Amendment No. 230

S. 333

AMENDMENT NO. **230**

Purpose: To add additional provisions relating to risk assessments

IN THE SENATE OF THE UNITED STATES—104th Cong., 1st Sess.

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.

February 3 (legislative day, January 30), 1995

Referred to the Committee on Energy and Natural Resources and ordered to be printed

AMENDMENT intended to be proposed by Mr. MURKOWSKI (for himself and Mr. LOTT)

Viz:

At the end of the bill add the following:

SEC. 11. AMENDMENT OF TITLE 5, UNITED STATES CODE.

(a) IN GENERAL.—Chapter 6 of title 5, United States Code, is amended by adding at the end the following:

''SUBCHAPTER II—RISK ASSESSMENTS

''§ 621. Definitions

''In this subchapter—

''(1) AGENCY.—The term 'agency' has the meaning stated in section 551(1).

''(2) BENEFIT.—The term 'benefit' means the reasonably identifiable significant benefits, including social and economic benefits, that are expected to result directly or indirectly from implementation of a rule or an alternative to a rule.

''(3) BEST ESTIMATE.—The term 'best estimate' means an estimate that, to the extent feasible and scientifically appropriate, is based on one or more of the following:

''(A) Central estimates of risk using the most plausible assumptions.

''(B) An approach that combines multiple estimates based on different scenarios and weighs the probability of each scenario.

''(C) Any other methodology designed to provide the most unbiased representation of the most plausible level of risk, given the current scientific information available to the agency concerned.

''(4) COST.—The term 'cost' means the reasonably identifiable significant costs and adverse effects, including social and economic costs, reduced consumer choice, substitution effects, and impeded technological advancement, that are expected to re-

sult directly or indirectly from implementation of, or compliance with, a rule or an alternative to a rule.

''(5) EMERGENCY.—The term 'emergency' means a clearly imminent and substantial endangerment to public health, safety, or natural resources.

''(6) MAJOR RULE.—The term 'major rule'—

''(A) means—

''(i) a rule or a group of closely related rules that the agency proposing the rule or the President reasonably determines is likely to have a gross annual effect on the economy of $50,000,000 or more in reasonably quantifiable increased direct and indirect costs, or has a significant impact on a sector of the economy; or

''(ii) a rule or a group of closely related rules that is otherwise designated a major rule by the agency proposing the rule, or by the President on the ground that the rule is likely to result in—

''(I) a substantial increase in costs or prices for wage earners, consumers, individual industries, nonprofit organizations, Federal, State,

or local government agencies, or geographic regions; or

''(II) significant adverse effects on competition, employment, investment, productivity, innovation, the environment, public health or safety, or the ability of enterprises whose principal places of business are in the United States to compete in domestic or export markets; but

''(B) does not include—

''(i) a rule that involves the internal revenue laws of the United States; or

''(ii) a rule that authorizes the introduction into commerce, or recognizes the marketable status, of a product;.

''(7) PERSON.—The term 'person' has the meaning stated in section 551(2).

''(8) PLAUSIBLE.—The term 'plausible' means realistic and scientifically probable.

''(9) RISK ASSESSMENT.—The term 'risk assessment' means—

''(A) the process of identifying hazards, and quantifying (to the extent practicable) or describing the degree of toxicity, exposure, or

other risk the hazards pose for exposed individuals, populations, or resources; and

''(B) the document containing the explanation of how the assessment process has been applied to an individual substance, activity, or condition.

''(10) RISK CHARACTERIZATION.—The term 'risk characterization'—

''(A) means the element of a risk assessment that involves presentation of the degree of risk to individuals and populations expected to be protected, as presented in any regulatory proposal or decision, report to Congress, or other document that is made available to the public; and

''(B) includes discussions of uncertainties, conflicting data, estimates, extrapolations, inferences, and opinions.

''(11) RULE.—The term 'rule' has the meaning stated in section 551(4).

''(12) SUBSTITUTION RISK.—The term 'substitution risk' means a potential increased risk to human health, safety, or the environment from a regulatory option designed to decrease other risks.

"§ 622. Applicability

''(a) Except as provided in subsection (b), this subchapter shall apply to all risk assessments and risk characterizations prepared by, or on behalf of, or prepared by others and adopted by, any agency in connection with health, safety, and risk to natural resources.

''(b)(1) This subchapter shall not apply to risk assessments or risk characterizations performed with respect to—

''(A) a situation that the head of the agency considers to be an emergency;

''(B) a rule that authorizes the introduction into commerce, or recognizes the marketable status of a product; or

''(C) a screening analysis.

''(2)(A) An analysis shall not be treated as screening analysis for the purposes of paragraph (1)(B) if the result of the analysis is used—

''(i) as the basis for imposing a restriction on a substance or activity; or

''(ii) to characterize a positive finding of risks from a substance or activity in any agency document or other communication made available to the public, the media, or Congress.

''(B) Among the analyses that may be treated as a screening analyses for the purposes of paragraph (1)(B)

are product registrations, reregistrations, tolerance settings, and reviews of premanufacture 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.).

''(3) This subchapter shall not apply to any food, drug, or other product label or to any risk characterization appearing on any such label.

"§ 623. Rule of construction

''Nothing in this subchapter shall be construed to—

''(1) preclude the consideration of any data or the calculation of any estimate to more fully describe risk or provide examples of scientific uncertainty or variability; or

''(2) require the disclosure of any trade secret or other confidential information.

"§ 624. Requirement to prepare risk assessments

''(a) Except as provided in section 622, the head of each agency shall prepare for each major rule relating to human health, safety, or natural resources that is proposed by the agency after the date of enactment of this subchapter, is pending on the date of enactment of this subchapter, or is subject to a granted petition for review pursuant to section 627—

''(1) a risk assessment in accordance with this subchapter;

''(2) for each such proposed or final rule, an assessment, quantified to the extent feasible, of incremental risk reduction or other benefits associated with each significant regulatory alternative to the rule or proposed rule; and

''(3) for each such proposed or final rule, quantified to the extent feasible, a comparison of any human health, safety, or natural resource risks addressed by the regulatory alternatives to other relevant risks chosen by the head of the agency, including at least 3 other risks regulated by the agency and to at least 3 other risks with which the public is familiar.

''(b) A risk assessment prepared pursuant to this subchapter shall be a component of and used to develop the cost-benefit analysis required by subchapter II, and shall be made part of the administrative record for judicial review of any final agency action.

''§ 625. Principles for risk assessment

''(a)(1) The head of each agency shall apply the principles set forth in subsection (b) when preparing any risk assessment, whether or not required by section 624, to ensure that the risk assessment and all of its components—

''(A) distinguish scientific findings and best estimates of risk from other considerations;

''(B) are, to the maximum extent practicable scientifically objective, unbiased and inclusive of all relevant data; and

''(C) rely, to the extent available and practicable, on scientific findings.

''(2) Discussions or explanations required under this section need not be repeated in each risk assessment document as long as there is a reference to the relevant discussion or explanation in another agency document.

''(b) The principles to be applied when preparing risk assessments are as follows:

''(1)(A) When assessing human health risks, a risk assessment shall be based on the most reliable laboratory, epidemiological, and exposure assessment data that finds, or fails to find, a correlation between a health risk and a potential toxin or activity. Other relevant data may be summarized.

''(B) When conflicts among such data appear to exist, or when animal data are used as a basis to assess human health, the assessment shall include discussion of possible reconciliation of conflicting information, and, as appropriate, differences in study designs, comparative physiology, routes of exposure,

bioavailability, pharmacokinetics, and any other relevant factor, including the availability of raw data for review. Greatest emphasis shall be placed on data that indicates a biological basis of the resulting harm in humans. Animal data shall be reviewed with regard to relevancy to humans.

''(2) When a risk assessment involves selection of any significant assumption, inference, or model, the agency shall—

''(A) describe the plausible and alternative assumptions, inferences, or models;

''(B) explain the basis for any choices among such assumptions, inferences, or models;

''(C) identify any policy or value judgments involved in choosing from among such alternative assumptions, inferences, or models;

''(D) fully describe any model used in the risk assessment and make explicit the assumptions incorporated in the model; and

''(E) indicate the extent to which any significant model has been validated by, or conflicts with, empirical data.

''(3) 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.

"§ 626. Principles for risk characterization and communication

''In characterizing risk in any risk assessment document, regulatory proposal or decision, report to Congress, or other document that is made available to the public, each agency characterizing the risk shall comply with each of the following:

''(1)(A) The head of the agency shall describe the populations or natural resources that are the subject of the risk characterization.

''(B) If a numerical estimate of risk is provided, the head of the agency, to the extent feasible and scientifically appropriate—

''(i) shall provide—

''(I) the best estimate or estimates for the specific populations or natural resources which are the subject of the characterization (based on the information available to the department, agency, or instrumentality) or, in lieu of a single best estimate, an array of multiple estimates (showing the distribution of estimates and the best estimate) based on assumptions,

inferences, or models which are equally plausible, given current scientific understanding;

''(II) a statement of the reasonable range of scientific uncertainties; and

''(III) to the extent practicable and appropriate, descriptions of the distribution and probability of risk estimates to reflect differences in exposure variability in populations and uncertainties;

''(ii) in addition to a best estimate or estimates, may present plausible upper-bound or conservative estimates, but only in conjunction with equally plausible lower-bound estimates; and

''(iii) shall ensure that, where a safety factor, as distinguished from inherent quantitative or qualitative uncertainties, is used, such factor shall be similar in degree to safety factors used to ensure safety in human activities.

''(2) The head of the agency shall explain the exposure scenarios used in any risk assessment, and, to the extent feasible, provide a statement of the size of the corresponding population or natural resource at risk and the likelihood of such exposure scenarios.

''(3)(A) To the extent feasible, the head of the agency shall provide a statement that places the nature and magnitude of individual and population risks to human health in context.

''(B) A statement under subparagraph (A) shall—

''(i) include appropriate comparisons with estimates of risks that are familiar to and routinely encountered by the general public as well as other risks; and

''(ii) identify relevant distinctions among categories of risk and limitations to comparisons.

''(4) When an 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 identified by the agency or contained in information provided to the agency by a commenter.

''(5) If—

''(A) an agency provides a public comment period with respect to a risk assessment or regulation;

''(B) a commenter provides a risk assessment, and a summary of results of such risk assessment; and

''(C) such risk assessment is reasonably consistent with the principles and the guidance provided under this subtitle,

the agency shall present such summary in connection with the presentation of the agency's risk assessment or the regulation.

"§ 627. Regulations; plan for assessing new information

''(a)(1) Not later than 1 year after the date of enactment of this subchapter, the President shall issue a final regulation that has been subject to notice and comment under section 553 for agencies to implement the risk assessment and characterization principles set forth in sections 625 and 626 and shall provide a format for summarizing risk assessment results.

''(2) The regulation under paragraph (1) shall be sufficiently specific to ensure that risk assessments are conducted consistently by the various agencies.

''(b)(1) Review of the risk assessment for any major rule shall be conducted by the head of the agency on the written petition of a person showing a reasonable likelihood that—

''(A) the risk assessment is inconsistent with the principles set forth in section 625 and 626;

''(B) the risk assessment produces substantially different results;

''(C) the risk assessment is inconsistent with a rule issued under subsection (a); or

''(D) the risk assessment does not take into account material significant new scientific data or scientific understanding.

''(2) Not later than 90 days after receiving a petition under paragraph (1), the head of the agency shall respond to the petition by agreeing or declining to review the risk assessment referred to in the petition, and shall state the basis for the decision.

''(3) If the head of the agency agrees to review the petition, the agency shall complete its review within 180 days, unless the Director of the Office of Management and Budget agrees in writing with an agency determination that an extension is necessary in view of limitations on agency resources.

''(4) Denial of a petition by the agency head shall be subject to judicial review in accordance with chapter 7 of title 5, United States Code.

''(c) The regulations under this section shall be developed after notice and opportunity for public comment, and

after consultation with representatives of appropriate State agencies and local governments, and such other departments and agencies, offices, organizations, or persons as may be advisable.

''(d) At least every 4 years, the President shall review, and when appropriate, revise the regulations published under this section.

"§ 628. Decisional criteria

''For each major rule subject to this subchapter, the head of the agency, subject to review by the President, shall make a determination that—

''(1) the risk assessment under section 624 is based on a scientific and unbiased evaluation, reflecting realistic exposure scenarios, of the risk addressed by the major rule and is supported by the best available scientific data, as determined by a peer review panel in accordance with section 640; and

''(2) there is no alternative that is allowed by the statute under which the major rule is promulgated that would provide greater net benefits or that would achieve an equivalent reduction in risk in a more cost-effective and flexible manner.

"§ 629. Regulatory priorities

''(a) In exercising authority under any laws protecting human health and safety or the environment, the head of an agency shall prioritize the use of the resources available under such laws to address the risks to human health, safety, and natural resources that—

''(1) the agency determines are the most serious; and

''(2) can be addressed in a cost-effective manner, with the goal of achieving the greatest overall net reduction in risks with the public and private sector resources to be expended.

''(b) In identifying the sources of the most serious risks under subsection (a), the head of the agency shall consider, at a minimum—

''(1) the plausible likelihood and severity of the effect; and

''(2) the plausible number and groups of individuals potentially affected.

''(c) The head of the agency shall incorporate the priorities identified in subsection (a) into the budget, strategic planning, and research activities of the agency by, in the agency's annual budget request to Congress—

''(1) identifying which risks the agency has determined are the most serious and can be addressed

in a cost-effective manner under subsection (a), and the basis for that determination;

''(2) explicitly identifying how the agency's requested funds will be used to address those risks;

''(3) identifying any statutory, regulatory, or administrative obstacles to allocating agency resources in accordance with the priorities established under subsection (a); and

''(4) explicitly considering the requirements of subsection (a) when preparing the agency's regulatory agenda or other strategic plan, and providing an explanation of how the agenda or plan reflects those requirements and the comparative risk analysis when publishing any such agenda or strategic plan.

''(d) In March of each year, the head of each agency shall submit to Congress specific recommendations for repealing or modifying laws that would better enable the agency to prioritize its activities to address the risks to human health, safety, and the environment that are the most serious and can be addressed in a cost-effective manner consistent with the requirements of subsection (a).

''§ 630. Establishment of program

''(a) The President shall develop a systematic program for the peer review of work products covered by sub-

section (c), which program shall be used uniformly across the agencies.

''(b) The program under subsection (a)—

''(1) shall provide for the creation of peer review panels consisting of independent and external experts who are broadly representative and balanced to the extent feasible;

''(2) shall not exclude peer reviewers merely because they represent entities that may have a potential interest in the outcome, if that interest is fully disclosed;

''(3) shall exclude, to the maximum extent practicable, any peer reviewer who has been involved in any previous analysis of the tests and evidence presented for certification by the peer review panel; and

''(4) shall provide for a timely completed peer review, meeting agency deadlines, which contains a balanced presentation of all considerations, including minority reports and an agency response to all significant peer review comments.

''(c) The peer review and the agency's responses shall be made available to the public and shall be made part of the administrative record for purposes of judicial review of any final agency action.''.

(b) CONFORMING AMENDMENT AND TECHNICAL CORRECTIONS.—

(1) CONFORMING AMENDMENTS.—Part I of title 5, United States Code, is amended by striking the chapter analysis for chapter 6 and inserting the following:

"CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS

"SUBCHAPTER I—REGULATORY ANALYSIS

"SUBCHAPTER II—RISK ASSESSMENTS

"SUBCHAPTER I—REGULATORY ANALYSIS".

(2) TECHNICAL CORRECTIONS.—The part analysis for part I of title 5, United States Code, is amended—

(A) in the item relating to chapter 5 by striking ''**501**'' and inserting ''**500**''; and

(B) by inserting after the item relating to chapter 5 the following:

''6. The Analysis of Regulatory Functions ..... 601''.