

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

# H. R. 690

To improve the use of risk assessment and cost-benefit analysis by Federal agencies.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 25, 1995

Mr. ZIMMER introduced the following bill; which was referred to the Committee on Government Reform and Oversight and, in addition, to the Committees on Science and Commerce, 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 improve the use of risk assessment and cost-benefit analysis by Federal agencies.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Risk Assessment and  
5 Cost-Benefit Analysis Act of 1995”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

8 (1) Risk assessment and cost-benefit analysis  
9 are useful tools that serve to enhance the informa-

1       tion available in developing public health and envi-  
2       ronmental regulations and programs.

3           (2) Risk assessment and cost-benefit analysis  
4       can also serve as useful tools in setting priorities  
5       and evaluating the success of public health and envi-  
6       ronmental protection programs.

7           (3) Public and private resources available to ad-  
8       dress health and environmental concerns are limited.  
9       Those resources need to be allocated carefully so  
10      that the country addresses the greatest needs in the  
11      most cost-effective manner.

12          (4) To provide more cost-effective protection to  
13      human health and the environment regulatory prior-  
14      ities should be based upon risk assessment, com-  
15      parative risk analysis that incorporates societal val-  
16      ues, and risk management choices that consider  
17      cost-benefit principles.

18          (5) Regulatory priorities have often not been  
19      based upon consideration of potential risk nor has  
20      the opportunity for risk reduction been fully consid-  
21      ered.

22          (6) Risk assessment has proved to be a useful  
23      scientific decisionmaking tool. However, pertinent  
24      scientific data must be better collected, organized,  
25      and evaluated by risk assessors and information

1 must be more effectively communicated from risk as-  
2 sessors to decisionmakers and from decisionmakers  
3 to the public.

4 (7) Research provides the scientific foundation  
5 for risk assessment, yet risk assessment research is  
6 fragmented within and across Federal agencies, com-  
7 plicating the setting of risk assessment research pri-  
8 orities.

9 (8) The risk assessment practices of Federal  
10 agencies must be significantly improved if risk as-  
11 sessment is to provide maximum utility to  
12 decisionmakers.

13 (9) Federal agencies need to improve the degree  
14 and timeliness with which they incorporate scientific  
15 advances into their risk assessment methods and  
16 guidelines.

17 (10) The risk assessment activities of Federal  
18 agencies are poorly coordinated, such that risk as-  
19 sessment procedures and outcomes within and across  
20 Federal agencies are often incompatible.

21 (11) The data gaps, variability, and uncertain-  
22 ties inherent in risk assessment are neither ade-  
23 quately communicated by risk assessors nor clearly  
24 recognized by decisionmakers and the public.

1           (12) Improving the reliability, accuracy, and va-  
2           lidity of risk assessments will require additional re-  
3           search to fill data gaps and improve risk assessment  
4           methodologies, including comparative risk analysis  
5           methodologies.

6           (13) Federal agencies require a more effective  
7           mechanism to ensure scientific peer review is ade-  
8           quately reported in risk assessments.

9           (14) There is a lack of broadly skilled risk as-  
10          sors and insufficient resources to provide multi-  
11          disciplinary training and curricula needed for risk  
12          assessors and decisionmakers.

13          (15) There is no common mechanism for col-  
14          lecting risk data, for disseminating such data to all  
15          relevant Federal agencies, and for updating risk as-  
16          sessment methodologies.

17 **SEC. 3. PURPOSES.**

18          The purposes of this Act are the following:

19               (1) To establish an Office of Risk Assessment  
20               and Cost-Benefit Analysis in each covered agency,  
21               that will—

22                       (A) oversee the development, periodic revi-  
23                       sion, and implementation of risk assessment  
24                       guidelines throughout the covered agency;

1 (B) provide for appropriate scientific peer  
2 review of and public comment on risk assess-  
3 ment guidelines and risk assessments through-  
4 out the process of development and implementa-  
5 tion;

6 (C) identify, prioritize, and recommend to  
7 the head of the agency, research needed to ad-  
8 vance the science of risk assessment; and

9 (D) develop risk characterization guidance  
10 and oversee its implementation in order to com-  
11 municate a description of the full range of risks  
12 and uncertainties.

13 (2) To direct the head of each covered agency  
14 to prioritize research and regulatory initiatives to  
15 achieve the greatest risk reductions by—

16 (A) prioritizing threats to human health  
17 and the environment according to the serious-  
18 ness of the risk they pose; and

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

22 (3) To direct the head of each covered agency  
23 to incorporate risk-based priorities into the budget,  
24 strategic planning, and research activities of the  
25 agency.

1 **SEC. 4. REQUIREMENT FOR COVERED AGENCIES.**

2 In exercising authority under any Federal law to pro-  
3 tect human health and the environment, the head of each  
4 covered agency shall—

5 (1) conduct risk assessment and cost-benefit  
6 analysis for all major rules protecting human health  
7 and the environment;

8 (2) demonstrate that for all major rules the  
9 benefits to human health or the environment justify  
10 the costs;

11 (3) publish with each final rule an identification  
12 of the most flexible and cost effective regulatory op-  
13 tion and, if those options are not employed, an ex-  
14 planation justifying why they are not employed;

15 (4) prioritize threats to human health, safety,  
16 and the environment according to—

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

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

22 (5) prioritize the use of resources available to  
23 the agency under those laws to reduce those risks in  
24 accordance with the priorities established under  
25 paragraph (4), including applying the priorities to

1 the budget, strategic planning, and research activi-  
2 ties of the agency; and

3 (6) apply peer review to each risk assessment  
4 and each cost-benefit analysis that may have a sig-  
5 nificant impact on that exercise of authority.

6 **SEC. 5. ESTABLISHMENT OF OFFICE OF RISK ASSESSMENT**  
7 **AND COST BENEFIT ANALYSIS IN EACH COV-**  
8 **ERED AGENCY.**

9 (a) ESTABLISHMENT.—There is established in each  
10 covered agency an Office of Risk Assessment and Cost-  
11 Benefit Analysis.

12 (b) DIRECTOR, GENERALLY.—There shall be at the  
13 head of the Office of each covered agency a Deputy Assist-  
14 ant Secretary or Deputy Assistant Administrator (as spec-  
15 ified by the head of the covered agency), who shall be ap-  
16 pointed by the head of the covered agency from among  
17 individuals having appropriate expertise in risk assess-  
18 ment.

19 (c) FUNCTIONS OF THE DIRECTOR.—The head of  
20 each covered agency, acting through the Director for the  
21 agency, shall ensure that all risk assessments and cost  
22 benefit analyses conducted by the agency under section  
23 4(2) are performed in accordance with risk assessment  
24 guidelines issued by the Director under subsection (f) and  
25 use relevant, reliable, and reasonably obtainable data.

1 (d) SCIENTIFIC PEER REVIEW.—

2 (1) IN GENERAL.—The head of each covered  
3 agency, acting through the Director, shall develop  
4 and apply a process to conduct external and inde-  
5 pendent scientific peer review, involving qualified in-  
6 dividuals from a variety of disciplines and a bal-  
7 anced representation of all interested persons, of all  
8 risk assessment guidelines and risk assessments and  
9 cost-benefit analyses required by this Act.

10 (2) RESPONSE OF DIRECTOR.—As part of the  
11 peer review process, the head of a covered agency,  
12 acting through the Director, shall provide a written  
13 response to comments made by the persons conduct-  
14 ing the peer review. The response shall indicate that  
15 the Director explicitly considered the comments, the  
16 degree to which such comments have been incor-  
17 porated into the risk assessment guidelines or risk  
18 assessment, as applicable, and the reason why a  
19 comment has not been incorporated.

20 (3) SELECTION OF PEER REVIEWERS.—The  
21 head of each covered agency, acting through the Di-  
22 rector, shall provide for the conduct of scientific peer  
23 review required by this Act by one or more of the  
24 following entities:

1 (A) Science advisory boards or panels es-  
2 tablished under other existing laws.

3 (B) Any other person determined by the  
4 Director to be appropriate.

5 (4) GRANTS, CONTRACTS, AND AGREEMENTS.—  
6 The head of a covered agency, acting through the  
7 Director and subject to the availability of appropria-  
8 tions, may enter into grants, contracts, and inter-  
9 agency or other cooperative agreements for the con-  
10 duct of peer review under this Act.

11 (5) REPORTS.—Not later than 180 days after  
12 the date of the enactment of this Act, the head of  
13 each covered agency, acting through the Director,  
14 shall submit to the Congress a report on a plan for  
15 conducting scientific peer review under this Act, and  
16 shall also report to the Congress whenever signifi-  
17 cant modifications are made to the plan.

18 (e) USE OF SERVICES; CONSULTATION.—In conduct-  
19 ing activities under this Act, the Director of a covered  
20 agency may—

21 (1) use services of consultants,

22 (2) establish advisory boards, and

23 (3) to the extent practicable consult with—

24 (A) science advisory boards and panels es-  
25 tablished under other laws,

1 (B) State and local government agencies,

2 (C) appropriate professional groups,

3 (D) appropriate representatives of indus-  
4 try, universities, agriculture, labor, consumers,  
5 conservation organizations, other public interest  
6 groups and organizations, and

7 (E) individuals.

8 (f) ISSUANCE OF RISK ASSESSMENT GUIDELINES.—

9 (1) IN GENERAL.—The Director of each covered  
10 agency shall develop, issue, and publish risk assess-  
11 ment guidelines that provide consistency and tech-  
12 nical quality among risk assessments performed by  
13 the agency.

14 (2) NOTICE AND COMMENT.—Before issuing  
15 guidelines under this subsection, the Director of a  
16 covered agency shall—

17 (A) publish all proposed guidelines for the  
18 purpose of seeking public comment; and

19 (B) publish notice of the intent to revise  
20 existing guidelines or to develop new guidelines  
21 and a list of the issues the Director intends to  
22 address and upon which the Director seeks pub-  
23 lic comment.

24 (3) REVIEW AND UPDATES.—The Director of a  
25 covered agency shall review and, as necessary, up-

1 date guidelines issued under this subsection every 3  
2 years.

3 (4) PROCEDURES FOR REVIEW OF RISK ASSESS-  
4 MENTS.—Within 1 year after the date of the enact-  
5 ment of this Act, the head of each covered agency  
6 shall develop and publish procedures for the review  
7 and revision of any risk assessment performed by  
8 the agency. The procedures shall provide for receiv-  
9 ing and considering new information from the public  
10 and criteria for appropriate use of peer review and  
11 public comment in evaluating new information.

12 (5) LIMITATION ON JUDICIAL REVIEW.—The  
13 development, issuance, and publication of risk as-  
14 sessment guidelines under this subsection shall not  
15 be subject to judicial review.

16 (g) USE OF GUIDELINES.—The Director of each cov-  
17 ered agency shall oversee the use of risk assessment guide-  
18 lines and the conduct of risk assessments by the agency.  
19 The Director shall seek to ensure consistency in the use  
20 of such guidelines to the extent such consistency is appro-  
21 priate.

22 (h) USE OF COST-BENEFIT ANALYSIS.—The head of  
23 each covered agency acting through the Director shall con-  
24 duct a cost-benefit analysis before issuing any major rule.  
25 The analysis shall include an assessment of incremental

1 costs and incremental risk reduction or other benefits as-  
2 sociated with significant regulatory alternatives considered  
3 in connection with the rule or proposed rule.

4 (i) RESEARCH AND TRAINING IN RISK ASSESS-  
5 MENT.—

6 (1) EVALUATION.—The Director of each cov-  
7 ered agency shall regularly evaluate risk assessment  
8 research and training needs of the agency, including  
9 the following:

10 (A) Research to improve model sensitivity  
11 and otherwise reduce generic data gaps, par-  
12 ticularly those common to multiple risk assess-  
13 ments.

14 (B) Research leading to improvement of  
15 methods to quantify and communicate uncer-  
16 tainty and variability throughout risk assess-  
17 ment.

18 (C) Emerging and future areas of re-  
19 search, including research on comparative risk  
20 analysis, exposure to multiple chemicals,  
21 noncancer endpoints, biological makers of expo-  
22 sure and effect, mechanisms of action in both  
23 mammalian and nonmammalian species, eco-  
24 system exposures, and prediction of ecosystem-  
25 level response.

1 (D) Long-term needs to adequately train  
2 individuals in risk assessment and risk assess-  
3 ment application. Evaluations under this para-  
4 graph shall include an estimate of the resources  
5 needed to provide necessary training and rec-  
6 ommendations on appropriate educational risk  
7 assessment curricula.

8 (2) STRATEGY AND ACTIONS TO MEET IDENTI-  
9 FIED NEEDS.—The Director shall develop a strategy,  
10 schedule, and delegation of responsibility for carry-  
11 ing out research and training to meet the needs  
12 identified in paragraph (1).

13 (3) REPORT.—Not later than 120 days after  
14 the date of the enactment of this Act, the head of  
15 each covered agency shall submit to the Congress a  
16 report on evaluations conducted under paragraph (1)  
17 and the strategy and schedule developed under para-  
18 graph (2). The head of each covered agency shall re-  
19 port to the Congress whenever the evaluations, strat-  
20 egy, and schedule are updated or modified.

21 **SEC. 6. RISK CHARACTERIZATION.**

22 (a) IN GENERAL.—The head of each covered agency,  
23 acting through the Director, shall ensure that all risk  
24 characterizations make apparent the distinction between  
25 data and policy assumptions to facilitate interpretation

1 and appropriate use of the characterization by  
2 decisionmakers.

3 (b) CONTENTS.—

4 (1) IN GENERAL.—At a minimum, risk charac-  
5 terizations shall contain the following:

6 (A) Relevant information on data selection  
7 and rejection in the risk assessment, including  
8 a specific rationale justifying the basis for the  
9 selection.

10 (B) Identification of limitations and as-  
11 sumptions, and the rationale and extent of sci-  
12 entific support with respect to their use.

13 (C) A discussion of major uncertainties  
14 and their influence upon the risk assessment.

15 (D) Identification of key data gaps and the  
16 likely impact of additional data on the risk as-  
17 sessment.

18 (2) REQUIREMENTS REGARDING QUANTITATIVE  
19 ESTIMATES OF RISK.—At a minimum, a risk charac-  
20 terization that includes quantitative estimates of risk  
21 shall contain the following:

22 (A) When scientifically feasible, the range  
23 and distribution of exposures derived from ex-  
24 posure scenarios used in the risk assessment of  
25 which the risk characterization is a component,

1 including upper bound estimates and central es-  
2 timates and, when appropriate and practicable,  
3 the identification of susceptible groups, species,  
4 and subpopulations whose exposure exceeds the  
5 general population.

6 (B) When scientifically feasible, a descrip-  
7 tion of appropriate statistical expressions of the  
8 range and variability of the risk estimate, in-  
9 cluding the population or populations addressed  
10 by any risk estimates, central estimates of risk  
11 for each such specific population, any appro-  
12 priate upper bound estimates, the reasonable  
13 range, or other description of uncertainties in  
14 the risk assessment of which the risk character-  
15 ization is a component.

16 **SEC. 7. INTERAGENCY COORDINATION.**

17 To promote the conduct, application, and practice of  
18 risk assessment in a consistent manner under Federal law  
19 and with respect to different environmental media, and to  
20 identify risk assessment data and research needs common  
21 to more than one Federal agency, the Director of the Of-  
22 fice of Science and Technology Policy shall—

23 (1) periodically survey the manner in which  
24 each Federal agency involved in risk assessment is  
25 conducting such risk assessment to determine the

1 scope and adequacy of risk assessment practices in  
2 use by the Federal Government;

3 (2) provide advice and recommendations to the  
4 President and the Congress based on the surveys  
5 conducted and determinations made under para-  
6 graph (1);

7 (3) establish appropriate interagency mecha-  
8 nisms to promote coordination among Federal agen-  
9 cies conducting risk assessment with respect to the  
10 conduct, application, and practice of risk assessment  
11 and to promote the use of state-of-the-art risk as-  
12 sessment practices throughout the Federal Govern-  
13 ment;

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

17 (5) periodically convene meetings with State  
18 government representatives and Federal and other  
19 leaders to assess the effectiveness of Federal-State  
20 cooperation in the development and application of  
21 risk assessment.

22 **SEC. 8. ANNUAL ENVIRONMENTAL QUALITY REPORT.**

23 (a) IN GENERAL.—Section 201 of the National Envi-  
24 ronmental Policy Act of 1969 (42 U.S.C. 4341), requiring  
25 the President to transmit an annual Environmental Qual-

1 ity Report, is amended by striking “The President” and  
2 inserting “The Director of the Office of Science and Tech-  
3 nology”.

4 (b) CONFORMING AMENDMENTS.—

5 (1) Section 204 of such Act (42 U.S.C. 4344)  
6 is amended by repealing paragraph (1).

7 (2) Section 11(d) of the Federal Nonnuclear  
8 Energy Research and Development Act of 1974 is  
9 amended—

10 (A) in the first sentence by inserting “the  
11 Director of the Office of Science and Tech-  
12 nology,” after “the Secretary,”; and

13 (B) in the second sentence by striking  
14 “The President” and inserting “The Director of  
15 the Office of Science and Technology”.

16 **SEC. 9. SAVINGS PROVISION.**

17 Nothing in this Act shall be construed to modify any  
18 requirement or standard provided for in another provision  
19 of law that provides for risk assessment or is designed to  
20 protect health, safety, or the environment.

21 **SEC. 10. DEFINITIONS.**

22 For the purposes of this Act:

23 (1) The term “major rule” means any rule (as  
24 that term is defined in section 551(4) of title 5,

1 United States Code) that is likely to result in an an-  
2 nual effect on the economy of \$25,000,000 or more.

3 (2) The term “risk assessment” means a proc-  
4 ess that uses a factual base to—

5 (A) identify, characterize, and to the ex-  
6 tent practicable quantify the potential adverse  
7 effects of exposure of individuals, populations,  
8 habitats, ecosystems, or materials to hazardous  
9 pollutants or other stressors; and

10 (B) to the extent practicable, identify and  
11 characterize identifiable important uncertain-  
12 ties.

13 (3) The term “risk characterization” means the  
14 final component of a risk assessment, that quali-  
15 tatively or quantitatively (or both) describes the  
16 magnitude and consequences of that risk in terms of  
17 the population exposed to the risk and the types of  
18 potential effects of exposure.

19 (4) The term “uncertainty” means the quantifi-  
20 able and unquantifiable potential error in the esti-  
21 mation of risk that is caused by the quality or ab-  
22 sence of data, or the assumptions used in risk esti-  
23 mation.

24 (5) The term “Director” means the Director of  
25 an Office.

1           (6) The term “Office” means the Office of Risk  
2           Assessment and Cost-Benefit Analysis of a covered  
3           agency.

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

6                   (A) The Environmental Protection Agency.

7                   (B) The Consumer Product Safety Com-  
8           mission.

9                   (C) The Occupational Health and Safety  
10          Administration.

11                   (D) The Department of Labor.

12                   (E) The Department of Transportation.

13                   (F) The Department of Energy.

14                   (G) The Department of Agriculture.

15                   (H) The Department of the Interior.

16                   (I) The Nuclear Regulatory Commission.

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