106TH CONGRESS
1ST SESSION

S. 746

To provide for analysis of major rules, to promote the public's right to know the costs and benefits of major rules, and to increase the accountability and quality of Government.

IN THE SENATE OF THE UNITED STATES

MARCH 25, 1999

Mr. LEVIN (for himself, Mr. THOMPSON, Mr. VOINOVICH, Mr. ROBB, Mr. ABRAHAM, Mr. ROCKEFELLER, Mr. ROTH, Mr. DASCHLE, Mr. STEVENS, Mr. MOYNIHAN, Mr. COCHRAN, Mr. BREAUX, Mr. FRIST, Mr. ENZI, Mr. GRAMS, Mr. GRASSLEY, and Mrs. LINCOLN) introduced the following bill; which was read twice and referred to the Committee on Governmental Affairs

---

A BILL

To provide for analysis of major rules, to promote the public's right to know the costs and benefits of major rules, and to increase the accountability and quality of Government.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "Regulatory Improvement Act of 1999".

SEC. 2. FINDINGS.

Congress finds the following:

(1) Effective regulatory programs provide important benefits to the public, including improving the environment, worker safety, and public health. Regulatory programs also impose significant costs on the public, including individuals, businesses, and State, local, and tribal governments.

(2) Improving the ability of Federal agencies to use scientific and economic analysis in developing regulations should yield increased benefits and more effective protections while minimizing costs.

(3) Cost-benefit analysis and risk assessment are useful tools to better inform agencies in developing regulations, although such analyses and assessments do not replace the need for good judgment and consideration of values.

(4) The evaluation of costs and benefits must involve the consideration of the relevant information, whether expressed in quantitative or qualitative terms, including factors such as social values, distributional effects, and equity.

(5) Cost-benefit analysis and risk assessment should be presented with a clear statement of the analytical assumptions and uncertainties, including an explanation of what is known and not known and

what the implications of alternative assumptions might be.

(6) The public has a right to know about the costs and benefits of regulations, the risks addressed, the risks reduced, and the quality of scientific and economic analysis used to support decisions. Such knowledge will promote the quality, integrity and responsiveness of agency actions.

(7) The Administrator of the Office of Information and Regulatory Affairs should oversee regulatory activities to raise the quality and consistency of cost-benefit analysis and risk assessment among all agencies.

(8) The Federal Government should develop a better understanding of the strengths, weaknesses, and uncertainties of cost-benefit analysis and risk assessment and conduct the research needed to improve these analytical tools.

SEC. 3. REGULATORY ANALYSIS.

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

''SUBCHAPTER II—REGULATORY ANALYSIS

''§ 621. Definitions

''For purposes of this subchapter the definitions under section 551 shall apply and—

''(1) the term 'Administrator' means the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget;

''(2) the term 'benefit' means the reasonably identifiable significant favorable effects, quantifiable and nonquantifiable, including social, health, safety, environmental, economic, and distributional effects, that are expected to result from implementation of, or compliance with, a rule;

''(3) the term 'cost' means the reasonably identifiable significant adverse effects, quantifiable and nonquantifiable, including social, health, safety, environmental, economic, and distributional effects, that are expected to result from implementation of, or compliance with, a rule;

''(4) the term 'cost-benefit analysis' means an evaluation of the costs and benefits of a rule, quantified to the extent feasible and appropriate and otherwise qualitatively described, that is prepared in accordance with the requirements of this subchapter at

the level of detail appropriate and practicable for reasoned decisionmaking on the matter involved, taking into consideration uncertainties, the significance and complexity of the decision, and the need to adequately inform the public;

''(5) the term 'Director' means the Director of the Office of Management and Budget, acting through the Administrator of the Office of Information and Regulatory Affairs;

''(6) the term 'flexible regulatory options' means regulatory options that permit flexibility to regulated persons in achieving the objective of the statute as addressed by the rule making, including regulatory options that use market-based mechanisms, outcome oriented performance-based standards, or other options that promote flexibility;

''(7) the term 'major rule' means a rule that—

''(A) the agency proposing the rule or the Director reasonably determines is likely to have an annual effect on the economy of $100,000,000 or more in reasonably quantifiable costs; or

''(B) is otherwise designated a major rule by the Director on the ground that the rule is likely to adversely affect, in a material way, the

economy, a sector of the economy, including small business, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, or communities;

''(8) the term 'reasonable alternative' means a reasonable regulatory option that would achieve the objective of the statute as addressed by the rule making and that the agency has authority to adopt under the statute granting rule making authority, including flexible regulatory options;

''(9) the term 'risk assessment' means the systematic, objective process of organizing hazard and exposure information, based on a careful analysis of the weight of the scientific evidence, to estimate the potential for specific harm to an exposed population, subpopulation, or natural resource including, to the extent feasible, a characterization of the distribution of risk as well as an analysis of uncertainties, variabilities, conflicting information, and inferences and assumptions;

''(10) the term 'rule' has the same meaning as in section 551(4), and shall not include—

''(A) a rule exempt from notice and public comment procedure under section 553;

"(B) a rule that involves the internal revenue laws of the United States, or the assessment or collection of taxes, duties, or other debts, revenue, or receipts;

"(C) a rule of particular applicability that approves or prescribes for the future rates, wages, prices, services, corporate or financial structures, reorganizations, mergers, acquisitions, accounting practices, or disclosures bearing on any of the foregoing;

"(D) a rule relating to monetary policy proposed or promulgated by the Board of Governors of the Federal Reserve System or by the Federal Open Market Committee;

"(E) a rule relating to the operations, safety, or soundness of federally insured depository institutions or any affiliate of such an institution (as defined in section 2(k) of the Bank Holding Company Act of 1956 (12 U.S.C. 1841(k)); credit unions; the Federal Home Loan Banks; government-sponsored housing enterprises; a Farm Credit System Institution; foreign banks, and their branches, agencies, commercial lending companies or representative offices that operate in the United States and

any affiliate of such foreign banks (as those terms are defined in the International Banking Act of 1978 (12 U.S.C. 3101)); or a rule relating to the payments system or the protection of deposit insurance funds or Farm Credit Insurance Fund;

''(F) a rule relating to the integrity of the securities or commodities futures markets or to the protection of investors in those markets;

''(G) a rule issued by the Federal Election Commission or a rule issued by the Federal Communications Commission under sections 312(a)(7) and 315 of the Communications Act of 1934 (47 U.S.C. 312(a)(7) and 315);

''(H) a rule required to be promulgated at least annually pursuant to statute;

''(I) a rule or agency action relating to the public debt or fiscal policy of the United States; or

''(J) a rule or agency action that authorizes or bars the introduction into or removal from commerce, or recognizes or cancels recognition of the marketable status, of a product under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.); and

''(11) the term 'substitution risk'—

''(A) means a reasonably identifiable significant increased risk to health, safety, or the environment expected to result from a regulatory option; and

''(B) shall not include risks attributable to the effect of an option on the income of individuals.

"§ 622. Applicability and effect

''(a) Except as provided in section 623(f), this subchapter shall apply to all proposed and final major rules.

''(b) Nothing in this subchapter shall be construed to alter or modify—

''(1) the substantive standards applicable to a rule making under other statutes;

''(2)(A) the range of regulatory options that an agency has the authority to adopt under the statute authorizing the agency to promulgate the rule; or

''(B) the deference otherwise accorded to the agency in construing such statute; or

''(3) any opportunity for judicial review made applicable under other statutes.

"§ 623. Regulatory analysis

''(a)(1) Before publishing a notice of a proposed rule making for any rule, each agency shall determine whether

the rule is or is not a major rule covered by this subchapter.

''(2) The Director may designate any rule to be a major rule under section 621(7)(B), if the Director—

''(A) makes such designation not later than 30 days after the close of the comment period for the rule; and

''(B) publishes such designation in the Federal Register, together with a succinct statement of the basis for the designation, within 30 days after such designation.

''(b)(1)(A) When an agency publishes a notice of proposed rule making for a major rule, the agency shall—

''(i) prepare and place in the rule making file an initial regulatory analysis; and

''(ii) include a summary of such analysis consistent with subsection (e) in the notice of proposed rule making.

''(B)(i) When the Director has published a designation that a rule is a major rule after the publication of the notice of proposed rule making for the rule, the agency shall—

''(I) promptly prepare and place in the rule making file an initial regulatory analysis for the rule; and

''(II) publish in the Federal Register a summary of such analysis consistent with subsection (e).

''(ii) Following the issuance of an initial regulatory analysis under clause (i), the agency shall give interested persons an opportunity to comment under section 553 in the same manner as if the initial regulatory analysis had been issued with the notice of proposed rule making.

''(2) Each initial regulatory analysis shall contain—

''(A) a cost-benefit analysis of the proposed rule that shall contain—

''(i) an analysis of the benefits of the proposed rule, including any benefits that cannot be quantified, and an explanation of how the agency anticipates that such benefits will be achieved by the proposed rule, including a description of the persons or classes of persons likely to receive such benefits;

''(ii) an analysis of the costs of the proposed rule, including any costs that cannot be quantified, and an explanation of how the agency anticipates that such costs will result from the proposed rule, including a description of the persons or classes of persons likely to bear such costs;

''(iii) an evaluation of the relationship of the benefits of the proposed rule to its costs, including the determinations required under subsection (d), taking into account the results of any risk assessment;

''(iv) an evaluation of the benefits and costs of a reasonable number of reasonable alternatives reflecting the range of regulatory options that would achieve the objective of the statute as addressed by the rule making, including, where feasible, alternatives that—

''(I) require no government action or utilize voluntary programs;

''(II) provide flexibility for small entities under subchapter I and for State, local, or tribal government agencies delegated to administer a Federal program;

''(III) employ flexible regulatory options; and

''(IV) assure protection of sensitive subpopulations, or populations exposed to multiple and cumulative risks; and

''(v) a description of the scientific or economic evaluations or information upon which the agency substantially relied in the cost-ben-

efit analysis and risk assessment required under this subchapter, and an explanation of how the agency reached the determinations under subsection (d);

''(B) if required, the risk assessment in accordance with section 624; and

''(C) when scientific information on substitution risks to health, safety, or the environment is reasonably available to the agency, an identification and evaluation of such risks.

''(c)(1) When the agency publishes a final major rule, the agency shall prepare and place in the rule making file a final regulatory analysis.

''(2) Each final regulatory analysis shall address each of the requirements for the initial regulatory analysis under subsection (b)(2), revised to reflect—

''(A) any material changes made to the proposed rule by the agency after publication of the notice of proposed rule making;

''(B) any material changes made to the cost-benefit analysis or risk assessment; and

''(C) agency consideration of significant comments received regarding the proposed rule and the initial regulatory analysis, including regulatory review communications under subchapter IV.

''(d)(1)(A) The agency shall include in the statement of basis and purpose for a proposed or final major rule a reasonable determination, based upon the rule making record considered as a whole—

''(i) whether the rule is likely to provide benefits that justify the costs of the rule;

''(ii) whether the rule is likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the other reasonable alternatives considered by the agency; and

''(iii) whether the rule adopts a flexible regulatory option.

''(B) Consistent with section 621 (2) and (3), net benefits analysis shall not be construed to be limited to quantifiable effects.

''(2) If the agency head determines that the rule is not likely to provide benefits that justify the costs of the rule or is not likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the other reasonable alternatives considered by the agency, the agency head shall—

''(A) explain the reasons for selecting the rule notwithstanding such determination, including iden-

tifying any statutory provision that required the agency to select such rule;

''(B) describe any reasonable alternative considered by the agency that would be likely to provide benefits that justify the costs of the rule and be likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the alternative selected by the agency; and

''(C) describe any flexible regulatory option considered by the agency and explain why that option was not adopted by the agency if that option was not adopted.

''(e) Each agency shall include an executive summary of the regulatory analysis, including any risk assessment, in the regulatory analysis and in the statement of basis and purpose for the proposed and final major rule. Such executive summary shall include a succinct presentation of—

''(1) the benefits and costs expected to result from the rule and any determinations required under subsection (d);

''(2) if applicable, the risk addressed by the rule and the results of any risk assessment;

''(3) the benefits and costs of reasonable alternatives considered by the agency; and

''(4) the key assumptions and scientific or economic information upon which the agency relied.

''(f)(1) A major rule may be adopted without prior compliance with this subchapter if—

''(A) the agency for good cause finds that conducting the regulatory analysis under this subchapter before the rule becomes effective is impracticable or contrary to an important public interest; and

''(B) the agency publishes the rule in the Federal Register with such finding and a succinct explanation of the reasons for the finding.

''(2) If a major rule is adopted under paragraph (1), the agency shall comply with this subchapter as promptly as possible unless the Director determines that compliance would be clearly unreasonable.

''(g) Each agency shall develop an effective process to permit elected officers of State, local, and tribal governments (or their designated employees with authority to act on their behalf) to provide meaningful and timely input in the development of regulatory proposals that contain significant Federal intergovernmental mandates. The process developed under this subsection shall be consistent

with section 204 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1534).

"§ 624. Principles for risk assessments

''(a)(1)(A) Subject to paragraph (2), each agency shall design and conduct risk assessments in accordance with this subchapter for—

''(i) each proposed and final major rule the primary purpose of which is to address health, safety, or environmental risk; or

''(ii) any risk assessment that is not the basis of a rule making that the Director—

''(I) reasonably anticipates is likely to have an annual effect on the economy of $100,000,000 or more in reasonably quantifiable costs; and

''(II) determines shall be subject to the requirements of this section.

''(B)(i) Risk assessments conducted under this subchapter shall be conducted in a manner that promotes rational and informed risk management decisions and informed public input into and understanding of the process of making agency decisions.

''(ii) The scope and level of analysis of such a risk assessment shall be commensurate with the significance and complexity of the decision and the need to adequately

inform the public, consistent with any need for expedition, and designed for the nature of the risk being assessed.

''(2) If a risk assessment under this subchapter is otherwise required by this section, but the agency determines that—

''(A) a final rule subject to this subchapter is substantially similar to the proposed rule with respect to the risk being addressed;

''(B) a risk assessment for the proposed rule has been carried out in a manner consistent with this subchapter; and

''(C) a new risk assessment for the final rule is not required in order to respond to comments received during the period for comment on the proposed rule,

the agency may publish such determination along with the final rule in lieu of preparing a new risk assessment for the final rule.

''(b) Each agency shall consider in each risk assessment all relevant, reliable, and reasonably available scientific information and shall describe the basis for selecting such scientific information.

''(c)(1) When a risk assessment involves a choice of assumptions, the agency shall, with respect to significant assumptions—

''(A) identify the assumption and its scientific and policy basis, including the extent to which the assumption has been validated by, or conflicts with, empirical data;

''(B) explain the basis for any choices among assumptions and, where applicable, the basis for combining multiple assumptions; and

''(C) describe reasonable alternative assumptions that—

''(i) would have had a significant effect on the results of the risk assessment; and

''(ii) were considered but not selected by the agency for use in the risk assessment.

''(2) Significant assumptions used in a risk assessment shall incorporate all reasonably available, relevant, and reliable scientific information.

''(d) The agency shall inform the public when the agency is conducting a risk assessment subject to this section and, to the extent practicable, shall solicit relevant and reliable data from the public. The agency shall consider such data in conducting the risk assessment.

''(e) Each risk assessment under this subchapter shall include, as appropriate, each of the following:

''(1) A description of the hazard of concern.

''(2) A description of the populations or natural resources that are the subject of the risk assessment.

''(3) An explanation of the exposure scenarios used in the risk assessment, including an estimate of the corresponding population or natural resource at risk and the likelihood of such exposure scenarios.

''(4) A description of the nature and severity of the harm that could reasonably occur as a result of exposure to the hazard.

''(5) A description of the major uncertainties in each component of the risk assessment and their influence on the results of the assessment.

''(f) To the extent scientifically appropriate, each agency shall—

''(1) express the estimate of risk as 1 or more reasonable ranges and, if feasible, probability distributions that reflects variabilities, uncertainties, and lack of data in the analysis;

''(2) provide the ranges and distributions of risks, including central and high end estimates of the risks, and their corresponding exposure scenarios for the potentially exposed population and, as appropriate, for more highly exposed or sensitive subpopulations; and

''(3) describe the qualitative factors influencing the ranges, distributions, and likelihood of possible risks.

''(g) When scientific information that permits relevant comparisons of risk is reasonably available, each agency shall use the information to place the nature and magnitude of a risk to health, safety, or the environment being analyzed in relationship to other reasonably comparable risks familiar to and routinely encountered by the general public. Such comparisons should consider relevant distinctions among risks, such as the voluntary or involuntary nature of risks, well understood or newly discovered risks, and reversible or irreversible risks.

''§ 625. Peer review

''(a) Each agency shall provide for an independent peer review in accordance with this section of—

''(1) a cost-benefit analysis of a major rule that the agency or Director reasonably anticipates is likely to have an annual effect on the economy of $500,000,000 in reasonably quantifiable costs; and

''(2) a risk assessment required by this subchapter.

''(b)(1) Peer review required under subsection (a) shall—

''(A) be conducted through panels, expert bodies, or other formal or informal devices that are broadly representative and involve participants—

''(i) with expertise relevant to the sciences, or analyses involved in the regulatory decisions; and

''(ii) who are independent of the agency;

''(B) be governed by agency standards and practices governing conflicts of interest of non-governmental agency advisors;

''(C) provide for the timely completion of the peer review including meeting agency deadlines;

''(D) contain a balanced presentation of all considerations, including minority reports and an agency response to all significant peer review comments; and

''(E) provide adequate protections for confidential business information and trade secrets, including requiring panel members or participants to enter into confidentiality agreements.

''(2) Each agency shall provide a written response to all significant peer review comments. All peer review comments and any responses shall be made—

''(A) available to the public; and

''(B) part of the rule making record for purposes of judicial review of any final agency action.

''(3) If the head of an agency, with the concurrence of the Director, publishes a determination in the rule making file that a cost-benefit analysis or risk assessment, or any component thereof, has been previously subjected to adequate peer review, no further peer review shall be required under this section for such analysis, assessment, or component.

''(c) For each peer review conducted by an agency under this section, the agency head shall include in the rule making record a statement by a Federal officer or employee who is not an employee of the agency rule making office or program—

''(1) whether the peer review participants reflect the independence and expertise required under subsection (b)(1)(A); and

''(2) whether the agency has adequately responded to the peer review comments as required under subsection (b)(2).

''(d) The formality of the peer review conducted under this section shall be commensurate with the significance and complexity of the subject matter.

''(e) The peer review required by this section shall not be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

''(f) A member of an agency advisory board (or comparable organization) established by statute shall be considered independent of the agency for purposes of subsection (b)(1)(A)(ii).

''(g) The status of a person as a contractor or grantee of the agency conducting the peer review shall not, in and of itself, exclude such person from serving as a peer reviewer for such agency because of the requirement of subsection (b)(1)(A)(ii).

''(h) Nothing in this section shall require more than one peer review of a cost-benefit analysis or a risk assessment during a rule making. A peer review required by this section shall occur to the extent feasible before the notice of proposed rule making.

''§ 626. Deadlines for rule making

''(a) All statutory deadlines that require an agency to propose or promulgate any major rule during the 2-year period beginning on the effective date of this section shall be suspended until the earlier of—

''(1) the date on which the requirements of this subchapter are satisfied; or

''(2) the date occurring 180 days after the date of the applicable deadline.

''(b) In any proceeding involving a deadline imposed by a court of the United States that requires an agency to propose or promulgate any major rule during the 2-year period beginning on the effective date of this section, the United States shall request, and the court may grant, an extension of such deadline until the earlier of—

''(1) the date on which the requirements of this subchapter are satisfied; or

''(2) the date occurring 180 days after the date of the applicable deadline.

''(c) In any case in which the failure to promulgate a major rule by a deadline occurring during the 2-year period beginning on the effective date of this section would create an obligation to regulate through individual adjudications, the deadline shall be suspended until the earlier of—

''(1) the date on which the requirements of this subchapter are satisfied; or

''(2) the date occurring 180 days after the date of the applicable deadline.

''§ 627. Judicial review

''(a) Compliance by an agency with the provisions of this subchapter shall be subject to judicial review only—

''(1) in connection with review of final agency action;

''(2) in accordance with this section; and

''(3) in accordance with the limitations on timing, venue, and scope of review imposed by the statute authorizing judicial review.

''(b) Any determination of an agency whether a rule is a major rule under section 621(7)(A) shall be set aside by a reviewing court only upon a showing that the determination is arbitrary or capricious.

''(c) Any designation by the Director that a rule is a major rule under section 621(7), or any failure to make such designation, shall not be subject to judicial review.

''(d) The cost-benefit analysis, cost-benefit determination under section 623(d), and any risk assessment required under this subchapter shall not be subject to judicial review separate from review of the final rule to which such analysis or assessment applies. The cost-benefit analysis, cost-benefit determination under section 623(d), and any risk assessment shall be part of the rule making record and shall be considered by a court to the extent relevant, only in determining under the statute granting the rule making authority whether the final rule is arbitrary, capricious, an abuse of discretion, or is unsupported

by substantial evidence where that standard is otherwise provided by law.

''(e) If an agency fails to perform the cost-benefit analysis, cost-benefit determination, or risk assessment, or to provide for peer review, a court may, giving due regard to prejudicial error, remand or invalidate the rule. The adequacy of compliance with the specific requirements of this subchapter shall not otherwise be grounds for remanding or invalidating a rule under this subchapter. If the court allows the rule to take effect, the court shall order the agency to promptly perform such analysis, determination, or assessment or provide for such peer review.

''§ 628. Guidelines, interagency coordination, and research

''(a)(1) Not later than 270 days after the date of enactment of this section, the Director, in consultation with the Council of Economic Advisors, the Director of the Office of Science and Technology Policy, and relevant agency heads, shall issue guidelines for cost-benefit analyses, risk assessments, and peer reviews as required by this subchapter. The Director shall oversee and periodically revise such guidelines as appropriate.

''(2) As soon as practicable and not later than 18 months after issuance of the guidelines required under paragraph (1), each agency subject to section 624 shall

adopt detailed guidelines for risk assessments as required by this subchapter. Such guidelines shall be consistent with the guidelines issued under paragraph (1). Each agency shall periodically revise such agency guidelines as appropriate.

''(3) The guidelines under this subsection shall be developed following notice and public comment. The development and issuance of the guidelines shall not be subject to judicial review, except in accordance with section 706(1).

''(b) To promote the use of cost-benefit analysis and risk assessment in a consistent manner and to identify agency research and training needs, the Director, in consultation with the Council of Economic Advisors and the Director of the Office of Science and Technology Policy, shall—

''(1) oversee periodic evaluations of Federal agency cost-benefit analysis and risk assessment;

''(2) provide advice and recommendations to the President and Congress to improve agency use of cost-benefit analysis and risk assessment;

''(3) utilize appropriate interagency mechanisms to improve the consistency and quality of cost-benefit analysis and risk assessment among Federal agencies; and

''(4) utilize appropriate mechanisms between Federal and State agencies to improve cooperation in the development and application of cost-benefit analysis and risk assessment.

''(c)(1) The Director, in consultation with the head of each agency, the Council of Economic Advisors, and the Director of the Office of Science and Technology Policy, shall periodically evaluate and develop a strategy to meet agency needs for research and training in cost-benefit analysis and risk assessment, including research on modelling, the development of generic data, use of assumptions and the identification and quantification of uncertainty and variability.

''(2)(A) Not later than 180 days after the date of enactment of this section, the Director, in consultation with the Director of the Office of Science and Technology Policy, shall enter a contract with an accredited scientific institution to conduct research to—

''(i) develop a common basis to assist risk communication related to both carcinogens and non-carcinogens; and

''(ii) develop methods to appropriately incorporate risk assessments into related cost-benefit analyses.

''(B) Not later than 2 years after the date of enactment of this section, the results of the research conducted under this paragraph shall be submitted to the Director and Congress.

''§ 629. Risk based priorities study

''(a) Not later than 1 year after the date of enactment of this section, the Director, in consultation with the Director of the Office of Science and Technology Policy, shall enter into a contract with an accredited scientific institution to conduct a study that provides—

''(1) a systematic comparison of the extent and severity of significant risks to human health, safety, or the environment (hereafter referred to as a comparative risk analysis);

''(2) a study of methodologies for using comparative risk analysis to compare dissimilar risks to human health, safety, or the environment, including development of a common basis to assist comparative risk analysis related to both carcinogens and noncarcinogens; and

''(3) recommendations on the use of comparative risk analysis in setting priorities for the reduction of risks to human health, safety, or the environment.

''(b) The Director shall ensure that the study required under subsection (a) is—

''(1) conducted through an open process providing peer review consistent with section 625 and opportunities for public comment and participation; and

''(2) not later than 3 years after the date of enactment of this section, completed and submitted to Congress and the President.

''(c) Not later than 4 years after the date of enactment of this section, each relevant agency shall, as appropriate, use the results of the study required under subsection (a) to inform the agency in the preparation of the agency's annual budget and strategic plan and performance plan under section 306 of this title and sections 1115, 1116, 1117, 1118, and 1119 of title 31.

''(d) Not later than 5 years after the date of enactment of this section, and periodically thereafter, the President shall submit a report to Congress recommending legislative changes to assist in setting priorities to more effectively and efficiently reduce risks to human health, safety, or the environment.

''SUBCHAPTER III—EXECUTIVE OVERSIGHT

''§ 631. Definitions

''For purposes of this subchapter—

''(1) the definitions under sections 551 and 621 shall apply; and

''(2) the term 'regulatory action' means any one of the following:

''(A) Advance notice of proposed rule making.

''(B) Notice of proposed rule making.

''(C) Final rule making, including interim final rule making.

"§ 632. Presidential regulatory review

''(a) This subchapter shall apply to all proposed and final major rules and to any other rules designated by the President for review.

''(b) The President shall establish a process for the review and coordination of Federal agency regulatory actions. Such process shall be the responsibility of the Director.

''(c) For the purpose of carrying out subsection (c), the Director shall—

''(1) develop and oversee uniform regulatory policies and procedures, including those by which each agency shall comply with the requirements of this chapter;

''(2) develop policies and procedures for the review of regulatory actions by the Director; and

''(3) develop and oversee an annual governmentwide regulatory planning process that shall include review of planned significant regulatory actions and publication of—

''(A) a summary of and schedule for promulgation of planned agency major rules;

''(B) agency specific schedules for review of existing rules, including under section 610;

''(C) a summary of regulatory review actions undertaken in the prior year;

''(D) a list of major rules promulgated in the prior year for which an agency could not make the determinations that the benefits of a rule justify the costs under section 623(d);

''(E) identification of significant agency noncompliance with this chapter in the prior year; and

''(F) recommendations for improving compliance with this chapter and increasing the efficiency and effectiveness of the regulatory process.

''(d)(1) The review established under subsection (b) shall be conducted as expeditiously as practicable and shall be limited to not more than 90 days.

''(2) A review may be extended longer than the 90-day period referred to under paragraph (1) by the Director or at the request of the rule making agency to the Director. Notice of such extension shall be published promptly in the Federal Register.

"§ 633. Public disclosure of information

''(a) The Director, in carrying out section 632, shall establish procedures to provide public and agency access to information concerning review of regulatory actions under this subchapter, including—

''(1) disclosure to the public on an ongoing basis of information regarding the status of regulatory actions undergoing review;

''(2) disclosure to the public, not later than the date of publication of a regulatory action, of—

''(A) all written correspondence relating to the substance of a regulatory action, including drafts of all proposals and associated analyses, between the Administrator or employees of the Administrator and the regulatory agency;

''(B) all written correspondence relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government; and

''(C) a list identifying the dates, names of individuals involved, and subject matter discussed in significant meetings and telephone conversations relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government; and

''(3) disclosure to the regulatory agency, on a timely basis, of—

''(A) all written correspondence relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government; and

''(B) a list identifying the dates, names of individuals involved, and subject matter discussed in significant meetings and telephone conversations relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government.

''(b) Before the publication of any proposed or final rule, the agency shall include in the rule making record—

''(1) a document identifying in a complete, clear, and simple manner, the substantive changes between the draft submitted to the Administrator for review and the rule subsequently published;

''(2) a document identifying and describing those substantive changes in the rule that were made as a result of the regulatory review and a statement if the Administrator suggested or recommended no changes; and

''(3) all written correspondence relating to the substance of a regulatory action between the Administrator and the agency during the review of the rule, including drafts of all proposals and associated analyses.

''(c) In any meeting relating to the substance of a regulatory action under review between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government, a representative of the agency submitting the regulatory action shall be invited.

''§ 634. Judicial review

''The exercise of the authority granted under this subchapter by the President, the Director, or the Administrator shall not be subject to judicial review in any manner.''.

(b) PRESIDENTIAL AUTHORITY.—Nothing in this Act shall limit the exercise by the President of the authority and responsibility that the President otherwise possesses under the Constitution and other laws of the United States with respect to regulatory policies, procedures, and programs of departments, agencies, and offices.

(c) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) TABLE OF SECTIONS.—Part I of title 5, United States Code, is amended by striking the chapter heading and table of sections for chapter 6 and inserting the following:

"CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS

"SUBCHAPTER I—ANALYSIS OF REGULATORY FLEXIBILITY

"SUBCHAPTER II—REGULATORY ANALYSIS

''SUBCHAPTER III—EXECUTIVE OVERSIGHT

''631. Definitions.
''632. Presidential regulatory review.
''633. Public disclosure of information.
''634. Judicial review.''.

(2) SUBCHAPTER HEADING.—Chapter 6 of title 5, United States Code, is amended by inserting immediately before section 601, the following subchapter heading:

''SUBCHAPTER I—ANALYSIS OF REGULATORY FLEXIBILITY''.

SEC. 4. COMPLIANCE WITH THE UNFUNDED MANDATES REFORM ACT OF 1995.

Compliance with the requirements of subchapter II of chapter 6 of title 5, United States Code (as added by section 3 of this Act), shall constitute compliance with the requirements pertaining to the costs and benefits of a Federal mandate to the private sector in sections 202, 205(a)(2), and 208 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532, 1535(a)(2), and 1538).

SEC. 5. EFFECTIVE DATE.

Except as otherwise provided in this Act, this Act shall take effect 180 days after the date of enactment of this Act, but shall not apply to any agency rule for which a notice of proposed rule making is published on or before 60 days before the date of enactment of this Act.

○