

104<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 1022

To provide regulatory reform and to focus national economic resources on the greatest risks to human health, safety, and the environment through scientifically objective and unbiased risk assessments and through the consideration of costs and benefits in major rules, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 23, 1995

Mr. WALKER (for himself and Mr. BLILEY) introduced the following bill; which was referred to the Committee on Science and, in addition, to the Committees on Commerce and Government Reform and Oversight, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To provide regulatory reform and to focus national economic resources on the greatest risks to human health, safety, and the environment through scientifically objective and unbiased risk assessments and through the consideration of costs and benefits in major rules, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Risk Assessment and  
3 Cost-Benefit Act of 1995”.

4 **SEC. 2. FINDINGS.**

5 The Congress finds that:

6 (1) Environmental, health, and safety regula-  
7 tions have led to dramatic improvements in the envi-  
8 ronment and have significantly reduced human  
9 health risk; however, the Federal regulations that  
10 have led to these improvements have been more cost-  
11 ly and less effective than they could have been; too  
12 often, regulatory priorities have not been based upon  
13 a realistic consideration of risk, risk reduction op-  
14 portunities, and costs.

15 (2) The public and private resources available  
16 to address health, safety, and environmental con-  
17 cerns are not unlimited; those resources need to be  
18 allocated to address the greatest needs in the most  
19 cost-effective manner and so that the incremental  
20 costs of regulatory alternatives are reasonably relat-  
21 ed to the incremental benefits.

22 (3) To provide more cost-effective and cost-reas-  
23 onable protection to human health and the environ-  
24 ment, regulatory priorities should be based upon re-  
25 alistic consideration of risk; the priority setting proc-  
26 ess must include scientifically sound, objective, and

1 unbiased risk assessments, comparative risk analy-  
2 sis, and risk management choices that are grounded  
3 in cost-benefit principles.

4 (4) Risk assessment has proven to be a useful  
5 decision making tool; however, improvements are  
6 needed in both the quality of assessments and the  
7 characterization and communication of findings; sci-  
8 entific and other data must be better collected, orga-  
9 nized, and evaluated; most importantly, the critical  
10 information resulting from a risk assessment must  
11 be effectively communicated in an objective and un-  
12 biased manner to decision makers, and from decision  
13 makers to the public.

14 (5) The public stake holders must be fully in-  
15 volved in the risk-decision making process. They  
16 have the right-to-know about the risks addressed by  
17 regulation, the amount of risk to be reduced, the  
18 quality of the science used to support decisions, and  
19 the cost of implementing and complying with regula-  
20 tions. This knowledge will allow for public scrutiny  
21 and promote quality, integrity, and responsiveness of  
22 agency decisions.

23 (6) Although risk assessment is one important  
24 method to improve regulatory decision-making, other  
25 approaches to secure prompt relief from the burden

1 of unnecessary and overly complex regulations will  
2 also be necessary.

3 **SEC. 3. COVERAGE OF ACT.**

4 This Act does not apply to any of the following:

5 (1) A situation that the head of an affected  
6 Federal agency determines to be an emergency. In  
7 such circumstance, the head of the agency shall com-  
8 ply with the provisions of this Act within as reason-  
9 able a time as is practical.

10 (2) Activities necessary to maintain military  
11 readiness.

12 (3) Any individual food, drug, or other product  
13 label, or to any risk characterization appearing on  
14 any such label, if the individual product label is re-  
15 quired by law to be approved by a Federal depart-  
16 ment or agency prior to use.

17 (4) Approval of State programs or plans by  
18 Federal agencies.

19 **SEC. 4. DEFINITIONS**

20 For purposes of this Act:

21 (1) COSTS.—The term “costs” includes the di-  
22 rect and indirect costs to the United States Govern-  
23 ment, to State, local, and tribal governments, and to  
24 the private sector, wage earners, consumers, and the

1 economy, of implementing and complying with a rule  
2 or alternative strategy.

3 (2) BENEFIT.—The term “benefit” means the  
4 reasonably identifiable significant health, safety, en-  
5 vironmental, social and economic benefits that are  
6 expected to result directly or indirectly from imple-  
7 mentation of a rule or alternative strategy.

8 (3) MAJOR RULE.—The term “major rule”  
9 means any regulation that is likely to result in an  
10 annual increase in costs of \$25,000,000 or more.  
11 Such term does not include any regulation or other  
12 action taken by an agency to authorize or approve  
13 any individual substance or product.

14 (4) PROGRAM DESIGNED TO PROTECT HUMAN  
15 HEALTH.—The term “program designed to protect  
16 human health” does not include regulatory programs  
17 concerning health insurance, health provider serv-  
18 ices, or health care diagnostic services.

## 19 **Title I—Risk Assessment and** 20 **Communication**

### 21 **SEC. 101. SHORT TITLE.**

22 This title may be cited as the “Risk Assessment and  
23 Communication Act of 1995”.

### 24 **SEC. 102. PURPOSES.**

25 The purposes of this title are—

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

7 (2) to provide for full consideration and discus-  
8 sion of relevant data and potential methodologies;

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

12 (4) to improve consistency within the executive  
13 branch in preparing risk assessments and risk char-  
14 acterizations.

15 **SEC. 103. EFFECTIVE DATE; APPLICABILITY; SAVINGS PRO-**  
16 **VISIONS.**

17 (a) **EFFECTIVE DATE.**—Except as otherwise specifi-  
18 cally provided in this title, the provisions of this title shall  
19 take effect 18 months after the date of enactment of this  
20 title.

21 (b) **APPLICABILITY.**—

22 (1) **IN GENERAL.**—Except as provided in para-  
23 graph (3), this title applies to all significant risk as-  
24 sessment documents and significant risk character-  
25 ization documents, as defined in paragraph (2).

1           (2) SIGNIFICANT RISK ASSESSMENT DOCUMENT  
2           OR SIGNIFICANT RISK CHARACTERIZATION DOCU-  
3           MENT.—(A) As used in this title, the terms “signifi-  
4           cant risk assessment document” and “significant  
5           risk characterization document” include, at a mini-  
6           mum, risk assessment documents or risk character-  
7           ization documents prepared by or on behalf of a cov-  
8           ered Federal agency in the implementation of a reg-  
9           ulatory program designed to protect human health,  
10          safety, or the environment, used as a basis for one  
11          of the items referred to in subparagraph (B), and—

12                   (i) included by the agency in that item; or  
13                   (ii) inserted by the agency in the adminis-  
14                  trative record for that item.

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

17                   (i) Any proposed or final major rule, in-  
18                  cluding any analysis or certification under title  
19                  II, promulgated as part of any Federal regu-  
20                  latory program designed to protect human  
21                  health, safety, or the environment.

22                   (ii) Any proposed or final environmental  
23                  clean-up plan for a facility or Federal guidelines  
24                  for the issuance of any such plan. As used in  
25                  this clause, the term “environmental clean-up”

1 means a corrective action under the Solid  
2 Waste Disposal Act, a removal or remedial ac-  
3 tion under the Comprehensive Environmental  
4 Response, Compensation, and Liability Act of  
5 1980, and any other environmental restoration  
6 and waste management carried out by or on be-  
7 half of a covered Federal agency with respect to  
8 any substance other than municipal waste.

9 (iii) Any proposed or final permit condition  
10 placing a restriction on facility siting or oper-  
11 ation under Federal laws administered by the  
12 Environmental Protection Agency or the De-  
13 partment of the Interior.

14 (iv) Any report to Congress.

15 (v) Any regulatory action to place a sub-  
16 stance on any official list of carcinogens or  
17 toxic or hazardous substances or to place a new  
18 health effects value on such list, including the  
19 Integrated Risk Information System Database  
20 maintained by the Environmental Protection  
21 Agency.

22 (vi) Any guidance, including protocols of  
23 general applicability, establishing policy regard-  
24 ing risk assessment or risk characterization.

1 (C) The terms “significant risk assessment doc-  
2 ument” and “significant risk characterization docu-  
3 ment” shall also include the following:

4 (i) Any such risk assessment and risk  
5 characterization documents provided by a cov-  
6 ered Federal agency to the public and which are  
7 likely to result in an annual increase in costs of  
8 \$25,000,000 or more.

9 (ii) Environmental restoration and waste  
10 management carried out by or on behalf of the  
11 Department of Defense with respect to any sub-  
12 stance other than municipal waste.

13 (D) Within 15 months after the date of the en-  
14 actment of this Act, each covered Federal agency ad-  
15 ministering a regulatory program designed to protect  
16 human health, safety, or the environment shall pro-  
17 mulgate a rule establishing those additional cat-  
18 egories, if any, of risk assessment and risk charac-  
19 terization documents prepared by or on behalf of the  
20 covered Federal agency that the agency will consider  
21 significant risk assessment documents or significant  
22 risk characterization documents for purposes of this  
23 title. In establishing such categories, the head of the  
24 agency shall consider each of the following:

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

4 (ii) The administrative burdens of includ-  
5 ing documents in the categories.

6 (iii) The need to make expeditious admin-  
7 istrative decisions regarding documents in the  
8 categories.

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

15 (v) Such other factors as may be appro-  
16 priate.

17 (E)(i) Not later than 18 months after the date  
18 of the enactment of this Act, the President, acting  
19 through the Director of the Office of Management  
20 and Budget, shall determine whether any other Fed-  
21 eral agencies should be considered covered Federal  
22 agencies for purposes of this title. Such determina-  
23 tion, with respect to a particular Federal agency,  
24 shall be based on the impact of risk assessment doc-  
25 uments and risk characterization documents on—

1 (I) regulatory programs administered by  
2 that agency; and

3 (II) the communication of risk information  
4 by that agency to the public.

5 The effective date of such a determination shall be  
6 no later than 6 months after the date of the deter-  
7 mination.

8 (ii) Not later than 15 months after the Presi-  
9 dent, acting through the Director of the Office of  
10 Management and Budget, determines pursuant to  
11 clause (i) that a Federal agency should be consid-  
12 ered a covered Federal agency for purposes of this  
13 title, the head of that agency shall promulgate a rule  
14 pursuant to subparagraph (D) to establish addi-  
15 tional categories of risk assessment and risk charac-  
16 terization documents described in that subpara-  
17 graph.

18 (3) EXCEPTIONS.—(A) This title does not apply  
19 to risk assessment or risk characterization docu-  
20 ments containing risk assessments or risk character-  
21 izations performed with respect to the following:

22 (i) A screening analysis, where appro-  
23 priately labeled as such, including a screening  
24 analysis for purposes of product regulation or  
25 premanufacturing notices.

1           (ii) Any health, safety, or environmental  
2 inspections.

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

6           (B) No analysis shall be treated as a screening  
7 analysis for purposes of subparagraph (A) if the re-  
8 sults of such analysis are used as the basis for im-  
9 posing restrictions on substances or activities.

10          (C) The risk assessment principle set forth in  
11 section 104(b)(1) need not apply to any risk assess-  
12 ment or risk characterization document described in  
13 clause (iii) of paragraph (2)(B). The risk character-  
14 ization and communication principle set forth in sec-  
15 tion 105(4) need not apply to any risk assessment  
16 or risk characterization document described in  
17 clause (v) or (vi) of paragraph (2)(B).

18          (c) SAVINGS PROVISIONS.—The provisions of this  
19 title shall be supplemental to any other provisions of law  
20 relating to risk assessments and risk characterizations, ex-  
21 cept that nothing in this title shall be construed to modify  
22 any statutory standard or statutory requirement designed  
23 to protect health, safety, or the environment. Nothing in  
24 this title shall be interpreted to preclude the consideration  
25 of any data or the calculation of any estimate to more

1 fully describe risk or provide examples of scientific uncer-  
2 tainty or variability. Nothing in this title shall be con-  
3 strued to require the disclosure of any trade secret or  
4 other confidential information.

5 **SEC. 104. PRINCIPLES FOR RISK ASSESSMENT.**

6 (a) IN GENERAL.—The head of each covered Federal  
7 agency shall apply the principles set forth in subsection  
8 (b) in order to assure that significant risk assessment doc-  
9 uments and all of their components distinguish scientific  
10 findings from other considerations and are, to the extent  
11 feasible, scientifically objective, unbiased, and inclusive of  
12 all relevant data and rely, to the extent available and prac-  
13 ticable, on scientific findings. Discussions or explanations  
14 required under this section need not be repeated in each  
15 risk assessment document as long as there is a reference  
16 to the relevant discussion or explanation in another agency  
17 document which is available to the public.

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

20 (1) When discussing human health risks, a sig-  
21 nificant risk assessment document shall contain a  
22 discussion of both relevant laboratory and relevant  
23 epidemiological data of sufficient quality which finds,  
24 or fails to find, a correlation between health risks  
25 and a potential toxin or activity. Where conflicts

1 among such data appear to exist, or where animal  
2 data is used as a basis to assess human health, the  
3 significant risk assessment document shall, to the  
4 extent feasible and appropriate, include discussion of  
5 possible reconciliation of conflicting information, and  
6 as relevant, differences in study designs, compara-  
7 tive physiology, routes of exposure, bioavailability,  
8 pharmacokinetics, and any other relevant factor, in-  
9 cluding the sufficiency of basic data for review. The  
10 discussion of possible reconciliation should indicate  
11 whether there is a biological basis to assume a re-  
12 sulting harm in humans. Animal data shall be re-  
13 viewed with regard to its relevancy to humans.

14 (2) Where a significant risk assessment docu-  
15 ment involves selection of any significant assump-  
16 tion, inference, or model, the document shall, to the  
17 extent feasible—

18 (A) present a representative list and expla-  
19 nation of plausible and alternative assumptions,  
20 inferences, or models;

21 (B) explain the basis for any choices;

22 (C) identify any policy or value judgments;

23 (D) fully describe any model used in the  
24 risk assessment and make explicit the assump-  
25 tions incorporated in the model; and

1 (E) indicate the extent to which any sig-  
2 nificant model has been validated by, or con-  
3 flicts with, empirical data.

4 **SEC. 105. PRINCIPLES FOR RISK CHARACTERIZATION AND**  
5 **COMMUNICATION.**

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

8 (1) ESTIMATES OF RISK.—The risk character-  
9 ization shall describe the populations or natural re-  
10 sources which are the subject of the risk character-  
11 ization. If a numerical estimate of risk is provided,  
12 the agency shall, to the extent feasible, provide—

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

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

20 In addition to such best estimate or estimates, the  
21 risk characterization document may present plau-  
22 sible upper-bound or conservative estimates in con-  
23 junction with plausible lower bounds estimates.

24 Where appropriate, the risk characterization docu-  
25 ment may present, in lieu of a single best estimate,

1 multiple best estimates based on assumptions, infer-  
2 ences, or models which are equally plausible, given  
3 current scientific understanding. To the extent prac-  
4 tical and appropriate, the document shall provide de-  
5 scriptions of the distribution and probability of risk  
6 estimates to reflect differences in exposure varia-  
7 bility or sensitivity in populations and attendant un-  
8 certainties.

9 (2) EXPOSURE SCENARIOS.—The risk charac-  
10 terization document shall explain the exposure sce-  
11 narios used in any risk assessment, and, to the ex-  
12 tent feasible, provide a statement of the size of the  
13 corresponding population at risk and the likelihood  
14 of such exposure scenarios.

15 (3) COMPARISONS.—The document shall con-  
16 tain a statement that places the nature and mag-  
17 nitude of risks to human health, safety, or the envi-  
18 ronment in context. Such statement shall, to the ex-  
19 tent feasible, provide comparisons with estimates of  
20 greater, lesser, and substantially equivalent risks  
21 that are familiar to and routinely encountered by the  
22 general public as well as other risks, and, where ap-  
23 propriate and meaningful, comparisons of those risks  
24 with other similar risks regulated by the Federal  
25 agency resulting from comparable activities and ex-

1       posure pathways. Such comparisons should consider  
2       relevant distinctions among risks, such as the vol-  
3       untary or involuntary nature of risks and the pre-  
4       ventability or nonpreventability of risks.

5           (4) SUBSTITUTION RISKS.—Each significant  
6       risk assessment or risk characterization document  
7       shall include a statement of any significant substi-  
8       tution risks to human health, where information on  
9       such risks has been provided to the agency.

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

12           (A) a commenter provides a covered Fed-  
13       eral agency with a relevant risk assessment doc-  
14       ument or a risk characterization document, and  
15       a summary thereof, during a public comment  
16       provided by the agency for a significant risk as-  
17       sessment document or a significant risk charac-  
18       terization document, or, where no comment pe-  
19       riod is provided but a commenter provides the  
20       covered Federal agency with the relevant risk  
21       assessment document or risk characterization  
22       document, and a summary thereof, in a timely  
23       fashion, and

24           (B) the risk assessment document or risk  
25       characterization document is consistent with the

1 principles and the guidance provided under this  
2 title,  
3 the agency shall, to the extent feasible, present such  
4 summary in connection with the presentation of the  
5 agency's significant risk assessment document or  
6 significant risk characterization document. Nothing  
7 in this paragraph shall be construed to limit the in-  
8 clusion of any comments or material supplied by any  
9 person to the administrative record of any proceed-  
10 ing.

11 A document may satisfy the requirements of paragraph  
12 (3), (4) or (5) by reference to information or material oth-  
13 erwise available to the public if the document provides a  
14 brief summary of such information or material.

15 **SEC. 106. RECOMMENDATIONS OR CLASSIFICATIONS BY A**  
16 **NON-UNITED STATES-BASED ENTITY.**

17 No covered Federal agency shall automatically incor-  
18 porate or adopt any recommendation or classification  
19 made by a non-United States-based entity concerning the  
20 health effects value of a substance without an opportunity  
21 for notice and comment, and any risk assessment docu-  
22 ment or risk characterization document adopted by a cov-  
23 ered Federal agency on the basis of such a recommenda-  
24 tion or classification shall comply with the provisions of  
25 this title.

1 **SEC. 107. GUIDELINES AND REPORT.**

2 (a) **GUIDELINES.**—Within 15 months after the date  
3 of enactment of this title, the President shall issue guide-  
4 lines for Federal agencies consistent with the risk assess-  
5 ment and characterization principles set forth in sections  
6 104 and 105 and shall provide a format for summarizing  
7 risk assessment results. In addition, such guidelines shall  
8 include guidance on at least the following subjects: criteria  
9 for scaling animal studies to assess risks to human health;  
10 use of different types of dose-response models; thresholds;  
11 definitions, use, and interpretations of the maximum toler-  
12 ated dose; weighting of evidence with respect to extrapo-  
13 lating human health risks from sensitive species; evalua-  
14 tion of benign tumors, and evaluation of different human  
15 health endpoints.

16 (b) **REPORT.**—Within 3 years after the enactment of  
17 this title, each covered Federal agency shall provide a re-  
18 port to the Congress evaluating the categories of policy  
19 and value judgments identified under subparagraph (C)  
20 of section 104(b)(2).

21 (c) **PUBLIC COMMENT AND CONSULTATION.**—The  
22 guidelines and report under this section, shall be developed  
23 after notice and opportunity for public comment, and after  
24 consultation with representatives of appropriate State,  
25 local, and tribal governments, and such other departments

1 and agencies, offices, organizations, or persons as may be  
2 advisable.

3 (d) REVIEW.—The President shall review and, where  
4 appropriate, revise the guidelines published under this sec-  
5 tion at least every 4 years.

6 **SEC. 108. RESEARCH AND TRAINING IN RISK ASSESSMENT.**

7 (a) EVALUATION.—The head of each covered agency  
8 shall regularly and systematically evaluate risk assessment  
9 research and training needs of the agency, including,  
10 where relevant and appropriate, the following:

11 (1) Research to reduce generic data gaps, to  
12 address modelling needs (including improved model  
13 sensitivity), and to validate default options, particu-  
14 larly those common to multiple risk assessments.

15 (2) Research leading to improvement of meth-  
16 ods to quantify and communicate uncertainty and  
17 variability among individuals, species, populations,  
18 and, in the case of ecological risk assessment, eco-  
19 logical communities.

20 (3) Emerging and future areas of research, in-  
21 cluding research on comparative risk analysis, expo-  
22 sure to multiple chemicals and other stressors,  
23 noncancer endpoints, biological markers of exposure  
24 and effect, mechanisms of action in both mammalian  
25 and nonmammalian species, dynamics and prob-

1 abilities of physiological and ecosystem exposures,  
2 and prediction of ecosystem-level responses.

3 (4) Long-term needs to adequately train indi-  
4 viduals in risk assessment and risk assessment appli-  
5 cation. Evaluations under this paragraph shall in-  
6 clude an estimate of the resources needed to provide  
7 necessary training.

8 (b) STRATEGY AND ACTIONS TO MEET IDENTIFIED  
9 NEEDS.—The head of each covered agency shall develop  
10 a strategy and schedule for carrying out research and  
11 training to meet the needs identified in subsection (a).

12 (c) REPORT.—Not later than 6 months after the date  
13 of the enactment of this Act, the head of each covered  
14 agency shall submit to the Congress a report on the eval-  
15 uations conducted under subsection (a) and the strategy  
16 and schedule developed under subsection (b). The head of  
17 each covered agency shall report to the Congress periodi-  
18 cally on the evaluations, strategy, and schedule.

19 **SEC. 109. STUDY OF COMPARATIVE RISK ANALYSIS.**

20 (a) IN GENERAL.—(1) The Director of the Office of  
21 Management and Budget, in consultation with the Office  
22 of Science and Technology Policy, shall conduct, or pro-  
23 vide for the conduct of, a study using comparative risk  
24 analysis to rank health, safety, and environmental risks  
25 and to provide a common basis for evaluating strategies

1 for reducing or preventing those risks. The goal of the  
2 study shall be to improve methods of comparative risk  
3 analysis.

4 (2) Not later than 90 days after the date of the enact-  
5 ment of this Act, the Director, in collaboration with the  
6 heads of appropriate Federal agencies, shall enter into a  
7 contract with the National Research Council to provide  
8 technical guidance on approaches to using comparative  
9 risk analysis and other considerations in setting health,  
10 safety, and environmental risk reduction priorities.

11 (b) SCOPE OF STUDY.—The study shall have suffi-  
12 cient scope and breadth to evaluate comparative risk anal-  
13 ysis and to test approaches for improving comparative risk  
14 analysis and its use in setting priorities for health, safety,  
15 and environmental risk reduction. The study shall com-  
16 pare and evaluate a range of diverse health, safety, and  
17 environmental risks.

18 (c) STUDY PARTICIPANTS.—In conducting the study,  
19 the Director shall provide for the participation of a range  
20 of individuals with varying backgrounds and expertise,  
21 both technical and nontechnical, comprising broad rep-  
22 resentation of the public and private sectors.

23 (d) DURATION.—The study shall begin within 180  
24 days after the date of the enactment of this Act and termi-  
25 nate within 2 years after the date on which it began.

1 (e) RECOMMENDATIONS FOR IMPROVING COMPARA-  
2 TIVE RISK ANALYSIS AND ITS USE.—Not later than 90  
3 days after the termination of the study, the Director shall  
4 submit to the Congress the report of the National Re-  
5 search Council with recommendations regarding the use  
6 of comparative risk analysis and ways to improve the use  
7 of comparative risk analysis for decision-making in appro-  
8 priate Federal agencies.

9 **SEC. 110. DEFINITIONS.**

10 For purposes of this title:

11 (1) RISK ASSESSMENT DOCUMENT.—The term  
12 “risk assessment document” means a document con-  
13 taining the explanation of how hazards associated  
14 with a substance, activity, or condition have been  
15 identified, quantified, and assessed. The term also  
16 includes a written statement accepting the findings  
17 of any such document.

18 (2) RISK CHARACTERIZATION DOCUMENT.—The  
19 term “risk characterization document” means a doc-  
20 ument quantifying or describing the degree of tox-  
21 icity, exposure, or other risk posed by hazards asso-  
22 ciated with a substance, activity, or condition to  
23 which individuals, populations, or resources are ex-  
24 posed. The term also includes a written statement  
25 accepting the findings of any such document.

1           (3) BEST ESTIMATE.—The term “best esti-  
2           mate” means a scientifically appropriate estimate  
3           which is based, to the extent feasible, on one of the  
4           following:

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

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

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

15           (4) SUBSTITUTION RISK.—The term “substi-  
16           tution risk” means a potential risk to human health,  
17           safety, or the environment from a regulatory alter-  
18           native designed to decrease other risks.

19           (5) COVERED FEDERAL AGENCY.—The term  
20           “covered Federal agency” means each of the follow-  
21           ing:

22                   (A) The Environmental Protection Agency.

23                   (B) The Occupational Safety and Health  
24                   Administration.

1 (C) The Department of Transportation  
2 (including the National Highway Transpor-  
3 tation Safety Administration).

4 (D) The Food and Drug Administration.

5 (E) The Department of Energy.

6 (F) The Department of the Interior.

7 (G) The Department of Agriculture.

8 (H) The Consumer Product Safety Com-  
9 mission.

10 (I) The National Oceanic and Atmospheric  
11 Administration

12 (J) The United States Army Corps of En-  
13 gineers.

14 (K) The Mine Safety and Health Adminis-  
15 tration.

16 (L) The Nuclear Regulatory Commission.

17 (M) Any other Federal agency considered  
18 a covered Federal agency pursuant to section  
19 103(b)(2)(E)

20 (6) FEDERAL AGENCY.—The term “Federal  
21 agency” means an executive department, military de-  
22 partment, or independent establishment as defined  
23 in part I of title 5 of the United States Code, except  
24 that such term also includes the Office of Tech-  
25 nology Assessment.

1 (7) DOCUMENT.—The term “document” in-  
2 cludes material stored in electronic or digital form.

3 **Title II—Analysis of Risk**  
4 **Reduction Benefits and Costs**

5 **SEC. 201. ANALYSIS OF RISK REDUCTION BENEFITS AND**  
6 **COSTS.**

7 (a) IN GENERAL.—The President shall require each  
8 Federal agency to prepare the following for each major  
9 rule within a program designed to protect human health,  
10 safety, or the environment that is proposed or promul-  
11 gated by the agency after the date of enactment of this  
12 Act:

13 (1) An identification of reasonable alternative  
14 strategies, including strategies that—

15 (A) require no government action;

16 (B) will accommodate differences among  
17 geographic regions and among persons with dif-  
18 ferent levels of resources with which to comply;

19 and

20 (C) employ performance or other market-  
21 based mechanisms that permit the greatest  
22 flexibility in achieving the identified benefits of  
23 the rule.

24 The agency shall consider reasonable alternative  
25 strategies proposed during the comment period.

1           (2) An analysis of the incremental costs and in-  
2           cremental risk reduction or other benefits associated  
3           with each alternative strategy identified or consid-  
4           ered by the agency. Costs and benefits shall be  
5           quantified to the extent feasible and appropriate and  
6           may otherwise be qualitatively described.

7           (3) A statement that places in context the na-  
8           ture and magnitude of the risks to be addressed and  
9           the residual risks likely to remain for each alter-  
10          native strategy identified or considered by the agen-  
11          cy. Such statement shall, to the extent feasible, pro-  
12          vide comparisons with estimates of greater, lesser,  
13          and substantially equivalent risks that are familiar  
14          to and routinely encountered by the general public  
15          as well as other risks, and, where appropriate and  
16          meaningful, comparisons of those risks with other  
17          similar risks regulated by the Federal agency result-  
18          ing from comparable activities and exposure path-  
19          ways. Such comparisons should consider relevant  
20          distinctions among risks, such as the voluntary or  
21          involuntary nature of risks and the preventability or  
22          nonpreventability of risks.

23          (4) For each final rule, an analysis of whether  
24          the identified benefits of the rule are likely to exceed  
25          the identified costs of the rule.

- 1 (5) An analysis of the effect of the rule—  
2 (A) on small businesses with fewer than  
3 100 employees;  
4 (B) on net employment; and  
5 (C) to the extent practicable, on the cumu-  
6 lative financial burden of compliance with the  
7 rule and other existing regulations on persons  
8 producing products.

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

15 **SEC. 202. DECISION CRITERIA.**

16 (a) IN GENERAL.—No final rule subject to the provi-  
17 sions of this title shall be promulgated unless the agency  
18 certifies the following:

- 19 (1) That the analyses under section 201 are  
20 based on objective and unbiased scientific and eco-  
21 nomic evaluations of all significant and relevant in-  
22 formation and risk assessments provided to the  
23 agency by interested parties relating to the costs,  
24 risks, and risk reduction and other benefits ad-  
25 dressed by the rule.

1           (2) That the incremental risk reduction or other  
2 benefits of any strategy chosen will be likely to jus-  
3 tify, and be reasonably related to, the incremental  
4 costs incurred by State, local, and tribal govern-  
5 ments, the Federal Government, and other public  
6 and private entities.

7           (3) That other alternative strategies identified  
8 or considered by the agency were found either (A)  
9 to be less cost-effective at achieving a substantially  
10 equivalent reduction in risk, or (B) to provide less  
11 flexibility to State, local, or tribal governments or  
12 regulated entities in achieving the otherwise applica-  
13 ble objectives of the regulation, along with a brief  
14 explanation of why alternative strategies that were  
15 identified or considered by the agency were found to  
16 be less cost-effective or less flexible.

17 (b) EFFECT OF DECISION CRITERIA.—

18           (1) IN GENERAL.—Notwithstanding any other  
19 provision of Federal law, the decision criteria of sub-  
20 section (a) shall supplement and, to the extent there  
21 is a conflict, supersede the decision criteria for rule-  
22 making otherwise applicable under the statute pur-  
23 suant to which the rule is promulgated.

24           (2) SUBSTANTIAL EVIDENCE.—Notwithstanding  
25 any other provision of Federal law, no major rule

1 shall be promulgated by any Federal agency pertain-  
2 ing to the protection of health, safety, or the envi-  
3 ronment unless the requirements of section 201 and  
4 subsection (a) are met and the certifications re-  
5 quired therein are supported by substantial evidence  
6 of the rulemaking record.

7 (c) PUBLICATION.—The agency shall publish in the  
8 Federal Register, along with the final regulation, the cer-  
9 tifications required by subsection (a).

10 (d) NOTICE.—Where the agency finds a conflict be-  
11 tween the decision criteria of this section and the decision  
12 criteria of an otherwise applicable statute, the agency shall  
13 so notify the Congress in writing.

14 **SEC. 203. OFFICE OF MANAGEMENT AND THE BUDGET**  
15 **GUIDANCE.**

16 The Office of Management and Budget shall issue  
17 guidance consistent with this title—

18 (1) to assist the agencies, the public, and the  
19 regulated community in the implementation of this  
20 title, including any new requirements or procedures  
21 needed to supplement prior agency practice; and

22 (2) governing the development and preparation  
23 of analyses of risk reduction benefits and costs.

## **Title III—Peer Review**

### **2 SEC. 301. PEER REVIEW PROGRAM.**

3 (a) ESTABLISHMENT.—For regulatory programs de-  
4 signed to protect human health, safety, or the environ-  
5 ment, the head of each Federal agency shall develop a sys-  
6 tematic program for independent and external peer review  
7 required by subsection (b). Such program shall be applica-  
8 ble across the agency and—

9 (1) shall provide for the creation of peer review  
10 panels consisting of experts and shall be broadly rep-  
11 resentative and balanced and to the extent relevant  
12 and appropriate, may include representatives of  
13 State, local, and tribal governments, small busi-  
14 nesses, other representatives of industry, univer-  
15 sities, agriculture, labor, consumers, conservation or-  
16 ganizations, or other public interest groups and or-  
17 ganizations;

18 (2) may provide for differing levels of peer re-  
19 view and differing numbers of experts on peer review  
20 panels, depending on the significance or the com-  
21 plexity of the problems or the need for expeditious-  
22 ness;

23 (3) shall not exclude peer reviewers with sub-  
24 stantial and relevant expertise merely because they  
25 represent entities that may have a potential interest

1 in the outcome, provided that interest is fully dis-  
2 closed to the agency and in the case of a regulatory  
3 decision affecting a single entity, no peer reviewer  
4 representing such entity may be included on the  
5 panel;

6 (4) may provide specific and reasonable dead-  
7 lines for peer review panels to submit reports under  
8 subsection (c); and

9 (5) shall provide adequate protections for con-  
10 fidential business information and trade secrets, in-  
11 cluding requiring peer reviewers to enter into con-  
12 fidentiality agreements.

13 (b) REQUIREMENT FOR PEER REVIEW.—In connec-  
14 tion with any rule that is likely to result in an annual  
15 increase in costs of \$100,000,000 or more (other than any  
16 rule or other action taken by an agency to authorize or  
17 approve any individual substance or product), each Fed-  
18 eral agency shall provide for peer review in accordance  
19 with this section of any risk assessment or cost analysis  
20 which forms the basis for such rule or of any analysis  
21 under section 201(a). In addition, the Director of the Of-  
22 fice of Management and Budget may order that peer re-  
23 view be provided for any major risk assessment or cost  
24 assessment that is likely to have a significant impact on  
25 public policy decisions.

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

5 (d) RESPONSE TO PEER REVIEW.—The head of the  
6 Federal agency shall provide a written response to all sig-  
7 nificant peer review comments.

8 (e) AVAILABILITY TO PUBLIC.—All peer review com-  
9 ments or conclusions and the agency's responses shall be  
10 made available to the public and shall be made part of  
11 the administrative record.

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

17 (g) NATIONAL PANELS.—The President shall appoint  
18 National Peer Review Panels to annually review the risk  
19 assessment and cost assessment practices of each Federal  
20 agency for programs designed to protect human health,  
21 safety, or the environment. The Panel shall submit a re-  
22 port to the Congress no less frequently than annually con-  
23 taining the results of such review.

## 1           **Title IV—Judicial Review**

### 2   **SEC. 401. JUDICIAL REVIEW.**

3           Compliance or noncompliance by a Federal agency  
4 with the requirements of this Act shall be reviewable pur-  
5 suant to the statute granting the agency authority to act  
6 or, as applicable, that statute and the Administrative Pro-  
7 cedure Act. The court with jurisdiction to review final  
8 agency action under the statute granting the agency au-  
9 thority to act shall have jurisdiction to review, at the same  
10 time, the agency's compliance with the requirements of  
11 this Act. When a significant risk assessment document or  
12 risk characterization document subject to title I is part  
13 of the administrative record in a final agency action, in  
14 addition to any other matters that the court may consider  
15 in deciding whether the agency's action was lawful, the  
16 court shall consider the agency action unlawful if such sig-  
17 nificant risk assessment document or significant risk char-  
18 acterization document does not substantially comply with  
19 the requirements of sections 104 and 105.

## 20           **Title V—Plan**

### 21   **SEC. 501. PLAN FOR ASSESSING NEW INFORMATION.**

22           (a) PLAN.—Within 18 months after the date of en-  
23 actment of this Act, each covered Federal agency (as de-  
24 fined in title I) shall publish a plan to review and, where  
25 appropriate revise any significant risk assessment docu-

1 ment or significant risk characterization document pub-  
2 lished prior to the expiration of such 18-month period if,  
3 based on information available at the time of such review,  
4 the agency head determines that the application of the  
5 principles set forth in sections 104 and 105 would be likely  
6 to significantly alter the results of the prior risk assess-  
7 ment or risk characterization. The plan shall provide pro-  
8 cedures for receiving and considering new information and  
9 risk assessments from the public. The plan may set prior-  
10 ities and procedures for review and, where appropriate, re-  
11 vision of such risk assessment documents and risk charac-  
12 terization documents and of health or environmental ef-  
13 fects values. The plan may also set priorities and proce-  
14 dures for review, and, where appropriate, revision or re-  
15 peal of major rules promulgated prior to the expiration  
16 of such period. Such priorities and procedures shall be  
17 based on the potential to more efficiently focus national  
18 economic resources within Federal regulatory programs  
19 designed to protect human health, safety, or the environ-  
20 ment on the most important priorities and on such other  
21 factors as such Federal agency considers appropriate.

22 (b) PUBLIC COMMENT AND CONSULTATION.—The  
23 plan under this section, shall be developed after notice and  
24 opportunity for public comment, and after consultation  
25 with representatives of appropriate State, local, and tribal

1 governments, and such other departments and agencies,  
2 offices, organizations, or persons as may be advisable.

## 3 **Title VI—Priorities**

### 4 **SEC. 601. PRIORITIES.**

5 (a) IDENTIFICATION OF OPPORTUNITIES.—In order  
6 to assist in the public policy and regulation of risks to  
7 public health, the President shall identify opportunities to  
8 reflect priorities within existing Federal regulatory pro-  
9 grams designed to protect human health in a cost-effective  
10 and cost-reasonable manner. The President shall identify  
11 each of the following:

12 (1) The likelihood and severity of public health  
13 risks addressed by current Federal programs.

14 (2) The number of individuals affected.

15 (3) The incremental costs and risk reduction  
16 benefits associated with regulatory or other strate-  
17 gies.

18 (4) The cost-effectiveness of regulatory or other  
19 strategies to reduce risks to public health.

20 (5) Intergovernmental relationships among Fed-  
21 eral, State, and local governments among programs  
22 designed to protect public health.

23 (6) Statutory, regulatory, or administrative ob-  
24 stacles to allocating national economic resources  
25 based on the most cost-effective, cost-reasonable pri-

1 orities considering Federal, State, and local pro-  
2 grams.

3 (b) BIENNIAL REPORTS.—The President shall issue  
4 biennial reports to Congress, after notice and opportunity  
5 for public comment, to recommend priorities for modifica-  
6 tions to, elimination of, or strategies for existing Federal  
7 regulatory programs designed to protect public health.  
8 Within 6 months after the issuance of the report, the  
9 President shall notify the Congress in writing of the rec-  
10 ommendations which can be implemented without further  
11 legislative changes and the agency shall consider the prior-  
12 ities set forth in the report when preparing a budget or  
13 strategic plan for any such regulatory program.

○

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