

103<sup>D</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4306

To establish a comprehensive risk assessment program within the Environmental Protection Agency, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 28, 1994

Mr. KLEIN (for himself, Mr. ZIMMER, Mr. BROWN of California, Mr. STUDDS, Mrs. LLOYD, Mr. SYNAR, Mr. STENHOLM, Mr. VALENTINE, Mrs. MORELLA, Mr. PALLONE, Mr. ROEMER, Mr. SWETT, Mr. DEAL, Ms. EDDIE BERNICE JOHNSON of Texas, Mrs. THURMAN, and Mr. BOEHLERT) introduced the following bill; which was referred to the Committee on Science, Space, and Technology

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## A BILL

To establish a comprehensive risk assessment program within the Environmental Protection Agency, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Risk Assessment Im-  
5 provement Act of 1994”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

1           (1) Risk assessment is a scientific procedure for  
2           evaluating and quantifying the magnitude and sever-  
3           ity of environmental hazards which may threaten  
4           human health and ecological resources and is an im-  
5           portant tool for informed policy and decisionmaking.

6           (2) Research provides the scientific foundation  
7           for risk assessment, yet risk assessment research is  
8           fragmented within and across the Environmental  
9           Protection Agency and the Federal agencies, com-  
10          plicating the setting of risk assessment research pri-  
11          orities.

12          (3) The risk assessment practices of the Envi-  
13          ronmental Protection Agency and other Federal  
14          agencies must be significantly improved if risk as-  
15          sessment is to provide maximum utility to  
16          decisionmakers.

17          (4) The Environmental Protection Agency and  
18          other Federal agencies need to improve the degree  
19          and timeliness with which they incorporate scientific  
20          advances into their risk assessment methods and  
21          guidelines.

22          (5) The risk assessment activities of the Envi-  
23          ronmental Protection Agency and other Federal  
24          agencies are poorly coordinated, such that risk as-

1        assessment procedures and outcomes within and across  
2        Federal agencies are often incompatible.

3            (6) The data gaps, variability, and uncertainties  
4        inherent in risk assessments are neither adequately  
5        communicated by risk assessors nor clearly recog-  
6        nized by decisionmakers and the public.

7            (7) Improving the reliability, accuracy, and va-  
8        lidity of risk assessments will require additional re-  
9        search to fill data gaps and to improve risk assess-  
10       ment methodologies, including comparative risk  
11       analysis methodologies.

12           (8) The Environmental Protection Agency and  
13        other Federal agencies require a more effective  
14        mechanism to ensure scientific peer review of risk  
15        assessments.

16           (9) There is a lack of broadly skilled risk asses-  
17        sors and insufficient resources to provide multidisci-  
18        plinary training and curricula needed for risk asses-  
19        sors and decisionmakers.

20           (10) There is no common mechanism for col-  
21        lecting risk data, for disseminating such data to all  
22        relevant Federal agencies, and for updating risk as-  
23        sessment methodologies.

24 **SEC. 3. PURPOSES.**

25        It is the purpose of this Act—

1 (1) to establish a Risk Assessment Program in  
2 the Environmental Protection Agency that—

3 (A) develops and periodically revises risk  
4 assessment guidelines within the Environmental  
5 Protection Agency which reflect scientific ad-  
6 vances;

7 (B) oversees the implementation of the  
8 guidelines and ensures consistent application of  
9 the guidelines throughout the Agency;

10 (C) provides for appropriate scientific peer  
11 review of the risk assessment guidelines and  
12 risk assessments;

13 (D) identifies and conducts research need-  
14 ed to advance the science of risk assessment;  
15 and

16 (E) develops risk characterization guidance  
17 and oversees its implementation in order to  
18 communicate the full range of risks and uncer-  
19 tainties;

20 (2) to establish a pilot program on comparative  
21 risk analysis; and

22 (3) to establish an interagency coordinating  
23 process within the Office of Science and Technology  
24 Policy, acting through the National Science Tech-

1 nology Council, to promote more compatible risk as-  
2 sessment procedures across Federal agencies.

3 **SEC. 4. ESTABLISHMENT OF RISK ASSESSMENT PROGRAM.**

4 (a) ESTABLISHMENT.—There is established a Risk  
5 Assessment Program in the Environmental Protection  
6 Agency.

7 (b) DIRECTOR; CONDUCT OF PROGRAM.—The Ad-  
8 ministrator shall appoint a Director of the Program, who  
9 has appropriate expertise in risk assessment, and acting  
10 through the Director, shall conduct the activities of the  
11 Environmental Protection Agency under the Program as  
12 provided in this Act.

13 (c) SCIENTIFIC PEER REVIEW.—The Director shall  
14 develop a process to conduct scientific peer review of all  
15 risk assessment guidelines developed by the Environ-  
16 mental Protection Agency. The Director shall ensure that  
17 the guidelines provide for an independent scientific peer  
18 review process for risk assessment activities that contrib-  
19 utes to the quality and objectivity of risk assessment. The  
20 Director may award grants and enter into contracts for  
21 the conduct of scientific peer review. Not later than 120  
22 days after the date of the enactment of this Act, the Ad-  
23 ministrator shall submit to the Congress a report on a  
24 plan for conducting scientific peer review described in this

1 subsection. The Administrator shall report to the Congress  
2 whenever significant modifications are made to the plan.

3 (d) ADVICE TO THE ADMINISTRATOR.—The Director  
4 shall regularly provide to the Administrator advice and  
5 recommendations on the conduct of risk assessment, re-  
6 search needs, and the development of risk assessment  
7 guidelines within the Environmental Protection Agency.

8 (e) USE OF SERVICES; CONSULTATION.—In conduct-  
9 ing activities under the Program, the Director may use  
10 the services of consultants, establish advisory boards, and,  
11 to the extent practicable, consult with the Science Advi-  
12 sory Board established under the Environmental Re-  
13 search, Development, and Demonstration Authorization  
14 Act of 1978, State and local government agencies, appro-  
15 priate professional groups, and such representatives (with  
16 expertise in risk assessment) of industry, universities, ag-  
17 riculture, labor, consumers, conservation organizations,  
18 and other public interest groups, organizations, and indi-  
19 viduals as appropriate.

20 (f) GUIDELINE DEVELOPMENT.—

21 (1) IN GENERAL.—The Director shall regularly  
22 and systematically develop, issue, and, not less than  
23 every 3 years for each guideline, review the need to  
24 update risk assessment guidelines consistent with  
25 the requirements of paragraph (2) that establish

1 methods for conducting scientifically sound risk as-  
2 sements. Whenever the Director determines that  
3 there has been a significant scientific advancement  
4 which warrants the updating of a guideline or that  
5 a specific risk assessment need has arisen which is  
6 not addressed by a guideline, the Director, after ap-  
7 propriate scientific peer review, shall provide interim  
8 guidance on the use of the guidelines and the con-  
9 duct of the risk assessments.

10 (2) CONTENTS.—The risk assessment guide-  
11 lines shall include the following:

12 (A) An explanation of the scope and appli-  
13 cability of the guidelines, including appropriate  
14 limitations or restrictions on their use, and an  
15 identification of appropriate Offices at the En-  
16 vironmental Protection Agency to contact for  
17 further information on risk assessment.

18 (B) Criteria for accepting and evaluating  
19 data, and a complete description of any mathe-  
20 matical models or other assumptions used in  
21 the risk assessment.

22 (C) Criteria for selecting default options  
23 based upon explicitly stated science policy  
24 choices and consideration of relevant scientific  
25 information. The guidelines should set forth the

1 justification and validation for the default op-  
2 tions, and provide criteria for departing from or  
3 substituting any such default option.

4 (D) An evaluation of the technical jus-  
5 tification and the degree of conservatism each  
6 default option imposes upon the risk assess-  
7 ment.

8 (E) Criteria for using iterative or tiered  
9 approaches to the risk assessment, with increas-  
10 ing levels of effort and data requirements based  
11 on the need for accuracy of the risk estimate.

12 (F) Criteria for conducting formal uncer-  
13 tainty analysis during the course of the risk as-  
14 sessment, and an explanation of the data needs  
15 for such analysis.

16 (G) Criteria for risk characterization in  
17 order to facilitate accurate interpretation and  
18 appropriate use of the assessment by  
19 decisionmakers.

20 (H) Effective methods for reporting risk  
21 assessment, including formats which clearly  
22 identify and distinguish sources of uncertainty  
23 and variability in the risk assessment.

24 (3) REPORT.—Not later than 180 days after  
25 the date of the enactment of this Act, the Adminis-



1 trator shall submit to the Congress a report on risk  
2 assessment guidelines which the Environmental Pro-  
3 tection Agency has developed, issued, and updated  
4 and on the schedule within the Environmental Pro-  
5 tection Agency for reviewing the guidelines. The Ad-  
6 ministrator shall report to the Congress whenever  
7 the guidelines are updated.

8 (g) USE OF GUIDELINES.—

9 (1) IN GENERAL.—The Director shall oversee  
10 the use of risk assessment guidelines by the Pro-  
11 gram and Regional Offices of the Environmental  
12 Protection Agency in the conduct of any risk assess-  
13 ments that may be conducted by the Environmental  
14 Protection Agency. The Director shall seek to ensure  
15 consistency in the use of such guidelines, to the ex-  
16 tent such consistency is appropriate in application to  
17 various environmental media or environmental haz-  
18 ards. The Director shall supervise the use of such  
19 guidelines within the Environmental Protection  
20 Agency to ensure that risk assessment is, to the ex-  
21 tent permitted by law, conducted, applied, and prac-  
22 ticed throughout the Offices of the Agency in ac-  
23 cordance with the guidelines and that advances  
24 made in one area of risk assessment are applied as

1 appropriate within the Agency to other areas of risk  
2 assessment.

3 (2) DEPARTURES FROM GUIDELINES.—A Pro-  
4 gram or Regional Office of the Environmental Pro-  
5 tection Agency may not depart from a guideline un-  
6 less the departure is consistent with guidance pro-  
7 vided by the Director under subsection (f)(1). Any  
8 interested person may petition the Director for re-  
9 view of a decision by a Program or Regional Office  
10 to depart from a guideline. Within 120 days after  
11 receiving the petition, the Director shall, using ap-  
12 propriate scientific peer review, review the decision  
13 to determine whether the departure was warranted  
14 and whether to issue interim guidance under sub-  
15 section (f)(1).

16 (h) RISK CHARACTERIZATION.—

17 (1) IN GENERAL.—The Director shall regularly  
18 and systematically develop, issue, and update guid-  
19 ance within the Environmental Protection Agency  
20 for any risk characterizations that may be conducted  
21 by the Agency. The Director shall oversee the use of  
22 such guidance within the Agency to ensure that any  
23 such risk characterizations are complete and provide  
24 for informed evaluation and use of risk assessment.

1           (2) CONTENTS.—The guidance shall include  
2 guidance on the following:

3           (A) Relevant information on data and as-  
4 sessment methods that significantly influence  
5 the risk estimate.

6           (B) Limitations, assumptions, and default  
7 options included in the assessment and the ra-  
8 tionale and extent of scientific consensus with  
9 respect to their use.

10          (C) A statement that identifies major un-  
11 certainties and their influence upon the assess-  
12 ment. The statement shall characterize uncer-  
13 tainties associated with experimental measure-  
14 ment errors and uncertainties associated with  
15 the choice of specific models and default op-  
16 tions.

17          (D) The ranges of exposures derived from  
18 exposure scenarios, their estimated prob-  
19 abilities.

20          (E) The use of both quantitative and quali-  
21 tative descriptors to present the full range of  
22 risks encountered by the various populations  
23 and individuals in a human health risk assess-  
24 ment, or by the various species and ecological  
25 communities in an ecological risk assessment,

1 exposed to the environmental hazard being eval-  
2 uated in the risk assessment.

3 (F) A description of all appropriate statis-  
4 tical expressions of the range and variability of  
5 the risk estimate.

6 (3) REPORT.—Not later than 180 days after  
7 the date of the enactment of this Act, the Adminis-  
8 trator shall submit to the Congress a report on risk  
9 characterization guidance developed, issued, and up-  
10 dated under this subsection. The Administrator shall  
11 report to the Congress whenever risk characteriza-  
12 tion guidance under this subsection is updated.

13 (i) RISK COMMUNICATION.—The Director shall pro-  
14 mote open dialogue among scientists, decisionmakers, and  
15 the public in order to improve the use of risk assessments  
16 by decisionmakers and to accurately, objectively, and  
17 clearly communicate risk characterizations.

18 (j) RESEARCH AND TRAINING IN RISK ASSESS-  
19 MENT.—

20 (1) EVALUATION.—The Director shall regularly  
21 and systematically evaluate risk assessment research  
22 and training needs of the Environmental Protection  
23 Agency, including the following needs:

24 (A) Research with respect to data gaps,  
25 modeling needs, and validation of default op-

1 tions, particularly those common to multiple  
2 risk assessments.

3 (B) Research to examine the causes and  
4 extent of variability within and among individ-  
5 uals, species, populations, and, in the case of  
6 ecological risk assessment, ecological commu-  
7 nities.

8 (C) Research leading to the improvement  
9 of methods to quantify and communicate uncer-  
10 tainty and variability throughout the risk as-  
11 sessment, and risk assessment reporting meth-  
12 ods that clearly distinguish between uncertainty  
13 and variability.

14 (D) Emerging and future areas of re-  
15 search, including research on comparative risk  
16 analysis, exposure to multiple chemicals and  
17 other stressors, noncancer endpoints, mecha-  
18 nisms of action in both mammalian and non-  
19 mammalian species, and prediction of eco-  
20 system-level responses.

21 (E) Long-term needs to adequately train  
22 individuals in risk assessment and risk assess-  
23 ment applications. An evaluation under this  
24 paragraph shall include an estimate of the re-  
25 sources needed to provide necessary training

1 and recommendations on appropriate edu-  
2 cational risk assessment curricula.

3 (2) DEVELOPMENT OF STRATEGY.—The Direc-  
4 tor shall develop a strategy, schedule, and delegation  
5 of responsibility for carrying out research and train-  
6 ing to meet the needs identified in paragraph (1).

7 (3) REPORT.—Not later than 120 days after  
8 the date of the enactment of this Act, the Adminis-  
9 trator shall submit to the Congress a report on the  
10 evaluations conducted under paragraph (1) and the  
11 strategy and schedule developed under paragraph  
12 (2). The Administrator shall report to the Congress  
13 whenever the evaluations, strategy, and schedule are  
14 updated or modified.

15 **SEC. 5. PILOT PROJECT ON COMPARATIVE RISK ANALYSIS.**

16 (a) IN GENERAL.—As part of the Program, the Di-  
17 rector shall conduct, or provide for the conduct of, a pilot  
18 project using comparative risk analysis to rank dissimilar  
19 environmental risks and to provide a common basis for  
20 evaluating strategies for reducing or preventing those  
21 risks. The goal of the pilot project shall be to develop and  
22 test methods of comparative risk analysis which produce  
23 results that are replicable, testable, and objective.

24 (b) SCOPE OF PROJECT.—The pilot project shall have  
25 sufficient scope and breadth to rigorously and scientif-

1 ically test the feasibility and utility of employing compara-  
2 tive risk analysis. The pilot project shall compare and rank  
3 a range of diverse environmental risks, both as to risks  
4 to and within an environmental medium and risks across  
5 environmental media. The project shall draw on appro-  
6 priate social science literature in formulating methods of  
7 comparative risk analysis.

8 (c) PROJECT PARTICIPANTS.—In conducting the  
9 pilot project, the Director shall provide for the participa-  
10 tion of a range of individuals with varying backgrounds  
11 and expertise, both technical and nontechnical, comprising  
12 broad representation of the public and private sectors.

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

16 (e) EVALUATION OF USE OF COMPARATIVE RISK  
17 ANALYSIS.—Not later than 90 days after the termination  
18 of the pilot project, the Director shall submit to the Ad-  
19 ministrator a report that evaluates the results of the pilot  
20 project and that has been subject to scientific peer review.  
21 Not later than 30 days after receiving the report from the  
22 Director, the Administrator shall forward the report to the  
23 Congress with the results of the scientific peer review and  
24 recommendations regarding the advantages, disadvan-  
25 tages, and practical utility of using comparative risk anal-

1 ysis for decisionmaking in the Environmental Protection  
2 Agency.

3 **SEC. 6. INTERAGENCY COORDINATION.**

4 To promote the conduct, application, and practice of  
5 risk assessment in a consistent manner under Federal law  
6 and with respect to different environmental media, and to  
7 identify risk assessment data and research needs common  
8 to more than one Federal agency, the Director of the Of-  
9 fice of Science and Technology Policy shall—

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

15 (2) provide advice and recommendations to the  
16 President based on the surveys conducted and deter-  
17 minations made under paragraph (1);

18 (3) establish appropriate interagency mecha-  
19 nisms to promote coordination among Federal agen-  
20 cies conducting risk assessment with respect to the  
21 conduct, application, and practice of risk assessment  
22 and to promote the use of state-of-the-art risk as-  
23 sessment practices throughout the Federal Govern-  
24 ment; and



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

4 **SEC. 7. SAVINGS PROVISION.**

5           Nothing in this Act shall be construed to modify any  
6           requirement or standard provided for in another provision  
7           of law that provides for risk assessment or is designed to  
8           protect health, safety, or the environment. Nothing in this  
9           Act shall be construed to require the conduct of a risk  
10          assessment or a risk characterization by the Environ-  
11          mental Protection Agency that is not required by law.

12 **SEC. 8. DEFINITIONS.**

13          For purposes of this Act:

14           (1) The term “Administrator” means the Ad-  
15          ministrator of the Environmental Protection Agency.

16           (2) The term “comparative risk analysis”  
17          means a process to systematically measure, compare,  
18          and rank the severity of environmental risks in order  
19          to provide a common basis for evaluating strategies  
20          for reducing or preventing those risks.

21           (3) The term “default option” means a condi-  
22          tion, assumption, or fact that is presumed unless in-  
23          formation is available which justifies an alternative.

1           (4) The term “Director” means the Director of  
2 the Risk Assessment Program established in section  
3 4.

4           (5) The term “environmental hazard” means  
5 any physical, chemical, or biological agent, or a situ-  
6 ation or circumstance presented through an environ-  
7 mental medium, which may impose an adverse effect  
8 upon human health or ecological resources.

9           (6) The term “environmental medium” means  
10 the natural occurrence of air, water, soil, or bio-  
11 logically-derived material, or any combination or  
12 process thereof.

13           (7) The term “risk assessment” means a rigor-  
14 ous and systematic characterization of the potential  
15 adverse health or ecological effects of exposure of  
16 human or nonhuman species to environmental haz-  
17 ards.

18           (8) The term “risk assessment guideline”  
19 means a peer-reviewed document of a Federal agen-  
20 cy that contains methodological recommendations  
21 pertaining to the practice or application of risk as-  
22 sessment.

23           (9) The term “risk characterization” means the  
24 characterization of a risk, based on a risk assess-  
25 ment, that quantitatively and qualitatively describes

1 the probability and severity of that risk in terms of  
2 the population exposed to the risk and the types of  
3 potential effects of the exposure and that explicitly  
4 states the range, variability, and attendant uncer-  
5 tainty of that risk.

6 (10) The term “scientific peer review” means  
7 the process of objectively evaluating the technical ac-  
8 curacy, validity, and clarity of a risk assessment by  
9 an impartial group of technically qualified individ-  
10 uals.

11 (11) The term “uncertainty analysis” means  
12 the systematic process of identifying that which is  
13 not known or defined, including measurement errors,  
14 as well as the lack of fundamental knowledge needed  
15 to choose among alternative hypotheses, assump-  
16 tions, or experimental models.

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