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H. R. 4306

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

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Risk Assessment Improvement Act of 1994''.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Risk assessment is a scientific procedure for evaluating and quantifying the magnitude and severity of environmental hazards which may threaten human health and ecological resources and is an important tool for informed policy and decisionmaking.

(2) Research provides the scientific foundation for risk assessment, yet risk assessment research is fragmented within and across the Environmental Protection Agency and the Federal agencies, complicating the setting of risk assessment research priorities.

(3) The risk assessment practices of the Environmental Protection Agency and other Federal agencies must be significantly improved if risk assessment is to provide maximum utility to decisionmakers.

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

(5) The risk assessment activities of the Environmental Protection Agency and other Federal agencies are poorly coordinated, such that risk as-

sessment procedures and outcomes within and across Federal agencies are often incompatible.

(6) The data gaps, variability, and uncertainties inherent in risk assessments are neither adequately communicated by risk assessors nor clearly recognized by decisionmakers and the public.

(7) Improving the reliability, accuracy, and validity of risk assessments will require additional research to fill data gaps and to improve risk assessment methodologies, including comparative risk analysis methodologies.

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

(9) There is a lack of broadly skilled risk assessors and insufficient resources to provide multidisciplinary training and curricula needed for risk assessors and decisionmakers.

(10) There is no common mechanism for collecting risk data, for disseminating such data to all relevant Federal agencies, and for updating risk assessment methodologies.

SEC. 3. PURPOSES.

It is the purpose of this Act—

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

(A) develops and periodically revises risk assessment guidelines within the Environmental Protection Agency which reflect scientific advances;

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

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

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

(E) develops risk characterization guidance and oversees its implementation in order to communicate the full range of risks and uncertainties;

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

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

nology Council, to promote more compatible risk assessment procedures across Federal agencies.

SEC. 4. ESTABLISHMENT OF RISK ASSESSMENT PROGRAM.

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

(b) DIRECTOR; CONDUCT OF PROGRAM.—The Administrator shall appoint a Director of the Program, who has appropriate expertise in risk assessment, and acting through the Director, shall conduct the activities of the Environmental Protection Agency under the Program as provided in this Act.

(c) SCIENTIFIC PEER REVIEW.—The Director shall develop a process to conduct scientific peer review of all risk assessment guidelines developed by the Environmental Protection Agency. The Director shall ensure that the guidelines provide for an independent scientific peer review process for risk assessment activities that contributes to the quality and objectivity of risk assessment. The Director may award grants and enter into contracts for the conduct of scientific peer review. Not later than 120 days after the date of the enactment of this Act, the Administrator shall submit to the Congress a report on a plan for conducting scientific peer review described in this

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

(d) ADVICE TO THE ADMINISTRATOR.—The Director shall regularly provide to the Administrator advice and recommendations on the conduct of risk assessment, research needs, and the development of risk assessment guidelines within the Environmental Protection Agency.

(e) USE OF SERVICES; CONSULTATION.—In conducting activities under the Program, the Director may use the services of consultants, establish advisory boards, and, to the extent practicable, consult with the Science Advisory Board established under the Environmental Research, Development, and Demonstration Authorization Act of 1978, State and local government agencies, appropriate professional groups, and such representatives (with expertise in risk assessment) of industry, universities, agriculture, labor, consumers, conservation organizations, and other public interest groups, organizations, and individuals as appropriate.

(f) GUIDELINE DEVELOPMENT.—

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

methods for conducting scientifically sound risk assessments. Whenever the Director determines that there has been a significant scientific advancement which warrants the updating of a guideline or that a specific risk assessment need has arisen which is not addressed by a guideline, the Director, after appropriate scientific peer review, shall provide interim guidance on the use of the guidelines and the conduct of the risk assessments.

(2) CONTENTS.—The risk assessment guidelines shall include the following:

(A) An explanation of the scope and applicability of the guidelines, including appropriate limitations or restrictions on their use, and an identification of appropriate Offices at the Environmental Protection Agency to contact for further information on risk assessment.

(B) Criteria for accepting and evaluating data, and a complete description of any mathematical models or other assumptions used in the risk assessment.

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

justification and validation for the default options, and provide criteria for departing from or substituting any such default option.

(D) An evaluation of the technical justification and the degree of conservatism each default option imposes upon the risk assessment.

(E) Criteria for using iterative or tiered approaches to the risk assessment, with increasing levels of effort and data requirements based on the need for accuracy of the risk estimate.

(F) Criteria for conducting formal uncertainty analysis during the course of the risk assessment, and an explanation of the data needs for such analysis.

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

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

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

trator shall submit to the Congress a report on risk assessment guidelines which the Environmental Protection Agency has developed, issued, and updated and on the schedule within the Environmental Protection Agency for reviewing the guidelines. The Administrator shall report to the Congress whenever the guidelines are updated.

(g) USE OF GUIDELINES.—

(1) IN GENERAL.—The Director shall oversee the use of risk assessment guidelines by the Program and Regional Offices of the Environmental Protection Agency in the conduct of any risk assessments that may be conducted by the Environmental Protection Agency. The Director shall seek to ensure consistency in the use of such guidelines, to the extent such consistency is appropriate in application to various environmental media or environmental hazards. The Director shall supervise the use of such guidelines within the Environmental Protection Agency to ensure that risk assessment is, to the extent permitted by law, conducted, applied, and practiced throughout the Offices of the Agency in accordance with the guidelines and that advances made in one area of risk assessment are applied as

appropriate within the Agency to other areas of risk assessment.

(2) DEPARTURES FROM GUIDELINES.—A Program or Regional Office of the Environmental Protection Agency may not depart from a guideline unless the departure is consistent with guidance provided by the Director under subsection (f)(1). Any interested person may petition the Director for review of a decision by a Program or Regional Office to depart from a guideline. Within 120 days after receiving the petition, the Director shall, using appropriate scientific peer review, review the decision to determine whether the departure was warranted and whether to issue interim guidance under subsection (f)(1).

(h) RISK CHARACTERIZATION.—

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

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

(A) Relevant information on data and assessment methods that significantly influence the risk estimate.

(B) Limitations, assumptions, and default options included in the assessment and the rationale and extent of scientific consensus with respect to their use.

(C) A statement that identifies major uncertainties and their influence upon the assessment. The statement shall characterize uncertainties associated with experimental measurement errors and uncertainties associated with the choice of specific models and default options.

(D) The ranges of exposures derived from exposure scenarios, their estimated probabilities.

(E) The use of both quantitative and qualitative descriptors to present the full range of risks encountered by the various populations and individuals in a human health risk assessment, or by the various species and ecological communities in an ecological risk assessment,

exposed to the environmental hazard being evaluated in the risk assessment.

(F) A description of all appropriate statistical expressions of the range and variability of the risk estimate.

(3) REPORT.—Not later than 180 days after the date of the enactment of this Act, the Administrator shall submit to the Congress a report on risk characterization guidance developed, issued, and updated under this subsection. The Administrator shall report to the Congress whenever risk characterization guidance under this subsection is updated.

(i) RISK COMMUNICATION.—The Director shall promote open dialogue among scientists, decisionmakers, and the public in order to improve the use of risk assessments by decisionmakers and to accurately, objectively, and clearly communicate risk characterizations.

(j) RESEARCH AND TRAINING IN RISK ASSESSMENT.—

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

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

tions, particularly those common to multiple risk assessments.

(B) Research to examine the causes and extent of variability within and among individuals, species, populations, and, in the case of ecological risk assessment, ecological communities.

(C) Research leading to the improvement of methods to quantify and communicate uncertainty and variability throughout the risk assessment, and risk assessment reporting methods that clearly distinguish between uncertainty and variability.

(D) Emerging and future areas of research, including research on comparative risk analysis, exposure to multiple chemicals and other stressors, noncancer endpoints, mechanisms of action in both mammalian and nonmammalian species, and prediction of ecosystem-level responses.

(E) Long-term needs to adequately train individuals in risk assessment and risk assessment applications. An evaluation under this paragraph shall include an estimate of the resources needed to provide necessary training

and recommendations on appropriate educational risk assessment curricula.

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

(3) REPORT.—Not later than 120 days after the date of the enactment of this Act, the Administrator shall submit to the Congress a report on the evaluations conducted under paragraph (1) and the strategy and schedule developed under paragraph (2). The Administrator shall report to the Congress whenever the evaluations, strategy, and schedule are updated or modified.

SEC. 5. PILOT PROJECT ON COMPARATIVE RISK ANALYSIS.

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

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

ically test the feasibility and utility of employing comparative risk analysis. The pilot project shall compare and rank a range of diverse environmental risks, both as to risks to and within an environmental medium and risks across environmental media. The project shall draw on appropriate social science literature in formulating methods of comparative risk analysis.

(c) PROJECT PARTICIPANTS.—In conducting the pilot project, the Director shall provide for the participation of a range of individuals with varying backgrounds and expertise, both technical and nontechnical, comprising broad representation of the public and private sectors.

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

(e) EVALUATION OF USE OF COMPARATIVE RISK ANALYSIS.—Not later than 90 days after the termination of the pilot project, the Director shall submit to the Administrator a report that evaluates the results of the pilot project and that has been subject to scientific peer review. Not later than 30 days after receiving the report from the Director, the Administrator shall forward the report to the Congress with the results of the scientific peer review and recommendations regarding the advantages, disadvantages, and practical utility of using comparative risk anal-

ysis for decisionmaking in the Environmental Protection Agency.

SEC. 6. INTERAGENCY COORDINATION.

To promote the conduct, application, and practice of risk assessment in a consistent manner under Federal law and with respect to different environmental media, and to identify risk assessment data and research needs common to more than one Federal agency, the Director of the Office of Science and Technology Policy shall—

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

(2) provide advice and recommendations to the President based on the surveys conducted and determinations made under paragraph (1);

(3) establish appropriate interagency mechanisms to promote coordination among Federal agencies conducting risk assessment with respect to the conduct, application, and practice of risk assessment and to promote the use of state-of-the-art risk assessment practices throughout the Federal Government; and

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

SEC. 7. SAVINGS PROVISION.

Nothing in this Act shall be construed to modify any requirement or standard provided for in another provision of law that provides for risk assessment or is designed to protect health, safety, or the environment. Nothing in this Act shall be construed to require the conduct of a risk assessment or a risk characterization by the Environmental Protection Agency that is not required by law.

SEC. 8. DEFINITIONS.

For purposes of this Act:

(1) The term ''Administrator'' means the Administrator of the Environmental Protection Agency.

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

(3) The term ''default option'' means a condition, assumption, or fact that is presumed unless information is available which justifies an alternative.

(4) The term ''Director'' means the Director of the Risk Assessment Program established in section 4.

(5) The term ''environmental hazard'' means any physical, chemical, or biological agent, or a situation or circumstance presented through an environmental medium, which may impose an adverse effect upon human health or ecological resources.

(6) The term ''environmental medium'' means the natural occurrence of air, water, soil, or biologically-derived material, or any combination or process thereof.

(7) The term ''risk assessment'' means a rigorous and systematic characterization of the potential adverse health or ecological effects of exposure of human or nonhuman species to environmental hazards.

(8) The term ''risk assessment guideline'' means a peer-reviewed document of a Federal agency that contains methodological recommendations pertaining to the practice or application of risk assessment.

(9) The term ''risk characterization'' means the characterization of a risk, based on a risk assessment, that quantitatively and qualitatively describes

the probability and severity of that risk in terms of the population exposed to the risk and the types of potential effects of the exposure and that explicitly states the range, variability, and attendant uncertainty of that risk.

(10) The term ''scientific peer review'' means the process of objectively evaluating the technical accuracy, validity, and clarity of a risk assessment by an impartial group of technically qualified individuals.

(11) The term ''uncertainty analysis'' means the systematic process of identifying that which is not known or defined, including measurement errors, as well as the lack of fundamental knowledge needed to choose among alternative hypotheses, assumptions, or experimental models.

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