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SENATE

{ REPORT
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DEPARTMENT OF ENERGY RISK MANAGEMENT ACT OF
1995

MAY 25 (legislative day, MAY 15), 1995.—Ordered to be printed

Mr. MURKOWSKI, from the Committee on Energy and Natural
Resources, submitted the following

REPORT

together with

MINORITY VIEWS

[To accompany S. 333]

The Committee on Energy and Natural Resources, to which was referred the bill (S. 333) to direct the Secretary of Energy to institute certain procedures in the performance of risk assessments in connection with environmental restoration activities and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill, as amended, do pass.

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Risk Management Act of 1995".

SEC. 2. TABLE OF CONTENTS.

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. Definitions.
- Sec. 4. Applicability.
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- Sec. 6. Requirement to prepare risk assessments.
- Sec. 7. Requirements for major rules and environmental management activities.
- Sec. 8. Principles for risk assessment.
- Sec. 9. Principles for risk communication.
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- Sec. 11. Risk assessment and program planning.
- Sec. 12. Risk assessment and budgetary priorities.

Sec. 13. Risk assessment improvement programs.
 Sec. 14. Judicial review.

SEC. 3. DEFINITIONS.

In this Act—

- (1) **AGENCY.**—The term “agency” has the meaning stated in section 551(1) of title 5.
- (2) **BENEFIT.**—The term “benefit” means the reasonably identifiable benefits and desired effects, including quantifiable and nonquantifiable social, environmental, and economic benefits, that are expected to result directly or indirectly from implementation of, or compliance with, a rule or an alternative to a rule.
- (3) **CAUSATION ASSESSMENT.**—The term “causation assessment” means a scientific evaluation of the relationship between the degree of exposure to a presumed cause of an adverse effect or condition and the incidence or severity of the adverse effect in question, with particular emphasis on the quantitative relation between the presumed cause and the effect.
- (4) **COST.**—The term “cost” means the reasonably identifiable costs and adverse effects, including quantifiable and nonquantifiable social, environmental, and economic costs that are expected to result directly or indirectly from implementation of, or compliance with, a rule or an alternative to a rule.
- (5) **EMERGENCY.**—The term “emergency” means an imminent and substantial endangerment to public health, safety, or natural resources.
- (6) **ENVIRONMENTAL MANAGEMENT ACTIVITY.**—The term “environmental management activity” means a corrective action under the Solid Waste Disposal Act, the treatment, disposal, or storage of radioactive or mixed waste, or a remedial or removal action under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.
- (7) **EXPOSURE ASSESSMENT.**—The term “exposure assessment” means the scientific determination of the intensity, frequency, and duration of actual or hypothetical exposures to the hazard in question.
- (8) **HAZARD.**—The term “hazard” means any activity, substance, or condition which might pose a risk to human health, safety, or the environment.
- (9) **HAZARD IDENTIFICATION.**—The term “hazard identification” means the scientific determination of whether exposure to a hazard can cause an increased incidence of adverse health or environmental effects that are of sufficient importance to warrant further scientific study or regulatory attention, as well as characterization of the nature and strength of the evidence of causation.
- (10) **MAJOR RULE.**—The term “major rule”—
 - (A) means a rule or group of closely related rules that the agency proposing the rule or the President reasonably determines is likely to have an effect on the economy of \$75,000,000 or more in reasonably quantifiable costs, in any one year; but
 - (B) does not include a rule that involves the internal revenue laws of the United States.
- (11) **MAJOR RISK COMMUNICATION.**—The term “major risk communication” means a written or broadcast public communication by an agency, or by another organization under a contract, cooperative agreement, or financial assistance award from an agency, to Congress, State, local or tribal governments, or the general public, which makes a recommendation as to risk that would, if implemented, be likely to have an effect on the economy of \$75,000,000 or more in reasonably quantifiable costs, in any one year.
- (12) **PERSON.**—The term “person” has the meaning stated in section 551(2) of title 5.
- (13) **PLAUSIBLE.**—The term “plausible” means realistic and scientifically supported.
- (14) **POLICY JUDGMENT.**—The term “policy judgment” means any assumptions, inferences, choices of models, or safety factors that are used in a risk assessment because of the absence of relevant available information.
- (15) **RISK ASSESSMENT.**—The term “risk assessment” means the systematic process of organizing and analyzing scientific knowledge and information for potentially hazardous situations and activities or for substances that might pose risks under specified conditions, taking into account both the intrinsic hazard as well as the exposure to that hazard. As appropriate for the specific risk involved, risk assessment includes hazard identification, causation assessment, exposure assessment, and risk characterization.
- (16) **RISK CHARACTERIZATION.**—The term “risk characterization” means the combination of assessments of exposure and response under various exposure conditions to estimate the probability of specific harm to an exposed individual, population, or natural resource including, to the extent feasible, a characteriza-

tion of the distribution of risk, and including an analysis of uncertainties, conflicting data, and inferences and assumptions in the assessment.

(17) **RULE.**—The term “rule” has the meaning stated in section 551(4) of title 5.

(18) **SCREENING ANALYSIS.**—The term “screening analysis” means an analysis using simple, conservative models and assumptions to arrive at an estimate of upper and lower bounds that permits the manager to eliminate risks from further consideration and analysis, or to help establish priorities for agency action.

(19) **SUBSTITUTION RISK.**—The term “substitution risk” means an increased risk to human health, safety, or the environment likely to result from a regulatory or nonregulatory option designed to decrease other risks.

SEC. 4. APPLICABILITY.

(a) Except as provided in subsection (b), this Act shall apply to all risk assessments prepared by, or on behalf of, an agency in connection with health, safety, and environmental risks.

(b) **EXCLUSIONS.**—The head of an agency shall not be required to prepare a risk assessment under this Act for—

- (1) any situation that the head of the agency finds to be an emergency;
- (2) a rule or agency action that authorizes the introduction into commerce, or recognizes the marketable status of a product;
- (3) a health, safety, or environmental inspection or individual facility permitting action;
- (4) product registrations, re-registrations, tolerance settings; and reviews of premanufacturing notices and existing chemicals under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. 2601 et seq.);
- (5) any food, drug, or other product label or any risk communication appearing on any such label or product insert; or
- (6) a screening analysis.

(c) An analysis shall not be treated as a screening analysis for the purposes of paragraph (b)(6) if the results of the analysis is used—

- (1) as the basis for imposing a restriction on a substance, product, or activity;
- or
- (2) to characterize a positive finding of risks from a substance or activity in any major risk communication.

SEC. 5. RULE OF CONSTRUCTION.

(a) Nothing in this Act shall be construed to modify any statutory standard or requirement to protect health, safety, or the environment.

(b) Nothing in this Act shall be construed to preclude the consideration of any reliable scientific data or the calculation of any estimate to describe more fully risk or to provide examples of scientific uncertainty or variability.

(c) Nothing in this Act shall be construed to require the disclosure of any trade secret or other commercial proprietary information or any other confidential information.

SEC. 6. REQUIREMENT TO PREPARE RISK ASSESSMENTS.

(a) **MAJOR RULES.**—An agency shall prepare a risk assessment under this Act for each major rule relating to human health, safety, or the environment that is—

- (1) proposed after the date of enactment of this Act; or
- (2) not published as a final rule before the date of enactment of this Act.

(b) **MAJOR RISK COMMUNICATION.**—An agency shall prepare a risk assessment under this Act for each major risk communication that is released after the date of enactment of this Act.

(c) **ENVIRONMENTAL MANAGEMENT ACTIVITY.**—Except where otherwise required by law or regulation, an agency shall prepare a risk assessment under this Act prior to conducting an environmental management activity to eliminate a risk or reduce it to reasonable limits, if the agency head determines that the estimated cost of the environmental management activity is more than \$25,000,000.

SEC. 7. REQUIREMENTS FOR MAJOR RULES AND ENVIRONMENTAL MANAGEMENT ACTIVITIES.

(a) **IN GENERAL.**—Except as provided in subsection (b), in promulgating any proposed or final major rule relating to human health, safety, or the environment or in conducting any environmental management activity, an agency shall publish in the Federal Register along with the rule, or make part of the publicly available record for the environmental management activity, a clear and concise statement that—

(1) describes and, to the extent practicable, quantifies the risks to human health, safety, and the environment to be addressed by the major rule or environmental management activity based on the conclusions of a risk assessment performed in accordance with this Act;

(2) compares the human health, safety, or environmental risk to be addressed by the major rule or environmental management activity to other risks chosen by the agency head, including—

(A) at least three other risks regulated by a Federal agency; and

(B) at least three other risks that are familiar to the general public;

(3) describes and, to the extent practicable, quantifies any known, plausible substitutions risks when information on such risks is known to or has been provided to the agency;

(4) estimates—

(A) the costs to the United States Government, State, and local governments, and the private sector of complying with or implementing the major rule or carrying out the environmental management activity; and

(B) the benefits of the regulation or environmental management activity including both quantifiable measures of costs and benefits, to the fullest extent that they can be estimated, and qualitative measures that are difficult to quantify; and

(5) contains a certification by the agency head that—

(A) the analyses performed under paragraphs (1), (2), and (3) are in accordance with the requirements of section 8;

(B) the major rule or environmental management activity is likely to reduce significantly the human health, safety, or environmental risks to be addressed;

(C) no regulatory alternative, or alternative environmental management activity, that would achieve an equivalent reduction in risk in a more cost-effective manner, is permitted under law, along with a brief explanation of why other such alternatives that were considered by the agency head were found to be less cost-effective; and

(D) the major rule or environmental management activity, is likely to produce incremental benefits to human health or the environment that will justify the incremental costs to the United States Government, State, local, or tribal governments, and the private sector.

(b) **SUBSTANTIALLY SIMILAR FINAL MAJOR RULES.**—If the agency head determines that a final major rule is substantially similar to the proposed version of the major rule with respect to each of the matters referred to in subsection (a), the agency head may publish in the Federal Register a reference to the statement published under subsection (a) for the proposed rule in lieu of publishing a new statement for such final rule.

(c) **REPORTING.**—If the agency head cannot certify with respect to one or more of the matters addressed in subsection (a), the agency head shall identify those matters for which certification cannot be made, and shall include a statement of the reasons therefor in the Federal Register along with the major rule or, in the case of an environmental management activity, the publicly available plan. Not later than April 1 of each year, the agency head shall submit a report to Congress identifying those major rules and environmental management activities, promulgated or carried out during the previous calendar year, for which complete certification was not made and summarizing the reasons therefor.

(d) **ADDITIONAL REQUIREMENTS FOR ENVIRONMENTAL MANAGEMENT ACTIVITIES.**—

(1) The agency head shall use the risk assessment for an environmental management activity to determine the need for the environmental management activity and to evaluate environmental management alternatives. A risk assessment conducted under this section shall be incorporated into any similar statement, assessment, or analysis conducted under any other statute for this environmental management activity.

(2) If the agency head cannot make a certification with respect to one or more of the matters described in subsection (a)(5) of this section, the agency head shall consider—

(A) funding research and development of new technologies for environmental management; and

(B) selecting the new technology, if any, achieving the greatest risk reduction and cost efficiencies for use in the environmental management activity.

SEC. 8. PRINCIPLES FOR RISK ASSESSMENT.

(A) **IN GENERAL.**—Except as provided in section 4, the head of an agency shall follow the principles set forth in this section when preparing risk assessments.

Agencies shall not be required to repeat discussions or explanations required under this section in each risk assessment if there is an unambiguous reference to a relevant discussion or explanation in another reasonably available agency document that was prepared in accordance with the principles of this section.

(b) **RELATIONSHIP TO RISK MANAGEMENT.**—An agency shall design and conduct risk assessments and report the results in a manner that promotes rational and informed risk management decision making and informed public input into the process of making agency decisions. In undertaking risk assessments, agencies should establish and maintain a clear distinction between the identification, qualification, and characterization of risks and the selection of methods for managing risks. Agency priorities for managing risks, and a consideration of the types of information that would be important in evaluating a full range of decisions, may play a role in developing priorities for risk assessment, activities.

(c) **ITERATIVE AND PROPORTIONATE APPROACH.**—(1) In conducting risk assessments, an agency shall—

(A) employ the level of detail and rigor appropriate and practicable for reasoned decision making on the matter involved, taking into account the significance and complexity of the potential agency action and the need for expedition; and

(B) develop and use an iterative approach to risk assessment, which may start with relatively inexpensive screening analyses and then progress to more rigorous analyses.

(2) In determining whether to proceed to more detailed analyses that might improve the scientific quality and completeness of the risk estimates, the agency head shall take into consideration—

(A) whether or not the available information has demonstrated that the estimated risk is below the applicable decision-making level;

(B) whether or not further improvements in scientific data or models would significantly change the risk estimate;

(C) whether or not the risk is significant enough to warrant further analysis.

(3) If an iterative risk assessment process results in the availability of more and better scientific information on a specific risk, and correspondingly less uncertainty in the analysis, the level of conservatism applied to the risk assessment should decrease.

(d) **USE OF POLICY JUDGMENTS IN RISK ASSESSMENT.**—Policy judgments used in developing a risk assessment, including assumptions, defaults, inferences, choices of models, and safety factors, shall be described explicitly in connection with each risk assessment in which they are used, along with—

(1) a description of the scientific and policy basis for each policy judgment;

(2) a description of any available scientific data, with emphasis on site- or situation-specific data, that was not used because a policy judgment was utilized in its place, the rationale for using the policy judgment, and a description of the sensitivity of the conclusions of the risk assessment to the available data had it been used;

(3) a description of reasonable alternative policy judgments that were not selected by the agency for use in the risk assessment, and a discussion of why the agency believes that the policy judgments selected for use are appropriate to the specific risk assessment;

(4) a description of the extent to which policy judgments used in the risk assessment are validated by, or conflict with, empirical data relevant to the assessment; and

(5) a description of the sensitivity of the conclusions of the risk assessment to the policy judgments used in the risk assessment.

Each agency shall develop a procedure and publish guidelines for choosing default policy judgments to use in risk assessments and for deciding when and how, in a specific risk assessment, to adopt alternative judgments or to use available scientific information in place of a policy judgment.

(e) **CONSIDERATION OF FUTURE LAND USE.**—In conducting a risk assessment for an environmental management activity under this Act, the agency head shall consider the reasonably anticipated future use of the land affected by the environmental management activity.

(f) **TREATMENT OF SCIENTIFIC DATA IN RISK ASSESSMENTS.**—

(1) The technical basis of a risk assessment shall be—

(A) the best available, scientifically replicable data that finds, or fails to find, a correlation between a potential hazard and adverse effects;

(B) the best available, scientifically replicable laboratory or experimental data that has relevance to understanding the potential hazard to humans or the environment; and

(C) hazard, dose, exposure, or other relevant physical conditions that are reasonably expected to be encountered under usual and realistic circumstances.

A risk assessment shall not exaggerate risks by inappropriately compounding multiple hypothetical conservative policy judgments.

(2) When conflicts among scientific data appear to exist, the assessment shall include an explanation for, or possible reconciliation of, conflicting information.

(3) When animal data are used as a basis to assess human health risks, the assessment shall include a discussion of the relevance of experimental animal responses to human outcomes, the basis for selecting any interspecies scaling factors that were used, and the correspondence among routes of exposure in humans and the exposure routes utilized in the animal studies.

(4) Any relevant scientific data meeting the requirements of subsection (f)(1) of this section that are submitted by interested parties shall be reviewed and considered in the risk assessment. The risk assessment shall include an explanation of whether such data were used and, if not, why not.

(g) PUBLIC INVOLVEMENT IN RISK ASSESSMENTS.—Agency heads shall provide for early involvement by all interested parties in the development of risk assessments. Agency heads shall provide appropriate opportunity for meaningful public participation and comment on risk assessment throughout the regulatory process commensurate with the consequences of the decision to be made.

(h) PEER REVIEW AND SCIENTIFIC PARTICIPATION IN RISK ASSESSMENTS.—(1) Each agency shall develop procedures that make the greatest possible use of peer review, scientific workshops, expert bodies, or other devices to ensure broad peer and scientific participation in its risk assessments, through a process that allows full public discussion and peer participation by the scientific community.

(2) Peer review panels shall consist of independent and external experts who are broadly representative and balanced to the extent feasible.

(3) A person shall not be excluded from participation in the scientific review of a risk assessment on the basis of potential interest in the outcome, if the interest is fully disclosed.

SEC. 9. PRINCIPLES FOR RISK COMMUNICATION.

(a) DESCRIPTION OF RISKS.—Except as provided in section 4, in any major risk communication, regulatory proposal or decision, report to Congress, or other document that is intended to communicate the conclusions of a risk assessment to the public, the head of the agency shall, to the appropriate degree—

(1) describe the hazard deemed to be harmful;

(2) describe the populations or natural resources that are the subject of the risk assessment;

(3) explain the exposure scenarios used in the risk assessment and provide an estimate of the corresponding population at risk and the likelihood of such exposure scenarios;

(4) describe the nature and severity of the harm that could plausibly occur; and

(5) briefly describe the major uncertainties in the hazard identification, causation assessment, and exposure assessment phases of the risk assessment and their influence on the results of the assessment.

(b) ESTIMATES OF RISK.—The estimate of risk shall, to the maximum extent practicable, be presented as an overall estimate of risk, expressed as a probability distribution that reflects variabilities and uncertainties in the analysis. If a single point estimate of risk is provided, it must be based on the most plausible inferences from the supporting scientific information. Where quantitative estimates of the range and distribution of risk estimates are not available, a list of qualitative factors influencing the range of possible risks shall be provided.

(c) COMPARISONS OF RISK.—The agency shall provide a statement that places the nature and magnitude of risks to human health, safety, and the environment being analyzed in context. Such statement shall include appropriate comparisons with other risks, including those that are familiar to and routinely encountered by the general public.

(d) SUBSTITUTION RISKS.—When the agency provides a risk assessment or risk characterization for a proposed or final regulatory action, such assessment or characterization shall include a statement of any significant substitution risks to human health or safety, where the agency is aware of such information, or it has been provided to the agency.

(e) SUMMARIES OF RISK ESTIMATES.—(1) Where an agency provides a summary of a risk assessment, the conclusion must include a description of the risk that reflects the information required in subsections (a), (b), (c), and (d) of this section; and

(2) if a commenter provides a risk assessment carried out in a manner consistent with the principles under section 8 of this Act, and a summary of results of such risk assessment, the agency shall present such summary in connection with the presentation of the agency's risk assessment.

(f) REVIEW OF MAJOR RISK COMMUNICATIONS.—The head of an agency shall ensure that major risk communications are peer-reviewed by appropriate scientific experts and tested with representative groups of the public prior to distribution of the major risk communications, to ensure that such communications are scientifically accurate and communicate the intended risk message without exaggeration.

SEC. 10. REVIEW OF EXISTING RISK ASSESSMENTS.

(a) REGULATION.—Not later than 18 months after the date of enactment of this Act, the President shall promulgate a final rule for the review and revision of risk assessments previously prepared by, or on behalf of, an agency. Such rule shall—

(1) provide procedures for the agency itself to identify risk assessments that should be reviewed and revised to conform to the principles of risk assessment in this Act or to accommodate new scientific information;

(2) provide procedures for receiving and considering new information relevant to risk assessments from any person;

(3) provide a mechanism whereby a person can petition the agency to review and revise a risk assessment because—

(A)(i) the risk assessment is inconsistent with the principles set forth in section 8 of this Act; or

(ii) the risk assessment does not take into account material and significant new scientific data or scientific understanding; and

(B) a revised risk assessment is likely to provide a basis for re-evaluating one or more major rules currently in effect or one or more major risk communications;

(4) provide for the creation of a permanent advisory committee to each agency head that shall—

(A) consist of independent and external experts in risk assessment and in the substantive scientific issues related to regulations under the purview of the agency, who are appointed pursuant to the principles of section 8(h);

(B) review new information, risk assessment, and petitions from the public regarding review and revisions of risk assessments;

(C) recommend to the agency head for each petition under subsection (a)(3)—

(i) whether a petition should be granted;

(ii) priorities for the review or revision; and

(iii) target dates for completion of the review or revision; and

(D) evaluate the adequacy of the agency's review or revision of a risk assessment, with respect to the principles in section 8 of this Act, and prior to publication of the review or revision, provide recommendations to the agency head.

(b) PUBLICATION OF RECOMMENDATIONS.—Recommendations provided to an agency head under subsections (a)(4) (C) and (D) shall be published in the Federal Register within 45 days of their transmittal to the agency head, along with the formal response of the agency head.

(c) COMPLETION OF AGENCY ACTION.—(1) If the agency head accepts the recommendation of the advisory committee provided under subsection (a)(4)(C), the agency shall, to the maximum extent practicable, complete its review or revision of the risk assessment within the time recommended by the advisory committee.

(2) An agency head may start or continue and environmental management activity during the pendency of a petition unless the petition reasonably indicates such action would result in an emergency.

(d) JUDICIAL REVIEW.—Agency action with respect to a petition that is substantially inconsistent with the recommendations provided by the advisory committee under subsections (a)(4)(C)(i), (a)(4)(C)(ii), or (a)(4)(D) may be judicially reviewed under any other applicable provision of law.

SEC. 11. RISK ASSESSMENT AND PROGRAM PLANNING.

(a) IN GENERAL.—In exercising authority under, or complying with applicable laws protecting human health, safety, or the environment, the head of an agency shall use risk assessment to set priorities for the use of the resources available under those laws, with the goals of—

(1) addressing preferentially the risks to human health, safety, and the environment that the agency determines are the most serious risks that can be addressed in a cost-effective manner, and

(2) structuring agency actions to achieve promptly the greatest overall net reduction in risks with the private and public sector resources to be expended. In identifying the most serious risk in paragraph (1), the head of the agency shall consider, at a minimum, the likelihood and severity of the hazard and the size of the population and natural resources potentially affected.

(b) ANNUAL REPORT ON RISK ASSESSMENT PRIORITIES AND PROGRAM AGENDA.—In conjunction with the April publication of the regulatory agenda required under section 602 of title 5, the head of an agency that plans to promulgate one or more major rules concerning human health, safety, or the environment shall publish a report on current risk assessment priorities of the agency to support such regulatory agenda. Such report shall include—

(1) a prioritized list combining—

(A) the most serious risk that the agency believes can be addressed in a cost-effective manner through additional major rules or major risk communication;

(B) any other risks that the agency is required by statute, court order, or consent decree to address through the promulgation of additional major rules or major risk communication; and

(C) any risks that are to be re-assessed by the agency pursuant to section 10 of this Act.

Such list shall rank risks on a comparative risk basis to each other, to the extent practicable and without regard to statutory, judicial, or administrative deadlines;

(2) a list of risk assessments and supporting assessments related to the risks in paragraph (1), including hazard identifications, causation assessments, and exposure assessments, under preparation or for which budgetary resources have been committed by the agency;

(3) a brief summary of the relevant issues addressed or to be addressed by each assessment in paragraph (2), and their relationship to the risks in paragraph (1);

(4) an approximate schedule for completing each listed assessment in paragraph (2);

(5) an identification of potential major rules in the regulatory agenda, potential guidance, or other potential agency actions supported or affected by each assessment in paragraph (2), including any deadlines for such major rules pursuant to statute, court order, or consent decree; and

(6) the name, address, and telephone number of an agency official knowledgeable concerning each assessment in paragraph (2).

The identification and ranking of risks in paragraph (1) may be carried out on the basis of screening analyses, if more complete information is not reasonably available.

SEC. 12. RISK ASSESSMENT AND BUDGETARY PRIORITIES.

(a) INCORPORATION OF RISK-BASED PRIORITIES INTO BUDGETS AND PLANNING.—To the extent consistent with other statutory requirements, the head of an agency shall incorporate the priorities identified in section 11 into the budget and planning activities of the agency by, in the agency's annual budget request to Congress—

(1) explicitly identifying how the agency's requested funds will be used to address the risks listed in the most recent report under section 11(b)(1); and

(2) identifying any statutory, judicial, or administrative obstacles to allocating agency resources in accordance with the priorities established under section 11(b)(1).

(b) RECOMMENDATION.—On April 1 of each year, the agency head shall submit to Congress specific recommendations for repealing or modifying laws that would enable the agency to set priority among its activities in accordance with the priorities established under section 11(b)(1).

SEC. 13. RISK ASSESSMENT IMPROVEMENT PROGRAMS.

(a) IMPROVING PEER REVIEW IN RISK ASSESSMENT.—The Director of the Office of Science and Technology Policy shall develop a systematic program to oversee the use of, and quality of, peer review by agencies developing risk assessments pursuant to this Act.

(b) IMPROVING COMPARATIVE RISK ASSESSMENT.—The Secretary of Energy, in consultation with the heads of other agencies, shall direct a national program to foster and improve comparative risk analysis as a tool in regulatory and environmental management decision making, using, among other research performers, the Department of Energy's National Laboratories.

SEC. 14. JUDICIAL REVIEW.

Except as provided for in section 10(d), a risk assessment, peer review, cost-benefit analysis, or certification provided for under this Act shall not be subject to judicial review separate and apart from any final agency action to which it relates, but shall be made part of the administrative record for judicial review of any final agency action to which it relates.

PURPOSE OF THE MEASURE

The purpose of S. 333, the “Risk Management Act of 1995,” is to require Federal agencies promulgating health, safety, and environmental regulations to: improve procedures for performing risk assessments; conduct cost-benefit analyses of major rules and major risk communications; and incorporate risk-based priorities in budgeting and strategic planning to more effectively manage risk in the regulatory process.

BACKGROUND AND NEED

Public policy makers must determine how society’s resources will be used to contribute most directly to the health and well-being of citizens and the environment. Although this is often a State or local government function, it is also accomplished through Federal agency implementation of health, safety, and environmental regulations authorized by Federal enabling legislation. The process of developing these regulations and providing resources to accomplish their goals is termed “risk management.” Over the past several decades, these regulations have grown in number, detail, and complexity, resulting in vastly increased costs for compliance. At the same time, the ability of these regulations to provide cost-effective health or environmental risk reduction has been called into question.

Managing risk through regulation now requires a significant allocation of available resources. Annual estimates of the cost of regulatory compliance range from \$450 to \$600 billion; of that \$100 to \$150 billion is estimated to be spent on environmental regulations alone. Both public and private resources are affected. For example, the Department of Energy spends approximately one-third of its annual budget of \$18 billion on environmental management activities such as hazardous waste storage and disposal and environmental restoration. All of these regulatory costs, whether publicly or privately incurred, are eventually passed on to individuals as taxpayers and consumers. In addition, technological and other scientific improvements in our ability to detect substances in minute quantities has increased our sensitivity to claimed or potential threats to human health and the environment at the same time budgetary resources are decreasing. To reduce costs and improve the effectiveness of regulations, the bill codifies use of risk assessment and cost-benefit analysis as analytical tools.

Risk assessment is the process for identifying the risks to be managed. It is generally defined as the use of a factual base to identify, characterize, and to the extent possible, quantify the potential adverse effects of exposure of individuals or natural resources to hazardous materials, activities, or situations. The risk assessment process recognizes that a complete factual base may not exist, and data gaps may occur. Risk assessors fill such gaps using default options—guidelines based on general scientific knowl-

edge and policy determinations. Default options tend to be a conservative assumption about what the science would indicate if it were available, and their use tends to overestimate rather than underestimate risk. When more than one default option is used in a risk assessment, as is often the case, the conservative aspect of the assumptions is multiplied. The ultimate characterization of a risk is substantially affected by the use of default options, and because they are often based on policy determinations, their use moves a risk assessment away from a factual or scientific basis toward the policy preferences that are the basis for the default options. In some instances, default options are used even if scientific data have become available.

Other problems with development of the scientific basis for determining a risk are lack of validation for methods or models used in analysis, sufficiency of data to support a risk characterization and explanations of uncertainty in the assessment. Additionally, assumptions about the exposure that will occur are often exaggerated or contrary to common sense and understanding. As a consequence, the risks these regulations seek to reduce or avoid are frequently less harmful or problematic than the consequences of many other basic, common activities or substances to which a citizen is regularly exposed.

Cost-benefit analysis evaluates the benefits of a regulation, such as reducing risk, to the monetary costs or possible adverse effects of the regulation. Since 1974, Federal agencies have been required by executive order to prepare comprehensive impact analyses for regulations. These techniques, alternatively termed cost-benefit, economic impact, or cost-effectiveness analysis, have also been widely adopted in various statutes.

The limited scientific basis for regulations, the questionable benefits of regulations as related to their costs, and the intrusiveness of regulations into the day-to-day behavior of individuals and businesses has called into question the authority, wisdom, and capability of the Federal government in enacting such measures. Improving risk assessment and requiring cost-benefit analysis in the regulatory process will provide a more understandable and rational basis for government officials to manage risk through the regulatory process. In addition, improved risk assessment and cost-benefit analysis will permit limited resources to be allocated in a manner that maximizes public health, safety, and environmental protection using the most cost-effective solutions to address the most dangerous risks.

LEGISLATIVE HISTORY

S. 333 was introduced by Chairman Murkowski (for himself and Messrs. Johnston and Lott) on February 2, 1995. Two printed amendments were introduced and referred to the Committee prior to consideration by the full Committee (Amendment 230 introduced by Chairman Murkowski for himself and Mr. Lott on February 3, 1995, and Amendment 316 to the bill introduced by Mr. Lott on March 2, 1995).

A hearing was held on March 6, 1995. At a business meeting on March 29, 1995, the Committee ordered S. 333 favorably reported with an amendment in the nature of a substitute.

Related legislation dealing with risk assessment was introduced in the Senate in the 102d Congress (S. 2132) and a hearing was held before the Committee on Environment and Public Works. An amendment similar to provisions in S. 333 was introduced and passed the Senate as part of reauthorization of the Safe Drinking Water Act in the 103d Congress, but was not enacted into law.

COMMITTEE RECOMMENDATIONS AND TABULATION OF VOTES

The Committee on Energy and Natural Resources, in open business session on March 29, 1995, by majority vote of a quorum present recommends that the Senate pass S. 333, if amended as described herein.

The roll call vote on reporting the measure was 10 yeas, 9 nays as follows:

YEAS	NAYS
Mr. Murkowski	Mr. Johnston
Mr. Hatfield ¹	Mr. Bumpers
Mr. Domenici	Mr. Ford
Mr. Nickles ¹	Mr. Bradley
Mr. Craig	Mr. Bingaman
Mr. Campbell ¹	Mr. Akaka
Mr. Thomas ¹	Mr. Wellstone ¹
Mr. Kyl ¹	Mr. Heflin ¹
Mr. Grams	Mr. Dorgan
Mr. Burns ¹	

¹ Indicates by proxy.

SECTION-BY-SECTION ANALYSIS

Section 1 entitles the bill the "Risk Management Act of 1995."

Section 2 is the table of contents.

Section 3 sets forth the definitions of certain terms used in the bill. The terms "causation assessment", "exposure assessment", "hazard identification", and "risk characterization", were taken or adopted from definitions given in the 1993 Report "Science and Judgment in Risk Assessment" prepared by the National Academy of Sciences.

Section 4 makes the bill applicable to all risk assessment prepared by an agency in connection with health, safety, and environmental risks. Subsection (b) excludes certain agency actions from the requirement in Section 6 to prepare risk assessments.

Section 5 provides that nothing in the bill shall be construed to modify any existing statutory standard or requirement to protect public health, safety, or the environment. The section also provides for consideration of reliable scientific data and protection of commercial proprietary information or trade secrets.

Section 6 establishes the requirement that a risk assessment be prepared for all major rules and major risk communications as those terms are defined in the bill, and environmental management activities costing more than \$25,000,000. This requirement is applied to rules proposed after enactment of the bill and to rules not published as final before enactment. Because risk assessment is currently used in the development of most major rules, the Com-

mittee believes few, if any, pending rules will be delayed or postponed in order to comply with this requirement.

Section 7 establishes the requirement for agencies to conduct cost-benefits analysis of major rules relating to human health, safety, or the environment and environmental management activities and certify that the regulations or environmental management activity will meet the criteria set out in the bill.

Section 8 sets out specific principles that an agency head must follow when conducting risk assessments.

Section 9 sets out the principles that an agency head must follow for any major risk communication, regulatory proposal or decision, report to Congress, or other document that is intended to communicate the conclusions of a risk assessment to the public.

Section 10 requires the President to promulgate a final rule setting out procedures for the review and revision of risk assessments previously prepared by, or on behalf of, an agency. Certain agency actions in the review process are made subject to judicial review. Such a rule must be promulgated no later than 18 months after the date of enactment, should the bill become law.

Section 11 requires the head of an agency to use risk assessment to set priorities for the use of the agency's resources in exercising authority under, or complying with, applicable laws protecting human health, safety, or the environment. The section also specifies that the head of an agency that plans to promulgate one or more major rules concerning human health, safety, or the environment must publish a report on current risk assessment priorities of the agency to support such regulatory agenda in conjunction with the April publication of the regulatory agenda required under section 602 of title 5 of the United States Code. This section also sets out requirements for the content of the report.

Section 12 requires agency heads to incorporate the priorities identified in Section 11 into the budget and planning activities of the agency to the extent consistent with other statutory requirements by providing certain specified information in the agency's annual budget request to Congress.

Subsection 13(a) requires the Director of the Office of Technology Policy to develop a systematic program to oversee the use of, and quality of, peer review by agencies developing risk assessments.

Subsection 13(b) establishes a national program to foster and improve comparative risk analysis as a tool in regulatory and environmental management decision making under the direction of the Secretary of Energy, in consultation with the heads of other agencies, using, among other research entities, the Department of Energy's National Laboratories.

Section 14 provides that a risk assessment, peer review, cost-benefit analysis, or certification provided for under this Act shall not be subject to judicial review separate and apart from any final agency action to which it relates, but shall be made part of the administrative record for judicial review of any final agency action to which it relates. It is the Committee's intent to prevent bifurcation of judicial review of agency rulemaking by prohibiting consideration of an analytical component of a rule such as a cost-benefit analysis separately from the rule to which it relates.

COST AND BUDGETARY CONSIDERATIONS

The following estimate of costs of this measure has been provided by the Congressional Budget Office:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 25, 1995.

Hon. FRANK H. MURKOWSKI,
Chairman, Committee on Energy and Natural Resources, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 333, as ordered reported by the Senate Committee on Energy and Natural Resources on March 29, 1995. The legislation would impose many requirements on federal agencies that issue regulations that would affect the economy by at least \$75 million annually and environmental management activities that would cost more than \$25 million.

The bill would affect direct spending and thus would be subject to pay-as-you-go procedures under section 252 of the Balanced Budget and Emergency Deficit Control Act.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

JUNE E. O'NEILL, *Director.*

Enclosure.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 333.
2. Bill title: Risk Management Act of 1995.
3. Bill status: As ordered reported by the Senate Committee on Energy and Natural Resources on March 29, 1995.
4. Bill purpose: S. 333 would impose many requirements on federal agencies that issue regulations that would affect the economy by at least \$75 million annually or that carry out environmental management activities that would cost more than \$25 million. The bill has three major provisions:

All agencies would be required to prepare cost-benefit analyses of complying with or implementing a regulation or carrying out an environmental management activity.

The President would be required to issue a rule establishing mechanisms for both the review and revision of existing risk assessments. The rule also would create an external advisory committee to review new information, risk assessments, and petitions from the public. The advisory committee would recommend to the agency head whether a petition would be granted, the priorities for the review or the revision, and the timetable for completion of the action.

Each agency would be required to issue an annual report on risk assessment priorities and how they would be addressed. The agency would also be required to incorporate the priorities into the agency's annual budget request to Congress and to submit annual recommendations for repealing or modifying laws in order to attain the priorities.

5. Estimated cost to the Federal Government: We estimate that enactment of S. 333 would increase the cost of issuing and reviewing regulations by the major federal regulatory agencies by at least \$150 million annually. Few of the agencies that would be affected by this bill, however, have had the time to study systematically the additional costs that it would impose.

Cost of issuing new regulations

The bill would require analyses that are similar to those most agencies currently conduct for regulations that affect the economy by more than \$100 million annually. This estimate assumes that agencies would try to adhere to their current schedules for implementing new regulations and revising existing rules. CBO has insufficient information at this time to estimate the cost impacts of this bill on all federal agencies; however, we believe the major cost impacts would fall upon the agencies discussed below.

The Environmental Protection Agency currently spends more than \$120 million annually on regulatory impact analysis to support rule making efforts for regulations expected to have an economic impact greater than \$100 million annually. Based on preliminary information from the agency we estimate that the analyses called for by this bill would cost \$50 million to \$100 million annually.

The Department of Agriculture (USDA) currently prepares regulatory impact assessments, environmental impact statements, and risk analyses for all regulatory actions affecting human health, safety, or the environment that are expected to result in annual costs to the economy of more than \$100 million. Based on information from USDA, we estimate that lowering the threshold for these analyses would increase the number of assessments and cost-benefit studies by 25 to 75 each year. The additional costs associated with such assessments and studies range from less than \$100,000 for a relatively routine rule to several million dollars for a major regulatory change. CBO estimates that most of the additional work would cost \$150,000 to \$250,000 per analysis, or an additional \$5 million to \$15 million annually for this department.

Based on information from the Food and Drug Administration, CBO estimates that the bill's requirements would add less than \$10 million annually to the agency's current spending on pre-market regulatory activities.

The Department of the Interior currently spends about \$50 million per year for regulatory analysis. This work is carried out primarily by the Office of Surface Mining, the Minerals Management Service, and the Bureau of Land Management as part of their overall regulatory enforcement activities. Lowering the threshold for regulatory analyses from \$100 million to \$75 million would increase the number of analyses these agencies would have to prepare, resulting in additional costs of less than \$20 million annually.

Requirements in S. 333 also would increase costs for the Occupational Safety and Health Administration, the Mine Safety and Health Administration, and the Consumer Product Safety Commission. Based on information from these agencies, CBO estimates that enactment of the bill would result in total additional costs of less than \$10 million per year for these agencies.

The Department of Energy, Department of Transportation, and Department of Defense would incur additional costs to implement the bill. Based on comparisons with estimated costs for other agencies, CBO estimates that the additional costs for these departments would total at least \$25 million annually.

Cost of reviewing existing regulations

The cost of reviewing existing regulations under S. 333 would depend on how the agencies fulfill the bill's requirements. For example, costs to review rules will depend on the time frame set by the advisory committee. Based on limited information from agencies, CBO estimates that the incremental costs resulting from the bill's review requirements would probably range from \$20 million to \$40 million annually.

6. Comparison with spending under current law: CBO estimates that enactment of this bill would add at least \$150 million annually to the cost of issuing and reviewing regulations.

7. Pay-as-you-go considerations: The Balanced Budget and Emergency Deficit Act of 1985 sets up pay-as-you-go procedures for legislation affecting direct spending or receipts through 1998. Enactment of S. 333 could affect direct spending; therefore, pay-as-you-go procedures would apply to the bill.

The additional regulatory requirements of S. 333 could lead to a delay in the implementation of rules relating to the collection of user fees or other charges. CBO cannot estimate the potential magnitude of any such effects.

8. Estimated cost to state and local governments: How enactment of S. 333 would affect the budgets of state and local governments is unclear. If regulations that would impose additional requirements on state and local governments are delayed by the enactment of these provisions, then costs to these entities would be less. It is also possible, however, that some regulatory actions that would otherwise provide relief to state and local governments could be delayed, thereby increasing their costs for various activities. CBO has no basis for predicting the direction, magnitude, or timing of such impacts.

9. Estimate comparison: None.

10. Previous CBO estimate: In addition to this estimate for S. 333, CBO has prepared estimates for the following regulatory reform bills:

S. 343 as ordered reported by the Senate Committee on the Judiciary on April 27, 1995.

S. 291 as ordered reported by the Senate Committee on Governmental Affairs on March 22, 1995.

S. 343 as ordered reported by the Senate Committee on Governmental Affairs on March 22, 1995.

H.R. 926 as ordered reported by the House Committee on the Judiciary on February 17, 1995.

H.R. 9 as ordered reported by the House Committee on Science on February 8, 1995.

The table summarizes these estimates by displaying for each bill the relevant thresholds, whether reviews or existing rules are required, and CBO's estimate of its cost. The current threshold for

cost-benefit analysis is an estimate economic impact of \$100 million.

Bill	Threshold ¹ (\$ millions)	Review of existing rules required?	CBO cost estimate (\$ millions/year)
S. 333	² 75/25	Yes	At least \$150.
S. 343 (Committee on the Judiciary)	50	Yes	At least \$180.
S. 291	100	Yes	\$10–\$20.
S. 343 (Committee on Governmental Affairs)	100	Yes	\$10–\$20.
H.R. 926	50	No	At least \$150.
H.R. 9	25	No	At least \$250.

¹ Annual economic impact of regulations subject to review.

² Agency rules expected to have an economic impact of at least \$75 million annually and any environmental management activity expected to cost more than \$25 million.

11. Estimate prepared by: Elizabeth Chambers.

12. Estimate approved by: Paul N. Van de Water, Assistant Director for Budget Analysis.

REGULATORY IMPACT EVALUATION

In compliance with paragraph 11(b) of Rule XXVI of the Standing Rules of the Senate, the Committee makes the following evaluation of the regulatory impact which would be incurred in carrying out S. 333. The bill is not a regulatory measure in the sense of imposing Government-established standards or significant economic responsibilities on private individuals and businesses.

No personal information would be collected in administering the program. Therefore, there would be no impact on personal privacy.

The paperwork that would result from the enactment of S. 333, as ordered reported is substantially similar to the paperwork currently produced under existing law and Executive Order.

EXECUTIVE COMMUNICATIONS

The testimony provided by the Office of Management and Budget and the Department of Energy at the Committee hearing follows:

STATEMENT OF SALLY KATZEN, ADMINISTRATOR, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET

Good afternoon, Mr. Chairman, and Members of the Committee. I am pleased to be here to discuss S. 333, the “Department of Energy Risk Management Act of 1995” as introduced, as well as the amendment to it. This is an important issue to the Administration, and we are eager to work with you in the coming months as we both continue to improve the regulatory system.

S. 333 and the amendment seek to bring greater scientific and economic rationality to the regulation of risks to our health, safety, and environment. This is a laudable goal, that the Administration fully and actively supports. Indeed, we have spoken frequently and forcefully of the importance of basing regulatory decisionmaking on good data and good analysis of cost, benefits, and risk, and of the desirability of an open and transparent process. More importantly, we have done a great deal to put these ideas into practice, beginning almost immediately after we took office.

Executive Order No. 12866, which President Clinton signed on September 30, 1993, represents the cornerstone of our efforts. It recognizes the important role that regulation plays in protecting the health, safety, environment, and well-being of the American people. At the same time, it emphasizes that Government has a basic responsibility to govern wisely and carefully, regulating only when necessary and only in the most cost-effective manner.

To implement this philosophy, the Order sets forth principles emphasizing the critical role of analysis (of costs, benefits, and risk) and of the use of that analysis in decisionmaking; consideration of different regulatory alternatives and of alternatives to regulation; the importance of private markets and the use of market incentives in regulating; the need for performance standards rather than command and control techniques; better consideration of the needs of small businesses and the roles of state and local governments; and the need for extensive consultation with all those affected by the regulation (both those who will benefit and those who will be burdened).

The Executive Order requires agencies to propose or adopt a regulation only after determining that the rule would achieve its objective in a cost-effective manner, and that its benefits would justify its costs. And it specifically calls for the use of the risk analysis in regulatory decisionmaking. The Executive Order states that in developing regulations, agencies are to consider “how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency.” It also provides that “[i]n setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.”

The Executive Order established the Regulatory Working Group, which I chair and which serves “as a forum to assist agencies in identifying and analyzing important regulatory issues (including * * * the methods, efficacy, and utility of comparative risk assessment in regulatory decision-making * * *)”. One of the subcommittees of the Regulatory Working Group has been focusing on the issue of risk analysis, and it recently produced a set of principles to give agencies more specific guidance in assessing, managing, communicating, and prioritizing risks.

Recognizing that risk assessments and cost-benefit analyses are valuable tools in helping agencies make regulatory decisions in a sensible and cost-effective manner, the Administration has expressed its support for risk and cost/benefit legislation. Indeed, two weeks ago, President Clinton stated, “[W]e’re attempting to work with members of both parties in Congress to further reform regulation. * * * For example, we want all agencies to carefully compare the cost and benefits of regulations so that we don’t impose any unnecessary burdens on business.”¹ The President would like to sign risk/cost-benefit legislation that improves the regulatory process. He has supported—indeed, encouraged—members of the Adminis-

¹ Remarks by President Clinton at a Regulatory Reform Event, Room 450, Old Executive Office Building, February 21, 1995.

tration to work with you to that end. At the same time, however, we cannot support legislation that is likely to burden the regulatory process with unnecessary or costly requirements that will cause delay or gridlock or are likely to have substantive consequences that are detrimental to the American public.

We have carefully reviewed S. 333 as introduced. Many of its features appear reasonable and workable. At the same time, however, we have serious concerns with several aspects of the bill—particularly its failure to preclude judicial review; its scope, extending to every environmental restoration, no matter how small; and its petition process. These features, we fear, would drown the Department in paper and process, rather than helping it direct its resources to where they are most needed. These issues warrant further discussion, and it may be that we will be able to resolve them.

We have also reviewed the amendment to S. 333 and regret to report that it is not a workable legislative proposal. The Amendment fails to meet our standards of fair, effective, and affordable legislation—indeed, it fails to live up to its own professed standards of regulatory efficiency. It is, in the President's words, an "extreme" proposal. The amendment not only dramatically extends the scope problems but, as the President said, "could pile so many new requirements on government that nothing would ever get done. It would add to the very things that people have been complaining about for years." In the comments that follow, I will discuss some of the broader issues that we have focused on to date.

II

S. 333 as introduced focuses on a narrow problem—Department of Energy environmental restoration activities under CERCLA—and presents a relatively tailored approach to addressing that problem. While it provides substantial guidance to the agency concerning how risks are to be assessed and communicated, for the most part it stops short of being unnecessarily prescriptive. For example, while it requires the Secretary to consider laboratory and epidemiological data when assessing health risks, it does not tell her precisely which tests to run. Nor does it impose on the Department unnecessary reports and paperwork. Also, while it requires the Secretary to indicate where risk-based priorities cannot be acted upon because of existing statutory requirements, it does not (as the House has done) seek to change those statutory requirements without even identifying the particular provisions that are being changed.

The amendment, to its credit, appears to avoid the pitfall of superseding existing law, instead requiring the agency head to make a finding that no alternative allowed under the statute would be more cost-effective, flexible, or likely to produce greater net benefits.² It does, however, change the bill as introduced in two significant ways. First, it expands the applicability of the bill from the Department of Energy's environmental restoration activities to all risk assessments undertaken and all "major" regulations proposed

²Section 9 of the bill explicitly states that it shall not be construed to "modify any statutory standard or requirement designed to protect health, safety, or the environment." However, curiously, Section 623 of the amendment, which covers rules of construction, contains no similar language.

or promulgated by all Federal agencies. Second, it changes virtually all of the standards and requirements of the original bill, presumably superseding the original standards and requirements for the Department of Energy—although that is by no means clear.

This amendment is subject to many of the criticisms that have legitimately been leveled at the regulatory system it is seeking to fix: its provisions apply too broadly and are not tailored to the particular problems that should be remedied; they are too prescriptive, relying on command and control rather than performance standards; and they require excessive paperwork and invite limitless opportunities for litigation. Let me be more specific.

The amendment creates risk assessment, cost-effectiveness, peer review, and prioritization requirements for agencies in connection with regulatory programs designed to protect “health, safety, and risk to natural resources.” This phrase, which at its core is an apt description of a category of well-defined regulatory programs, would—as used here—apply a series of requirements to a large number of regulatory activities that do not warrant, and could not conceivably profit from, a full-blown risk assessment and cost/benefit analysis. For example, do you really want the Department of Commerce to have to go through the risk assessment, certification, and peer review process before issuing a rule opening a fishing season at a particular set of fisheries? The Department of Interior before it authorizes the seasonal hunting of certain migratory birds otherwise illegal to shoot? The Internal Revenue Service before it revises its income tax regulations concerning the electric vehicle or the alternative fuel tax credit? The Bureau of Alcohol, Tobacco, and Firearms before it restricts the sale of a type of explosive? The Department of Transportation before it issues mirror requirements to help school bus drivers see children near the bus? The Federal Aviation Administration before it prohibits runways from being used for both takeoffs and landings at the same time? The Occupational Safety and Health Administration before it can protect forklift drivers, scores of whom are, each year, crushed in roll over accidents because of inadequate training? The Food and Drug Administration before it can prohibit the importation of cans containing lead?

Section 625(b)(3) states that a risk assessment “shall be prepared at the level of detail appropriate and practicable for reasoned decisionmaking on the matter involved, taking into consideration the significance and complexity of the decision and any need for expedition.” This provision makes sense; it permits agencies to spend resources on risk analysis that are commensurate with the significance of the regulatory decision to be made. Unfortunately, however, other provisions of the section and the one that follows it effectively negate that sensible language. Read literally, as a statute should be, the amendment requires an agency to perform a full-blown risk assessment (including a discussion of comparative physiology, route of exposure, bioavailability, and pharmacokinetics; a presentation of plausible and alternative assumptions, a full description of the model used in the risk assessment and the assumptions incorporated therein, and an indication of the extent to which this model has been validated by empirical data; a statement of the reasonable range of scientific uncertainties; a best estimate of risk;

an explanation of the exposure scenarios employed by the risk analysis; comparisons to other health risks; and an analysis of any substitution risks) every time it makes any characterization about any risk that it wishes to communicate to the public or to Congress or that it wishes to rely on in pursuing virtually any regulatory activity.³

Congress has in some cases specified the factors that agencies are to consider in issuing health, safety, and environmental regulations, and it has on occasion explicitly or implicitly precluded the consideration of risk in decisionmaking. Technology-based standards are one example. In those instances, what purpose is served by requiring an agency to perform a rigorous risk assessment, let alone undertake each and every one of the specified steps? And even in those circumstances where the underlying statute does not preclude consideration of risk, the requirements in the amendment are overly broad and undifferentiated given the different missions of different agencies. For example, the focus of several of the amendment's provisions appear to be on cancer risks. That may be one of several factors relevant to EPA's regulation of toxic chemicals, but does it make sense when evaluating a Department of Agriculture proposal designed to reduce the instances of bacterial contamination of meat? What purpose would be served by requiring the FAA, in determining whether an airplane should be grounded because of icing problems, to "explain the exposure scenarios" used in its risk assessments, or the Department of Commerce, in regulating against overfishing of fisheries, to compare the risk of fish depletion to six other risks?

The excessive breadth of the amendment's one-size-fits-all risk assessment model is also reflected in the many ways its provisions would be triggered. To be sure, the amendment contains one necessary feature that S. 333 as introduced is lacking—namely, a dollar threshold. As noted above, under S. 333 as drafted, the Department of Energy would have to do a full risk and cost/benefit analysis regardless of whether the price of an environmental restoration would be \$5,000 or \$500 million. The amendment moves a small distance toward addressing this problem, but the threshold it sets is clearly inadequate.

Under Section 624, the amendment's risk assessment requirements would apply to a "major rule," which is defined as a rule that "is likely to have a gross annual effect on the economy of \$50,000,000 or more * * * or has a significant impact on the economy," or "is likely to result in a substantial increase in costs or prices" or to have "significant adverse effects" on competition, employment, investment, innovation, the environment, public health or safety, etc.

Since President Ford, every President has had an executive order establishing regulatory review. An essential ingredient of these orders is a distinction between that which is important and that which is more routine or administrative. For over 20 years, that distinction has been drawn at an aggregate annual effect on the economy of \$100 million.

³There are very limited exceptions in Section 622 for use of risk assessments for screening analyses that do not result in positive findings of risk and in emergencies.

In developing Executive Order No. 12866, the Administration consciously retained \$100 million as the threshold for requiring a cost/benefit analysis, having determined that the resources devoted to regulatory analysis should be commensurate with the significance of the decision to be made. Allocating resources where they are most productive (i.e., getting the biggest bang for the buck) is a tenet embraced by proponents of risk and cost/benefit analysis. But by setting the threshold for such analysis at one-half of what President Reagan used (14 years ago) in his Executive Order, the amendment dilutes this distinction.

The situation is compounded by introducing a series of non-numerical factors in the definition of a "major rule." These phrases are appropriate for an executive order that is not subject to judicial review. But once written into statute, to be interpreted by the courts, they would start us down a slippery slope. Is there a "substantial increase" in price if there is a 5 cent increase in a 15 cent item? A 5 cent increase in a \$1.00 item? What if you use 1,000 of those \$1.00 items? Is it still "substantial" if the 1,000 items account for less than 1% of your cost of service? Are there not some cases where the cost of following the detailed assessment and communication procedures set forth in the amendment would overwhelm the benefits to be derived such analysis? How are agencies to know where the line should be drawn and what criteria would be used by the courts in reviewing whatever decision is made?

There is general agreement that agencies should use objectively verifiable scientific methods, provide sufficient information so that their scientific analysis could be replicated, explain and make transparent their assumptions (including who or what is being protected and why), and provide meaningful explanations of risks (including comparisons that are meaningful to the public and relevant to the decision being made). The amendment, however, is quintessential command and control. Rather than specifying what is to be achieved (or, in regulatory parlance, the performance standard that is to be met), it tells agencies not only what to do, but also how to do it and when to do it.

III

Let me turn now to another problem that pertains to both S. 333 and the amendment: the availability of judicial review.

The objective of risk legislation should be to improve the regulatory decisionmaking process, not to create unproductive paper record requirements or additional opportunities for litigation. Because neither the bill nor the amendment preclude judicial review, the Administrative Procedure Act, which authorizes judicial review of final agency action, would apply. In addition, Section 624(b) and Section 630(c) of the amendment require that risk assessments and peer review reports be made part of the administrative record for purposes of judicial review of final agency action. Presumably, then, both an agency's compliance with the bill and the amendment's procedural steps and the contents of the agency's risk/cost-benefit analyses could become the subject of court challenges once a final rule is promulgated. Such a result would be most unfortunate.

Last year the Administration and the Senate reached agreement, in the context of the Johnston Amendment to the Safe Drinking Water Act, that risk analysis should not be subject to judicial review. The Executive, with oversight by Congress, should be responsible for determining the processes by which agencies make their decisions, particularly when the decisions are to be informed by substantial doses of science and economics. We should think twice before inviting generalist judges to evaluate the quality of the science and scientific judgment used in risk assessments; before we give economists the opportunity to serve as expert witnesses opining on the sufficiency or accuracy of the cost and cost-effectiveness estimates an agency made before promulgating a regulation; and before requiring Federal agencies to spend added time satisfying (with the extra margin needed to assure affirmance in court) each step, producing even more paper and an even larger record—efforts that would consume a great deal of time and resources without producing sounder regulations.

If there is one thing that the last 30 years of administrative law has taught us, it is that courts are not always good at second guessing agency rulemaking. Judicial interpretations that emerge in the context of an individual, hard-fought litigation do not always make sense in the broader context of setting priorities and reducing risks in a cost-effective manner. Given the ready availability of congressional oversight, the cost of adding a judicial component to risk/cost-benefit legislation far exceeds the benefits that judicial enforcement is likely to provide.

IV

Another issue that warrants comment is that both the original bill and the amendment establish a petition process for revising a previously conducted risk assessment. The bill gives the Secretary of Energy 60 days to such respond to the petition; the amendment provides an agency head with 90 days.

This Administration strongly supports the idea that agencies should review the effectiveness and efficiency of existing rules—particularly those that have been on the books for a number of years. On February 21, the President specifically instructed the Federal regulatory agencies “to go over every single regulation and cut those regulations which are obsolete.” The issue, then, is not principle; we agree on the objective. The issue is how to do it (and continue to have it done) in the most effective way.

We believe the petition process in Section 5 of S. 333 and Section 627 of the amendment is unworkable and, if enacted as drafted, would, in the President’s words, “paralyze the government by process.” First, the task facing an agency is likely to be formidable. Under the amendment, petitions could be filed to request the revision of previously completed risk assessments that do not satisfy the requirements of Sections 625 and 626, which contain the highly-prescriptive requirements for risk assessment and risk communication discussed above. It is likely that many, if not most, of the risk assessments already completed did not follow each and every one of the steps outlined in the amendment.

Second, consider the short time frame provided for response. Presumably, responding to a petition would take priority over even the

high risk, priority issues the agencies would otherwise address. Even so, the time pressure will be severe. Recall also that if an agency were to deny a petition, under either S. 333 or the amendment, judicial review would be available to the petitioning party, thus exacerbating the strain on agency resources.

Most significantly, however, the agencies' task will not be determined by the President or the people he appoints, or by the Congress. Rather, the agencies' priorities will be set by the special interests who are the first to flood the agencies with their petitions and sufficiently well-financed to keep the petitions coming. Thus the management of the agencies will be turned over to those pursuing their own parochial interests.

V

Like the risk assessment/risk characterization requirements, the peer review requirements of the amendment reflect a "one-size-fits-all" approach. Section 630 requires the President to develop a "systematic program for the peer review," which is to be "used uniformly across the agencies." Of course, different agencies have very different missions, and not surprisingly their peer review needs and requirements will vary accordingly. Thus, for example, the Department of Transportation, which possesses very concrete data concerning automobile and airplane accidents, is less likely to require the same type or scope of peer review as the Environmental Protection Agency's program office that is working on global climate change issues.

The peer review requirements are troubling for two additional reasons. First, Section 628(1) requires that each agency head certify that its risk assessments are "supported by the best available scientific data, as determined by the peer review panel. * * *" This provision would take ultimate authority away from the agencies and vest it in individuals who do not work for, and are not responsible to, the Federal government. Such a delegation of ultimate power is, to my knowledge, unprecedented since the days of President Roosevelt's National Recovery Administration. Second, the amendment carries micromanagement so far that it explicitly makes an exception to customary standards of ethical conduct by prohibiting agencies from restricting those with an interest in the outcome from participating on the panel.

Would it not be more productive for the legislation simply to require agencies to have a peer review plan, tailored to the types of risks they address and the relevant sciences that are involved? The plan could indicate which types of risk assessments would be subject to peer review, whether external or internal, and could be made available to the public—indeed, there could be public comment on the plan. Here, as above, we urge that whatever legislation is passed set forth the objective and not seek to specify each and every detail along the way.

If the layering of the regulatory process with complicated requirements were costless, we would not object so much to portions of S. 333 and to the overall prescriptiveness and inflexibility of the amendment. But we must be clear about what is at stake. The effect of these requirements is not to bring sound science and solid economics to bear on regulation, but to create more bureaucracy,

more paperwork, and less efficiency in government—to the point that the regulatory system could not move forward and our ability to take sensible steps to protect human health and human safety and the environment would be substantially retarded.

I regret that I have spent so much time speaking to matters on which we disagree rather than on the areas where we do agree. As President Clinton said, “We all want the benefits of regulation. We all want clean air and clean water and safe food and toys that our children can play with. But let’s face it, we all know the regulatory system needs repair. Too often the rule writers here in Washington have such detailed lists of dos and don’ts that the dos and don’ts undermine the very objectives they seek to achieve, when clear goals and operation for cooperation would work better. Too often, especially small businesses, face a profusion of overlapping and sometimes conflicting rules. * * * We need to change this system.”

Working together, I am confident that we will be able to help bring the American people a rational regulatory system that works for them, not against them, and that improves our quality of life, promotes our health and safety, and protects the environment, without imposing undue costs or burdens.

Thank you, Mr. Chairman. I am happy to answer your questions.

STATEMENT OF THOMAS P. GRUMBLY, ASSISTANT SECRETARY FOR ENVIRONMENTAL MANAGEMENT, U.S. DEPARTMENT OF ENERGY, BEFORE THE COMMITTEE ON ENERGY AND NATURAL RESOURCES, MARCH 6, 1995

Mr. Chairman, and Members of the Committee. I appreciate this opportunity to appear before you to discuss the Department of Energy’s comments on S. 333, the “Department of Energy Risk Management Act of 1995.”

In my testimony, I will:

Begin with some background of the Environmental Management program and describe the challenges we face.

Describe a risk-based approach we have put in place to assist us in establishing priorities and in managing the wastes and the cleanup activities from the nuclear weapons complex.

Discuss our comments on the proposed legislation.

The Department of Energy favors the use of sound science in the conduct of risk assessments, the use of risk assessments and cost benefit analyses as tools for decision-making, and the consideration of risk to human health and the environment in establishing priorities. Our Administration appreciates this Committee’s leadership on this important matter and we are prepared to work with this Committee to evolve a sound and effective approach that captures many of the essential principles in S. 333 as introduced by Senators Murkowski, Johnston and Lott.

I. INTRODUCTION

The Department of Energy’s Environmental Management program faces many responsibilities and challenges, including how to reduce the threat of explosion of tanks filled with highly radioactive waste; how to decontaminate and decommission some of the largest buildings in the world, which are contaminated with radio-

active and other hazardous materials; how to safely store almost three thousand tons of spent nuclear fuel, some of which has been in pools for over 30 years and is not corroding; and how to stabilize and safeguard 26 metric tons of plutonium scraps and residues—enough to make several thousand thermonuclear warheads while protecting the safety and health of our workers and the public in communities around our sites. Answers to many of these questions rely on the successful development of effective and affordable technologies and innovative methods for data collection and assessment. Furthermore, the Environmental Management program has extensive site management responsibilities consisting of a wide range of activities including fire safety, providing for basic utilities, roadway maintenance, and security.

The Department of Energy's Environmental Management program is making significant strides in reducing the environmental and public health risks and hazards from more than fifty years of nuclear weapons production, testing, and research. While it has been said the Department moved slowly in the past, we have a number of accomplishments that are unparalleled in the corporate sector in a similar period of time. For example, we have:

- Decommissioned 100 facilities across the complex.

- Cleaned up 16 former nuclear weapons and industrial sites and 14 sites associated with uranium mining and milling since 1989.

- Remediated 5,000 public and private properties contaminated with uranium tailings since 1989.

- Treated 2.4 billion gallons of ground water and 1.8 billion gallons of surface water since 1989.

- Recycled 16 million pounds of scrap metal.

- Safely transported one million tons of hazardous materials in 140,000 shipments since 1989.

- Made safety improvements to Building 707 and begun to stabilize inventories of pyrophoric plutonium at the Rocky Flats Plant in Colorado in Fiscal Year 1995. This material poses a fire hazard since, under certain conditions, plutonium ignites in air.

- Received 153 spent nuclear fuel elements of United States origin from foreign research reactors. Accepting these fuel elements helps support the Nation's nonproliferation policy since they contain weapons-usable highly-enriched uranium.

- Safely transferred 199 spent nuclear fuel elements to safer storage facilities in Idaho.

- Developed, installed, and operated a pump that has virtually eliminated the threat of explosion in a high-level waste tank at our Hanford site.

- Saved over \$115 million through the use of new technologies.

DOE's continuing environmental challenge includes a legacy of hazardous, radioactive, and mixed wastes from nuclear weapons complex facilities encompassing:

- 3,300 square miles of land in 36 states;

- 3,700 contaminated sites;

- Over 100 million gallons of radioactive/mixed waste in 332 tanks at Hanford, Washington, Oak Ridge, Tennessee, Savannah River, Georgia, Idaho, and Fernald, Ohio;

169,000 cubic meters of stored mixed low level waste;
 3,000,000 cubic meters of radioactive or hazardous buried waste;
 250,000 cubic meters of contaminated soils (from landfills and plumes);
 Over 600 billion gallons of contaminated groundwater;
 1,200 facilities for decontamination and decommissioning.

The DOE Strategic Plan's Environmental Quality Strategy states that the principal environmental quality objective—and greatest challenge—of the Department of Energy is to eliminate the risks and imminent threats posed by past departmental activities and decisions. Consistent with this objective, the primary mission of DOE's Environmental Management Program is protecting human health and the environment. The goals that have been developed for the program since I became Assistant Secretary address: Urgent risks and threats, a safe workplace, managerial and financial control, outcome orientation, focused technology development, and strong partnerships with stakeholders.

Credible risk assessment and good risk management are and will be major keys to success for these goals. Risk assessment is the process by which we evaluate the potential adverse effects to humans, workers and the environment: risk management involves the steps we take to control and reduce these risks. The Environmental Management program must employ the best risk assessment techniques if it is to set priority goals for cleanup responsibly. The "rightness" of selected priorities and goals has important implications for public health and environmental protection. The uncertainty surrounding even the best risk assessment requires that all assumptions be explicitly stated and be transparent to the public. This is critical to the credibility of risk assessment as a tool for decision-making.

II. REAL WORLD ISSUES

The Environmental Management program is focused on real world issues: Keeping nuclear materials safe; maintaining or stabilizing our facilities; and minimizing the spread of radioactive and chemical contamination and exposure to the environment, workers and the public. In addition, we are working to return land and facilities to productive use. We are investing in technological solutions where there were none before and in order to do things cheaper, faster, and better. Environmental Management deals with risks, costs, benefits, communication, priority-setting, and decisions on a daily and routine basis, at all levels of management. It is not an academic exercise, and we cannot afford to get lost in "theoretical" exercises. Risk is one of several factors considered in our decision-making and for us, risk and risk assessment are not about "theology" but about the application and use of powerful tools. Our responsibilities parallel those of major corporations in the private sector, who are subject to the laws of the land. We are meeting our legal obligations, but as we do so, tougher resource allocation decisions will have to be made.

Some of the difficult decisions the Department faces with regard to the management of these problems include:

How do we insure that special nuclear materials are managed safely?

Where will we dispose of the wastes generated in the clean-up process?

How will our land and facilities be used in the future?

To what extent can we control access to our facilities and the contamination we leave in place?

To what extent should we put our workers at risk during the cleanup of our site and facilities and what are the benefits from these exposures?

To what extent are we willing to affect sensitive ecosystems to clean-up soil contamination?

How do we protect valuable water resources from further degradation?

III. NATIONAL ACADEMY OF SCIENCES—NATIONAL RESEARCH COUNCIL REPORT

We cannot answer and/or address all of these questions at once. Logically, risk assessment could be an invaluable tool in making some of these decisions. When I became Assistant Secretary for Environmental Management, I identified that the major problem faced by the department is that we have not been able to define what the risks are on a site-by-site basis and in a systematic way. In addition, I believe that it matters “who” does the risk assessment. Although risk assessment is valuable, there are many methodology questions about these risks and how to assess them.

Knowing the controversy surrounding risk and the use of a risk-based approach for Environmental Management, I requested in July 1993, two months after assuming my current responsibilities, that the National Academy of Sciences—National Research Council advise the Department on whether and how risk and risk-based decisions could be incorporated into the Environmental Management Program. The National Academy of Sciences was chartered by the Congress in 1863 to advise the federal government on scientific and technical matters and has long been recognized for its distinguished contributions to national science, engineering, and medical fields.

My request to the National Research Council resulted in the January 1994 report, “Building Consensus Through Risk Assessment and Management of the Department of Energy’s Environmental Remediation Program.” In the report, the Council identified the following obstacles to a risk-based management approach:

Use of risk assessment to set priorities for remediation is viewed with skepticism by many in the public.

Risk assessment is viewed as a process without opportunity for public input.

Risk assessment is viewed as a mechanical process.

Risk assessment is viewed as a process that does not give proper weight to those affected stakeholders.

Risk assessment is viewed with concern by stakeholders as a method for allocating financial resources between facilities, and to a lesser degree, to allocate resources within facilities without adequate consideration of other important criteria.

The National Research Council report identified critical risk assessment issues the Environmental Management Program needed to overcome, the first of which was to understand and state the limitations of risk assessment and that risk assessment is just one part of the overall decision-making process. Further and specifically to Environmental Management's Program, assumptions needed to be clearly stated about the future use of the land to be remediated. Such assumptions are critical to determining future risks.

The National Research Council report also identified barriers to implementing a risk-based approach within Environmental Management, including:

- Coordinating risk management programs within DOE, preserving flexibility, yet implementing common methods and approaches for different facilities.

- Coordinating methodology and developing working relationships with other federal and state agencies.

- Understanding (by stakeholders and DOE managers) the strengths/limitations of risk assessment.

Nevertheless, the National Research Council concluded that the use of risk assessments and a risk-based approach would be feasible, even with little current information, provided its purposes and limitations are clearly defined. If risk assessments are conducted as an iterative process, then the initial analyses could help define where more information is needed.

Further, the National Research Council stated that risk assessments are desirable because they can help build consensus to set overall priorities for spending limited funds, including those of stakeholders and citizens. Such assessments can provide information and interpretation for managing risks for public and worker health and safety, in addition to comparing potential outcomes and cost effectiveness of possible actions. Early and full public involvement and consideration of cultural, socioeconomic, historic and religious values, need to be pursued for the process to be successful.

IV. REPORT TO CONGRESS

At the same time the National Research Council prepared its report. Congress reflected its increasing concern over the budget for the program, as well as the concern for the costs and effectiveness of its risk reduction efforts. Congress directed the Department to submit a report by June 30, 1995 to the Committees on Appropriations, evaluating the risks to the public health and safety posed by the conditions at weapons complex facilities that are subject to compliance agreements with our state and federal regulators. The Congressional conferees further agreed that the Department needed to develop a mechanism for establishing priorities among competing cleanup requirements. We are on schedule to deliver this report to you in June.

V. RISK PRINCIPLES

Obviously, risk has become a highly visible topic. Public discussions on risk assessments and analysis have been particularly prominent in the Congress and the press lately, yet the discussion itself is not new. Policy makers, scientists, economists, and students of public administration have long debated the subject. The

growing body of literature that has been generated is now receiving increased visibility, capturing the attention of both the Congress and many citizens throughout the Department of Energy's far reaching community.

Because of this increased emphasis on risk activities, the Department has needed to give focus to, and guidance for, all such initiatives now being conducted or anticipated. A general framework for risk analysis is a timely and appropriate aid to policy making.

The Clinton Administration recognized the importance of applying sound risk analysis procedures to regulatory decision-making early on. An interagency regulatory work group has established a set of risk principles to guide decision makers in the areas of risk assessment, risk management, risk communication and priority-setting. DOE is the first agency to adopt these principles, which were modified to apply more specifically to Department of Energy programs and processes, to accommodate our citizen values, to more specifically address inter-generational issues, and to clarify the role of prevention programs and social and economic considerations in risk management. These modifications are a tailoring that does not depart from the basic tenets of general principles. The Environmental Management Program was the principle driver in the department for adopting these principles and for modifying them for specific activities and situations unique to DOE. We sent these principles out to all of our field offices for comment for them to use as guidance. We know we will need to use these principles to prioritize our work at each site—particularly if we move to a site based budgeting scheme. The principles are designed to be a first cut at defining and communicating how risk analysis will be used within the Department and fall into four major categories (described in greater detail below): (1) risk assessment; (2) risk management; (3) risk communication, and (4) priority setting.

The DOE Principles for Risk Assessment recommend using the best available information from all sources. Characterization should be qualitative and quantitative (descriptive and mathematical). Judgments and assumptions, should be explicitly stated. All appropriate hazards to human health, worker health and the environment should be included. Peer review should be used to ensure high standards. The principles stress the importance of consistent approaches.

The DOE Principles for Risk Management recommend an analysis of the distribution of risks and costs/benefits of potential risk management strategies, using the best available tools and techniques. Where programs have the discretion to choose among alternative approaches to reducing risk, they should do so in the context of prevention programs and broad social and economic considerations, such as equity. Programs should develop criteria and methods to evaluate the effectiveness of decisions.

The DOE Principles for Risk Communication involve the open, 2-way exchange of information between professionals and the public. The principles emphasize the importance of stating risk management goals, assumptions, uncertainties and comparisons clearly, accurately, and meaningfully. Public access should be provided in a timely manner.

The DOE Principles for Priority Setting Using Risk Analysis seeks to compare risks by grouping them into broad categories of concern (e.g., high, medium, low) and identifying the population at risk. Programs should set priorities in managing risks to account for relevant management and social considerations. The setting of priorities should be informed by as broad a range of views as possible, ideally with consensus.

VI. COMMENTS ON RISK LEGISLATION

Overall position

As I stated earlier, the Department of Energy favors the use of sound science in the conduct of risk assessments, and the use of risk assessments and cost benefit analyses as tools for decision-making and in establishing priorities. S. 333 as introduced provides a basis for the development of a risk framework for legislation that the Department could support.

S. 333 principles for risk assessments too prescriptive

The bill introduced to date raises several important concerns. S. 333 requires a certification that proposed measures will reduce risks, generate benefits that justify costs in the broad sense of Executive Order 12866, and are cost-effective among the legally relevant options. The Secretary must report to Congress if certification cannot be made. The bill does not incorporate sufficient flexibility to allow the Department to address other important factors such as public involvement in priority setting. This flexibility is currently embedded in DOE programs and is reflected in the DOE Risk Principles.

An example where public involvement has played a major role in the decision-making process will be discussed later in the hearing by John Applegate, the Chairman of Environmental Management's Site-Specific Advisory Board for Fernald, Ohio. Although his views may be different from the Department's, as a result of public involvement in our program regulators, technical and management staff, cost-effective solutions were agreed to for the contamination issues. The proposed legislation would make it more difficult for DOE and other federal agencies to address these important elements. As part of the regulated community and as a preparer of risk assessments, DOE expects compliance with these provisions will delay certain DOE activities, and thus could increase health, safety and environmental risks and program costs over time.

Second, S. 333 goes well beyond the attempt at standardization of risk assessment methods under Superfund that the Clinton Administration supported in the last Congress. The risk assessment approach outlined in S. 333 is prescriptive and dictates a framework for assessing risk that is most suitable for the evaluation of health impacts from exposure to environmental toxins, most of which are assumed to be carcinogens. Consideration must also be given to operational risks such as those involving nuclear safety, risks related to birth defects effects, and immediate health effects related to exposure to hazardous materials. Most importantly, the principles in S. 333 do not incorporate risks to workers and the en-

vironment during remediation. Incorporation of such risks would be a major improvement to the legislation.

Review requirements

The requirement in S. 333 for the Secretary to review and revise risk assessments if significant new information or methodologies become available, or if there are other reasons why such a review and revision should be conducted causes us concern about our ability to implement decisions that involve actions—building of waste treatment and disposal facilities, containing or transporting materials. Members of the public could petition the Secretary for review of particular risk assessments not to their liking and cause significant delays in actual clean-up work.

VII. SPECIFIC IMPACTS OF S. 333 LEGISLATION ON ENVIRONMENTAL MANAGEMENT

The long-term decisions that Environmental Management as a regulated entity must be concerned about are: the future use of the lands for which we are now responsible; the short-term and long-term solutions for disposal and treatment of the nuclear and chemical wastes that were produced during weapons production and during stabilization treatment and remediation at the sites; and the extent of institutional controls that must be maintained to prevent exposure to, or releases of, the nuclear and/or chemical materials at our sites.

The clean-up decisions that Environmental Management must implement are based on regulatory decisions, often made without cost-benefit information. S. 333 would require that benefit/cost assessment be completed and available in the decision process. We would expect that this information would then be used by regulators in their decisions. This could be very important. In Environmental Management's Environmental Restoration program, approximately 90 percent of approximately 280 decisions have required clean-up action by DOE. We do not have benefit/cost assessment on these actions but a number of studies that have been done generally tend to show that if positive net benefits were a decision criterion, fewer actions would result.

The underlying assumption in S. 333 is that increased understanding of the risks, costs, and benefits will lead to better and more balanced decisions. We believe that for the Environmental Management Program, the direct cost of conducting the assessment of risks, costs, and benefits will have a relatively small impact on an annual basis. Indirect costs will increase because of delays in deactivating and decommissioning activities resulting in increasing surveillance and maintenance costs. While indirect costs are difficult to estimate because the number of factors to consider, we believe that they would be small on an annual basis.

Properly structured legislation building on the Committee's original proposal in S. 333 would provide the framework to provide regulators, decision makers, and the public with very useful information about risks and cost-benefit assessment in making decisions. We believe the net overall impact of such revised legislation would be positive. However, the revised legislation should incorporate the following.

It should have a reasonable dollar or other threshold for the requirements of the legislation to be applicable,

It should state clearly that the legislation does not provide an independent basis for judicial review, and

It should not override the substantive standards or requirements of other statutes.

VIII. EXAMPLE

In closing, I want to share with you an example of the types of decisions and priority setting activities that Environmental Management has addressed and resolved. This example demonstrates the flexibility that we as public managers need to have in our decision-making and managing of risk reduction actions. As we state in our DOE principles, risk is a component in decision-making, but not the only consideration. Values, justice, benefits, and costs have been factors that must be considered to arrive at successful decisions.

In the 1950s, the United States began the Plowshare program, an attempt to find peaceful uses of nuclear explosions. One such attempt, Project Chariot, was hoped to allow enlargement of a harbor near Point Hope in Northern Alaska. More than thirty years later, Environmental Management had to deal with the legacy in cooperation with the State of Alaska.

Briefly, 26 millicuries of radioactive Cesium were placed on the tundra in a remote area of Northwest Alaska, as an experiment to learn what would happen to the material under those climatic conditions. No safeguards for the Native Americans were provided and no information about the "experiment" was provided until fairly recently.

After over 30 years, the radioactive material left in place had decayed to 3 millicuries. There was a small possibility that up to 5 curies might have been brought to the site, but no firm evidence has been uncovered to support this possibility.

From a technical assessment of the risks, the health risks to the Native American population were assessed to be low, due to the lack of exposure and remoteness of the site. However, the level of public concern was very high on the part of the citizens of the North Slope and Point Hope, Alaska. Environmental Management removed the contaminated soil in a manner acceptable to the citizens in Northwest Alaska for \$7 million.

This example demonstrates practical, real-world decisions and issues that our program faces every day. We in the DOE have materials that pose unique challenges unlike other waste management and restoration programs. Flexibility and judgment are needed within a defined framework to be able to manage a successful, cost-effective program that reduces the risks to public health, worker health, and the environment.

IX. CONCLUSION

In conclusion, Mr. Chairman and members of the Committee, I am pleased to have had this opportunity to share with you our views on S. 333 and how it would relate to our program. We believe, in principle, that a properly and carefully structured risk assessment program can have significant benefits. We are prepared

to work with the Congress to evolve a sound and effective approach to such a risk analysis program.

MINORITY VIEWS OF SENATOR JOHNSTON

I want to make clear that my vote against reporting this bill does not indicate a lack of support for legislation requiring risk assessment and cost-benefit analysis when promulgating major regulations. In fact, as many of my colleagues know, I authored a risk assessment amendment that passed the Senate in 1993 by a vote of 95-3. I then made certain modifications to the amendment before passing it again in 1994 by a vote of 90-8.

I voted against reporting this bill solely because I became concerned that the judicial review provisions in the bill, when applied to the specific requirements of the bill, could well lead to extensive litigation. The bill contains at least 44 steps or requirements that the agency must comply with in performing the risk assessment and cost-benefit analysis. For example, the bill requires that risk assessment must be based on the "best available, scientifically replicable data."

I agree that we should include specific steps in the statute, but I became concerned that, under the bill's judicial review provision, a failure by the agency to fully comply with each of these steps might lead a court to overturn the regulation, even if the failure to comply was relatively trivial in nature. The basis for the judge's action would be the language in section 706 of the Administrative Procedures Act that a rule may be held invalid if it is "not in accordance with law," or is "without observance of procedure required by law."

To avoid this potential pitfall, I intend to propose changes to the bill's judicial review language before the bill reaches the floor. Essentially, I want to make clear that the adequacy of compliance with this Act may be considered by the court solely for the purpose of determining whether the final agency action is arbitrary and capricious or an abuse of discretion. Otherwise, I fear that this important legislation may become a lawyers' dream by allowing litigation regarding the adequacy of compliance with each and every requirement of the bill, no matter how inconsequential the failure to comply may have been.

J. BENNETT JOHNSTON.

CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, the Committee notes that no changes in existing law are made by the bill S. 333, as ordered reported.

