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H. R. 1022

IN THE SENATE OF THE UNITED STATES

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AN ACT

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. UNFUNDED MANDATES.**

20 Nothing in this Act itself shall, without Federal fund-
21 ing and further Federal agency action, create any new ob-
22 ligation or burden on any State or local government or
23 otherwise impose any financial burden on any State or
24 local government in the absence of Federal funding, except
25 with respect to routine information requests.

1 **SEC. 5. DEFINITIONS.**

2 For purposes of this Act:

3 (1) COSTS.—The term “costs” includes the di-
4 rect and indirect costs to the United States Govern-
5 ment, to State, local, and tribal governments, and to
6 the private sector, wage earners, consumers, and the
7 economy, of implementing and complying with a rule
8 or alternative strategy.

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

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

20 (4) PROGRAM DESIGNED TO PROTECT HUMAN
21 HEALTH.—The term “program designed to protect
22 human health” does not include regulatory programs
23 concerning health insurance, health provider serv-
24 ices, or health care diagnostic services.

25 (5) EMERGENCY.—As used in this Act, the
26 term “emergency” means a situation that is imme-

1 diately impending and extraordinary in nature, de-
2 manding attention due to a condition, circumstance,
3 or practice reasonably expected to cause death, seri-
4 ous illness, or severe injury to humans, or substan-
5 tial endangerment to private property or the envi-
6 ronment if no action is taken.

7 **SEC. 6. AVAILABILITY OF INFORMATION AMONG FEDERAL**
8 **AGENCIES.**

9 Covered Federal agencies shall make existing
10 databases and information developed under this Act avail-
11 able to other Federal agencies, subject to applicable con-
12 fidentiality requirements, for the purpose of meeting the
13 requirements of this Act. Within 15 months after the date
14 of enactment of this Act, the President shall issue guide-
15 lines for Federal agencies to comply with this section.

16 **TITLE I—RISK ASSESSMENT AND**
17 **COMMUNICATION**

18 **SEC. 101. SHORT TITLE.**

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

21 **SEC. 102. PURPOSES.**

22 The purposes of this title are—

23 (1) to present the public and executive branch
24 with the most scientifically objective and unbiased
25 information concerning the nature and magnitude of

1 health, safety, and environmental risks in order to
2 provide for sound regulatory decisions and public
3 education;

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

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

9 (4) to improve consistency within the executive
10 branch in preparing risk assessments and risk char-
11 acterizations.

12 **SEC. 103. EFFECTIVE DATE; APPLICABILITY; SAVINGS PRO-**
13 **VISIONS.**

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

18 (b) APPLICABILITY.—

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

23 (2) SIGNIFICANT RISK ASSESSMENT DOCUMENT
24 OR SIGNIFICANT RISK CHARACTERIZATION DOCU-
25 MENT.—(A) As used in this title, the terms “signifi-

1 cant risk assessment document” and “significant
2 risk characterization document” include, at a mini-
3 mum, risk assessment documents or risk character-
4 ization documents prepared by or on behalf of a cov-
5 ered Federal agency in the implementation of a reg-
6 ulatory program designed to protect human health,
7 safety, or the environment, used as a basis for one
8 of the items referred to in subparagraph (B), and—

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

10 (ii) inserted by the agency in the adminis-
11 trative record for that item.

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

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

19 (ii) Any proposed or final environmental
20 clean-up plan for a facility or Federal guidelines
21 for the issuance of any such plan. As used in
22 this clause, the term “environmental clean-up”
23 means a corrective action under the Solid
24 Waste Disposal Act, a removal or remedial ac-
25 tion under the Comprehensive Environmental

1 Response, Compensation, and Liability Act of
2 1980, and any other environmental restoration
3 and waste management carried out by or on be-
4 half of a covered Federal agency with respect to
5 any substance other than municipal waste.

6 (iii) Any proposed or final permit condition
7 placing a restriction on facility siting or oper-
8 ation under Federal laws administered by the
9 Environmental Protection Agency or the De-
10 partment of the Interior. Nothing in this sec-
11 tion (iii) shall apply to the requirements of sec-
12 tion 404 of the Clean Water Act.

13 (iv) Any report to Congress.

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

21 (vi) Any guidance, including protocols of
22 general applicability, establishing policy regard-
23 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. Sensitive subpopulations or highly ex-
9 posed subpopulations include, where relevant and
10 appropriate, children, the elderly, pregnant women,
11 and disabled persons.

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

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

1 appropriate and meaningful, comparisons of those risks
2 with other similar risks regulated by the Federal
3 agency resulting from comparable activities and ex-
4 posure pathways. Such comparisons should consider
5 relevant distinctions among risks, such as the vol-
6 untary or involuntary nature of risks and the pre-
7 ventability or nonpreventability of risks.

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

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

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

1 document, and a summary thereof, in a timely
2 fashion, and

3 (B) the risk assessment document or risk
4 characterization document is consistent with the
5 principles and the guidance provided under this
6 title,

7 the agency shall, to the extent feasible, present such
8 summary in connection with the presentation of the
9 agency's significant risk assessment document or
10 significant risk characterization document. Nothing
11 in this paragraph shall be construed to limit the in-
12 clusion of any comments or material supplied by any
13 person to the administrative record of any proceed-
14 ing.

15 A document may satisfy the requirements of paragraph
16 (3), (4) or (5) by reference to information or material oth-
17 erwise available to the public if the document provides a
18 brief summary of such information or material.

19 **SEC. 106. RECOMMENDATIONS OR CLASSIFICATIONS BY A**
20 **NON-UNITED STATES-BASED ENTITY.**

21 No covered Federal agency shall automatically incor-
22 porate or adopt any recommendation or classification
23 made by a non-United States-based entity concerning the
24 health effects value of a substance without an opportunity
25 for notice and comment, and any risk assessment docu-

1 ment or risk characterization document adopted by a cov-
2 ered Federal agency on the basis of such a recommenda-
3 tion or classification shall comply with the provisions of
4 this title. For the purposes of this section, the term “non-
5 United States-based entity” means—

6 (1) any foreign government and its agencies;

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

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

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

14 **SEC. 107. GUIDELINES AND REPORT.**

15 (a) GUIDELINES.—Within 15 months after the date
16 of enactment of this title, the President shall issue guide-
17 lines for Federal agencies consistent with the risk assess-
18 ment and characterization principles set forth in sections
19 104 and 105 and shall provide a format for summarizing
20 risk assessment results. In addition, such guidelines shall
21 include guidance on at least the following subjects: criteria
22 for scaling animal studies to assess risks to human health;
23 use of different types of dose-response models; thresholds;
24 definitions, use, and interpretations of the maximum toler-
25 ated dose; weighting of evidence with respect to extrapo-

1 lating human health risks from sensitive species; evalua-
2 tion of benign tumors, and evaluation of different human
3 health endpoints.

4 (b) REPORT.—Within 3 years after the enactment of
5 this title, each covered Federal agency shall provide a re-
6 port to the Congress evaluating the categories of policy
7 and value judgments identified under subparagraph (C)
8 of section 104(b)(2).

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

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

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

20 (a) EVALUATION.—The head of each covered agency
21 shall regularly and systematically evaluate risk assessment
22 research and training needs of the agency, including,
23 where relevant and appropriate, the following:

24 (1) Research to reduce generic data gaps, to
25 address modelling needs (including improved model

1 sensitivity), and to validate default options, particu-
2 larly those common to multiple risk assessments.

3 (2) Research leading to improvement of meth-
4 ods to quantify and communicate uncertainty and
5 variability among individuals, species, populations,
6 and, in the case of ecological risk assessment, eco-
7 logical communities.

8 (3) Emerging and future areas of research, in-
9 cluding research on comparative risk analysis, expo-
10 sure to multiple chemicals and other stressors,
11 noncancer endpoints, biological markers of exposure
12 and effect, mechanisms of action in both mammalian
13 and nonmammalian species, dynamics and prob-
14 abilities of physiological and ecosystem exposures,
15 and prediction of ecosystem-level responses.

16 (4) Long-term needs to adequately train indi-
17 viduals in risk assessment and risk assessment appli-
18 cation. Evaluations under this paragraph shall in-
19 clude an estimate of the resources needed to provide
20 necessary training.

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

1 (c) REPORT.—Not later than 6 months after the date
2 of the enactment of this Act, the head of each covered
3 agency shall submit to the Congress a report on the eval-
4 uations conducted under subsection (a) and the strategy
5 and schedule developed under subsection (b). The head of
6 each covered agency shall report to the Congress periodi-
7 cally on the evaluations, strategy, and schedule.

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

9 (a) IN GENERAL.—(1) The Director of the Office of
10 Management and Budget, in consultation with the Office
11 of Science and Technology Policy, shall conduct, or pro-
12 vide for the conduct of, a study using comparative risk
13 analysis to rank health, safety, and environmental risks
14 and to provide a common basis for evaluating strategies
15 for reducing or preventing those risks. The goal of the
16 study shall be to improve methods of comparative risk
17 analysis.

18 (2) Not later than 90 days after the date of the enact-
19 ment of this Act, the Director, in collaboration with the
20 heads of appropriate Federal agencies, shall enter into a
21 contract with the National Research Council to provide
22 technical guidance on approaches to using comparative
23 risk analysis and other considerations in setting health,
24 safety, and environmental risk reduction priorities.

1 (b) SCOPE OF STUDY.—The study shall have suffi-
2 cient scope and breadth to evaluate comparative risk anal-
3 ysis and to test approaches for improving comparative risk
4 analysis and its use in setting priorities for health, safety,
5 and environmental risk reduction. The study shall com-
6 pare and evaluate a range of diverse health, safety, and
7 environmental risks.

8 (c) STUDY PARTICIPANTS.—In conducting the study,
9 the Director shall provide for the participation of a range
10 of individuals with varying backgrounds and expertise,
11 both technical and nontechnical, comprising broad rep-
12 resentation of the public and private sectors.

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

16 (e) RECOMMENDATIONS FOR IMPROVING COMPARA-
17 TIVE RISK ANALYSIS AND ITS USE.—Not later than 90
18 days after the termination of the study, the Director shall
19 submit to the Congress the report of the National Re-
20 search Council with recommendations regarding the use
21 of comparative risk analysis and ways to improve the use
22 of comparative risk analysis for decision-making in appro-
23 priate Federal agencies.

24 **SEC. 110. DEFINITIONS.**

25 For purposes of this title:

1 (1) RISK ASSESSMENT DOCUMENT.—The term
2 “risk assessment document” means a document con-
3 taining the explanation of how hazards associated
4 with a substance, activity, or condition have been
5 identified, quantified, and assessed. The term also
6 includes a written statement accepting the findings
7 of any such document.

8 (2) RISK CHARACTERIZATION DOCUMENT.—The
9 term “risk characterization document” means a doc-
10 ument quantifying or describing the degree of tox-
11 icity, exposure, or other risk posed by hazards asso-
12 ciated with a substance, activity, or condition to
13 which individuals, populations, or resources are ex-
14 posed. The term also includes a written statement
15 accepting the findings of any such document.

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

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

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

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

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

10 (5) COVERED FEDERAL AGENCY.—The term
11 “covered Federal agency” means each of the follow-
12 ing:

13 (A) The Environmental Protection Agency.

14 (B) The Occupational Safety and Health
15 Administration.

16 (C) The Department of Transportation
17 (including the National Highway Transpor-
18 tation Safety Administration).

19 (D) The Food and Drug Administration.

20 (E) The Department of Energy.

21 (F) The Department of the Interior.

22 (G) The Department of Agriculture.

23 (H) The Consumer Product Safety Com-
24 mission.

1 (I) The National Oceanic and Atmospheric
2 Administration

3 (J) The United States Army Corps of En-
4 gineers.

5 (K) The Mine Safety and Health Adminis-
6 tration.

7 (L) The Nuclear Regulatory Commission.

8 (M) Any other Federal agency considered
9 a covered Federal agency pursuant to section
10 103(b)(2)(E).

11 (6) FEDERAL AGENCY.—The term “Federal
12 agency” means an executive department, military de-
13 partment, or independent establishment as defined
14 in part I of title 5 of the United States Code, except
15 that such term also includes the Office of Tech-
16 nology Assessment.

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

19 **TITLE II—ANALYSIS OF RISK RE-**
20 **DUCTION BENEFITS AND**
21 **COSTS**

22 **SEC. 201. ANALYSIS OF RISK REDUCTION BENEFITS AND**
23 **COSTS.**

24 (a) IN GENERAL.—The President shall require each
25 Federal agency to prepare the following for each major

1 rule within a program designed to protect human health,
2 safety, or the environment that is proposed or promul-
3 gated by the agency after the date of enactment of this
4 Act:

5 (1) An identification of reasonable alternative
6 strategies, including strategies that—

7 (A) require no government action;

8 (B) will accommodate differences among
9 geographic regions and among persons with dif-
10 ferent levels of resources with which to comply;
11 and

12 (C) employ performance or other market-
13 based mechanisms that permit the greatest
14 flexibility in achieving the identified benefits of
15 the rule.

16 The agency shall consider reasonable alternative
17 strategies proposed during the comment period.

18 (2) An analysis of the incremental costs and in-
19 cremental risk reduction or other benefits associated
20 with each alternative strategy identified or consid-
21 ered by the agency. Costs and benefits shall be
22 quantified to the extent feasible and appropriate and
23 may otherwise be qualitatively described.

24 (3) A statement that places in context the na-
25 ture and magnitude of the risks to be addressed and

1 the residual risks likely to remain for each alter-
2 native strategy identified or considered by the agen-
3 cy. Such statement shall, to the extent feasible, pro-
4 vide comparisons with estimates of greater, lesser,
5 and substantially equivalent risks that are familiar
6 to and routinely encountered by the general public
7 as well as other risks, and, where appropriate and
8 meaningful, comparisons of those risks with other
9 similar risks regulated by the Federal agency result-
10 ing from comparable activities and exposure path-
11 ways. Such comparisons should consider relevant
12 distinctions among risks, such as the voluntary or
13 involuntary nature of risks and the preventability or
14 nonpreventability of risks.

15 (4) For each final rule, an analysis of whether
16 the identified benefits of the rule are likely to exceed
17 the identified costs of the rule.

18 (5) An analysis of the effect of the rule—

19 (A) on small businesses with fewer than
20 100 employees;

21 (B) on net employment; and

22 (C) to the extent practicable, on the cumu-
23 lative financial burden of compliance with the
24 rule and other existing regulations on persons
25 producing products.

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

7 **SEC. 202. DECISION CRITERIA.**

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

11 (1) That the analyses under section 201 are
12 based on objective and unbiased scientific and eco-
13 nomic evaluations of all significant and relevant in-
14 formation and risk assessments provided to the
15 agency by interested parties relating to the costs,
16 risks, and risk reduction and other benefits ad-
17 dressed by the rule.

18 (2) That the incremental risk reduction or other
19 benefits of any strategy chosen will be likely to jus-
20 tify, and be reasonably related to, the incremental
21 costs incurred by State, local, and tribal govern-
22 ments, the Federal Government, and other public
23 and private entities.

24 (3) That other alternative strategies identified
25 or considered by the agency were found either (A)

1 to be less cost-effective at achieving a substantially
2 equivalent reduction in risk, or (B) to provide less
3 flexibility to State, local, or tribal governments or
4 regulated entities in achieving the otherwise applica-
5 ble objectives of the regulation, along with a brief
6 explanation of why alternative strategies that were
7 identified or considered by the agency were found to
8 be less cost-effective or less flexible.

9 (b) EFFECT OF DECISION CRITERIA.—

10 (1) IN GENERAL.—Notwithstanding any other
11 provision of Federal law, the decision criteria of sub-
12 section (a) shall supplement and, to the extent there
13 is a conflict, supersede the decision criteria for rule-
14 making otherwise applicable under the statute pur-
15 suant to which the rule is promulgated.

16 (2) SUBSTANTIAL EVIDENCE.—Notwithstanding
17 any other provision of Federal law, no major rule
18 shall be promulgated by any Federal agency pertain-
19 ing to the protection of health, safety, or the envi-
20 ronment unless the requirements of section 201 and
21 subsection (a) are met and the certifications re-
22 quired therein are supported by substantial evidence
23 of the rulemaking record.

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

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

8 **SEC. 203. OFFICE OF MANAGEMENT AND THE BUDGET**
9 **GUIDANCE.**

10 The Office of Management and Budget shall issue
11 guidance consistent with this title—

12 (1) to assist the agencies, the public, and the
13 regulated community in the implementation of this
14 title, including any new requirements or procedures
15 needed to supplement prior agency practice; and

16 (2) governing the development and preparation
17 of analyses of risk reduction benefits and costs.

18 **SEC. 204. ENVIRONMENTAL CLEAN-UP.**

19 For purposes of this title, any determination by a
20 Federal agency to approve or reject any proposed or final
21 environmental clean-up plan for a facility the costs of
22 which are likely to exceed \$5,000,000 shall be treated as
23 major rule subject to the provisions of this title (other
24 than the provisions of section 201(a)(5)). As used in this
25 section, the term “environmental clean-up” means a cor-

1 rective action under the Solid Waste Disposal Act, a reme-
2 dial action under the Comprehensive Environmental Re-
3 sponse, Compensation, and Liability Act of 1980, and any
4 other environmental restoration and waste management
5 carried out by or on behalf of a Federal agency with re-
6 spect to any substance other than municipal waste.

7 **TITLE III—PEER REVIEW**

8 **SEC. 301. PEER REVIEW PROGRAM.**

9 (a) ESTABLISHMENT.—For regulatory programs de-
10 signed to protect human health, safety, or the environ-
11 ment, the head of each Federal agency shall develop a sys-
12 tematic program for independent and external peer review
13 required by subsection (b). Such program shall be applica-
14 ble across the agency and—

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

24 (2) may provide for differing levels of peer re-
25 view and differing numbers of experts on peer review

1 panels, depending on the significance or the com-
2 plexity of the problems or the need for expeditious-
3 ness;

4 (3) shall not exclude peer reviewers with sub-
5 stantial and relevant expertise merely because they
6 represent entities that may have a potential interest
7 in the outcome, provided that interest is fully dis-
8 closed to the agency and in the case of a regulatory
9 decision affecting a single entity, no peer reviewer
10 representing such entity may be included on the
11 panel;

12 (4) may provide specific and reasonable dead-
13 lines for peer review panels to submit reports under
14 subsection (c); and

15 (5) shall provide adequate protections for con-
16 fidential business information and trade secrets, in-
17 cluding requiring peer reviewers to enter into con-
18 fidentiality agreements.

19 (b) REQUIREMENT FOR PEER REVIEW.—In connec-
20 tion with any rule that is likely to result in an annual
21 increase in costs of \$100,000,000 or more (other than any
22 rule or other action taken by an agency to authorize or
23 approve any individual substance or product), each Fed-
24 eral agency shall provide for peer review in accordance
25 with this section of any risk assessment or cost analysis

1 which forms the basis for such rule or of any analysis
2 under section 201(a). In addition, the Director of the Of-
3 fice of Management and Budget may order that peer re-
4 view be provided for any major risk assessment or cost
5 assessment that is likely to have a significant impact on
6 public policy decisions.

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

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

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

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

23 (g) NATIONAL PANELS.—The President shall appoint
24 National Peer Review Panels to annually review the risk
25 assessment and cost assessment practices of each Federal

1 agency for programs designed to protect human health,
2 safety, or the environment. The Panel shall submit a re-
3 port to the Congress no less frequently than annually con-
4 taining the results of such review.

5 **TITLE IV—JUDICIAL REVIEW**

6 **SEC. 401. JUDICIAL REVIEW.**

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

TITLE V—PLAN**2 SEC. 501. PLAN FOR ASSESSING NEW INFORMATION.**

3 (a) PLAN.—Within 18 months after the date of en-
4 actment of this Act, each covered Federal agency (as de-
5 fined in title I) shall publish a plan to review and, where
6 appropriate revise any significant risk assessment docu-
7 ment or significant risk characterization document pub-
8 lished prior to the expiration of such 18-month period if,
9 based on information available at the time of such review,
10 the agency head determines that the application of the
11 principles set forth in sections 104 and 105 would be likely
12 to significantly alter the results of the prior risk assess-
13 ment or risk characterization. The plan shall provide pro-
14 cedures for receiving and considering new information and
15 risk assessments from the public. The plan may set prior-
16 ities and procedures for review and, where appropriate, re-
17 vision of such risk assessment documents and risk charac-
18 terization documents and of health or environmental ef-
19 fects values. The plan may also set priorities and proce-
20 dures for review, and, where appropriate, revision or re-
21 peal of major rules promulgated prior to the expiration
22 of such period. Such priorities and procedures shall be
23 based on the potential to more efficiently focus national
24 economic resources within Federal regulatory programs
25 designed to protect human health, safety, or the environ-

1 ment on the most important priorities and on such other
2 factors as such Federal agency considers appropriate.

3 (b) PUBLIC COMMENT AND CONSULTATION.—The
4 plan under this section, shall be developed after notice and
5 opportunity for public comment, and after consultation
6 with representatives of appropriate State, local, and tribal
7 governments, and such other departments and agencies,
8 offices, organizations, or persons as may be advisable.

9 **TITLE VI—PRIORITIES**

10 **SEC. 601. PRIORITIES.**

11 (a) IDENTIFICATION OF OPPORTUNITIES.—In order
12 to assist in the public policy and regulation of risks to
13 public health, the President shall identify opportunities to
14 reflect priorities within existing Federal regulatory pro-
15 grams designed to protect human health in a cost-effective
16 and cost-reasonable manner. The President shall identify
17 each of the following:

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

20 (2) The number of individuals affected.

21 (3) The incremental costs and risk reduction
22 benefits associated with regulatory or other strate-
23 gies.

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

1 (5) Intergovernmental relationships among Fed-
2 eral, State, and local governments among programs
3 designed to protect public health.

4 (6) Statutory, regulatory, or administrative ob-
5 stacles to allocating national economic resources
6 based on the most cost-effective, cost-reasonable pri-
7 orities considering Federal, State, and local pro-
8 grams.

9 (b) STATE, LOCAL, AND TRIBAL PRIORITIES.—In
10 identifying national priorities, the President shall consider
11 priorities developed and submitted by State, local, and
12 tribal governments.

13 (c) BIENNIAL REPORTS.—The President shall issue
14 biennial reports to Congress, after notice and opportunity
15 for public comment, to recommend priorities for modifica-
16 tions to, elimination of, or strategies for existing Federal
17 regulatory programs designed to protect public health.
18 Within 6 months after the issuance of the report, the
19 President shall notify the Congress in writing of the rec-
20 ommendations which can be implemented without further
21 legislative changes and the agency shall consider the prior-
22 ities set forth in the report and priorities developed and
23 submitted by State, local, and tribal governments when

1 preparing a budget or strategic plan for any such regu-
2 latory program.

Passed the House of Representatives February 28,
1995.

Attest:

ROBIN H. CARLE,

Clerk.