

**Union Calendar No. 474**

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

**H. R. 4306**

**[Report No. 103-8571]**

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**A BILL**

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

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OCTOBER 7, 1994

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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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

OCTOBER 7, 1994

Additional sponsors: Mr. MINGE, Mr. BARCA of Wisconsin, Mr. MCHALE, Mr. HUGHES, Mr. BEILENSEN, Ms. ESHOO, Mr. SANDERS, Mr. JOHNSON of Georgia, Mr. INSLEE, and Mr. PORTER

OCTOBER 7, 1994

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on April 28, 1994]

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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:*

8            (1) *Risk assessment is a rigorous and systematic*  
9 *procedure for evaluating and quantifying environ-*  
10 *mental hazards which may threaten human health*  
11 *and ecological resources and is an important tool for*  
12 *informed policy and decisionmaking.*

13            (2) *While risk assessment is important to the en-*  
14 *vironmental decisionmaking process, risk assessment*  
15 *alone is not a sufficient basis for environmental deci-*  
16 *sionmaking, which must also ensure the consideration*  
17 *of a full range of political, economic, environmental,*  
18 *and social equity concerns, and societal values.*

19            (3) *Research provides the scientific foundation*  
20 *for risk assessment, yet risk assessment research is*  
21 *fragmented within and across the Environmental*  
22 *Protection Agency and the Federal agencies, com-*  
23 *plicating the setting of risk assessment research prior-*  
24 *ities.*

1           (4) *The risk assessment practices of the Environ-*  
2 *mental Protection Agency and other Federal agencies*  
3 *must be significantly improved if risk assessment is*  
4 *to provide maximum utility to decisionmakers.*

5           (5) *The Environmental Protection Agency and*  
6 *other Federal agencies need to improve the degree and*  
7 *timeliness with which they incorporate scientific ad-*  
8 *vances into their risk assessment methods and guide-*  
9 *lines.*

10          (6) *The risk assessment activities of the Environ-*  
11 *mental Protection Agency and other Federal agencies*  
12 *are poorly coordinated, such that risk assessment pro-*  
13 *cedures and outcomes within and across Federal*  
14 *agencies are often incompatible.*

15          (7) *The data gaps, variability, and uncertainties*  
16 *inherent in risk assessments are neither adequately*  
17 *communicated by risk assessors nor clearly recognized*  
18 *by decisionmakers and the public.*

19          (8) *Improving the reliability, accuracy, and va-*  
20 *lidity of risk assessments will require additional re-*  
21 *search to fill data gaps and to improve risk assess-*  
22 *ment methodologies, including comparative risk anal-*  
23 *ysis methodologies.*

24          (9) *The Environmental Protection Agency and*  
25 *other Federal agencies require a more effective mecha-*

1        *nism to ensure scientific peer review of risk assess-*  
2        *ments.*

3            (10) *There is a lack of broadly skilled risk asses-*  
4        *sors and insufficient resources to provide multidisci-*  
5        *plinary training and curricula needed for risk asses-*  
6        *sors and decisionmakers.*

7            (11) *There is no common mechanism for collect-*  
8        *ing risk data, for disseminating such data to all rel-*  
9        *evant Federal agencies, and for updating risk assess-*  
10       *ment methodologies.*

11       **SEC. 3. PURPOSES.**

12       *It is the purpose of this Act—*

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

15            (A) *develops and periodically revises risk*  
16        *assessment guidelines within the Environmental*  
17        *Protection Agency which reflect scientific ad-*  
18        *vances;*

19            (B) *oversees the implementation of the*  
20        *guidelines and ensures consistent application of*  
21        *the guidelines throughout the Agency;*

22            (C) *provides for appropriate scientific peer*  
23        *review of and public comment on the risk assess-*  
24        *ment guidelines and risk assessments throughout*

1           the process of guideline development and imple-  
2           mentation;

3                   (D) identifies and conducts research needed  
4           to advance the science of risk assessment; and

5                   (E) develops risk characterization guidance  
6           and oversees its implementation in order to com-  
7           municate a scientifically sound, unbiased, and  
8           accurate description of the full range of risks and  
9           significant uncertainties;

10           (2) to establish a study of comparative risk anal-  
11           ysis; and

12                   (3) to direct the Office of Science and Technology  
13           Policy, acting through the National Science Tech-  
14           nology Council, to establish an interagency coordinat-  
15           ing process to promote more compatible risk assess-  
16           ment procedures across Federal agencies.

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

18           (a) *ESTABLISHMENT.*—There is established a Risk As-  
19           sessment Program in the Environmental Protection Agency.

20           (b) *DIRECTOR; CONDUCT OF PROGRAM.*—The Admin-  
21           istrator shall appoint a Director of the Program, who has  
22           appropriate expertise in risk assessment, and acting  
23           through the Director, shall conduct the activities of the En-  
24           vironmental Protection Agency under the Program as pro-  
25           vided in this Act. The Director shall be compensated at the

1 *rate authorized for level V of the Executive Schedule in sec-*  
2 *tion 5316 of title 5, United States Code.*

3 *(c) SCIENTIFIC PEER REVIEW.—*

4 *(1) IN GENERAL.—The Director shall develop a*  
5 *process to conduct independent scientific peer review,*  
6 *involving qualified individuals from a variety of dis-*  
7 *ciplines and interests, of all risk assessment guidelines*  
8 *developed by the Environmental Protection Agency.*

9 *(2) RESPONSE OF DIRECTOR.—As part of the*  
10 *peer review process, the Director shall provide a writ-*  
11 *ten response to comments made by the persons con-*  
12 *ducting the peer review. The response shall indicate*  
13 *that the Director explicitly considered the comments,*  
14 *the degree to which such comments have been incor-*  
15 *porated into the guidelines, and, the reasons why a*  
16 *comment has not been fully incorporated.*

17 *(3) SELECTION OF PEER REVIEWERS.—The Ad-*  
18 *ministrator shall provide for the conduct of scientific*  
19 *peer review required by this Act by one or more of the*  
20 *following entities:*

21 *(A) The Science Advisory Board established*  
22 *under the Environmental Research, Develop-*  
23 *ment, and Demonstration Authorization Act of*  
24 *1978.*

1           (B) Any other appropriate science advisory  
2           panel of the Environmental Protection Agency.

3           (C) Any other person, agency, or institu-  
4           tion. The Director may award a grant to, and  
5           enter into a contract, interagency agreement, or  
6           cooperative agreement with, such person, agency,  
7           or institution for the conduct of such scientific  
8           peer review.

9           (4) *REPORT.*—Not later than 180 days after the  
10          date of the enactment of this Act, the Administrator  
11          shall submit to the Congress a report on a plan for  
12          conducting scientific peer review described in this  
13          subsection. The Administrator shall report to the Con-  
14          gress whenever significant modifications are made to  
15          the plan.

16          (d) *ADVICE TO THE ADMINISTRATOR.*—The Director  
17          shall regularly provide to the Administrator advice and rec-  
18          ommendations on the conduct of risk assessment, research  
19          needs, and the development of risk assessment guidelines  
20          within the Environmental Protection Agency.

21          (e) *USE OF SERVICES; CONSULTATION.*—In conduct-  
22          ing activities under the Program, the Director may use the  
23          services of consultants, establish advisory boards, and, to  
24          the extent practicable, consult with the Science Advisory  
25          Board established under the Environmental Research, De-

1 *velopment, and Demonstration Authorization Act of 1978,*  
2 *State and local government agencies, appropriate profes-*  
3 *sional groups, and such representatives (with expertise in*  
4 *risk assessment) of industry, universities, agriculture, labor,*  
5 *consumers, conservation organizations, and other public in-*  
6 *terest groups, organizations, and individuals as appro-*  
7 *priate.*

8 (f) *GUIDELINE DEVELOPMENT.—*

9 (1) *DEVELOPMENT.—*

10 (A) *IN GENERAL.—The Director shall regu-*  
11 *larly and systematically develop and issue,*  
12 *through publication in the Federal Register, risk*  
13 *assessment guidelines that seek to provide con-*  
14 *sistency and technical quality and ensure that*  
15 *risk assessments conducted by the Agency shall be*  
16 *scientifically objective and unbiased and that*  
17 *significant uncertainties regarding facts, sci-*  
18 *entific knowledge, and the validity of analytical*  
19 *techniques, or numerical risk estimates are clear-*  
20 *ly disclosed in terms readily understandable to*  
21 *the public. The guidelines shall ensure that risk*  
22 *assessments performed by the Agency make use of*  
23 *the best information and the most plausible and*  
24 *unbiased assumptions, given the scientific infor-*  
25 *mation available to the Administrator.*

1           (B) *DEADLINES FOR COMPLIANCE.*—The  
2           Director shall ensure that risk assessment guide-  
3           lines issued by the Environmental Protection  
4           Agency are consistent with the requirements of  
5           paragraph (3) according to the following sched-  
6           ule:

7                   (i) *Not later than 3 years after the*  
8                   *date of the enactment of this Act, for guide-*  
9                   *lines that were issued by the Environmental*  
10                  *Protection Agency, or are under develop-*  
11                  *ment, prior to the date of the enactment of*  
12                  *this Act.*

13                  (ii) *On the date of their issuance, for*  
14                  *guidelines that are developed and issued by*  
15                  *the Environmental Protection Agency after*  
16                  *the date of the enactment of this Act.*

17           (C) *UPDATES.*—The Director shall review  
18           the need to update the guidelines referred to in  
19           clauses (i) and (ii) of subparagraph (B) not less  
20           than once every 3 years after the date by which  
21           such guidelines are made consistent with the re-  
22           quirements of paragraph (4).

23           (D) *INTERIM GUIDANCE.*—Whenever the Di-  
24           rector determines that there has been a signifi-  
25           cant scientific advancement which warrants the

1           *updating of a guideline or that a specific risk*  
2           *assessment need has arisen which is not ad-*  
3           *ressed by a guideline, the Director, after provid-*  
4           *ing for appropriate scientific peer review and*  
5           *opportunity for public participation, shall pro-*  
6           *vide interim guidance on the use of the guide-*  
7           *lines and the conduct of the risk assessments. The*  
8           *Director shall make available to the public any*  
9           *interim guidance provided, the results of any sci-*  
10          *entific peer review conducted, and any public*  
11          *comment received, under this paragraph. The*  
12          *Director shall issue the interim guidance in ac-*  
13          *cordance with paragraph (2) and, as appro-*  
14          *priate, shall incorporate the interim guidance*  
15          *into the guideline when the Director next reviews*  
16          *the need to update that guideline under subpara-*  
17          *graph (C).*

18           (2) *PROCESS FOR GUIDELINE DEVELOPMENT.—*  
19          *When developing or revising a risk assessment guide-*  
20          *line or interim guidance, the Director shall publish in*  
21          *the Federal Register a declaration of the intent to*  
22          *issue the guideline or interim guidance, together with*  
23          *the text of the proposed guideline or interim guidance,*  
24          *and shall provide an opportunity for public notice*  
25          *and comment on the proposal. After the close of the*

1 *comment period and any informal hearing that may*  
2 *be held, the Director shall prepare and place in the*  
3 *public record a response to the comments that were*  
4 *submitted on the proposal and shall issue the new or*  
5 *revised guideline or interim guidance by publishing*  
6 *the document in the Federal Register along with a*  
7 *summary of the Director's response to comments.*

8 (3) *SCOPE AND APPLICABILITY OF GUIDE-*  
9 *LINES.—The guidelines shall address issues relevant*  
10 *to human and ecological risk assessments and to fun-*  
11 *damental aspects of risk assessment procedures and*  
12 *practices. The Administrator shall conduct risk as-*  
13 *sessments in accordance with all appropriate guide-*  
14 *lines. Discussions or explanations required under*  
15 *paragraph (4) need not be repeated in each risk as-*  
16 *essment as long as there is reference to the relevant*  
17 *discussion or explanation in another Agency docu-*  
18 *ment. Exercises conducted by the Environmental Pro-*  
19 *tection Agency which serve an internal planning*  
20 *function, and which do not support a final Agency*  
21 *action or rule, may be determined by the Director not*  
22 *to be subject to the provisions of this Act. Screening*  
23 *analyses where the results of such analyses are not*  
24 *used as the basis for imposing restrictions on sub-*  
25 *stances or activities and the results of the analyses*

1        *are not used to characterize a positive finding of risks*  
2        *from substances or activities in any final Agency doc-*  
3        *ument made available to the general public shall be*  
4        *excluded from the provisions of this Act. A risk assess-*  
5        *ment which departs from a guideline and which is*  
6        *conducted in support of an emergency action, an ex-*  
7        *pedited formal adjudication, emergency rule, or emer-*  
8        *gency order which does not permit adequate time for*  
9        *adherence to the procedures set forth in section*  
10       *4(g)(2), shall be exempt from the provisions of section*  
11       *4(g)(2).*

12            (4) *CONTENTS.—The risk assessment guidelines*  
13        *shall, at a minimum, include each of the following:*

14            (A) *An explanation of the scope and appli-*  
15        *cability of the guidelines, including appropriate*  
16        *limitations or restrictions on their use, and an*  
17        *identification of appropriate Offices at the Envi-*  
18        *ronmental Protection Agency to contact for fur-*  
19        *ther information on risk assessment.*

20            (B) *Criteria for accepting and evaluating*  
21        *data.*

22            (C) *A complete description of any mathe-*  
23        *matical models or other assumptions likely to be*  
24        *used in the risk assessment, including a discus-*  
25        *sion of their plausibility.*

1           (D) A description of the default options, the  
2           justification and validation for the default op-  
3           tions, and an explicit statement of the rationale  
4           for selecting a particular default option, in the  
5           absence of adequate data, based on explicitly  
6           stated science policy choices and consideration of  
7           relevant scientific information.

8           (E) The technical justification for, and a  
9           description of the degree of, conservatism each  
10          default option imposes upon the risk assessment.

11          (F) Criteria for using iterative or tiered ap-  
12          proaches to risk assessment, with varying levels  
13          of effort and data requirements in the conduct of  
14          risk assessment based on the need for accuracy of  
15          the risk estimate.

16          (G) Criteria for conducting uncertainty  
17          analysis during the course of the risk assessment,  
18          and an explanation of the data needs for such  
19          analysis.

20          (H) Guidance for risk characterization de-  
21          veloped, issued, and updated under subsection  
22          (h).

23          (I) Effective methods for reporting risk as-  
24          sessment, to ensure that the results are reason-  
25          ably understandable by interested persons, in-

1           cluding formats which clearly identify and dis-  
2           tinguish sources of uncertainty and variability  
3           in the risk assessment.

4                   (J) Criteria for identification and use of the  
5           most plausible and unbiased methodologies and  
6           assumptions, given the scientific information  
7           available to the Administrator.

8           (5) REPORT.—Not later than 180 days after the  
9           date of the enactment of this Act, the Administrator  
10          shall submit to the Congress a report that describes  
11          (A) the status of all risk assessment guidelines issued  
12          before such date with respect to the extent to which  
13          such guidelines are consistent with the requirements  
14          of paragraph (4) and a schedule for making such  
15          guidelines consistent with such requirements; (B) a  
16          schedule for issuing any risk assessment guidelines  
17          which are being developed by the Environmental Pro-  
18          tection Agency on such date, including a plan for  
19          making such guidelines consistent with the require-  
20          ments of paragraph (4); and (C) a plan for identify-  
21          ing and developing future risk assessment guidelines  
22          consistent with the requirements of paragraph (4).  
23          The Administrator shall annually thereafter submit to  
24          the Congress an update of the schedule referred to in

1 *subparagraph (B) and the plans referred to in sub-*  
2 *paragraphs (B) and (C).*

3 *(g) USE OF GUIDELINES.—*

4 *(1) IN GENERAL.—The Director shall oversee the*  
5 *use of risk assessment guidelines by the Program and*  
6 *Regional Offices of the Environmental Protection*  
7 *Agency in the conduct of any risk assessments that*  
8 *may be conducted by the Environmental Protection*  
9 *Agency. The Director shall seek to ensure consistency*  
10 *in the use of such guidelines, to the extent such con-*  
11 *sistency is appropriate in application to various en-*  
12 *vironmental media or environmental hazards. The*  
13 *Director shall supervise the use of such guidelines*  
14 *within the Environmental Protection Agency to en-*  
15 *sure that risk assessment is, to the extent permitted*  
16 *by law, conducted, applied, and practiced throughout*  
17 *the Offices of the Agency in accordance with the*  
18 *guidelines and that advances made in one area of risk*  
19 *assessment are applied as appropriate within the*  
20 *Agency to other areas of risk assessment.*

21 *(2) DEPARTURES FROM GUIDELINES.—A Pro-*  
22 *gram or Regional Office of the Environmental Protec-*  
23 *tion Agency may not depart from a guideline unless*  
24 *(A) interim guidance is provided by the Director*  
25 *under subsection (f)(1) which permits that departure;*

1       or (B) that departure is for a specific risk assessment  
2       and is approved in writing by the Director. The Di-  
3       rector shall seek appropriate scientific peer review of  
4       any such departure. Any such departure shall seek to  
5       ensure the consistency referred to in subsection (g)(1)  
6       and shall be included in any public record of the spe-  
7       cific risk assessment for which the departure was  
8       made together with the justification for why that de-  
9       parture was made.

10       (h) RISK CHARACTERIZATION.—

11               (1) IN GENERAL.—The Director shall regularly  
12       and systematically develop, issue, and update guid-  
13       ance within the Environmental Protection Agency for  
14       any risk characterizations that may be conducted by  
15       the Agency. The Director shall oversee the use of such  
16       guidance within the Agency to ensure that all such  
17       risk characterizations are as complete as practicable  
18       to make apparent the distinction between data and  
19       policy assumptions and to facilitate accurate inter-  
20       pretation and appropriate use of the assessment by  
21       decisionmakers and interested persons. The Director  
22       shall oversee the use of such guidance within the  
23       Agency to ensure that all such risk characterizations  
24       distinguish human health risks from ecological and  
25       other risks. The Environmental Protection Agency

1     *shall consider and incorporate, as appropriate, the*  
2     *recommendations from the study of the Committee on*  
3     *Risk Characterization of the National Academy of*  
4     *Sciences on risk characterization and report to the*  
5     *Congress on the inclusion of such recommendations in*  
6     *the risk characterization guidance.*

7             (2) *DEADLINES.*—*The Director shall ensure that*  
8     *initial risk characterization guidance is issued,*  
9     *through publication in the Federal Register, within 2*  
10    *years after the date of the enactment of this Act.*

11            (3) *CONTENTS.*—*At a minimum, the guidance*  
12    *shall require that any risk characterization contain*  
13    *the following:*

14                    (A) *Relevant information on data and as-*  
15                    *essment methods that significantly influence the*  
16                    *risk estimate.*

17                    (B) *A statement of the limitations, assump-*  
18                    *tions, and default options included in the assess-*  
19                    *ment and a statement of the rationale and extent*  
20                    *of scientific consensus with respect to their use.*

21                    (C) *A statement that identifies major uncer-*  
22                    *tainties and their influence upon the assessment.*  
23                    *The statement shall characterize uncertainties*  
24                    *associated with experimental measurement errors*

1           *and uncertainties associated with the choice of*  
2           *specific models and default options.*

3           *(D) The range and distribution of exposures*  
4           *derived from exposure scenarios used in a risk*  
5           *assessment, including, for example, upper-bound*  
6           *and central estimate(s) and their qualitative, or*  
7           *where possible quantitative, likelihood, and,*  
8           *when available and appropriate, the identifica-*  
9           *tion of highly susceptible groups, species, indi-*  
10           *viduals, and subpopulations whose exposure ex-*  
11           *ceeds that of the general population.*

12           *(E) The use of both quantitative and quali-*  
13           *tative descriptors, when available and appro-*  
14           *priate, to present a comprehensive range of risks*  
15           *which are or may be encountered by the various*  
16           *populations and individuals in a human health*  
17           *risk assessment, or by the various species and ec-*  
18           *ological communities in an ecological risk assess-*  
19           *ment, exposed to the environmental hazard being*  
20           *evaluated in the risk assessment.*

21           *(F) A description of appropriate statistical*  
22           *expressions of the range and variability of the*  
23           *risk estimate, including the population or popu-*  
24           *lations addressed by any risk estimate(s), central*  
25           *estimates of the risk for the specific population,*

1           *any appropriate upper-bound and lower-bound*  
2           *estimates, and the reasonable range or other de-*  
3           *scription of uncertainties in the assessment proc-*  
4           *ess.*

5           *(G) When providing estimates of risk to*  
6           *public health, appropriate comparisons with es-*  
7           *timates of other risks to health, including those*  
8           *that are familiar to and routinely encountered*  
9           *by the general public, and relevant substitution*  
10          *risks, where information on such risks is made*  
11          *available to the Administrator. In stating com-*  
12          *parisons, the Administrator shall identify rel-*  
13          *evant distinctions among categories or risks and*  
14          *limitations to comparisons.*

15          *(4) REPORT.—Not later than 180 days after the*  
16          *date of the enactment of this Act, the Administrator*  
17          *shall submit to the Congress a report on risk charac-*  
18          *terization guidance developed, issued, and updated*  
19          *under this subsection. The Administrator shall report*  
20          *to the Congress whenever risk characterization guid-*  
21          *ance under this subsection is updated.*

22          *(i) RISK COMMUNICATION.—The Director shall insti-*  
23          *tute a program to promote open dialogue among scientists,*  
24          *decisionmakers, and the public in order to improve the un-*

1 *derstanding of risk assessments by decisionmakers and to*  
2 *accurately and clearly communicate risk characterizations.*

3 *(j) RESEARCH AND TRAINING IN RISK ASSESSMENT.—*

4 *(1) EVALUATION.—The Director shall regularly*  
5 *and systematically evaluate risk assessment research*  
6 *and training needs of the Environmental Protection*  
7 *Agency, including the following needs:*

8 *(A) Research with respect to data gaps or*  
9 *redundancies, modelling needs, and validation of*  
10 *default options, particularly those common to*  
11 *multiple risk assessments.*

12 *(B) Research to examine the causes and ex-*  
13 *tent of variability within and among individ-*  
14 *uals, species, populations, and, in the case of eco-*  
15 *logical risk assessment, ecological communities.*

16 *(C) Research leading to the improvement of*  
17 *methods to quantify and communicate uncer-*  
18 *tainty and variability throughout the risk assess-*  
19 *ment, and risk assessment reporting methods*  
20 *that clearly distinguish between uncertainty and*  
21 *variability.*

22 *(D) Emerging and future areas of research,*  
23 *including research on comparative risk analysis,*  
24 *exposure to multiple chemicals and other*  
25 *stressors, noncancer endpoints, biological mark-*

1           *ers, mechanisms of action in both mammalian*  
2           *and non-mammalian species, dynamics and*  
3           *probabilities of physiological and ecosystem expo-*  
4           *sure, and prediction of ecosystem-level responses.*

5           *(E) Long-term needs to adequately train in-*  
6           *dividuals in risk assessment and risk assessment*  
7           *applications. An evaluation under this para-*  
8           *graph shall include an estimate of the resources*  
9           *needed to provide necessary training and rec-*  
10          *ommendations on appropriate educational risk*  
11          *assessment curricula.*

12          *(2) DEVELOPMENT OF STRATEGY.—The Director*  
13          *shall develop a strategy, schedule, and delegation of*  
14          *responsibility for carrying out research and training*  
15          *to meet the needs identified in paragraph (1).*

16          *(3) REPORT.—Not later than 120 days after the*  
17          *date of the enactment of this Act, the Administrator*  
18          *shall submit to the Congress a report on the evalua-*  
19          *tions conducted under paragraph (1) and the strategy*  
20          *and schedule developed under paragraph (2). The Ad-*  
21          *ministrator shall report to the Congress whenever the*  
22          *evaluations, strategy, and schedule are updated or*  
23          *modified.*

24          *(k) REVIEW OF RISK CHARACTERIZATIONS.—*

1           (1) *PROVISION FOR INDEPENDENT REVIEW.*—On  
2           an annual basis for a period of three years following  
3           the date of issuance of risk characterization guidance  
4           by the Environmental Protection Agency under the  
5           provisions of this Act, and every three years there-  
6           after, the Director shall provide for review of the con-  
7           formance of the Agency’s risk characterizations with  
8           its risk characterization guidance. The review shall be  
9           conducted by an independent body composed of indi-  
10          viduals from outside the Agency who are technically  
11          qualified in risk characterization. By publication in  
12          the Federal Register of the intent to convene each re-  
13          view and of a period for public comment, the public  
14          will be provided an opportunity for comment to the  
15          independent body on the Agency’s conformance with  
16          the guidance.

17          (2) *ANNUAL REPORT.*—Not later than December  
18          1 each year, the independent body shall provide to the  
19          Congress, through the Administrator, a report that  
20          evaluates the degree to which the risk characterization  
21          issued by the Environmental Protection Agency dur-  
22          ing the preceding calendar year conform to the risk  
23          characterization guidance issued under subsection (h).  
24          The report shall include an identification of those risk  
25          characterizations, if any, that the independent body

1        *finds failed to conform in a significant respect with*  
2        *applicable risk characterization guidance.*

3            (3) *RESPONSE TO REPORT.*—*Within 12 months*  
4        *of receiving a report pursuant to paragraph (2), the*  
5        *Administrator shall prepare and issue revised ver-*  
6        *sions of any risk characterization that the independ-*  
7        *ent body identified as failing to conform in a signifi-*  
8        *cant respect with applicable risk characterization*  
9        *guidance. Such revised risk characterizations shall*  
10       *conform to the applicable risk characterization guid-*  
11       *ance or include an explanation of why the Adminis-*  
12       *trator considers such conformance to be inappropri-*  
13       *ate.*

14       **SEC. 5. STUDY OF COMPARATIVE RISK ANALYSIS.**

15            (a) *IN GENERAL.*—*As part of the Program, the Direc-*  
16       *tor shall conduct, or provide for the conduct of, a study*  
17       *using comparative risk analysis to rank dissimilar environ-*  
18       *mental risks and to provide a common basis for evaluating*  
19       *strategies for reducing or preventing those risks. The goal*  
20       *of the study shall be to develop and rigorously test methods*  
21       *of comparative risk analysis. The Director shall consult*  
22       *with the Director of the Office of Science and Technology*  
23       *Policy regarding the scope of the study. Not later than 90*  
24       *days after the date of the enactment of this Act, the Admin-*  
25       *istrator, in collaboration with other appropriate Federal*

1 agencies, shall enter into a contract with the National Re-  
2 search Council to provide technical guidance on approaches  
3 to using comparative risk analysis and other considerations  
4 in setting environmental priorities.

5 (b) *SCOPE OF STUDY.*—The study shall have sufficient  
6 scope and breadth to evaluate comparative risk analysis  
7 and to test approaches for improving comparative risk  
8 analysis and its use in setting priorities for environmental  
9 risk reduction. The study shall compare and evaluate a  
10 range of diverse environmental risks, both as to risks to and  
11 within an environmental medium and risks across environ-  
12 mental media.

13 (c) *STUDY PARTICIPANTS.*—In conducting the study,  
14 the Director shall provide for the participation of a range  
15 of individuals with varying backgrounds and expertise, both  
16 technical and nontechnical, comprising broad representa-  
17 tion of the public and private sectors.

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

21 (e) *RECOMMENDATIONS FOR IMPROVING COMPARATIVE*  
22 *RISK ANALYSIS AND ITS USE.*—Not later than 90 days  
23 after the termination of the study, the Director shall submit  
24 to the Administrator a report that evaluates the results of  
25 the study and that has been subject to scientific peer review.

1 *Not later than 30 days after receiving the report from the*  
2 *Director, the Administrator shall forward a final report to*  
3 *the Congress with the results of the scientific peer review*  
4 *and recommendations regarding the use of comparative risk*  
5 *analysis and ways to improve the use of comparative risk*  
6 *analysis for decisionmaking in the Environmental Protec-*  
7 *tion Agency.*

8 *(f) SAVINGS.—Nothing in this section shall be con-*  
9 *strued to prohibit or discourage the performance after the*  
10 *date of the enactment of this Act of any comparative risk*  
11 *analysis.*

12 **SEC. 6. INTERAGENCY COORDINATION.**

13 *To promote the conduct, application, and practice of*  
14 *risk assessment in a consistent manner under Federal law*  
15 *and with respect to different environmental media, and to*  
16 *identify risk assessment data and research needs common*  
17 *to more than one Federal agency, the Director of the Office*  
18 *of Science and Technology Policy, acting through the Na-*  
19 *tional Science Technology Council, shall—*

20 *(1) periodically survey the manner in which*  
21 *each Federal agency involved in risk assessment is*  
22 *conducting such risk assessment to determine the*  
23 *scope and adequacy of risk assessment practices in*  
24 *use by the Federal Government;*

1           (2) *provide advice and recommendations to the*  
2 *President and the Congress based on the surveys con-*  
3 *ducted and determinations made under paragraph*  
4 *(1);*

5           (3) *establish appropriate interagency mecha-*  
6 *nisms to promote coordination among Federal agen-*  
7 *cies conducting risk assessment with respect to the*  
8 *conduct, application, and practice of risk assessment*  
9 *and to promote the use of state-of-the-art risk assess-*  
10 *ment practices throughout the Federal Government;*

11          (4) *disseminate to all relevant Federal agencies*  
12 *the results of the study referred to in section 5 and*  
13 *any activity of the National Research Council that is*  
14 *complementary to the study and, as appropriate, co-*  
15 *ordinate the implementation of such results by all*  
16 *such agencies;*

17          (5) *establish appropriate mechanisms between*  
18 *Federal and State agencies to communicate state-of-*  
19 *the-art risk assessment practices; and*

20          (6) *periodically convene meetings with State gov-*  
21 *ernment representatives and Federal and other leaders*  
22 *to assess the effectiveness of Federal-State cooperation*  
23 *in the development and application of risk assess-*  
24 *ment.*

1 **SEC. 7. SAVINGS PROVISION.**

2 *Nothing in this Act shall be construed to modify any*  
3 *requirement or standard provided for in another provision*  
4 *of law that provides for risk assessment or is designed to*  
5 *protect health, safety, or the environment. Nothing in this*  
6 *Act shall be construed to require the conduct of a risk assess-*  
7 *ment or a risk characterization by the Environmental Pro-*  
8 *tection Agency that is not required by law.*

9 **SEC. 8. RISK ASSESSMENT RESEARCH PRIORITIES.**

10 *(a) IDENTIFICATION OF PRIORITY RISK ASSESSMENT*  
11 *RESEARCH ISSUES.—*

12 *(1) REPORT.—Within six months after the date*  
13 *of the enactment of this Act, the Administrator shall*  
14 *submit to the Congress a report that identifies at least*  
15 *10 environmental research issues—*

16 *(A) correlating to the environmental haz-*  
17 *ards which the Administrator estimates to be in*  
18 *the category of highest risk;*

19 *(B) regarding which there are, as deter-*  
20 *mined by the Administrator, significant sci-*  
21 *entific uncertainties with respect to the assess-*  
22 *ment of such environmental risks; and*

23 *(C) with respect to which such uncertainties*  
24 *could be significantly reduced through research.*

1           (2) *CONTENTS OF REPORT.*—In addition to the  
2           identification required by paragraph (1), the report  
3           referred to in such paragraph shall include—

4                   (A) *an assessment of the research that has*  
5                   *been, or is being, conducted by the Environ-*  
6                   *mental Protection Agency with respect to each*  
7                   *issue identified under such paragraph;*

8                   (B) *an identification, with respect to each*  
9                   *such issue, of the significant scientific uncertain-*  
10                  *ties that exist with respect to the assessment of*  
11                  *the environmental risks posed by the issue;*

12                  (C) *an identification of the research that*  
13                  *needs to be conducted by the Environmental Pro-*  
14                  *tection Agency to reduce significantly such sci-*  
15                  *entific uncertainties, the amount of time nec-*  
16                  *essary to conduct such research, and the cost of*  
17                  *such research; and*

18                  (D) *a list that identifies such issues in*  
19                  *order of the priority in which such research*  
20                  *should be conducted and includes the reasons for*  
21                  *that priority.*

22           (b) *RESEARCH PROGRAM.*—The Administrator shall  
23           carry out a research program within the Office of Research  
24           and Development to reduce the scientific uncertainties with  
25           respect to the assessment of the environmental risks posed

1 *by the issues identified under subsection (a). In conducting*  
2 *the research, the Administrator shall consider the priority*  
3 *list referred to in subsection (a)(2)(D).*

4 *(c) BUDGET COORDINATION.—In the first budget sub-*  
5 *mitted by the President to the Congress immediately follow-*  
6 *ing the submission required by subsection (a), and in the*  
7 *next four budgets submitted immediately after such budget,*  
8 *the Administrator shall include a report that identifies the*  
9 *research conducted by the Administrator in accordance with*  
10 *the priority list referred to in subsection (a)(2)(D).*

11 **SEC. 9. DEFINITIONS.**

12 *For purposes of this Act:*

13 *(1) The term “Administrator” means the Admin-*  
14 *istrator of the Environmental Protection Agency.*

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

20 *(3) The term “default option” means a condi-*  
21 *tion, assumption, or fact that is presumed on the*  
22 *basis of available data and prevailing theory.*

23 *(4) The term “Director” means the Director of*  
24 *the Risk Assessment Program established in section 4.*

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

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

10          (7) *The term “risk assessment” means the proc-*  
11 *ess or procedure by which the potential adverse health*  
12 *or ecological effects of exposure of human or*  
13 *nonhuman species to environmental hazards is char-*  
14 *acterized.*

15          (8) *The term “risk assessment guideline” means*  
16 *a document of a Federal agency that contains prin-*  
17 *ciples pertaining to the practice or application of risk*  
18 *assessment.*

19          (9) *The term “risk characterization” means the*  
20 *final component of a risk assessment, that quali-*  
21 *tatively or quantitatively (or both) describes the mag-*  
22 *nitude and consequences of that risk in terms of the*  
23 *population exposed to the risk and the types of poten-*  
24 *tial effects of the exposure.*

1           (10) *The term “scientific peer review” means the*  
2           *process of rigorously evaluating the technical accu-*  
3           *racy, validity, and clarity of a risk assessment by an*  
4           *impartial group of technically qualified individuals.*

5           (11) *The term “uncertainty analysis” means the*  
6           *systematic process of identifying that which is not*  
7           *known or is unclear, including measurement errors,*  
8           *the lack of fundamental knowledge needed to choose*  
9           *among alternative hypotheses, and assumptions, or*  
10          *experimental models.*

11          (12) *The term “central estimates” means esti-*  
12          *mates of central tendencies or expected risk based, to*  
13          *the extent feasible, on the most plausible and unbiased*  
14          *assumptions, given the scientific information avail-*  
15          *able to the Administrator.*

16          (13) *The term “substitution risk” means a po-*  
17          *tential increase in certain types of risk from a strat-*  
18          *egy designed to decrease other risks.*

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