the leaders on both sides. I believe it is imperative and important that this entity, non-U.S.-based entity, be defined.

I would be willing to accept the judgment and work out language, and if necessary offer that on the Floor, or for whatever other remedy can be obtained.

Rather than going into it at this hour, I ask unanimous consent that my amendment be withdrawn and be given consideration for the conference.

The CHAIRMAN. Without objection.

Let me say to the gentleman that he has my assurance that we will work with him.

As I said, either we can do report language on this that does provide the definition—he has raised a legitimate point. I hope I made that clear. I think it is a legitimate issue.

Since this is not—I checked with counsel earlier to find out whether or not there was a definition of such entities in the U.S. Code.

I am told that there is not.

So, therefore, we probably do need to do a definition here.

The gentleman has been most helpful in withdrawing so that we can be sure that the definition that we work out is the right definition.

I assure him we will work with him to see to it that we come up with that right definition.

All right, are there further amendments to Subtitle A?

[No response.}

The CHAIRMAN. Hearing none, I will close out Subtitle A and we will go to Subtitle B.

Are there amendments to Subtitle B?

The gentleman from Virginia, Mr. Davis.

Mr. DAVIS. I have Amendment No. 20 that is in front of everyone.

It is fairly lengthy. I will try to explain it briefly.

SIMULTANEOUS VOICES. Aye. [Laughter.]

Mr. DAVIS. This applies to major rules to protect human health, safety, environment. The amendment forces the considering agency to identify reasonable alternatives which would achieve the identified benefits of the proposed rule.

It offers alternatives that take into account, alternatives that may require no Government action that would look at geographic

differences, that would employ performance or market-based standards, and provide flexibility to achieve identified benefits, an assessment of the aggregate effects on small business, and a cost benefit analysis based on the net benefits to society.

I think the key is that the amendment expands on the alternatives identified in the base text. I think it's very pro-small business, recognizes many times we're getting $50 solutions to five dollar problems.

And I hope the Committee will approve it.

The CHAIRMAN. The gentleman does elaborate on the types of alternatives that should be considered during rulemaking. I see no problem with the items that he adds to those alternatives, and the Chair is prepared to accept the amendment.

If there further discussion on the amendment?

Mr. OLVER. Mr. Chairman.

The CHAIRMAN. The gentleman from Massachusetts.

Mr. OLVER. Just for clarification, are we talking about Amendment 20?

The CHAIRMAN. Amendment 20.

Mr. OLVER. The regular order?

The CHAIRMAN. The gentleman's correct.

If there's no further discussion, the Chair will put the question on the amendment.

Those in favor will say aye.

[Chorus of ayes.]

The CHAIRMAN. those opposed, no?

[No response.]

The CHAIRMAN. The ayes have it. The amendment's agreed to.

The next amendment in the package is an amendment by Mr. Wamp.

Mr. WAMP. Thank you, Mr. Chairman.

Actually, it's 3201(a)(3) and not 3201(a)(4) I think, as it says on the chart, which would pick the language up there at the end of the period (.), and say "including, to the maximum extent practicable, a quantitative assessment of the cumulative financial burden that persons producing products that are regulated by the rule will bear in order to comply with the rule and with related existing standards that affect the product or other similar products produced by such persons."

It should be in your packet.

Mr. Chairman, regulatory reform should require departments and agencies to meaningfully quantify, in a rulemaking, the cumulative burden on manufacturers or other affected parties, of multiple regulations by the same agency on different products or subjects affecting the same manufacturer or party.

Further, departments and agencies should meaningfully quantify in a rulemaking the cumulative burden on manufacturers or other affected parties of related regulations by different agencies on the same product or subject.

Let me give you an example.

Full line appliance manufacturers are subject to Department of Energy energy efficiency standards for up to seven individual product standards. DOE undertakes no consideration of the cumulative

financial or technical resource burden of continuously redesigning seven major products.

At the same time, under the Clean Air Act, EPA is regulating industry's use of vital chemicals for refrigerator and room air conditioners which are critical to meeting the DOE standards, yet neither EPA nor DOE coordinate with one another or fully take into account the problems of meeting separate standards at the same time.

EPA and DOE standards are often technically at cross purposes, which only serves to add to the burden of compliance.

Currently, Mr. Chairman, full line manufacturers are each investing hundreds of millions of dollars in new equipment and designs to meet energy standards for six major product categories, and this drain on corporate research and development funds and human resources impedes product innovation and is exacerbated by Clean Air Act requirements relating to ozone depleting substances and other Federal requirements.

And I move for approval.

The CHAIRMAN. The Chair's examined the gentleman's amendment. What the amendment does is tries to shed light on whether or not the impact reaches the $25 million threshold. I think it's an excellent amendment. It strengthens the bill, and I'm prepared to accept the amendment.

Is there further discussion on the amendment?

[No response.]

The CHAIRMAN. If not, the Chair will put the question.

Those in favor of the amendment will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say no.

[Chorus of nays.]

The CHAIRMAN. The ayes appear to have it. The amendment is agreed to.

Any other amendments to Subsection B?

Mr. DAVIS. Mr. Chairman? I'm not going to offer number 23 because I think that your substitute basically takes care of those concerns, but I would note on page 20 of your substitute on line 22, just in reading it, if members would want to turn to that, line 22 on page 20, you have "or the environment unless the requirements of section 3201(a) are met . . ."

Trying to move this back to what I had in amendment number 22, wouldn't you want to say 3201(a) and (b).

I might just offer that as a technical change for the staff to consider to just make it comply. I would think that might have been the intent of that.

The CHAIRMAN. Well, let me say to the gentleman, we'll examine that and make certain. I don't want to talk off the cuff.

Mr. DAVIS. And that's fine.

The CHAIRMAN. Let me check with counsel.

Mr. DAVIS. That's fine. I throw that out just for everybody's consideration.

Mr. BERINGER. I believe that's correct, but we will check that out further.

The CHAIRMAN. Yes, we'll check that out as a technical change.

Mr. DAVIS. I have nothing else to offer.

The CHAIRMAN. Okay. Any other amendments in Subtitle B?

[No response.]

The CHAIRMAN. If there are no further amendments——

Ms. JACKSON-LEE. I have.

The CHAIRMAN. Ms. Jackson-Lee?

Ms. JACKSON-LEE. Yes, Mr. Chairman. I have an amendment at the desk, I believe.

[Pause.]

The CHAIRMAN. The gentlelady is recognized. I apologize to her.

Ms. JACKSON-LEE. That's all right, Mr. Chairman. Thank you very much.

We had this discussion earlier when I inquired of counsel the further refinement or my thought on seeing the need for further refinement of the definition of the words "major rule."

And in inquiring to counsel, I think we established that a further refinement certainly might be welcomed. I would hope the Chairman would welcome this further refinement as it relates to life-threatening situations.

Many Federal regulatory reviews reveal high risk situations in the midst of a risk assessment or other regulatory proceeding.

In recent years, for example, many regulatory reviews have been made of chemicals, drugs and other regulated products that were grandfathered in as more rigorous regulatory standards have been passed.

When regulatory agencies have undertaken reviews to update their toxic and other effects data as a part of a full risk assessment, they have discovered previously unknown risks of a very significant nature.

This has frequently triggered the need for an agency to take immediate action on a chemical or drug in advance of a complete risk assessment.

We need to continue, I believe, giving agencies this flexibility. This is complementary. This is a clarifying which in life threatening situations. For example, the situation with ethylene dibromide, EDB, which was suspended in the mid-1980s, I think clearly because it seemed to cause cancer in a major way, that this and the effort and direction that we're trying to go, complements and provides leeway for life-threatening situations.

This does not, I think, get answered in the provision dealing with emergencies. This is directly what I'm speaking of, life-threatening situations.

I mentioned earlier the issue of lead paint as it impacts children, and there are a variety of other situations, pesticides, particularly under review by EPA, which would warrant the further explanation that an agency could take immediate action in life-threatening situations.

And I would ask for support of this refinement of "major rule."

The CHAIRMAN. I thank the gentlelady for her explanation.

I would point out to the gentlelady and to the members of the Committee that at the beginning of Subtitle A, the emergency provisions of the rest of the bill do apply. And so we do in fact have the emergency section of the bill that would be applicable to the major rulemaking.

The emergency situation, in my opinion, is something where there is a longstanding belief that it would certainly include life-threatening situations.

However, because the gentlelady has raised the point, it seems to me that this is something that we could cover in report language to make absolutely certain that it's clear that emergency, for the purpose of the bill, does include any kind of life-threatening situation.

I think to put an exception in the part of the bill where she is intending to do so does in fact complicate our ability to deal with the bill in a responsible way.

We have exceptions in the other sections of the bill. So I would simply say that I agree with the gentlelady that she has made an important contribution. It is covered under the emergencies, but we want to clarify that.

And I am prepared to clarify that, using her terminology in terms of life-threatening situations in report language.

Ms. JACKSON-LEE. Mr. Chairman, we probably would disagree somewhat in terms of the necessity or validity of having an exception.

I'm willing to work with the Chairman in terms of having that language specifically clarified with the language emergency.

I would argue somewhat differently that the emergency does not necessarily go to the highest level of life-threatening, speaking clearly as it relates to human impact.

But I would welcome that clarification and ask that I be allowed to work with staff and the Chair to make that clarification in the report.

The CHAIRMAN. We will certainly clear any language that we would put into the report language with the gentlelady to make certain that it fits with her intent.

Yet, I'm hoping that we can make clear that if in fact she has some concerns that emergency does not properly cover the kind of life-threatening situations that she is referring to, that we make it clear that for the purposes of this bill, it's going to.

Ms. JACKSON-LEE. All right, thank you.

I will then ask unanimous consent, Mr. Chairman, to withdraw this amendment at this time.

The CHAIRMAN. I thank the gentlelady.

Any other amendments to Subtitle B?

Mr. DOGGETT. Mr. Chairman, I had another amendment but it may well be, rather than lay it out, that a quick question to counsel can resolve it, and it could be handled with report language.

That was with regard to Subsection (f)(1) that refers to ''not withstanding any other provision of law.''

Would it be possible for you to simply identify, either here or in the report, which public laws you anticipate supplementing or superseding by this legislation?

[Pause.]

The CHAIRMAN. The Chair recognizes counsel.

Mr. BERINGER. I think it would be a difficult task to do it with exactness in a short amount of time.

Mr. DOGGETT. Do you know which ones you're superseding? Do you know any of them?

Mr. BERINGER. Yes, we do. We have an illustrative chart which——

Mr. DOGGETT. Could you perhaps just attach that as an illustrative chart that is not an exclusive list but an example of what you're superseding?

Mr. BERINGER. Yes, we could, sir.

Mr. DOGGETT. I think that'd be fine.

Mr. BERINGER. OK, thank you.

The CHAIRMAN. I thank the gentleman.

Mr. OLVER. Mr. Chairman.

The CHAIRMAN. Who seeks recognition?

Mr. Olver.

Mr. OLVER. Mr. Chairman, I would like to explore the same area just a little bit further. I would like to know if counsel can tell me what is the intent of that?

Does that have to do with the future or does that have to do with going back into law which we, as members of Congress, may have passed in the past where there were not risk assessments as are defined under this Act, and carefully laid forward as to procedures and definitions and such?

Would this mean that if we, as a Congress, had passed legislation, the Clear Air Act, for instance, and defined what had to be done without really doing or ordering risk assessment as defined by this Act, would that mean that now all those things that hadn't been done and in keeping consistent could not be continued, or is this meant to be prospective for the possibility that Congress would again pass legislation without reflecting in the legislation the risk assessment procedures herein, and which we've done from time to time, as the Chairman knows?

What is the intent here?

And I think it goes really not just to (f)(1) but also (f)(2), but (f)(1) is a little bit, one can at least, that's a little bit more limited in its language and, therefore, I think easier to try to understand here under the circumstances.

The CHAIRMAN. Counsel.

Mr. BERINGER. This is meant to be prospective in nature, Mr. Olver.

Mr. OLVER. Is there anything in the language that, I mean, we have done things which related to the NRC and transportation or storage of wastes and management of dangerous materials of other sorts, and the Clean Air, Clean Water, things of that sort.

Mr. BERINGER. This is meant to be prospective in nature, Mr. Olver.

Mr. OLVER. Is there anything in the language that, I mean, we have done things which related to the NRC and transportation or storage of wastes and management of dangerous materials of other sorts, and the Clean Air, Clean Water, things of that sort.

What is there here to assure us that this does not affect retrospectively laws that have already been passed?

Mr. BERINGER. Well, in general, the applicability of the effective date of the legislation is 18 months from the date of enactment.

Now what this applies to prospectively is new rules under old acts. So it, for instance, it would say that if you did a new assess-

ment under the Clean Air Act, then in the applicability section in (f)(1), it would be supplemental.

Or in other cases where they are specifically required to do risk assessments, it should be supplemental.

But to the extent that there is no conflict, it would supersede decisional criteria for rulemaking, but again that's prospective rules, that's not the rules that are currently on the books.

Mr. OLVER. So then all rules that are currently on the books—how would I see that in the language that is here? How would I, as a lay person, non-lawyer, in essence see that in this language of the proposed law to know that the rules presently promulgated are not affected by this, but yet that those that might be promulgated in the future under the same laws that are in effect would be affected under this?

How would I see that?

Mr. BERINGER. The only thing that I could reply on that is the effective date of the Act, sir.

Ms. MORELLA. Mr. Chairman?

The CHAIRMAN. The gentlelady from Maryland.

Ms. MORELLA. Thank you, Mr. Chairman.

On that point, reflecting on the response that Mr. Olver got, if in fact it would be applicable to new rules of old laws, and because of the fact that you have many facets of the Clean Air Act, the Safe Drinking Water Act that have not yet been promulgated, then this would apply.

Is that correct, this would apply to those new rules to laws in existence?

Mr. BERINGER. Yes, that is correct.

Legislative counsel, however, also has pointed out to me that unless otherwise stated, that all laws are prospective in nature rather than retrospective. So—but your interpretation is correct, Ms. Morella.

Ms. MORELLA. Because there are a lot of rules that have not yet been promulgated?

Mr. BERINGER. That is correct.

Mr. OLVER. Would the gentlelady yield? Do you yield on that point?

So if I'm understanding what now is clarified, it's often easier to clarify when questions to another member are being answered, rather than directly here.

That if there are rules yet to be promulgated under law already passed, where we, as Congress, have set standards, which may or may not, which didn't have risk assessment as promulgated in this, that this Act would supersede the act of Congress at prior times and in setting those standards?

Mr. BERINGER. Yes, sir.

Mr. OLVER. Yes. The answer to that is yes? Oh, my.

The CHAIRMAN. Well, the Chair would simply state that what we are assuring here is that any new rules promulgated even under old Acts would in fact require good science to be utilized.

I know that that disturbs some people but it is in fact something that we think that, even under old law, that if you're promulgating new rules under old law, that the best science ought to be used as a part of that process.

Ms. MORELLA. Thank you.

On that same point, actually, I guess a concern I have is not so much that they would be reviewed, but the cost benefit test, would that apply?

That's quite different.

Mr. BERINGER. Yes, ma'am.

Ms. MORELLA. It would. Thank you.

The CHAIRMAN. If there are no further—are there further amendments to Subtitle B?

[No response.]

The CHAIRMAN. If not, I'm closing Sub—does the gentleman have an amendment?

Mr. LUTHER. Mr. Chairman, if I could just ask a follow-up question on that point that relates to subpart B.

The CHAIRMAN. Well, the Chair will allow the question to go on. The Chair's been very lenient with regard to time and, you know, has not imposed the five-minute rule here, but if we're going to continue to explore this, the Chair will begin to suggest that the Rules of the House in regard to the five-minute rule should apply to these matters. But I do recognize the gentleman.

Mr. LUTHER. Excuse me. I will be brief, Mr. Chairman.

I wonder if counsel could indicate on the record why, when we're talking about the risk assessment, we talk about these requirements being supplemental, and yet when we get into the cost benefit part of the bill, we talk about them not just being supplemental but also superseding.

If you could just explain why there is that difference in the two parts?

Mr. BERINGER. It is the intention of the drafters that on risk assessment, that there are currently requirements in the law to do risk assessment. There are not many requirements in the law to do cost benefit analysis, and it is somewhat of a departure.

So therefore it is making explicit that this is a new law.

Mr. LUTHER. Mr. Chairman, then I think, if I could just follow up on Mr. Doggett's request, I think in those instances where there potentially could be a requirement that's supersede, I think if we could have a specific list attached or whatever, I think that would be extremely helpful.

Mr. BERINGER. We will clarify that to the best of our ability, sir.

Mr. OLVER. Mr. Chairman, I have an amendment.

The CHAIRMAN. Mr. Olver, is it in writing?

Mr. OLVER. It is in writing. It is under a different name, but it is to strike paragraph (f)(1) of the Section 3201 and renumber the remaining paragraphs appropriately. It is at the desk.

But I think after the discussion that we've had, I think it need not be distributed.

I must say, I am——

The CHAIRMAN. The gentleman's recognized for five minutes.

Mr. OLVER [continuing]. Mr. Chairman, I do not mind the application of this Act to future Acts as a decision that we make as a Congress.

What I think has come out from the discussion back and forth here by myself and the gentlewoman from New Jersey—Maryland, excuse me, sorry about that—that this in fact, where Congress itself may have set standards, and I'm a believer in the best science

being used in these risk assessments and everything, a complete believer in proper use of risk assessments in this process, that where we have specifically made a determination of what standards should be, that this language precludes decisions by the Congress, direct decisions by the Congress.

I would hope that in the future, we would not set standards and allow risk assessment, proper risk assessment to take proper science in that process to take over in deciding what should be the standards in the rule.

But we have done things in the past which set specific standards and which have gone forward in all parts of the country to a degree, and now to supersede those, at this point, I think would be incorrect.

And the unfortunate thing is, I don't know how, right at this time, to write the language which I would prefer to do, to make this prospective rather than retrospective on legislation which has already passed the Congress.

So, I'm offering instead the striking of the paragraph.

The CHAIRMAN. I thank the gentleman for his explanation.

This of course goes to the core of what we're attempting to achieve in this bill.

The fact is that the old structure has gone bad. That the regulatory climate that has been created under old laws has in fact created a terrible burden on businesses, on communities, and on a variety of phases of our economic life.

It is that correction that we are attempting to make here. We are not attempting to go back and reach back to laws that are presently in place and presently providing regulations.

However, as we proceed ahead with new rulemaking, even under old laws, we are attempting to assure that the best available information be utilized in that process.

To strike this section would in fact prevent us from getting rid of some of the bad practices that have crept into the system.

Again, the Chair is aware that there are some who believe that the regulatory climate that we have created has in fact been a positive for the country. In some instances it has been and in some instances it needs correction.

This is the bill that is attempting to do the correction, and we are hoping with this bill that we can make the proper judgments.

That means that some of the old standards set by Congress are in fact things that need to be changed in a positive way. And we are attempting to do that in this bill.

To strike this section will prevent that kind of positive rulemaking from going forward.

Is there further discussion?

Mr. OLVER. Mr. Chairman, in answer to the Chairman's comments, I believe I heard the Chairman say, in what you have just said, that you're not attempting to supersede what is already in law, but that seems to me to contradict what the counsel had said earlier, that in fact it did supersede.

The CHAIRMAN. There's no contradiction. There's no contradiction, I would say to the gentleman. Present law, as the regulations are laid down, is not affected by paragraph (f) in any way.

However, new rulemaking under the old law would in fact be affected.

And so all we're dealing with here is new rulemaking under previously passed law. If there are, in fact, rules to be promulgated under certain laws that are not on the books that are not now there, they would in fact be affected by this law.

Rules that are presently there would not be affected.

And so, you know, that's the only point that the gentleman is making.

Mr. OLVER. But that does involve superseding direct action by the Congress in setting standards for those laws.

The CHAIRMAN. It does mean that the 104th Congress is reviewing some of the Acts of previous Congresses and deciding that there may be in fact some things that were done in previous Congresses that we now want to change a little.

Ms. LOFGREN. Could I ask, I don't want to belabor this any more, but could I ask just one quick question to make sure I understand this?

If we now have controlled substances that are primarily narcotics, but additional illegal drugs can be added as they are designed, so that if a new psychedelic drug is cooked up in a lab in Berkeley, that would be subject to (f), whereas heroin would not be?

Is that right?

[Pause.]

Ms. LOFGREN. That's to counsel.

Mr. BERINGER. I believe that that would fall under the emergency exemption.

[Pause.]

The CHAIRMAN. Is there further discussion on the amendment by the gentleman from Massachusetts?

[No response.]

Mr. OLVER. Mr. Chairman, I move the previous question.

The CHAIRMAN. The gentleman moves the previous question on his amendment.

The Chair will put the question.

All those in favor of the gentleman's amendment will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say nay.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair, the nays have it.

Mr. OLVER. Mr. Chairman, I would like a roll call vote on the question.

The CHAIRMAN. The gentleman requests a roll call vote.

The Clerk will call the roll.

The CLERK. Mr. Walker?

The CHAIRMAN. No.

The CLERK. Mr. Walker votes no.

Mr Brown?

[No response.]

The CLERK. Mr. Sensenbrenner?

Mr. SENSENBRENNER. No.

The CLERK. Mr. Sensenbrenner votes no.

Mr. Hall?

Mr. HALL. No.

The CLERK. Mr. Hall votes no.
Mr. Boehlert?
[No response.]
The CLERK. Mr. Traficant?
Mr. TRAFICANT. No.
The CLERK. Mr. Traficant votes no.
Mr. Fawell?
Mr. FAWELL. No.
The CLERK. Mr. Fawell votes no.
Mr. Hayes?
[No response.]
The CLERK. Mrs. Morella?
Mrs. MORELLA. Aye.
The CLERK. Mrs. Morella votes aye.
Mr. Tanner?
[No response.]
The CLERK. Mr. Weldon of Pennsylvania?
Mr. CURT WELDON. No.
The CLERK. Mr. Weldon votes no.
Mr. Geren?
Mr. GEREN. No.
The CLERK. Mr. Geren votes no.
Mr. Rohrabacher?
Mr. ROHRABACHER. No.
The CLERK. Mr. Rohrabacher votes no.
Mr. Roemer?
Mr. ROEMER. No.
The CLERK. Mr. Roemer votes no.
Mr. Schiff?
Mr. SCHIFF. No.
The CLERK. Mr. Schiff votes no.
Mr. Cramer?
[No response.]
The CLERK. Mr. Barton?
[No response.]
The CLERK. Mr. Barcia?
Mr. BARCIA. Aye.
The CLERK. Mr. Barcia votes aye.
Mr. Calvert?
Mr. CALVERT. No.
The CLERK. Mr. Calvert votes no.
Mr. McHale?
Mr. MCHALE. Aye.
The CHAIRMAN. Mr. McHale votes aye.
Mr. Baker?
Mr. BAKER. No.
The CLERK. Mr. Baker votes no.
Ms. Harman?
[No response.]
The CLERK. Mr. Bartlett?
Mr. BARTLETT. No.
The CLERK. Mr. Bartlett votes no.
Ms. Johnson?
Ms. JOHNSON. Aye.

The CLERK. Ms. Johnson votes aye.
Mr. Ehlers?
Mr. EHLERS. No.
The CLERK. Mr. Ehlers votes no.
Mr. Minge?
Mr. MINGE. No.
The CLERK. Mr. Minge votes no.
Mr. Wamp?
Mr. WAMP. No.
The CLERK. Mr. Wamp votes no.
Mr. Olver?
Mr. OLVER. Yes.
The CLERK. Mr. Olver votes yes.
Mr. Weldon of Florida?
Mr. DAVE WELDON. No.
The CLERK. Mr. Weldon votes no.
Mr. Hastings?
[No response.]
The CLERK. Mr. Graham?
Mr. GRAHAM. No.
The CLERK. Mr. Graham votes no.
Ms. Rivers?
Ms. RIVERS. Aye.
The CLERK. Ms. Rivers votes aye.
Mr. Salmon?
Mr. SALMON. No.
The CLERK. Mr. Salmon votes no.
Ms. McCarthy?
[No response.]
The CLERK. Mr. Davis?
Mr. DAVIS. No.
The CLERK. Mr. Davis votes no.
Mr. Ward?
Mr. WARD. Yes.
The CLERK. Mr. Ward votes aye.
Mr. Stockman?
Mr. STOCKMAN. No.
The CLERK. Mr. Stockman votes no.
Ms. Lofgren?
Ms. LOFGREN. Aye.
The CLERK. Ms. Lofgren votes aye.
Mr. Gutknecht?
Mr. GUTKNECHT. No.
The CLERK. Mr. Gutknecht votes no.
Mr. Doggett?
Mr. DOGGETT. Aye.
The CLERK. Mr. Doggett votes aye.
Mrs. Seastrand?
Mrs. SEASTRAND. No.
The CLERK. Mrs. Seastrand votes no.
Mr. Doyle?
Mr. DOYLE. No.
The CLERK. Mr. Doyle votes no.
Mr. Tiahrt?

Mr. TIAHRT. No.
The CLERK. Mr. Tiahrt votes no.
Ms. Jackson-Lee?
Ms. JACKSON-LEE. Aye.
The CLERK. Ms. Jackson-Lee votes aye.
Mr. Largent?
Mr. LARGENT. No.
The CLERK. Mr. Largent votes no.
Mr. Luther?
Mr. LUTHER. Aye.
The CLERK. Mr. Luther votes aye.
Mr. Hilleary?
Mr. HILLEARY. No.
The CLERK. Mr. Hilleary votes no.
Mrs. Cubin?
Mrs. CUBIN. No.
The CLERK. Mrs. Cubin votes no.
Mr. Foley?
Mr. FOLEY. No.
The CLERK. Mr. Foley votes no.
Mrs. Myrick?
Mrs. MYRICK. No.
The CLERK. Mrs. Myrick votes no.
Mr. BARTON. Mr. Chairman?
The CHAIRMAN. Mr. Barton?
Mr. BARTON. How am I recorded.
The CHAIRMAN. How's Mr. Barton recorded?
The CLERK. Mr. Barton is not recorded.
Mr. BARTON. I would like to be recorded as no in person.
The CLERK. Mr. Barton votes no.
The CHAIRMAN. That's the only way you can be recorded these days.
Mr. BARTON. That's true.
The CHAIRMAN. The gentleman from New York.
Mr. BOEHLERT. How am I recorded?
The CLERK. Mr. Boehlert is not recorded.
Mr. BOEHLERT. Aye.
The CHAIRMAN. Mr. Boehlert votes aye.
The Clerk will report.
The CLERK. Mr. Chairman, I count 12 yeas and 31 nays.
The CHAIRMAN. The amendment is not agreed to.
Any other amendments to Section B?
Mr. Ward wanted to be recognized to explain——
Mr. WARD. I just would ask unanimous consent that I be not recorded but show, reflect that I was not here for the vote on Mr. Brown's amendment for Section 3002, the savings clause. Had I been here, I would have voted yes, and I would like the record to reflect that.
The CHARMAN. The record will reflect it. We thank the gentleman.
Are there further amendments to Subsection B, Subtitle B?
Mr. HALL. Mr. Chairman?
The CHAIRMAN. The gentleman from Texas.

Mr. HALL. Mrs. Harman had an amendment to Subtitle D and it involved the National Aeronautics and Space Administration, and I will not offer it but I would——

The CHAIRMAN. That's the new Title D, I would say.

Mr. HALL. Yes, it's to add a title.

The CHAIRMAN. Yes, it's to add a title.

Mr. HALL. But we're not requesting that. I just want to be assured that we can put something in the report language to show whether or not this applies to NASA and the space program.

The CHAIRMAN. Okay. We're not there yet, but I can assure the gentleman that we can put in report language the situation as it applies to NASA.

Mr. HALL. I thank the Chair.

The CHAIRMAN. Any further amendments to Subtitle B?

[No response.]

The CHAIRMAN. If not, the Chair moves now to Subtitle C. Amendments to Subtitle C?

Mr. ROEMER. Mr. Chairman?

The CHAIRMAN. Mr. Roemer?

Mr. ROEMER. Mr. Chairman, I have an amendment but before I, or as I'm asking the Clerk to distribute the amendment drafted to the Walker Amendment in the nature of a substitute, I would make a unanimous consent proposal that we begin to apply the five-minute rule.

It's after 10:00 o'clock at night. You've been exceedingly fair in allowing members to talk at length for the last few hours.

We've been here since 10:00 o'clock this morning, and I will live under the five-minute rule.

The CHAIRMAN. I'm delighted to be able to accommodate that unanimous consent request.

Is there objection?

[No response.]

The CHAIRMAN. Without objection, we will apply the five minute rule.

Mr. ROEMER. Mr. Chairman, first of all, my amendment deals with peer review, which is a very important section, especially to people such as myself that support this bill.

And I would like to compliment you on what you've done to strengthen the peer review process. It begins on page 22 and goes through page 25.

In particular, I'm supportive of your response to peer review, your availability to the public where you insist that all peer review comments or conclusions and the agencies' responses shall be made available to the public in addition to Section (f) on line 19 on page 24, 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.

I think these are all helpful in putting together a strong peer review process.

My amendment would do three things to further strengthen this provision.

One, it would make sure that peer review is used in a very focused and targeted manner, and not one where we waste tax-

payers' resources, or scientists' resources, so that the trigger is at a level whereby we're not going after superfluous things.

Secondly, that when we put these peer review panels together, that the participants be professionally qualified and that the scientists not have any conflict of interest that would bias their outcome.

Thirdly, that we establish a time line with deadlines in this process so that they cannot use dilatory tactics to delay this process from happening. That we don't have unnecessary bureaucratic delay.

That is what my amendment accomplishes, Mr. Chairman, I would encourage my colleagues to support it.

All done under five minutes, Mr. Chairman.

The CHAIRMAN. I thank the gentleman for doing that.

The Chair is having some problem because this is a different language than what the gentleman had submitted earlier as part of the package. And it appears now to be a total rewrite of the peer review process that's included in the bill.

My concern about that is that what we had included in the bill was very much related to that which we heard in testimony with regard to peer review.

In dealing with conflict of interest questions and so on, we heard questions raised by the Committee and then responded to by the witnesses, questioning, you know, who could participate in peer review, and got a fairly substantial record in the Committee that peer review should, in fact, include people who have some knowledge in the areas in which they're acting.

And it is not clear to me that the gentleman's attempt here to change the language with regard to conflict of interest isn't in conflict with the testimony we received before the Committee.

So I am concerned at this point in a Section that we thought we got pretty well in hand based upon what we heard in testimony is not being substantially rewritten without a clear reference to the record that was before the Committee.

Mr. ROEMER. Well, I would say to the Chairman's questions that what my amendment does, and I will read directly from the amendment:

"It shall result in the appointment of peer reviewers who are qualified on the basis of their professional training or expertise as reflected in the record of peer reviewed publications or equivalent."

I don't think that there's anything too controversial about a conflict of interest there.

Secondly, it says, and I will read from the amendment:

"May provide specific and reasonable deadlines for peer review panels to submit reports under subsection" so that they can't go at length.

I don't think that those are controversial. And while I cannot site somebody specifically at hearings saying that we should put deadlines in for this process or that we should make sure that they don't have ethical conflicts, I would think that these would make sense.

The CHAIRMAN. Well, I would say to the gentleman that in the bill already in the way it's written, we have the specific and reasonable deadlines for peer review panels. That's already in the bill.

By limiting, in the way he does, who may be selected for peer review panels to only those people who have published, I would say that the qualifications for people to be engaged in peer review panels go well beyond that criteria, and traditionally have.

And so the gentleman is, in what he has read to the Committee, providing a very, very severe limitation. And I'm not so certain that we are prepared, at this point, to accept a limitation that severe for who may be a part of a peer review panel.

Mr. ROEMER. Mr. Chairman, what about the language in the first paragraph of my amendment that says simply "and the peer reviewers do not have a financial or other interest that will or may reasonably be expected to create a bias in favor of retaining an outcome that is consistent with such financial or other interests"?

[Pause.]

The CHAIRMAN. What we have in the bill as it's written is on page 22, "shall not exclude peer reviewers with a substantial or relevant expertise merely because they represent entities that may have a potential interest in the outcome, providing the interest is fully disclosed to the agency, and in a case of regulatory decision affecting a single entity, no peer reviewer representing such agency may be included on the panel."

So we have in fact excluded people who would be directly involved, and required full disclosure for all others.

Again, based upon the testimony that we received, that appeared to be the right way to assure that potential conflict of interests were dealt with.

Mr. ROEMER. Mr. Chairman, since you were so gracious to me in accepting my first two amendments, I would certainly like to work with you in terms of clarifying both the financial interest and the deadlines, and I will withdraw the amendment.

The CHAIRMAN. Well, I thank the gentleman. We would certainly be glad to work with him to clarify in the report any questions that he might have with regard to the language we have here. If he doesn't feel that goes far enough, this would certainly be an amendment I think that could be taken to the floor at the appropriate time.

Mr. ROEMER. I thank the Chairman.

The CHAIRMAN. I think the gentleman, and the gentleman, with unanimous consent, withdraws the amendment.

Any other amendments in Subtitle C?

Mr. DOGGETT. Yes. Mr. Chairman.

I have an amendment dealing with the same subsection at the desk that I can explain as it's being distributed because it simply revises the subsection you were just reviewing with Mr. Roemer.

I have the same concern that he expressed and slightly different language in doing it.

But just to make it clear that there shall not be peer reviewers participating in these studies who have a potential interest in the outcome, rather than depending on them to recuse themselves, this would make it clear that peer reviewers are not to be participating. That it's not sufficient to simply have disclosure.

[Pause.]

The CHAIRMAN. Well, I thank the gentleman, and it's the discussion that we just had.

Again, the testimony before the Committee indicated that to ensure that we have the best minds involved in reviewing the quality of risk assessments, we can't afford to ignore talented and qualified individuals, regardless of where they come from, so long as any perceived or real interest in the outcome is fully disclosed. And that is what we're attempting to do in our amendment.

The gentleman would substantially narrow the numbers of people that could be brought into the process and in fact because of the broad nature of the language that he gives us, could assure that practically no one would be qualified to review anything that was actually in their field.

And it seems to me that that reduces the quality of the peer review process in ways that would be harmful. At least again that follows the testimony that we had before the Committee in that regard.

Mr. DOGGETT. Respecting the Chairman's view, I think it's important to have a strong conflict of interest provision in this statute and assure we don't have, as peer reviewers, people who have an axe to grind who are basically getting paid by the very folks who have a stake in what is occurring here, and that we don't have a situation of the peer reviewer being the fox guarding the henhouse.

And so I'd move adoption of the amendment.

The CHAIRMAN. Well, I thank the gentleman for his further explanation.

As I say, I think we have to have some trust that Federal officials do in fact exercise good judgment in these regards in picking the peer review panels.

And secondly, we in fact do, under our process, require full disclosure, and the gentleman obviously disagrees with the concept of full disclosure on that.

The gentleman has moved his amendment.

Those in favor of the amendment will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say no.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair, the noes have it.

Mr. ROEMER. Mr. Chairman, I would like a record vote on this because conflict of interest is an important provision.

The CHAIRMAN. The Clerk will call the roll.

The CLERK. Mr. Walker?

The CHAIRMAN. No.

The CLERK. Mr. Walker votes no.

Mr. Brown?

[No response.]

The CLERK. Mr. Sensenbrenner?

Mr. SENSENBRENNER. No.

The CLERK. Mr. Sensenbrenner votes no.

Mr. Hall?

Mr. HALL. Aye.

The CLERK. Mr. Hall votes aye.

Mr. Boehlert?

Mr. BOEHLERT. No.

The CLERK. Mr. Boehlert votes no.

Mr. Traficant?

Mr. TRAFICANT. Aye.
The CLERK. Mr. Traficant votes aye.
Mr. Fawell?
Mr. FAWELL. No.
The CLERK. Mr. Fawell votes no.
Mr. Hayes?
[No response.]
The CLERK. Mrs. Morella?
Ms. MORELLA. No.
The CLERK. Mrs. Morella votes no.
Mr. Tanner?
[No response.]
The CLERK. Mr. Weldon of Pennsylvania?
Mr. CURT WELDON. No.
The CLERK. Mr. Weldon votes no.
Mr. Geren?
Mr. GEREN. Aye.
The CLERK. Mr. Geren votes aye.
Mr. Rohrabacher?
Mr. ROHRABACHER. No.
The CLERK. Mr. Rohrabacher votes no.
Mr. Roemer?
[No response.]
The CLERK. Mr. Schiff?
Mr. SCHIFF. No.
The CLERK. Mr. Schiff votes no.
Mr. Cramer?
Mr. ROEMER. Mr. Chairman, how am I recorded?
The CLERK. Mr. Roemer, you're not recorded.
Mr. ROEMER. Yes.
The CLERK. Mr. Roemer votes yes.
The CLERK. Mr. Cramer?
[No response.]
The CLERK. Mr. Barton?
[No response.]
The CLERK. Mr. Barcia?
Mr. BARCIA. Yes.
The CLERK. Mr. Barcia votes aye.
Mr. Calvert?
Mr. CALVERT. No.
The CLERK. Mr. Calvert votes no.
Mr. McHale?
Mr. MCHALE. Aye.
The CLERK. Mr. McHale votes aye.
Mr. Baker?
Mr. BAKER. No.
The CLERK. Mr. Baker votes no.
Ms. Harman?
[No response.]
The CLERK. Mr. Bartlett?
Mr. BARTLETT. No.
The CLERK. Mr. Bartlett votes no.
Ms. Johnson?
Ms. JOHNSON. Aye.

The CLERK. Ms. Johnson votes aye.
Mr. Ehlers?
Mr. EHLERS. No.
The CLERK. Mr. Ehlers votes no.
Mr. Minge?
Mr. MINGE. Aye.
The CLERK. Mr. Minge votes aye.
Mr. Wamp?
Mr. WAMP. No.
The CLERK. Mr. Wamp votes no.
Mr. Olver?
Mr. OLVER. Yes.
The CLERK. Mr. Olver votes aye.
Mr. Weldon of Florida?
Mr. DAVE WELDON. No.
The CLERK. Mr. Weldon votes no.
Mr. Hastings?
[No response.]
The CLERK. Mr. Graham?
Mr. GRAHAM. No.
The CLERK. Mr. Graham votes no.
Ms. Rivers?
Ms. RIVERS. Aye.
The CLERK. Ms. Rivers votes aye.
Mr. Salmon?
Mr. SALMON. No.
The CLERK. Mr. Salmon votes no.
Ms. McCarthy?
[No response.]
The CLERK. Mr. Davis?
Mr. DAVIS. No.
The CLERK. Mr. Davis votes no.
Mr. Ward?
Mr. WARD. Aye.
The CLERK. Mr. Ward votes aye.
Mr. Stockman?
Mr. STOCKMAN. No.
The CLERK. Mr. Stockman votes no.
Ms. Lofgren?
Ms. LOFGREN. Aye.
The CLERK. Ms. Lofgren votes aye.
Mr. Gutknecht?
Mr. GUTKNECHT. No.
The CLERK. Mr. Gutknecht votes no.
Mr. Doggett?
[No response.]
The CLERK. Mrs. Seastrand?
Ms. SEASTRAND. No.
The CLERK. Mrs. Seastrand votes no.
Mr. Doyle?
Mr. DOYLE. Aye.
The CLERK. Mr. Doyle votes aye.
Mr. Tiahrt?
Mr. TIAHRT. No.

The CLERK. Mr. Tiahrt votes no.
Ms. Jackson Lee?
Ms. JACKSON LEE. Aye.
The CLERK. Ms. Jackson Lee votes aye.
Mr. Largent?
Mr. LARGENT. No.
The CLERK. Mr. Largent votes no.
Mr. Luther?
Mr. LUTHER. Aye.
The CLERK. Mr. Luther votes aye.
Mr. Hilleary?
Mr. HILLEARY. No.
The CLERK. Mr. Hilleary votes no.
Mrs. Cubin?
Ms. CUBIN. No.
The CLERK. Ms. Cubin votes no.
Mr. Foley?
Mr. FOLEY. No.
The CLERK. Mr. Foley votes no.
Mrs. Myrick?
Ms. MYRICK. No.
The CLERK. Mrs. Myrick votes no.
Mr. DOGGETT. Mr. Chairman, I'm not sure I heard my name repeated. Since I sponsored the amendment, I'd like to be sure I'm recorded in favor of it.
The CLERK. Mr. Doggett votes aye.
The CHAIRMAN. Are there any further members wishing to vote?
[No response.]
The CHAIRMAN. If not, the Clerk will report.
[Pause.]
The CLERK. Mr. Chairman, I count 16 yeas, 26 nays.
The CHAIRMAN. The amendment is not agreed to.
Any other amendments to Subtitle C?
Mr. BOEHLERT. Mr. Chairman, I ask unanimous consent to consider my amendment en bloc, and I think it's been passed out already.
The CHAIRMAN. Without objection.
It needs to be distributed.
[Pause.]
Mr. BOEHLERT. It's titled. This is a troika. Morella, Boehlert, Ehlers. What a team that is.
The CHAIRMAN. The Clerk will distribute the amendment.
Mr. BOEHLERT. Mr. Chairman, would you like me to start?
The CHAIRMAN. Yes, the gentleman's recognized for five minutes.
Mr. BOEHLERT. Mr. Chairman, this amendment would improve the bill, and I think facilitate its implementation.
This amendment reflects concerns which were raised by both industry and the environmental organizations and by various members of this Committee, Republicans and Democrats alike.
In the area of risk prioritization, specifically we propose a new Subtitle IV, page 2 in the bill, containing—
The CHAIRMAN. The gentleman will suspend. We will be in order so that the gentleman from New York has a chance to present his amendment.

Mr. BOEHLERT. Well, they were so excited about it, Mr. Chairman, the enthusiasm.

The CHAIRMAN. It didn't sound like cheers to me. [Laughter.]

So I wanted to get the Committee in order. [Laughter.]

Mr. BOEHLERT. I move that the Chairman get an examination, hearing.

First, in the new Section 3401, we would mandate the agencies to prioritize threats to human health and the environment.

Two, to identify opportunities for the most significant risk reductions; and

Three, to direct their resources accordingly.

I would point out that Title III, like other bills before the Congress, would erect new and potentially costly procedural hurdles to agency rulemaking.

This section would ensure that the agencies direct their relatively scarce resources in areas where they can do the most good for the American people and for the environment.

Another new section, Section 3402 in Subtitle IV would fill an important void in the original draft of Title III.

Although most of us would profess a belief in the usefulness of risk assessment techniques, I don't think any of us can really claim that risk assessment is a highly reliable or test science at this point. Further research is essential if risk assessments are to evolve into a mainstay of public policy decisionmaking.

Moreover, we do not know how many truly competent practitioners of risk assessment there are in this country. Clearly, HR 9 would place significant new demands on this professional group, both for assessments and for conducting peer reviews.

The new section 3402, formulated with help from our distinguished former colleague, Mr. Zimmer, would require regulatory agency heads to report regularly on risk research needs within the agencies. They would also have to assess needs for training individuals competent in risk assessment.

Agencies would have to develop strategies to address these needs and report regularly to Congress on their progress.

The research would address a variety of important unknowns in the risk field including the effect of multiple chemical exposures, the effect of toxins on ecological health, and the magnitude of noncancer risks posed by pollutants.

Finally, on page 1 and 2 of the amendment, we offer several technical and clarifying changes to the bill.

These changes would include improvements to the language on peer review, ensuring that these panels are broadly based and fully representative of the range of scientific opinion.

This amendment would streamline and strengthen Title III.

Let me add, in urging adoption of these changes, that I have other broad concerns remaining about the bill. I won't go into them, Mr. Chairman, but I think what we would like to see right now is these en bloc amendments, which are significant improvements to the original bill and also to the Chairman's part, be embraced.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank the gentleman.

The Chair is prepared to accept this amendment.

I would point out that in accepting an amendment earlier of Mr. Roemer's, we accepted language very similar to this, to some of the final sections in the bill.

It is almost exactly the same. In accepting this amendment, I want to assure the gentleman from Indiana and the authors of this amendment, that what we will do is work out whatever small points of difference there are, but I don't believe that there's really anything here that is in major conflict.

But I don't want to lend confusion here. Both are on the same path, and I think we can work it out.

Mr. BOEHLERT. I appreciate the Chair's enlightened approach to this

The CHAIRMAN. Okay.

Mr. ROEMER. Mr. Chairman, I'd be happy to work with the gentleman from New York on this. I offered mine in Subtitle A, Section 3106, and as you said, they are very similar in terms of the research and training in risk assessment, and I've offered amendments where we don't want to be duplicative either, and I would want to make sure that we're not doing that here, and look forward to working with him.

Mr. BOEHLERT. The gentlelady from Maryland authored this language on our side and I would recognize her.

Ms. MORELLA. Mr. Chairman, I just simply want to say I look forward to working with the other members of the Committee.

The CHAIRMAN. I thank the gentlelady.

Mr. GEREN. Mr. Chairman.

The CHAIRMAN. Mr. Geren.

Mr. GEREN. Mr. Chairman, I had planned to offer an amendment very similar to Mr. Boehlert's. In fact, the first part of it would be identical, and add some additional provisions which I discussed with your staff.

And I would like to just mention it briefly. I intend to withdraw the amendment, but I think that we need to go further than Mr. Boehlert has gone, and my amendment would add to the end of the risk prioritization section of the amendment. It would require each covered agency or department to submit a report to Congress on how it's implementing the program.

These reports would be a notification to Congress of any constraints that would impede each agency's ability to achieve cost effective reduction.

Additionally, this amendment would help set priorities across agencies or departments by requiring OMB to contract with an appropriate qualified organization to rank those risks to human health, safety, or the environment.

I feel like this would be an important addition to Mr. Boehlert's amendment, and I had prepared this amendment to offer tonight.

It's 31 in the packet, but at this time, Mr. Chairman, with your agreement to work with us on some of these issues, I'd like unanimous consent to withdraw the amendment.

The CHAIRMAN. Well, I thank the gentleman for that. I appreciate his not going ahead and offering the amendment. Obviously what he's doing has merit, and what we want to do is work with him. I will ask the staff to work with your staff and with the gentleman from New York and his colleagues, to see if we can't come

up with an agreed upon solution as we move toward Rules Committee.

If we can do that, I'm certainly prepared then to accept an amendment on the floor that everyone has worked out.

Mr. GEREN. Thank you, Mr. Chairman.

With that, I'll ask unanimous consent to withdraw my amendment.

The CHAIRMAN. I thank the gentleman.

Mr. ROEMER. Mr. Chairman, could I just add, I think that this is a very important part of the section, as well, too, and Mr. Geren and I would very much like to work with the gentlelady from Maryland and the gentleman from New York on this.

In clarifying it, I think we do need to go a little bit further. As these agencies come up with risk assessments, there are limited resources as to how to implement those risk assessments. They should, therefore, prioritize those risk assessments, given the diminishing resources that we have to implement them.

That only makes sense if we're going to go through this exercise.

So I think we do need to strengthen the last part of this language and I think we do need to work on making sure the first part isn't repetitive.

And I would thank the Chair.

The CHAIRMAN. Thank the gentleman.

The gentleman from New York moves his amendment.

Those in favor will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed, say no.

[No response.]

The CHAIRMAN. The ayes have it. The amendment is carried.

Further amendments to Subtitle C?

[No response.]

The CHAIRMAN. Hearing none, Subtitle C is closed.

We will not accept amendments coming at the end of the bill that would be in Subtitle D.

Mr. DOGGETT. Mr. Chairman, I have one at the desk.

The CHAIRMAN. The gentleman from Texas has an amendment at the desk.

Mr. DOGGETT. It's a very short amendment, one sentence, an amendment that I understand has been put on a number of bills that have come out of this Committee in the past. It is a sunset amendment.

I think that many of the problems that particularly the members of the majority have emphasized in the course of the debate of this bill would have been avoided, had there been sunset provisions on some of these regulatory programs.

I favor those. But I also favor them on other well-intentioned initiatives of which this is one.

And I think putting a limit on the life of this initiative and forcing the Committee and the Congress to look at it again would be healthy.

And so this places a five-year life on this legislation. That's all it does. One sentence.

The CHAIRMAN. Well, I thank the gentleman.

We are in fact attempting to deal with this across a broad base, and since what we are attempting to do here is acquire good science, I would suggest that maybe we ought not sunset good science as of the year 2000 and go back to bad science.

So the Chair would oppose this amendment as being something which does not further the aims of bringing about the reforms that this bill attempts to put into place.

Mr. DOGGETT. Thanking the Chairman.

There rarely have been legislators in any legislative body who've introduced legislation that was bad legislation for bad science or bad anything else; it's always good. But sometimes good intentions go astray and the only way to assure they don't is to force the legislative body for bills you support and bills you don't support to have to review it again.

And that's all this amendment does, and I would move its adoption.

The CHAIRMAN. Well, I would say to the gentleman that when you sunset provisions, what you do is you end their life. You don't force review. And in this particular case, I have a feeling that what we're doing here will be subject to much review in the Congress.

I would prefer to have that review aimed at either modifying or extending the program, not aimed at having a sure kill of the program at a particular time, and so would continue to say to the gentleman that I oppose the amendment.

Further discussion on the amendment?

[No response.]

The CHAIRMAN. If not, the Chair will put the question.

Those in favor of the amendment will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed, say no.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair, the noes have it.

Mr. DOGGETT. Mr. Chairman, I need a record vote on that one.

The CHAIRMAN. The gentleman likes record votes and is entitled to one.

And the Clerk will call the roll.

Mr. BOEHLERT. Mr. Chairman, can we do it by a show of hands?

The CHAIRMAN. The gentleman asked for a record vote. He's entitled to a record vote. He wants to have the names I think recorded.

Mr. BOEHLERT. Will the gentleman accept a division vote? You just want to see if you got the numbers?

Mr. DOGGETT. If our rules will permit the recording of the names of all the people who raise their hands, that's fine.

The CHAIRMAN. No. [Laughter.]

Mr. DOGGETT. Just as long as it's reflected in the report, I don't care how you record.

The CHAIRMAN. The Clerk will call the roll.

The CLERK. Mr. Walker?

The CHAIRMAN. No.

The CLERK. Mr. Walker votes no.

Mr. Brown?

[No response.]

The CLERK. Mr. Sensenbrenner?

Mr. SENSENBRENNER. No.

The CLERK. Mr. Sensenbrenner votes no.
Mr. Hall?
Mr. HALL. Aye.
The CLERK. Mr. Hall votes aye.
Mr. Boehlert?
Mr. BOEHLERT. No.
The CLERK. Mr. Boehlert votes no.
Mr. Traficant?
Mr. TRAFICANT. Aye.
The CLERK. Mr. Traficant votes aye.
Mr. Fawell?
Mr. FAWELL. No.
The CLERK. Mr. Fawell votes no.
Mr. Hayes?
[No response.]
The CLERK. Mrs. Morella?
Mrs. MORELLA. No.
The CLERK. Mrs. Morella votes no.
Mr. Tanner?
[No response.]
The CLERK. Mr. Weldon of Penssylvania?
Mr. CURT WELDON. No.
The CLERK. Mr. Weldon votes no.
Mr. Geren?
Mr. GEREN. No.
The CLERK. Mr. Geren votes no.
Mr. Rohrabacher?
Mr. ROHRABACHER. No.
The CLERK. Mr. Rohrabacher votes no.
Mr. Roemer?
Mr. ROEMER. No.
The CLERK. Mr. Roemer votes no.
Mr. Schiff?
Mr. SCHIFF. No.
The CLERK. Mr. Schiff votes no.
Mr. Cramer?
[No response.]
The CLERK. Mr. Barton?
[No response.]
The CLERK. Mr. Barcia?
Mr. BARCIA. No.
The CLERK. Mr. Barcia votes no.
Mr. Calvert?
Mr. CALVERT. No.
The CLERK. Mr. Calvert votes no.
Mr. McHale?
Mr. MCHALE. Aye.
The CLERK. Mr. McHale votes aye.
Mr. Baker?
Mr. BAKER. No.
The CLERK. Mr. Baker votes no.
Ms. Harman?
[No response.]
The CLERK. Mr. Bartlett?

Mr. BARTLETT. No.
The CLERK. Mr. Bartlett votes no.
Ms. Johnson?
Ms. JOHNSON. Aye.
The CLERK. Ms. Johnson votes aye.
Mr. Ehlers?
Mr. EHLERS. No.
The CLERK. Mr. Ehlers votes no.
Mr. Minge?
Mr. MINGE. Aye.
The CLERK. Mr. Minge votes aye.
Mr. Wamp?
Mr. WAMP. No.
The CLERK. Mr. Wamp votes no.
Mr. Olver?
Mr. OLVER. Yes.
The CLERK. Mr. Olver votes aye.
Mr. Weldon of Florida?
Mr. DAVE WELDON. No.
The CLERK. Mr. Weldon votes no.
Mr. Hastings?
[No response.]
The CLERK. Mr. Graham?
Mr. GRAHAM. No.
The CLERK. Mr. Graham votes no.
Ms. Rivers
Ms. RIVERS. Aye.
The CLERK. Ms. Rivers votes aye.
Mr. Salmon?
Mr. SALMON. No.
The CLERK. Mr. Salmon votes no.
Ms. McCarthy?
[No response.]
The CLERK. Mr. Davis?
Mr. DAVIS. No.
The CLERK. Mr. Davis votes no.
Mr. Ward?
Mr. WARD. Aye.
The CLERK. Mr. Ward votes aye.
Mr. Stockman?
Mr. STOCKMAN. No.
The CLERK. Mr. Stockman votes no.
Ms. Lofgren?
Ms. LOFGREN. Aye.
The CLERK. Ms. Lofgren votes aye.
Mr. Gutknecht?
Mr. GUTKNECHT. No.
The CLERK. Mr. Gutknecht votes no.
Mr. Doggett?
Mr. DOGGETT. Aye.
The CLERK. Mr. Doggett votes aye.
Mrs. Seastrand?
Mrs. SEASTRAND. No.
The CLERK. Mrs. Seastrant votes no.

Mr. Doyle?
Mr. DOYLE. Aye.
The CLERK. Mr. Doyle votes aye.
Mr. Tiahrt?
Mr. TIAHRT. No.
The CLERK. Mr. Tiahrt votes no.
Ms. Jackson-Lee?
Ms. JACKSON-LEE. Aye.
The CLERK. Ms. Jackson-Lee votes aye.
Mr. Largent?
Mr. LARGENT. No.
The CLERK. Mr. Largent votes no.
Mr. Luther?
Mr. LUTHER. Aye.
The CLERK. Mr. Luther votes aye.
Mr. Hilleary?
Mr. HILLEARY. No.
The CLERK. Mr. Hilleary votes no.
Mrs. Cubin?
Mrs. CUBIN. No.
The CLERK. Mrs. Cubin votes no.
Mr. Foley?
Mr. FOLEY. No.
The CLERK. Mr. Foley votes no.
Mrs. Myrick?
Mrs. MYRICK. No.
The CLERK. Mrs. Myrick votes no.
Mr. Chairman, I count 13 yeas, 29 nays.
The CHAIRMAN. The amendment is not agreed to.
Any other amendments to Subtitle D?
Mr. ROEMER. Mr. Chairman.
The CHAIRMAN. Mr. Roemer.
Mr. ROEMER. I happily offer the last amendment of the night, I hope, on a serious topic on judicial review, and I will be very brief in explaining this.
The CHAIRMAN. The faster you do it, the more we are assured that there won't be more amendments.
Mr. ROEMER. The move votes I get.
That aren't bred in the process.
I'm offering this amendment again to strength this bill Mr. Chairman, and many of us are concerned with the original bill which was silent, and I believe that now, with your Substitute, it is still vague with respect to judicial review and particularly interim judicial review.
The whole purpose of moving this legislation forward is to make sure that lawyers don't get more of a license to litigate, and they don't make money on this law.
This judicial review amendment clarifies that the money will go to implement risk assessment rather than to feed at the lawyers' troughs for them to litigate at every step of the way of trying to implement this new law.
So while this language in your new substitute I think is better than the original language, I think it is still vague.

Secondly, while I am not an attorney, in counsel, in drafting this amendment, I think it is very important for us to consider, what is in front of the court if they do try to litigate in this.

We want to make sure this law is implemented and exercised and not stopped and not delayed and bureaucrats at the different Federal agencies don't throw monkey wrenches into the works to try to stop a good law from going through.

That's what this amendment would try to do.

Finally, I think you could call this the one-bite-out-of-the-apple amendment. This will ensure that whether you are an interest group, an industry, environmental, public interest or business competitor, that you get one bite out of the apple and not a bunch of different bites out of the apple to try to stop this risk assessment law from being implemented, once it reaches the agency.

So I would encourage my colleagues to support this legislation, this amendment, and I think this seriously improves the rather vague language in your legislation as it reads now.

The CHAIRMAN. The gentleman from California wishes to be recognized.

Mr. BAKER. We described, during the hearings, and I'm sympathetic to what you're trying to do, but we described during the hearings, the case where the Corps of Engineers moves in on our project, that the city and the locality wants and the person building the project wants, finds three weeds that are indigenous to a wetlands and ties up your project.

You have not right of review, you have no time limit, there's no way to get your project out from under this cloud.

So when you say in the first paragraph, nothing in this Title creates any right to judicial or administrative review, you're leaving the law the way it is.

And we want the victims out there that are being squashed by the bureaucracies to have, when they feel they're not getting heard or in a timely manner, they have to have a right to somewhere in the court is that right.

So I think you're undoing judicial review where we want that safeguard there. None of this wants to turn this into a full employment act for lawyers, but you have almost said, in your first paragraph, you don't have the right to review.

Mr. ROEMER. If the gentleman would yield.

What this legislation says is nothing like that at all. It just says that you have one final actions. You cannot litigate at every step of the way as that agency tries to promulgate this risk assessment forward, you get one bite of the apple and that is once we have finally promulgated the risk assessment.

Mr. MINGE. Will the gentleman yield?

Mr. ROEMER. I'd be happy to yield.

Mr. MINGE. I don't claim a continuing expertise in this, but for seven years I taught administrative law in a law school

And the section that we have here that's been offered is an attempt to use language which is consistent with the Administrative Procedures Act. I've not had a chance to look at that, but it uses language which bears some resemblance to what's in the Administrative Procedures Act, and it really is designed to ensure that there is review of final agency action, meaning the rule itself.

And I think the ambiguity that's created by the language on page 25 is that the risk assessment process may be an independent basis for review and review may become available during that process.

Now I think it's a stretch to find that judicial review or that extra review feedbag for lawyers in the proposal, but arguably it's there somewhere and it'll take several years to shake this out with numerous appeals in the courts.

I think that the concern that you have, that you've expressed that you want people who are under the heel of a Federal agency to have the opportunity to get out from under that heel, is not forwarded by the legislation that we're considering in terms of quick judicial review, and it's not defeated by the amendment being offered.

We're talking essentially about apples and oranges, and if you want judicial review in that context, I think that it will take a section different than what's in the Walker Substitute.

So I'm not saying that the Roemer amendment is the best thing since sliced bread here. I don't want to imply that. But I do think it takes us one step further, one step beyond what's in the Walker Substitute, and makes it clear that we are not creating a feedbag for lawyers, if you want to characterize this problem in those terms.

Mr. ROEMER. I thank the gentleman from Minnesota for that pseudo-endorsement. [Laughter.]

Mr. HALL. Will the gentleman yield.

The CHAIRMAN. The gentleman from Pennsylvania, Mr. McHale is recognized.

Mr. MCHALE. Thank you, Mr. Chairman.

Mr. CHAIRMAN. I support Mr. Roemer's amendment. I listened carefully the other day as Professor McGarrity from the University of Texas Law School compared the content of the original draft of the legislative to the extensive litigation that has occurred regarding environmental impact statements under the National Environmental Policy Act.

Under NEPA, going back 20 years, we have had a whole body of case law develop interpreting the timing, the scope, and the adequacy of environmental impact statements.

It has been one of the most prolific areas of litigation in the last two decades.

Professor McGarrity said, and I think correctly, that if we enact this legislation without the Roemer amendment, in my opinion, we will see analogous legislation or analogous litigation over the next several decades, testing the validity, the scope, the adequacy, the timing of each and every risk assessment that occurs pursuant to the litigation.

I guarantee you Professor McGarrity is correct. If we don't accept the Roemer amendment, we're looking at a whole new field of litigation where individuals of a wide range of ideology will repeatedly, at great expense, over a long period of time, test the validity of individual risk assessments.

I don't think that's the intent of this legislation. I think the Roemer amendment is fully consistent with greater efficiency, better science and a limitation on litigation.

I urge its support.

Mr. SCHIFF. Mr. Chairman, I wonder if I could ask the sponsor of the amendment, so that I can follow this, is the sponsor saying that judicial review still exists but it's at the end of the process?

Is that the substance of the gentleman's amendment?

Mr. ROEMER. That's correct, and that's the way it exists in current law. So what we're saying to the gentleman from New Mexico is that if you are a drug company and you are competing with somebody else, and that drug company is two years ahead in terms of developing research for a new product, instead of waiting for the final rule to be issued and promulgated, they can try to make up for that two-year hiatus or delay by trying to litigate all along through this process, and unfairly catch up in that two-year period through litigation, rather than through competition.

That is how this loophole could be used to create a cottage industry for lawyers, and to really circumvent the intent of this law.

The intent of this law is to have the money go for risk assessment, not to lawyers for litigation.

Mr. SCHIFF. My only concern is when we say we don't want the money to go to litigation, we want the ability to litigate it at some point.

Mr. ROEMER. At one final point, once the rule has been issued, not all through every step of the process.

Mr. SCHIFF. All right. Let me just conclude by saying—I've obviously not had a lot of time to study this amendment—but it seems to me, from what I'm hearing, that the gentleman came up with the same compromise we came up with in the unfunded mandate legislation, which is to not allow interim stays and so forth.

Mr. ROEMER. That's correct.

Mr. SCHIFF. All right. I yield back, Mr. Chairman. Thank you.

The CHAIRMAN. Thank the gentleman.

Mr. HALL. Mr. Chairman?

The CHAIRMAN. Mr. Hall.

Mr. HALL. Strike the requisite number of words.

This seems to me, and I might ask the author, I think the amendment makes it clear that it doesn't expand the right to judicial review and Professor Minge, I took administrative law at Southern Methodist University, and I didn't have as good a professor as you probably were, but I did make the highest grade of all who failed that course. [Laughter.]

It seems to me that this does not spawn any new rights. It simply codifies existing rights.

Is that what you intend for it to do?

Mr. ROEMER. If the gentleman will yield, it doesn't expand, it simply preserves what the very esteemed and intelligent gentleman is talking about, despite his grades.

Mr. HALL. I yield back my time.

The CHAIRMAN. Thank the gentleman.

The Chair is concerned about this amendment because, while the gentleman says it tracks the Administrative Procedures Act, it is, in fact, new language beyond the Administrative Procedures Act.

If you want to stick with the Administrative Procedures Act, where we have a longstanding history of what the litigation is likely to do, that's exactly what we do in the language which is in the bill.

The language in the bill requires compliance. That in fact gets the one bite at the apple that the gentleman claims to be for.

Because under the Administrative Procedures Act, when you arrive at the end of the process, that's when judicial review is possible for those people affected by the rulemaking.

And so it seems to me that if we want to reduce the amount of potential litigation, what we do is stick with that which has at least some history, and we do not create new language that then can be newly interpreted by lawyers and giving them additional rights beyond the Administrative Procedures Act.

In my view, judicial review is essential and I am concerned that some of the language in this particular amendment seems to obviate judicial review, at least the initial parts of it.

We need some judicial review to assure that the Federal agencies are going to do what we tell them to do under this Act. We need to use a normal, time-tested judicial review procedure. That's what we do by referencing the Administrative Procedures Act.

Under our judicial review provision, a risk assessment, cost benefit certification, or peer review requirement could only be subject to judicial review when associated with a final agency action, like a rule, because that would be part of the Administrative record.

It seems to me that it is that kind of narrow administrative action that we want to encourage without expanding this into all kinds of litigation.

I think by expanding the language in the bill that we in fact are creating a situation where you are in fact making it more of a heyday for lawyers and I would be opposed to the amendment as offered by the gentleman.

Mr. ROEMER. If the gentleman would yield.

I don't think we're expanding the language at all. I think we are narrowing the language so that these smart lawyers in Washington, D.C. cannot drive a truck through this and exploit it.

And I would disagree with the Chairman's interpretation.

The CHAIRMAN. So what the gentleman is doing is narrowing the Administrative Procedures Act?

Mr. ROEMER. What I'm trying to do is clarify what we're doing here by this language, and——

The CHAIRMAN. I would simply say to the gentleman that by adding additional language, that tends not to clarify, it tends to obviate, and that the clearest language that we can have is simply to stick with where we are in the Administrative Procedures Act.

Mr. MINGE. Will the gentleman yield?

What we've created is a fairly significant overlay on the rulemaking process as it's set up in the Administrative Procedures Act.

And the question that will come up, and this will come up not just from, let's say, the industry side, but also from the environmental side. Has an agency complied with each provision along the step of the way, and is there a right to a restraining order to try to prevent agency action as it's proceeding.

And it's that litigation which I think Mr. McHale and Mr. Roemer are referring to, and it's that type of litigation that this language is designed to avoid.

So it's a two-edged sword that we face here. And there are several industry groups that have visited with me that have empha-

sized they recognize that the litigation risk is maybe not so much the agency being sued by regulated industry as the agency being sued by an environmental group that is hostile to what we're going through here.

So this is intended to be neutral, and I would support Mr. Roemer's efforts.

I'm not saying his language couldn't be improved upon; maybe it could.

The CHAIRMAN. The gentleman has made clear his position. I hope the Chair has made clear his position.

Mr. ROEMER. Mr. Chairman, I would move approval of my amendment.

The CHAIRMAN. With that, the Chair would call for the vote.

Those in favor will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed no, no?

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair, the noes have it.

Mr. ROEMER. Mr. Chairman, I'd ask for a recorded vote.

The CHAIRMAN. On that, the gentleman asks for a recorded vote. The Clerk will call the roll.

The CLERK. Mr. Walker?

The CHAIRMAN. No.

The CLERK. Mr. Walker votes no.

Mr. Brown?

[No response.]

The CLERK. Mr. Sensenbrenner?

Mr. SENSENBRENNER. No.

The CLERK. Mr. Sensenbrenner votes no.

Mr. Hall?

Mr. HALL. Aye.

The CLERK. Mr. Hall votes aye.

Mr. Boehlert?

Mr. BOEHLERT. Aye.

The CLERK. Mr. Boehlert votes aye.

Mr. Traficant?

Mr. TRAFICANT. Aye.

The CLERK. Mr. Traficant votes aye.

Mr. Fawell?

Mr. FAWELL. No.

The CLERK. Mr. Fawell votes no.

Mr. Hayes?

[No response.]

The CLERK. Mrs. Morella?

Ms. MORELLA. Aye.

The CLERK. Mrs. Morella votes aye.

Mr. Tanner?

[No response.]

The CLERK. Mr. Weldon of Pennsylvania?

Mr. CURT WELDON. No.

The CLERK. Mr. Weldon votes no.

Mr. Geren?

[No response.]

The CLERK. Mr. Rohrabacher?

Mr. ROHRABACHER. No.
The CLERK. Mr. Rohrabacher votes no.
Mr. Roemer?
Mr. ROEMER. Aye.
The CLERK. Mr. Roemer votes aye.
Mr. Schiff?
Mr. SCHIFF. No.
The CLERK. Mr. Schiff votes no.
Mr. Cramer?
[No response.]
The CLERK. Mr. Barton?
Mr. BARTON. No.
The CLERK. Mr. Barton votes no.
Mr. Barcia?
Mr. BARCIA. Aye.
The CLERK. Mr. Barcia votes aye.
Mr. Calvert?
Mr. CALVERT. No.
The CLERK. Mr. Calvert votes no.
Mr. McHale?
Mr. MCHALE. Aye.
The CLERK. Mr. McHale votes aye.
Mr. Baker?
Mr. BAKER. No.
The CLERK. Mr. Baker votes no.
Ms. Harman?
[No response.]
The CLERK. Mr. Bartlett?
Mr. BARTLETT. No.
The CLERK. Mr. Bartlett votes no.
Ms. Johnson?
Ms. JOHNSON. No.
The CLERK. Ms. Johnson votes no.
Mr. Ehlers?
Mr. EHLERS. No.
The CLERK. Mr. Ehlers votes no.
Mr. Minge?
Mr. MINGE. Aye.
The CLERK. Mr. Minge votes aye.
Mr. Wamp?
Mr. WAMP. No.
The CLERK. Mr. Wamp votes no.
Mr. Olver?
Mr. OLVER. Yes.
The CLERK. Mr. Olver votes aye.
Mr. Weldon of Florida?
Mr. DAVE WELDON. No.
The CLERK. Mr. Weldon votes no.
Mr. Hastings?
[No response.]
The CLERK. Mr. Graham?
Mr. GRAHAM. No.
The CLERK. Mr. Graham votes no.
Ms. Rivers?

Ms. RIVERS. Aye.
The CLERK. Ms. Rivers votes aye.
Mr. Salmon?
Mr. SALMON. No.
The CLERK. Mr. Salmon votes no.
Ms. McCarthy?
[No response.]
The CLERK. Mr. Davis?
Mr. DAVIS. No.
The CLERK. Mr. Davis votes no.
Mr. Ward?
Mr. WARD. Aye.
The CLERK. Mr. Ward votes aye.
Mr. Stockman?
Mr. STOCKMAN. No.
The CLERK. Mr. Stockman votes no.
Ms. Lofgren?
Ms. LOFGREN. Yes.
The CLERK. Ms. Lofgren votes aye.
Mr. Gutknecht?
Mr. GUTKNECHT. No.
The CLERK. Mr. Gutknecht votes no.
Mr. Doggett?
Mr. DOGGETT. Aye.
The CLERK. Mr. Doggett votes aye.
Mrs. Seastrand?
Mrs. SEASTRAND. No.
The CLERK. Mrs. Seastrand votes no.
Mr. Doyle?
Mr. DOYLE. Aye.
The CLERK. Mr. Doyle votes aye.
Mr. Tiahrt?
Mr. TIAHRT. No.
The CLERK. Mr. Tiahrt votes no.
Ms. Jackson Lee?
Ms. JACKSON LEE. No.
The CLERK. Ms. Jackson Lee votes no.
Mr. Largent?
Mr. LARGENT. No.
The CLERK. Mr. Largent votes no.
Mr. Luther?
Mr. LUTHER. Aye.
The CLERK. Mr. Luther votes aye.
Mr. Hilleary?
Mr. HILLEARY. No.
The CLERK. Mr. Hilleary votes no.
Mrs. Cubin?
Ms. CUBIN. No.
The CLERK. Ms.Cubin votes no.
Mr. Foley?
Mr. FOLEY. No.
The CLERK. Mr. Foley votes no.
Mrs. Myrick?
Ms. MYRICK. No.

The CLERK. Mrs. Myrick votes no.

Mr. GEREN. Mr. Chairman, may I ask how I'm recorded?

The CHAIRMAN. How's Mr. Geren recorded?

The CLERK. Mr. Geren is not recorded.

Mr. GEREN. Mr. Chairman, I'd ask to be recorded as aye.

The CLERK. Mr. Geren votes aye.

The CHAIRMAN. The Clerk will report.

The CLERK. Mr. Chairman, I count 16 yeas, 27 nays.

The CHAIRMAN. The amendment is not agreed to.

Are there further amendments to Section D?

Mr. BARTON. Mr. Chairman?

Mr. CHAIRMAN. The gentleman from Texas?

Mr. BARTON. Mr. Chairman, I have an amendment at the desk.

The CHAIRMAN. The Clerk will distribute the amendment.

Mr. BARTON. Barton 13.

[Pause.]

Mr. BARTON. It's the last one.

The CHAIRMAN. I hope this is the last one.

VOICES. No, no. [Laughter.]

Mr. BARTON. I would ask unanimous consent that the amendment be considered as read, and that will save some time.

The CHAIRMAN. Without objection.

Mr. BARTON. You want me to start explaining? Okay. Mr. Chairman, may I begin to explain the amendment as it's being circulated?

The CHAIRMAN. The gentleman can explain the amendment.

Mr. BARTON. I thank the Chairman.

Mr. Chairman, this amendment would be a substitute for Subtitle D. Under the bill as currently drafted, there is an 18-month period during which the affected Federal agencies can review existing rules and regulations.

And if it is the agency determination that there is new information or new methodology that would render the existing rule and regulation obsolete, then they can make a self-imposed decision to review the existing rules and regulations.

My amendment would substitute a petition process where outside parties that have a direct financial interest in the existing rules and regulations could petition that those rules and regulations be reviewed.

The Federal agency that receives the petition has a 90-day time period during which they can determine whether they believe that the petitioned rule or regulation should be reviewed.

If they accept the petition, there is a one-year time period where there is a public comment, and they go, they accept the additional information, and then make a final decision.

If, on the other hand, they decide the petition does not have validity, they have to publish in the Federal Register the reasons that they believe the petition is not valid.

If the party that rendered the petition feels that the rendering of the Federal agency is inappropriate, they can go then, under the existing law, into court and ask that the existing rule and regulation be reviewed.

Basically, what this amendment does is substitute an internal review by the Federal agency with an external petition process that has specific time periods.

The Energy and Commerce Committee adopted this amendment that's been circulated, with one change; they deleted the provision that limited the petition to people with a direct financial interest.

Congressman Markey of Massachusetts wanted to delete that, and so as passed by the Energy and Commerce Committee, this amendment allows any person to instigate petition.

So this is the case that gives us the ability to look at existing rules and regulations by allowing outside parties that have a direct financial interest to instigate or initiate the petition.

If you think the existing rules and regulations need to be reviewed and don't trust the existing Federal agencies to automatically review some of these rules and regulations, you should support this amendment.

Mr. DOGGETT. Will the gentleman yield?

Mr. BARTON. I'll be happy to yield.

Mr. DOGGETT. Do I understand then that you are offering it in the form that the Commerce Committee approved it, or are you offering it in the form that has been circulated?

Mr. BARTON. No, I'm offering it in the form that it's being circulated because I didn't want to confuse the Committee, but it was passed with a broadening amendment. But I'm offering it in its existing form because that's the form that was at the desk, and earlier this evening, we had a mixup where I had two different amendments, and I didn't want to embarrass the Committee again with that purpose.

But I want to tell the Committee that it has been adopted with that perfecting amendment in the Energy and Commerce Committee.

Mr. DOGGETT. Well, would you be—an amendment to your amendment would be out of order, I assume.

The CHAIRMAN. That would be an amendment in third degree and would be out of order.

Mr. DOGGETT. Right.

Mr. BARTON. It would require unanimous consent of the members present in this Committee to change the amendment, that's correct.

Mr. BOEHLERT. I would like to know what the Chairman thinks of the amendment?

The CHAIRMAN. Well, the Chair will comment on the amendment.

Do we have further discussion of the amendment?

Mr. BARTON. Not at this time.

The CHAIRMAN. The Chair is going to oppose the amendment. I think it has some merit to it, but the Chair has two problems with this particular amendment.

I believe that this would result in additional litigation and we have attempted, insofar as I have been involved in this process, to reduce the amount of litigation insofar as we can, I believe, to some of those questions.

And I do believe that this does provide a substantial reachback beyond that which has been included in the bill, and so, therefore, I am not disposed toward approving this amendment at this time.

Mr. Geren.

Mr. GEREN. Mr. Chairman, I'd like to speak in support of Mr. Barton's amendment.

The CHAIRMAN. The gentleman's recognized.

Mr. GEREN. I beg your pardon?

The CHAIRMAN. The gentleman is recognized.

Mr. GEREN. Oh, excuse me.

I think that it is a good middle ground that will give the citizens of the country an opportunity to review existing law, and we wouldn't be considering this bill that we have in front of us today if it weren't for some abuses that we have had to live with in the past.

And I think this is a good middle ground. It does give an opportunity on a case by case basis for citizens and other entities to petition our Government and seek review of these provisions.

Mr. BARTON. Would the gentleman yield?

Mr. GEREN. Yes, I'll be glad to yield.

Mr. BARTON. If the distinguished gentleman from Texas would yield, I want to say that I gratefully accept his support. And this did pass in the Commerce Committee with bipartisan support.

I hope we can also pass it here.

I would also like to comment on the distinguished Chairman's opposition. He and I have discussed this amendment and we certainly understand each other.

My position is that we should not automatically trust the existing Federal agencies during the 18-month period it's in the bill is drafted, to go out and review many of these existing rules and regulations.

In some ways, that's like allowing the fox to guard the henhouse.

What this amendment does, if passed, is allow outside parties to petition those agencies that there should be a review. So it gives grassroots America the opportunity to come in and require specific rules and regulations to be reviewed.

It is the only way that we automatically guarantee that some of the existing rules and regulations will be reviewed.

And that is a key difference in this amendment and the Committee print.

And I yield back to the gentleman from Texas.

Mr. DOGGETT. Mr. Chairman, I again just express my support for this amendment and yield back the balance of my time.

The CHAIRMAN. Is there further discussion?

[No response.]

The CHAIRMAN. If not, the question occurs on the amendment by the gentleman from Texas.

Those in favor will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed will say no.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair, the noes have it.

Mr. BARTON. Mr. Chairman, could I have a show of hands?

The CHAIRMAN. The gentleman asks for a division. A division is requested.

Those in favor of the amendment will raise their hand.

[Show of hands.]

The CHAIRMAN. Does the Clerk have them all?

Those opposed will raise their hands.

[Show of hands.] [Laughter.]

[Pause.]

The CHAIRMAN. The Clerk will report.

The CLERK. Mr. Chairman, I count 15 yeas, 25 nays.

The CHAIRMAN. On the division, the amendment is not agreed to.

It was nice here on the last vote to see kind of a bipartisan split on these things. It shows that we got more honest as we went.

Are there further amendments to Section D, Subtitle D?

[No response.]

The CHAIRMAN. If not, Subtitle D is closed.

Any other amendments to the Substitute?

[No response.]

The CHAIRMAN. If not, the Chair moves the Substitute as amended.

All those in favor will say aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed say no.

[Chorus of nays.]

The CHAIRMAN. In the opinion of the Chair, the ayes have it.

The Chair now moves the—oh, the gentleman from Texas, Mr. Hall.

Mr. HALL. Mr. Chairman, I would move that the Committee report on the bill HR 9 to the House as amended, with the recommendation that it pass.

Furthermore, I instruct the staff to prepare the legislative report and to make technical and conforming changes.

The CHAIRMAN. The Committee has heard the motion.

Those in favor of the motion will respond by saying aye.

[Chorus of ayes.]

The CHAIRMAN. Those opposed, no?

[Chorus of nays.]

The CHAIRMAN. The motion is agreed to, and the bill is reported.

Mr. HALL. Mr. Chairman?

The CHAIRMAN. The gentleman from Texas has some additional.

Mr. HALL. Mr. Chairman, under the Rules, I request three days within which members can file separate, additional and dissenting views.

The CHAIRMAN. Without objection.

Mr. HALL. Mr. Chairman, I also ask unanimous consent to allow members to include statements in the record.

The CHAIRMAN. Without objection.

Mr. Boehlert?

Mr. BOEHLERT. Mr. Chairman, I want to say that we've been at this since 10:00 o'clock this morning, and I want to commend the Chair for the fairness in which you've presided over this hearing.

Everyone had the opportunity to speak their piece and it was a darn good hearing, and I'm proud to serve on this Committee.

The CHAIRMAN. I thank the gentleman.

I want to say thank you to all the members on both sides. We did stick through a long period of time here, and I do appreciate the members participating in this.

Hopefully, we participated in a good, open discussion.

The Chair would also make the point that the Hydrogen Bill that was on the schedule is going to be postponed.

The Chair will recess the Committee at the call of the Chair and will reschedule in the near future to come back to do the Hydrogen Bill.

With that, the Committee stands in recess at the call of the Chair.

Thank you very much.

[Whereupon, at 11:20 p.m., Wednesday, February 8, 1995, the Committee was adjourned, subject to call of the Chair.]

STATEMENT OF KAREN McCARTHY

I would like to point out concerns I have with this section of the bill as it is currently written. However, before I enumerate these concerns, let me make a few remarks about risk assessment in general.

I do believe we can adopt legislation that allows agencies to conduct sound risk assessments. I support legislative efforts to develop risk assessment legislation that has the goal of providing more open and scientifically based risk assessments. No one can deny the need for agencies to make quantitative and qualitative regulatory decisions about the classification of health or environmental hazards based on sound regulatory decisions.

However, it is my belief that the bill the Science Committee has under consideration does not promote sound risk analysis and in fact creates greater regulatory burdens for federal agencies and thus greater costs for consumers and businesses. Therefore, I do feel obligated to state my concerns with Title III of H.R. 9, as currently written.

First, we have heard from agency heads about their specific concerns with the language. For instance, Deputy Commissioner for Policy at the Food and Drug Administration, William Schultz, stated before the committee that "the additional requirements of the bill would add layers of bureaucracy to the agency's decisionmaking process, increasing the cost of agency regulation, without any benefit to the consuming public or the regulated industry." It concerns me greatly to hear agencies talking about increasing bureaucracy when one of my goals is to reduce bureaucracy. I cannot see how I can support legislation that will have the effect of increasing the burdens caused by unnecessary new layers of government.

Second, the definition of a "major rule," set at $25 million, is too narrow and needs to be broadened. My fear is that the threshold for any regulation that is likely to result in an annual effect on economy of $25 million or more would include almost all federal regulations. Resources devoted to regulatory analysis should be commensurate with the significance of the regulatory decision. I would support raising the threshold to prevent the need for risk assessments and cost-benefit analysis for every regulation promulgated by agencies.

Third, of additional concern is the effect this legislation will have on state and local jurisdictions. Unless I have guarantees that stipulations in this bill will not require states and localities to comply with the risk assessment and cost-benefit provisions, then I have to withhold my support for the bill.

Finally, let me say something about the process used to consider this bill. I think it is difficult to consider health, safety and envi-

ronmental legislation under the expedited procedures that have been employed by the Science Committee. While I understand the need to meet deadlines, prudence and common sense would dictate that this committee take the time to fully evaluate provisions in the bill. We have held only two hearings on this bill. The last hearing occurred only three legislative days prior to the committee mark up of the bill. This is not enough time to analyze the comments and weigh the concerns of the witnesses who appeared at the hearing. Many of the agencies that would be affected by this legislation voiced serious concerns with the legislation. For example, the Department of Health and Human Services expressed this concern: "Rather than eliminating obstacles to more streamlined, cost-effective regulatory actions, Title III would add numerous burdensome and unproductive procedural requirements that would greatly increase the costs and delays of the regulatory process." We have given scant discussion to the fiscal implications of Title III to the federal budget.

Let me conclude by saying that I want to support risk assessment legislation. However, in light of the manner by which this legislation was rushed through the Science Committee and the concerns expressed by groups affected by Title III, I cannot support the bill in its current form.

ADDITIONAL VIEWS OFFERED BY MS. JACKSON LEE OF TEXAS

Although understanding that certain difficulties arise for businesses and industry when over-restrictive regulations are placed upon them, we cannot disregard the positive impact that many environmental regulations have had on the safety of women, children, and minorities in our inner-cities. Many of our inner-city dwellers face added environmental risks by living near or working in sectors of our manufacturing industries. I believe we can and we should assure their public health and safety, and at the same time, strike a balance so as not to unfairly burden our nation's businesses. We must be careful to ensure that the present legislation does that.

SHEILA JACKSON LEE.

ADDITIONAL VIEWS, SUBMITTED BY REPRESENTATIVE TIM ROEMER

Risk Assessment legislation is an important and necessary part of restructuring our government to be more effective, efficient and less expensive. We must use modern and scientific knowledge to help us establish intelligent policy. This will allow us to establish those regulations that are concise and reasonable, and avoid or eliminate unworkable and unneeded regulation.

We support this bill, but it needs improvement. Of particular importance are the provisions dealing with "judicial review." While judicial review is an important element of the regulatory process, it can be used in mischievous or even dilatory ways if not crafted carefully.

The bill, as drafted, is vague on potential new judicial review requirements, and may permit court challenges to a regulation before it has even been issued. This form of interim judicial review is not, in my estimation, an intention of this legislation.

It is not wise to allow interest groups—industry, environmental, public interest, business competitors, perhaps even other agencies—to protest a regulation in court before it has ever been finalized. Basing legal arguments on anticipated outcomes can be a hazard. There are other interim remedies, including the gathering of public testimony and public comment periods, to address concerns about potential rules without disrupting the rulemaking process. The complexity of the process created by this bill should not be underestimated. Without addressing the judicial review question, we risk eroding the solutions created by the bill.

We supported the Roemer amendment to remedy this flaw. Without this amendment, we are opening up an entire new area for legal action where none existed before, and it is almost certain that lawyers will create a new cottage industry in this field. The government cannot afford this litigation explosion: we must avoid committing scarce resources into this non-productive activity.

The Roemer amendment would clarify that judicial review is only available as a remedy to a final agency action. We should not surrender our responsibility for conducting scientific and technical debates to lawyers and judges. This amendment is virtually the same language as was adopted by the Senate last year on a large bipartisan basis during consideration of the Safe Drinking Water Act.

We have pledged to work with the Chairman and Ranking Member to improve language for floor consideration that would correct the vague language in this bill as adopted. We look forward to making these needed improvements to this necessary legislation during consideration by the full House.

TIM ROEMER.
DAVID MINGE.
MIKE DOYLE.

SUPPLEMENTAL VIEWS

We agree with the majority on the need to address risk assessment and cost-benefit analysis. However, we do have reservations about Title III of the Job Creation and Wage Enhancement Act, and we respectfully submit our supplemental views regarding judicial review, the major rule threshold, and preemptive law.

Under existing law, final agency rules and orders are judicially reviewable under the Administration Procedures Act. Without clarification in Title III of the Job Creation and Wage Enhancement Act, courts may hold that risk assessment guidelines themselves are reviewable, which is sure to lead to excessive litigation.

We believe that risk assessment guidelines should not be reviewable. Additionally, we believe that compliance with Title III requirements should be reviewable only in the context of a challenge to a final agency rule or order. Without such a provision, this legislation may exacerbate existing litigation problems and stifle efforts to resolve conflicts within a federal agency.

Title III requires federal agencies to conduct resource-intensive, formal risk assessments and cost-benefit analysis. Compliance would be required when an agency proposes a "major rule," a regulation that would have an annual impact on the economy of $25 million or more. This figure is equal to .0004% of the U.S. Gross Domestic Product.

The $25 million threshold is unreasonably low given Title III's analytic requirements. Doing meaningful cost-benefit analyses requires substantial time, data, and expertise. If these analyses are done poorly they are worse than useless, since the resulting "answers" have a spurious air of reliability that misleads the public and decisionmakers alike.

EPA estimates that the cost of preparing cost-benefits analyses ranges from just over $200,000 to more than $2,300,000, averaging $675,000. A $25 million threshold would require cost-benefit analyses to be prepared for several hundred major rules developed by federal agencies that regulate health, safety, and the environment. The annual cost to taxpayers is likely to be in the hundreds of millions of dollars.

In addition, Title III will apply to rules that implement statutes enacted prior to enactment of Title III, in effect amending specific provisions of those laws. The Committee was unable to identify which provisions would be affected, much less in what fashion. We believe that Title III should apply to prospective laws. Otherwise, Title III may undermine landmark laws that were enacted only after years of work and discussion to create a delicate balance of interested and affected parties—laws that range from protection of food and drinking water quality, to aviation safety, to hazardous waste management, and preservation of wildlife.

For these reasons, we submit supplemental views on various provisions of Title III of the Job Creation and Wage Enhancement Act.

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DISSENTING VIEWS

INTRODUCTION

In reporting H.R. 9, the Committee is missing an opportunity to report thoughtful, well-considered legislation to reform the regulatory agencies' risk assessment and cost-benefit procedures. Risk assessment and cost-benefit analysis are important, albeit limited, tools that can help agencies regulate in a more reasoned and cost-effective manner. We all support efforts to make the rulemaking process faster, cheaper, and more rational.

Instead of targeting specific areas needed for improvement, however, H.R. 9 sweeps across a wide range of activities of all agencies, guaranteeing dividends on the law of unintended consequences. It imposes strict new "one-size-fits-all" risk assessment procedures which are scientifically unsound. It sets up a cumbersome and costly procedural maze which is much more likely to lead to gridlock and costly new bureaucracy rather than to faster and more rational rulemaking. It gives any lawyer who wants to delay a regulation—whether representing industry, public interest groups, or competitors—a powerful new tool to prolong agency actions through diversionary and nonproductive litigation. It will impose costly new information requirements on industry.

As introduced, Title III of H.R. 9 was a modestly flawed bill that could have been improved with an opportunity for debate and thoughtful consideration. As reported, it is an even worse bill that will make the legitimate protection of our nation's health, safety, and the environment much more difficult, if not impossible. H.R. 9 now proposes to sweep away the substantive laws that have been debated and enacted by Congress over the last thirty years. If those laws need amending, we should do so directly, not through the back-door procedural requirements of H.R. 9.

We believe the bill, as reported, has the following major flaws:

It requires new and more extensive procedures for risk assessment and cost-benefit analysis, overriding existing substantive law on an indiscriminate basis;

It encourages additional litigation through expanded and confusing language on judicial review;

It failed to follow procedural safeguards in Committee to insure full and deliberate consideration of complex issues;

It purports to define and prescribe now scientists should do science;

It establishes a confusing and non-scientific process of "Comparative Risk Analysis" as a component of Risk Assessment and Cost-Benefit Analysis;

It permits peer review panels to be dominated by industry scientists with financial conflicts of interest; and

It imposes an inflexible and unrealistic requirement that agencies "certify" that benefits outweigh costs as a prerequisite to issuing final rules

These objections are set forth in greater detail below.

OVERRIDING EXISTING LAWS

As introduced, there was some question whether Title III of H.R. 9 would override existing, substantive law through its procedural requirements. The Walker amendment adopted by the majority erases any doubts: its clear and express intent is to override *any* health, safety, or environmental law that would conflict with the bill. The effect of this amendment, taken together with the expanded right of judicial review established by the bill, cannot be overstated: it will now be much more difficult for any agency to protect public health, safety, or the environment under any of the laws that Congress has passed over the last quarter of a century.

Section 3201(f) expressly states that the requirements of subtitle (b) "supersede the decisional criteria for rulemaking otherwise applicable under the statute pursuant to which the rule is promulgated." (While the bill purports not to override existing statutes or risk assessment, this provision is mooted by the much broader requirements of subtitle (b) which effectively require every agency to conduct risk assessments for virtually every rule.) More significantly, the bill prohibits any agency from acting to protect health, safety or the environment under its existing lawful authority unless it also complies with the bill's new requirements—including the requirement that the agency prove through detailed assessments that benefits will justify the costs.

With one broad stroke, H.R. 9 now overturns dozens of laws that were carefully considered by Congress and signed by Presidents (many of them Republican) after years of public debate on the best way to protect American workers, consumers, and the environment. In many case, Congress decides that laws requiring strict cost-benefit analyses would not provide the desired levels of protection, recognizing that costs and benefits can be very difficult to quantify and endlessly debated. After years of inaction by the EPA, for example, Congress set standards and deadlines for EPA to follow in setting criteria for safe drinking water and required the use of best available technologies to clean up hazardous air pollutants. Recognizing the difficulty of setting prices on wilderness, open spaces, and biological diversity, Congress in the Endangered Species Act and other acts set out clear standards for protecting natural areas and threatened species. Numerous health, safety and environmental laws are based on factors other than, or in addition to, costs and benefits.

Now these and many other unidentified laws will be swept away. Indeed, it is difficult even to know the potential scope and implications of this repeal. When asked at the markup, neither the Chairman nor the Committee Counsel could identify the laws being repealed. Given the fact that the bill applies to all agencies and virtually all regulations which could impact health, safety, or the environment, it is plain that this repeal will have widespread unintended effects. Will it apply to regulations relating to childhood immunization programs? Regulations by USDA relating to soil con-

servation programs or pest importation programs? Regulations by the Immigration and Naturalization Service relating to the immigration of persons with contagious diseases? Regulations by the Bureau of Prisons relating to the safety and health of federal prisoners?

It may well be that the environmental, health, and safety laws should be re-examined and amended in light of the current concerns about costly over regulation. Certainly every Member has heard the regulatory horror stories; everyone acknowledges that Superfund needs to be overhauled. But we should address those changes directly by debating and amending the underlying statutes, not by a back-door repeal that adds yet another layer of bureaucracy and litigation on top of an already costly and cumbersome regulatory process.

Litigation explosion

H.R. 9 could well be subtitled the "Full Employment for Lawyers Act." The Act directly expands the scope of judicial review for virtually every agency rule that protects the environment, health, or safety. The result will be a litigation explosion similar to the one experienced after the enactment of a similar " procedural" statute: The National Environmental Policy Act (NEPA). Litigation just drives up costs, creates legal uncertainty, delays regulations, and diverts scarce public and private resources into nonproductive activity. The expanded judicial review afforded by H.R. 9 provides a blunt weapon to any party interested in delaying a regulatory proceeding—whether an environmental group, industry, or even competitors.

Under the Administrative Procedures Act, any affected party already has the right to seek judicial review of final agency actions. If a court finds the agency's action to be arbitrary or capricious, it will overturn the agency action. The court will look at the agency's rulemaking record, which will include any risk, cost, or benefit assessments.

This existing right of judicial review is apparently not sufficient for the sponsors of H.R. 9. First, section 3201(f)(2) changes the standards by which a court reviews an agency rule from the existing "arbitrary and capricious" standard to the higher "substantial evidence" standard. Second, by adding numerous mandatory procedures, H.R. 9 changes the scope of judicial review. Instead of reviewing the agency's record as a while to determine whether the agency's action is arbitrary and capricious, the court will be able to overturn an agency's action solely on the basis that the agency failed to follow the exact procedures and certifications set out in the bill. For example, courts will have to review the agency's certification that the cost and risk assessments were based on "objective and unbiased scientific and economic information of all significant and relevant information." This inquiry will inevitably mire the courts in complex scientific and technical debates, a role that judges themselves, including Justice Stephen J. Breyer, have said is inappropriate.

The Walker amendment provision that judicial review is to be under the Administrative Procedures Act is apparently intended to preclude premature interim judicial reviews being sought while an

agency rulemaking is in progress. But this provision fixes only a part of the problem and in any event conflicts with section 3201(f)(2). In contrast, the Roemer amendment offered at markup would not enlarge judicial review by ensuring that the failure to follow the exact procedures of the bill would not in and of itself be a basis for overturning a rule. The Roemer amendment was identical to language offered by Senator Johnston and adopted twice by the Senate on large bipartisan margins in the last Congress.

Some have argued that expanded judicial review is necessary to ensure that agencies follow the new mandatory procedural requirements. The fact is that there are plenty of incentives to ensure the agencies's compliance. First, the agencies' compliance will be subject to Congressional oversight. Second, new requirements for public participation, transparency, and peer review should ensure the quality of the agency's work as well as its adherence to the bill's requirements. Third, the bill requires an independent National Peer Review panel to oversee the agency's compliance, as well as providing for separate reviews by the Office of Management and Budget (OMB). Finally, as a practical matter, agencies are likely to be at higher risk of having their rules reversed on judicial review if they fail substantially to follow the procedural requirements.

THE RUSH TO JUDGEMENT

In an effort to meet the arbitrary 100-day deadline of the Contract with America, the Committee abdicated its responsibility to fully consider this bill. Members had little, if any, time to consider the bill or amendments. The result is a poorly-drafted, ill-considered piece of legislation that will have widespread unintended consequences and make legitimate regulation to protect public health, safety, and the environment much more difficult. By sending this bill to the House floor without the benefit of this Committee's expertise, we are doing little more than sending a shell bill over to the Senate which will end up writing the real legislation.

Many of the Democratic Members of this Committee have been active participants in efforts to promote risk assessment legislation and sensible regulatory reform. In the last Congress, the Committee held four subcommittee hearings on risk assessment and worked on a risk assessment bill for many months before bringing it to markup. That bill was subject to extensive outside review and many negotiating sessions that were open to *all* Members of the Committee.

Yet that bill was far less complex and sweeping than the legislation before us now, which was developed behind closed doors and without any input from any Democratic Member despite repeated requests. Notice was provided to be as minimal as possible and still comply with the rules. Subcommittee hearings and markups were dispensed with. Initially, the Chairman proposed a single day of hearings, to be composed of a single panel of witnesses sympathetic to the bill, and rejected the Administration's requests to testify. We were forced to ask for a second day of hearings to even ensure that the Administration had an opportunity to present its views to the Committee. We also requested written information from the Cabinet Departments and several independent agencies to ensure that

Members had some information about the impacts of this wide-ranging bill.

The full committee markup commenced on February 8, the morning of the third day after the conclusion of testimony. The Committee had yet to receive many agency responses analyzing the impact of the bill or responses to questions requested from witnesses. Despite the Chairman's announced intention that all amendments should be submitted 24 hours in advance of the markup, the Chairman's own extensive amendments were not distributed to Members until the beginning of the markup. (A copy marked "draft" was provided to the Democratic staff at 6:15 p.m. the evening before, but it was clear that it was not a final draft and was not being provided for circulation. The final version, which contained several significant differences, was time-stamped 11:36 p.m. from Legislative Counsel's office but no copy was made available to the Democratic staff or Members until the morning of the markup). No other Republican amendments were made available until the morning of the markup.

The Chairman's amendments, presented to the Members for the first time at the mark-up, were extensive; they fundamentally changed the scope and application of the bill, added provisions on judicial review, and for the first time, clearly overrode existing laws. In addition, they were prepared as nearly 5 en bloc "cut and bite" amendments, a format to which we had previously indicated to the Republican staff that we would object. After objection, the amendments were redrafted as an amendment in the nature of a substitute, and the Chairman recessed the markup for two hours to permit Members to review it and to redraft amendments to it. The markup raised a number of unanswered questions about the bill's provisions.

TELLING SCIENTISTS HOW TO DO SCIENCE

As reported, this bill tells scientists how to *do* risk and cost-benefit assessments. The very prescriptive language in the bill reflects the belief that Members of Congress know better than scientists how to do risk and cost-benefit assessments.

Scientists are instructed to use the "most scientifically objective and unbiased information", and the "most plausible assumptions" to calculate "best estimates" (defined elsewhere as "central" estimates) of risk. While these terms sound innocuous and even appealing, they mean different things to scientists than they do to lay people. At best, they create enormous confusion: there is no consensus within the scientific community as to what is "most plausible", nor is there any way to judge this before the fact. At worst, they overrule by legislative fiat the considered judgement of the scientific community regarding risk assessment. Given the widespread confusion about these terms, and their potential for mischief, it is worth explaining these concerns in more detail.

1. "Most Plausible Assumptions."

In many cases, risk assessors are faced with an absence of good, quality data. In such cases, they must make assumptions, or use "default options." Obviously, the choice of those assumptions can affect the magnitude of the estimated risk. The National Research Council, in its 1994 report "Science and Judgement In Risk Assess-

ment," described default options used in the Agency's risk assessment guidelines as:

> Options used in the absence of convincing scientific knowledge on which of several competing models and theories is correct. The options are not rules that bind the Agency; rather, they constitute guidelines from which the Agency may depart when evaluating the risks posed by a specific substance.

The National Research Council recommended that principles be developed for choosing default options and for judging when and how to depart from them. In formulating such principles, the following criteria were identified: protecting the public health, ensuring scientific validity, minimizing serious errors in estimating risks, maximizing incentives for research, creating an orderly and predictable process, and fostering openness and trustworthiness. These principles inevitably exceed the domain of science and involve policy choices on how to balance such criteria.

The bill tells scientists to use the "most plausible assumption," but if scientists knew what the "most plausible" assumptions was, they wouldn't need to make an assumption in the first place; it is precisely because there is doubt about what is the most predictive "model" to use that assumptions must be made. Scientists don't know what "most plausible" means in any scientific or statistical sense. The phrase is simply meaningless.

Indeed, a standard that is based on "best estimates" (including use of "most plausible" assumptions) and "unbiased" information could lead an Agency to seriously underestimate the risks to those segments of the population most at-risk. These terms could be interpreted as excluding consideration of subsets of the population—such as children, the elderly, diabetics, asthmatics, and others who may be more highly exposed or more vulnerable that the average adults—simply because these subgroups have exposure or more vulnerable that the average adults—simply because these subgroups have exposure or susceptibility patterns that are different from most members of the population. In many cases, the greatest risk is often felt by the highly implausible combination of exposure and susceptibility, i.e., a highly exposed individual with greater than normal susceptibility to the hazard. Using a "most plausible" standard—whatever it means—might lead an Agency to ignore such cases in its risk estimate.

Lead poisoning is a good example of why the use of language such as "most plausible," while perhaps well intentioned, can have disastrous effects. Young children have both far higher exposure to lead, and far greater susceptibility to its adverse effects. Their exposure is greater because young children have a high rate of what doctors call hand-to-mouth behavior—meaning that toddlers go through the stage of putting their toys and other objects in their mouth as part of exploring their world. As a result, young children ingest far more dust and soil than do adults, dust and soil that is often contaminated with lead. Doing a risk assessment that makes the most plausible assumption about dust and soil ingestion could well be based on adult levels of dust ingestion since there are many

more adults than children in the overall population, but it would grossly underestimate risks to children.

Similarly, the best estimate of absorption of lead from the stomach into the blood is about 15% for adults, but close to 50% for children; thus, use of an "unbiased" or "most plausible" value for the overall population will fail to reflect serious risks to important subgroups.

The term "bias" and its converse "unbiased" are technical terms in mathematical modeling with a statistically exact meaning. Both the conventional linear, multi-stage cancer model and its maximum likelihood estimate are intentionally biased in their estimates of potency. Statistically unbiased estimates simply do not exist for the models that are generally employed in cancer risk assessment, making this provision technically infeasible. Further, as noted above by the National Research Council, all assumptions have inherent biases. What this language would appear to do is to prevent scientists from using assumptions and models which err on the side of protecting public health—a default option which is widely accepted throughout the scientific community as appropriate in many cases.

2. "Best Estimates," Uncertainty and Variability in Risk Assessment.

Section 3105 sets forth detailed prescriptive language for risk communications, particularly given the way the term "best estimates" is later defined in section 3109 to be a "central" estimate. The emphasis on "best estimate(s)" is contradictory to the recommendations of the National Research Council, which stresses the importance of providing a range of estimates and discussion of uncertainty of all estimates, rather than focusing on a single, best estimate. A sound risk characterization should present the full range of exposures, effects and risks, including but not limited to any single-point estimate such as the "best estimate" proposed here. In this context, the range of risk estimates should reflect both actual variability in people's exposures and their own physiologic susceptibility, as well as uncertainties resulting from difficulties in measuring these variables and from lack of understanding of how to extrapolate from available data.

Gaps in scientific knowledge lead to inevitable uncertainties in risk assessment. Some uncertainties dealing with measurement precision can be empirically quantified, while others, such as those related to the relevance of models for particular applications, cannot. For example, most single point estimates of risk do not convey the degree of uncertainty (and likewise the degree of conservatism) in the estimate. Similarly, variabilities within and among individuals, populations and species, variability in exposure and in susceptibility to a hazard related to age, lifestyle or habitat, genetic background, sex ethnicity as well as other factors, make it difficult, if not impossible, to accurately convey an environmental risk by a single point estimate.

For those reasons, the amendment offered by Mr. Olver would have required the risk characterization to communicate the "full range of risks." This requirement was intended to convey the comprehensive distribution of risks of all types to all segments of the population, including highly exposed and highly susceptible indi-

viduals or subpopulations. In order to accurately convey this breadth, a probability distribution of risks would typically be favored over any single, statistical point estimate (i.e., the "best estimate") representing a particular segment of the exposed population or exposed species. A single estimate of risk in probabilistic terms conveys a level of certainty and a relevance to the public at large that is rarely if ever justified.

The Olver amendment was consistent with the recommendations of the National Research Council that the entire risk range should be estimated and communicated in a risk characterization. This recommendation from the National Research Council was endorsed in a December 15, 1994 letter from the congressionally-mandated and Presidentially-appointed Commission on Risk Assessment and Risk Management to the authors of this legislation.

Nevertheless, Subtitle A requires the use of "best estimates of risk" defined as a "central estimate." This standard is not only misleading, but would fail to protect the half the population with slightly greater than average risk to an environmentally hazard.

POTENTIALLY MISLEADING COMPARISONS OF RISK

Subtitle A, Section 3105 and Subtitle B, Section 3201, call for risk comparisons that, at best, will confuse decisionmakers and the public and, at worst, will frighten and not educate them with respect to the seriousness of the risk in question. Few things have been as completely misunderstood as comparative risk analysis. The term has been widely misused and has clearly meant different things to different people.

As used in this bill, comparative risk analysis is used to mean a tool to communicate the significance of a particular environmental risk to the public by comparing it to "everyday" risks. But comparing the avoidable, involuntary risk of a toxic substance in drinking water to the risks of lightning or automobile travel is like trying to compare baseball statistics like RBIs and ERAs to determine who is a better baseball player. The risks are entirely dissimilar. The public may well be willing to take voluntary risks of equal magnitude with the risks that they want prevented by regulation.

In an August 19, 1994 letter to Mr. Brown, then Chairman of the Committee on Science, Space, and Technology, three past presidents of the Society for Risk Analysis, state that, "* * * comparative risk exercises conducted over the past decade have shown us that drawing quantitative comparisons among different kinds of risks * * * is almost impossible, and not credible if tried. The difficulty arises from our lack of understanding of how people value different kinds of losses * * *." They further note that not all comparisons communicate the risk in an equally relevant and meaningful way, and then go on to say, "For instance, saying that sky-diving is (for example) ten thousand times more risky than living in a house with 10 picocuries per liter of radon in the basement doesn't communicate very much. It is much more meaningful to know that having ten picocuries in your basement leads to as much extra radiation exposure as, say, ten airplane trips from New York to Los Angeles every year (or something of this sort.)"

To be meaningful, risk comparisons should be done within an appropriate decisionmaking sphere. The language in this bill will not

ensure that risk comparisons are done within an appropriate decisionmaking sphere and does not require that key determinants of acceptability of risk, such as whether the risk is voluntary or involuntary, preventable or not preventable, catastrophic or chronic, are included in the comparison.

Knowing that a particular environmental risk is lesser or greater than some familiar risk does not change the regulator's responsibility to carry out environmental statutes. For an individual citizen, knowing that breathing the air in his or her town is less risky than driving a car doesn't give the individual any information relevant to any decisions—such as how to reduce that risk. While Agencies need to do more to communicate the significance of environmental risks, inappropriate risk comparisons such as these are simply more likely to mislead rather than inform the public.

The most concise statement of problems with the type of comparative risk approach taken in the bill is contained in the following quotes from a February, 1995 editorial in Bioscience by Dr. Kristin Shrader-Frechette, a member of the National Academy of Sciences Board on Environmental Studies and Toxicology:

> Perhaps the biggest problem with comparative risk assessment is that it mixes radically different types of risk in a concession to bureaucratic number crunching. If one hazard (such as a chemical dump) is involuntarily imposed on citizens, whereas another (such as eating fatty foods) is voluntarily accepted or rejected by each individual, then the two risks may not be comparable on the basis of probability alone. Voluntariness or consent may trump probability. Also, the first example of risk is societal; it imposes costs on the public but awards benefits to the chemical company. The risk can be reduced by government regulation. The second example of risk is individual; it imposes costs and benefits on the same person and can be reduced by individual choices. Yet, proponents of comparative risk assessment, by considering only the probabilities, would say that the two risks are comparable. They would stop us from reducing preventable environmental risks simple because other risks have higher probabilities.
>
> Reducing decision making to comparative risk assessment presupposes that quantitative factors are more important than ethical values such as equity. Yet quantitative comparisons ignore questions such as who performs the assessment, how the risk figures are averaged, who is put at risk, why they are at risk, who pays to reduce the risk, who benefits from the risk, and who consents to the risk. No scientific technique can justify imposing hazards on a community without answering such questions. Scientific techniques such as comparative risk assessment are necessary but not sufficient for sound environmental policy. To assume they are sufficient is to confuse facts with values, technocracy with democracy.

PEER REVIEW AND AVOIDANCE OF CONFLICTS OF INTEREST

Subtitle C of the bill would establish extensive new requirements for peer review, many of which seem to conflict with existing standards. Under the bill as reported, peer review is likely to be carried out on a large number of relatively routine matters, wasting the resources of taxpayers and the scientific community alike. Scientists with serious conflicts of interest would be allowed to participate and apparently even to form a majority of the panel as long as their interests are disclosed to the agency.

As a result, one of the most critical elements of peer review—namely balance—will be rendered virtually impossible. It is regrettable that the language in the bill does not call for members of peer review panels to be free from serious conflicts of interest and to comply with existing ethical standards, consistent with the Federal Advisory Committee Act.

The bill provides for no definition of the word "external" when used with respect to experts in this subtitle. It is perfectly logical, therefore, to expect that agencies in implementing this provision will exclude all Federal Agency scientists from participating in the peer review, thereby excluding the people who may have the greatest expertise from serving. At the same time, industry scientists need only reveal their conflict of interest in order to be allowed to serve on the panel and are only precluded from serving as a member of a peer review panel, when that review is directed at a decision that only affects the company for which the expert works.

Specifically, the bill creates a peer review process with no protection from producing panels that are primarily composed of industry employees and consultants, and few or no truly independent scientists. This would occur because (i) the bill contains only extremely weak language calling for peer review panels to be balanced "to the extent feasible"; (ii) the bill forbids exclusion of individuals on the ground of conflict-of-interest, except in the most extreme case; and (iii) the language requiring the use of "external" experts, as noted above, could be interpreted as barring the participation of federal scientists from other agencies. (A practice allowed under current law.) This is a case of inviting the fox to guard the chicken coop.

In light of the linkage of the peer review process in Subtitle C with the "certification" requirements of Subtitle B, it is critical that the peer review process established by this bill be, in fact, a neutral forum for discussion, where the best experts come together to review agency risk and cost-benefit assessments. Unfortunately, the language in this bill will not ensure that such peer reviews are "scientifically objective and unbiased", a criterion which is emphasized in earlier parts of the bill.

COST-BENEFIT ANALYSIS REVISITED

Section 3201 of the bill would require the head of an agency to carry out extensive cost-benefit analyses and certify that "no regulatory alternative" would achieve a substantially equivalent risk reduction (1) more cost-effectively or (2) more flexibly for regulated entities.

The effort to reform the regulatory process is partly driven by a concern that the current rulemaking is not scientific enough. However, the cost-benefit process required in the bill obviously pushes beyond the state of the art in doing cost-benefit analysis. The answer the bill's sponsors offer up for questionable epidemiological studies will be questionable cost-benefit studies.

Cost-benefit analysis is notoriously difficult to do well. As experts testified before the committee, it is impossible to anticipate all benefits or costs; many human health and ecological benefits are difficult to estimate and cost-benefit analysis of environmental programs usually undercount benefits relative to costs; scientific understanding is often insufficient to support a particular valuation of benefits; and the bill's inclusion of "indirect costs and benefits" leads to additional ambiguities. For example, Prof. John Graham of Harvard University testified that "* * * both the scientific models and economic models often suffer from the same problem, which is that we are not able to validate, know for sure whether or not the prediction of the model in fact proved to be correct." Commenting on the same point, Dr. J. Clarence Davies III, former Assistant Administrator for Policy, Planning, and Evaluation at EPA during the Bush Administration, wrote, "* * * the economic analysis necessary for each individual regulation would be greatly increased and would involve the use of economic models that will make risk assessment models look like scientific perfection in comparison."

While cost-benefit analysis is an important decision-making tool that should be encouraged, requiring an agency head to "certify" that benefits will justify costs as a prerequisite for any regulation asks for a level of certainty and precision that cost-benefit analysis simply cannot offer. As Dr. Paul Portney of Resources for the Future testified, "If the word certification is construed to mean some kind of proof, then I am afraid that this provision is unworkable and my concern about that is by overloading too much on benefit cost analysis and expecting it to deliver something that I think it is inherently incapable of delivering, I am afraid we are going to lose not only the baby, but also the bassinet with the bath water here."

Further, H.R. 9 would make such a certification judicially reviewable, creating endless opportunities for litigating the myriad difficulties of conducting cost-benefit analysis. To make matters worse, H.R. 9 also requires the agency head to certify that the regulatory approach proposed is superior to the universe of other alternative fixes that may have been pursued—and makes such a certification also judicially reviewable.

In sum, H.R. 9 turns what is a laudable goal—encouraging better cost-benefit analysis—into an inflexible and unobtainable prerequisite for any regulation. As in the case with risk assessments, the result will not be faster, smarter, and cheaper regulation, but regulatory gridlock and a litigation explosion.

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