Calendar No. 364

105TH CONGRESS
2D SESSION

S. 981

[Report No. 105–188]

A BILL

To provide for analysis of major rules.

MAY 11, 1998
Reported with an amendment

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[Report No. 105–188]

To provide for analysis of major rules.

IN THE SENATE OF THE UNITED STATES

JUNE 27, 1997

Mr. LEVIN (for himself, Mr. THOMPSON, Mr. GLENN, Mr. ABRAHAM, Mr. ROBB, Mr. ROTH, Mr. ROCKEFELLER, Mr. STEVENS, Mr. GRAMS, Mr. COCHRAN, Mr. BREAUX, Mr. ENZI, Mr. WARNER, Mr. FRIST, Mr. GORTON, and Mr. INHOFE) introduced the following bill; which was read twice and referred to the Committee on Governmental Affairs

MAY 11, 1998

Reported by Mr. THOMPSON, with an amendment

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

A BILL

To provide for analysis of major rules.

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 1997".~~

★**(Star Print)**

SEC. 2. FINDINGS.

Congress finds the following:

(1) Current regulatory programs can be improved by being more firmly rooted in sound economic and scientific analysis.

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

(3) Cost and risk need to be considered in evaluating regulatory proposals which address health, safety, or the environment. Other factors such as social values, distributional effects, and equity, must also be considered.

(4) 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.

(5) The public has a right to know about the costs and benefits of regulations, the risks addressed, the amount of risk 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.

(6) The Administrator of the Office of Information and Regulatory Affairs should oversee regulatory activities to ensure consistent and valid use of cost-benefit analysis and risk assessment among all agencies.

(7) 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 '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 directly or indirectly from implementation of, or compliance with, a rule;

''(2) 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 directly or indirectly from implementation of, or compliance with, a rule;

''(3) 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;

''(4) 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;

''(5) 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 mecha-

nisms, outcome oriented performance-based standards, or other options that promote flexibility;

''(6) the term 'major rule' means a rule or a group of closely related rules 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;

''(7) 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;

''(8) the term 'risk assessment' means the systematic process of organizing hazard and exposure

assessments to estimate the potential for specific harm to exposed individuals, populations, or natural resources;

''(9) the term 'risk characterization' means the presentation of risk assessment results 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 in the assessment;

''(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 and collection of taxes, duties, or other 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 Gov-

ernors of the Federal Reserve System or by the Federal Open Market Committee;

''(E) a rule relating to the 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 or order relating to the financial responsibility, recordkeeping, or reporting of brokers and dealers (including Government securities brokers and dealers) or futures commission merchants, the safeguarding of investor securities and funds or commodity future or options customer securities and funds, the clear-

ance and settlement of securities, futures, or options transactions, or the suspension of trading under the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq.) or emergency action taken under the Commodity Exchange Act (7 U.S.C. 1 et seq.), or a rule relating to the protection of the Securities Investor Protection Corporation, that is promulgated under the Securities Investor Protection Act of 1970 (15 U.S.C. 78aaa et seq.), or a rule relating to the custody of Government securities by depository institutions under section 3121 or 9110 of title 31;

"(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; or

"(I) a rule or agency action relating to the public debt;

"(11) the term 'screening analysis' means an analysis using simple assumptions to arrive at an es-

timate of upper and lower bounds of risk as appropriate; and

''(12) the term 'substitution risk' means an increased risk to health, safety, or the environment reasonably likely to result from a regulatory option.

''§ 622. Applicability

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

''§ 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(6)(B), if the Director—

''(A) makes such designation no later than 30 days after the close of the comment period for the rule; and

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

''(b)(1)(A) When an agency publishes a notice of proposed rule making for a major rule, the agency shall prepare and place in the rule making file an initial regulatory

analysis, and shall include a summary of such analysis consistent with subsection (d) in the notice of proposed rule making.

''(B)(i) When the Director has published a determination that a rule is a major rule after the publication of the notice of proposed rule making for the rule, the agency shall promptly prepare and place in the rule making file an initial regulatory analysis for the rule and shall publish in the Federal Register a summary of such analysis consistent with subsection (d).

''(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; and

‘‘(iii) an evaluation of the relationship of the benefits of the proposed rule to its costs, including the determinations required under subsection (c)(3), 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;

‘‘(II) accommodate differences among geographic regions and among persons with differing levels of resources with which to comply; or

‘‘(III) employ flexible regulatory options;

‘‘(v) a description of the scientific or economic evaluations or information upon which the agency substantially relied in the cost-benefit analysis and risk assessment required under this subchapter, and an explanation of how the agency reached the determinations under subsection (c)(3); and

‘‘(B) if required, the risk assessment in accordance with section 624.

‘‘(c)(1) When the agency publishes a final major rule, the agency shall also prepare and place in the rule making file a final regulatory analysis, and shall prepare a summary of the analysis consistent with subsection (d).

‘‘(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.

‘‘(3)(A) The agency shall include in the statement of basis and purpose for the 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; and

‘‘(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.

‘‘(B) If the agency head cannot reasonably determine that the final rule is likely to provide benefits that justify the costs of the rule and 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—

‘‘(i) explain why such determinations cannot be made;

‘‘(ii) identify any statutory provision or other factor that prevents such determinations; and

‘‘(iii) describe a reasonable alternative considered by the agency, if feasible, that would allow the agency to determine that the benefits justify the costs and that the rule making objective would be

achieved in a more cost-effective manner or with greater net benefits than the other reasonable alternatives considered by the agency.

''(d) 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 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 (c)(3);

''(2) if applicable, the risk addressed by the rule, including the most plausible estimate of the risk 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.

''(e)(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 is contrary to the public interest due to an emergency, or an imminent threat to health or safe-

ty that is likely to result in significant harm to the public or the environment; and

''(B) the agency publishes in the Federal Register, together with such finding, a succinct statement of the basis 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 compliance would be unreasonable because the rule is, or soon will be, no longer in effect.

''§ 624. Principles for risk assessments

''(a)(1) Subject to paragraph (2), each agency shall design and conduct risk assessments in accordance with this subchapter for each proposed and final major rule the primary purpose of which is to address health, safety, or environmental risk, or which results in a significant substitution risk, 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.

''(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 reliable and reasonably available scientific information and shall describe the basis for selecting such scientific information.

''(c)(1) Each agency may use reasonable assumptions to the extent that relevant and reliable scientific information, including site-specific or substance-specific information, is not reasonably available.

''(2) When a risk assessment involves a choice of assumptions, the agency shall—

''(A) identify the assumption and its scientific or 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 were considered but not selected by the agency for use in the risk assessment, how such alternative assumptions would have changed the conclusions of the risk assessment, and the rationale for not using such alternatives.

''(d) Each agency shall provide appropriate opportunity for public comment and participation during the development of a risk assessment.

''(e) Each risk assessment supporting a major rule 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 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 overall estimate of risk as a reasonable range or probability distribution that reflects variabilities, uncertainties, and lack of data in the analysis;

''(2) provide the range and distribution of risks and the corresponding exposure scenarios, identifying the range and distribution and likelihood of risk to the general population and, as appropriate, to more highly exposed or sensitive subpopulations, including the most plausible estimates of the risks; and

''(3) where quantitative estimates are not available, describe the qualitative factors influencing the range, distribution, 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.

''(h) When scientifically appropriate information on significant substitution risks to health, safety, or the environment is reasonably available to the agency, the agency shall describe such risks in the risk assessment.

''§ 625. Peer review

''(a) Each agency shall provide for peer review in accordance with this section of any cost benefit analysis and risk assessment required by this subchapter that forms the basis of any major rule covered by this subchapter.

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

''(A) provide for the creation or utilization of peer review panels, expert bodies, or other formal or informal devices that are broadly representative and balanced and that consist of panel members or participants with expertise relevant to the sciences involved in the regulatory decisions and who are independent of the agency program;

''(B) exclude any person as a panel member or participant if such person has a financial interest in the outcome, unless such person fully discloses such interest to the agency and the public;

''(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) All peer review written comments or conclusions and the agency's written responses to significant peer review comments shall be made available to the public and shall be made 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 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.

“§ 626. Deadlines for rule making

“(a) All deadlines in statutes or imposed by a court of the United States, 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 6 months after the date of the applicable deadline.

“(b) 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 6 months after the date of the applicable deadline.

“§ 627. Judicial review

“(a) Compliance or noncompliance by an agency with the provisions of this subchapter shall only be subject to judicial review in accordance with this section.

“(b) Any determination of an agency whether a rule is or is not a major rule under section 621(6)(A) shall

be set aside by a reviewing court only upon a clear and convincing showing that the determination is erroneous in light of the information available to the agency at the time the agency made the determination.

''(c) Any determination by the Director that a rule is a major rule under section 621(6), or any failure to make such determination, shall not be subject to judicial review in any manner.

''(d) The cost-benefit analysis and any risk assessment required under this subchapter shall not be subject to judicial review separate from review of the final rule to which they apply. The cost-benefit analysis, cost-benefit determination under section 623(c)(3), and any risk assessment shall be part of the whole rule making record for purposes of judicial review of the rule and shall be considered by a court in determining whether the final rule is arbitrary or capricious unless the agency can demonstrate that the analysis or assessment would not be material to the outcome of the rule.

''(e) If an agency fails to perform the cost-benefit analysis, cost-benefit determination, or risk assessment, a court shall remand or invalidate the rule.

“§ 628. Guidelines, interagency coordination, and research

“(a)(1) No later than 9 months after the date of enactment of this section, the Director, in consultation with the Director of the Office of Science and Technology Policy and the relevant agency heads, shall develop guidelines for cost-benefit analyses and risk assessments required by this subchapter or with significant implications for public policy. To the extent feasible such guidelines shall apply the principles of sections 623 and 624. The Director shall oversee and periodically revise such guidelines as appropriate.

“(2) As soon as practicable and no later than 18 months after the date of enactment of this section, each relevant agency shall adopt detailed guidelines for risk assessments required by this subchapter or with significant implications for public policy. Such guidelines shall be consistent with the guidance 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) of this title.

‘‘(b) To promote the use of cost-benefit analysis and assessment in a consistent manner and to identify agency research and training needs, the Director, in consultation with 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) establish appropriate interagency mechanisms to improve the consistency and quality of cost-benefit analysis and risk assessment among Federal agencies; and

‘‘(4) establish 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 head of each agency, in consultation with the Director and the Director of the Office of Science and Technology Policy, shall regularly 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) No later than 6 months from 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 appropriate arrangements with an accredited scientific institution to conduct research to—

''(i) identify and evaluate a common basis to assist comparative risk analysis and risk communication related to both carcinogens and noncarcinogens; and

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

''(B) The results of the research conducted under this paragraph shall be submitted to the Director and Congress no later than 18 months after the date of enactment of this section.

''§ 629. Comparative risk analysis study

''(a) No later than 180 days after the effective date 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; and

"(3) technical guidance and recommendations on the use of comparative risk analysis to assist in allocating resources within and across agencies to set 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) completed and submitted to Congress and the President no later than 3 years after the effective date of this section.

"(c) No later than 5 years after the effective date 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—REVIEW OF RULES

''§ 631. Definitions

''For purposes of this subchapter the definitions under sections 551 and 621 shall apply.

''§ 632. Advisory committee on regulations

''(a)(1)(A) No later than 90 days after the date of enactment of this section and every 5 years thereafter, the head of each agency described under subparagraph (B) shall establish an advisory committee for the review of rules.

''(B) An agency referred to under subparagraph (A) is any agency that has promulgated a major rule during the 10-year period preceding the date of the establishment of an advisory committee under subparagraph (A).

''(2) The head of an agency described under paragraph (1) may establish panels under its advisory committee.

''(b)(1) Each such agency head shall appoint a reasonable number of members to serve on the agency's advisory committee and shall designate a chairman from the members of the committee. Membership on the committee shall represent a balanced cross-section of public and private interests affected by the regulations of the agency, including small businesses, small governments, and public interest groups. No employee of the agency establishing

the committee shall serve as a member of such agency's committee under this section.

''(2) Each member shall be appointed for the life of the advisory committee. The advisory committee shall terminate 1 year after the date on which the committee is established.

''(3) A vacancy on a committee shall be filled in the same manner as the original appointment.

''(4) Each committee shall solicit public comments and may solicit public participation through appropriate means including hearings, written comments, public meetings, and electronic mail.

''(5) Members of each committee shall receive travel expenses, including per diem in lieu of subsistence, in accordance with sections 5702 and 5703.

''(6) Each committee shall be subject to the provisions of the Federal Advisory Committee Act (5 U.S.C. App.).

''§ 633. Agency regulatory review

''(a) Each advisory committee appointed under section 632 shall develop a list of rules promulgated by the agency that the committee serves, which the committee determines should be reviewed by the agency and can reasonably be reviewed by the agency within a 5-year period. In

selecting rules for review, each committee shall consider the extent to which—

"(1) a rule could be revised to substantially increase net benefits, including through flexible regulatory options;

"(2) the rule is important relative to other rules being considered for review; and

"(3) the agency has discretion under the statute authorizing the rule to modify or repeal the rule.

"(b) In developing the list required under subsection (a), each advisory committee shall obtain comments and suggestions from the public.

"(c) No later than 1 year after an advisory committee is established, such committee shall deliver to the agency the committee's recommended list of rules to be reviewed in order of priority. The agency shall immediately publish the list in the Federal Register and forward a copy of the list to the appropriate committees of jurisdiction in the House of Representatives and the Senate.

"(d)(1) No later than 60 days after receiving and reviewing the list of rules from its committee, the agency shall publish in the Federal Register a preliminary schedule for review of rules based on such list.

"(2) The agency shall provide in the Federal Register at the time the preliminary schedule is published an expla-

nation of each modification to the list provided by the advisory committee and shall invite public comment on the preliminary schedule for a period of no less than 60 days.

''(e) The preliminary schedule under this section shall propose deadlines for review of each rule listed thereon, and such deadlines shall occur no later than 5 years from the date of publication of the final schedule.

''(f)(1) No later than 60 days after the close of the comment period, the agency shall publish a final schedule of rules to be reviewed by the agency under this section.

''(2) The schedule shall establish a deadline for completion of the review of each rule listed on the schedule. Each deadline shall occur no later than 5 years from the date of publication of the final schedule.

''(g) In preparing the preliminary and final schedule, the agency shall give deference to the recommendations of its advisory committee but may modify the list of rules to be reviewed, taking into account the factors contained in subsection (a) and the resource constraints of the agency.

''(h)(1) For each rule on the schedule under subsection (e), the agency shall—

''(A) no later than 2 years before the deadline in such schedule, publish in the Federal Register a notice that solicits public comment regarding wheth-

er the rule should be continued, amended, or repealed;

"(B) no later than 1 year before the deadline in such schedule, publish in the Federal Register a notice that—

"(i) addresses public comments generated by the notice in subparagraph (A);

"(ii) contains a preliminary analysis by the agency with respect to subsection (a) (1), (2), and (3);

"(iii) contains a preliminary determination whether the rule should be continued, amended, or repealed; and

"(iv) solicits public comment on the preliminary determination for the rule; and

"(C) no later than 60 days before the deadline in such schedule, publish in the Federal Register a final notice on the rule that—

"(i) addresses public comments generated by the notice in subsection (c);

"(ii) contains a determination to continue, amend, or repeal the rule and an explanation of such determination with respect to subsection (a) (1), (2), and (3); and

‘‘(iii) if the agency determines to amend or repeal the rule, contains, if required, a notice of proposed rule making under section 553.

‘‘(2) If the final determination of the agency is to continue the rule, such determination shall constitute final agency action 60 days after the publication in the Federal Register of the notice in paragraph (1)(C).

‘‘(i) If an agency makes a determination to amend or repeal a rule under subsection (h)(1)(C), the agency shall complete final agency action with regard to such rule no later than 2 years after the deadline established for such rule under subsection (f)(2).

‘‘(j) Nothing in this section shall limit the discretion of an agency to decide, after having proposed to modify or repeal a rule, not to promulgate such modification or repeal. Such decision shall constitute final agency action for the purposes of judicial review.

‘‘(k) Agency failure to take the actions required by this section shall be subject to judicial review only under section 706(1). There shall be no judicial review of the preliminary or final schedule.

‘‘(l) A court may remand a determination under subsection (h)(2) only upon a clear and convincing showing that the agency could have adopted a reasonable alternative that would substantially increase net benefits, in-

cluding through flexible regulatory options, while meeting the objectives of the statute as addressed by the rule making.

''SUBCHAPTER IV—EXECUTIVE OVERSIGHT

''§ 641. 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) An agenda or schedule for rule makings.

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

''(C) Notice of proposed rule making.

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

''§ 642. Presidential regulatory review

''(a) 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.

''(b) For the purpose of carrying out the review established under subsection (a), 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 agency major rules and other 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 under subchapter III;

‘‘(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(c)(3);

‘‘(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.

"(c) The review established under subsection (a) shall be conducted as expeditiously as practicable and the Director's review of any regulatory action shall be limited to no more than 90 days, unless extended for an additional 30 days at the written request of the rule making agency or the Director.

"§ 643. Public disclosure of information

"(a) The Director, in carrying out the provisions of section 642, shall establish procedures to provide public and agency access to information concerning regulatory review actions, 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, no later than publication of a regulatory action, of—

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

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

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

"(D) a written explanation of any review action and the date of such action; and

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

"(A) all written communications relating to the substance of a regulatory action between the Director or employees of the Director and any person who is not employed by the executive branch of the Federal Government;

"(B) a list identifying the dates, names of individuals involved, and subject matter discussed in substantive meetings and telephone

~~conversations, and an invitation to participate in meetings, relating to the substance of a regulatory action between the Director or employees of the Director and any person not employed by the executive branch of the Federal Government; and~~

~~"(C) a written explanation of any review action taken concerning an agency regulatory action.~~

~~"(b) Prior to 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 Director for review and the rule subsequently announced;~~

~~"(2) a document identifying those changes in the rule that were made at the suggestion or recommendation of the Director; and~~

~~"(3) all written communications exchanged between the Director and the agency during the review of the rule, including drafts of all proposals and associated analyses.~~

"§ 644. Judicial review

''The exercise of the authority granted under this subchapter by the Director or the President 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) 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

~~(2) 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. 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 rulemaking is published on or before August 1, 1997.~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Regulatory Improvement Act of 1998".

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 they 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 the introduction into commerce, or recognizes the marketable status of, a product; and

"(11) the term 'substitution risk' means a significant increased risk to health, safety, or the environment reasonably likely to result from a regulatory option.

"§ 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 the substantive standards otherwise applicable to a rule making under other statutes or 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 no 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 prepare and place in the rule making file an initial regulatory analysis, and shall 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 promptly prepare and place in the rule making file an initial regulatory analysis for the rule and shall 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 pro-

posed 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-benefit 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) 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—

"(A) whether the rule is likely to provide benefits that justify the costs of the rule;

"(B) 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

"(C) whether the rule adopts a flexible regulatory option.

"(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 compliance would be unreasonable because the rule is, or soon will be, no longer in effect.

"(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 reasonably determines is anticipated to have a substantial impact on a significant public policy or on the economy.

"(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) As relevant and reliable scientific information becomes reasonably available, each agency shall revise its significant assumptions to incorporate such information.

"(d) The agency shall notify the public of the agency's intent to conduct a risk assessment 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 the cost-benefit analysis and 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 nongovernmental 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 peer review required by this section shall not be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

"§ 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 6 months 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 6 months 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 6 months 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 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 shall remand or invalidate the rule.

"§ 628. Guidelines, interagency coordination, and research

"(a)(1) No later than 9 months 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 no 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) of this title.

"(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) No later than 6 months 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) No later than 24 months 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) No 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 non-carcinogens; 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) no later than 3 years after the date of enactment of this section, completed and submitted to Congress and the President.

"(c) No 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) No 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—REVIEW OF RULES

"§ 631. Definitions

"For purposes of this subchapter—

"(1) the definitions under section 551 shall apply; and

"(2) the term 'economically significant rule' means a rule that—

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

"(B) 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.

"§ 632. Review of rules

"(a)(1) No later than 1 year after the date of enactment of this section (and no later than every 5th year following the year in which this section takes effect) each agency shall publish in the Federal Register a preliminary

schedule for the review of economically significant rules previously promulgated by the agency. The preliminary schedule shall be subject to public comment for 60 days after the date of publication. Within 120 days after the close of the public comment period, each agency shall publish a final schedule in the Federal Register.

"(2) In selecting which economically significant rules it shall review, each agency shall consider the extent to which—

"(A) the rule could be revised to be substantially more cost-effective or to substantially increase net benefits, including through flexible regulatory options;

"(B) the rule is important relative to other rules being considered for review; and

"(C) the agency has discretion under the statute authorizing the rule to modify or repeal the rule.

"(3) Each preliminary and final schedule shall include—

"(A) a brief description of each rule selected for review;

"(B) a brief explanation of the reasons for the selection of each such rule for review; and

"(C) a deadline for the review of each rule listed thereon, and such deadlines shall occur no later than

5 years after the date of publication of the final schedule.

"(4) No later than 6 months after the deadline for a rule as provided under paragraph (3)(C), the agency shall publish in the Federal Register the determination made with respect to the rule and an explanation of such determination.

"(5)(A) If an agency makes a determination to amend or repeal a rule, the agency shall complete final agency action with regard to such rule no later than 2 years after the deadline established for such rule under paragraph (3).

"(B) The Director may extend a deadline under this section for no more than 1 year if the Director—

"(i) for good cause finds that compliance with such deadline is impracticable; and

"(ii) publishes in the Federal Register such finding and a succinct explanation of the reasons for the finding.

"(b) The agency shall include with the publication under subsection (a) the identification of any legislative mandate that requires the agency to impose rules that the agency determines are unnecessary, outdated or unduly burdensome.

"(c)(1) The Administrator shall work with interested entities, including small entities and State, local, and tribal governments, to pursue the objectives of this subchapter.

"(2) Consultation with representatives of State, local, and tribal governments shall be governed by the process established under section 204 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1534).

"SUBCHAPTER IV—EXECUTIVE OVERSIGHT

"§ 641. 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.

"§ 642. Presidential regulatory review

"(a) 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.

"(b) For the purpose of carrying out subsection (a), 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 government-wide 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 under subchapter III and 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.

"(c)(1) The review established under subsection (a) shall be conducted as expeditiously as practicable and shall be limited to no 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.

"§ 643. Public disclosure of information

"(a) The Director, in carrying out the provisions of section 642, 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, no later than publication of a regulatory action, of—

"(A) all written communications 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 communications 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;

"(C) a list identifying the dates, names of individuals involved, and subject matter discussed in substantive 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

"(D) a written explanation of any review action and the date of such action; and

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

"(A) all written communications 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) a list identifying the dates, names of individuals involved, and subject matter discussed in substantive 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

"(C) a written explanation of any review action taken concerning an agency regulatory action and the date of such action.

"(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 announced;

"(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 communications 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.

"§ 644. 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) PERIODIC REVIEW OF RULES.—Section 610 of title 5, United States Code, is amended—

(1) by striking subsection (a) and inserting the following:

"(a)(1)(A) No later than 60 days after the effective date of this section (and every fifth year following the year in which this section takes effect) each agency shall submit to the Administrator of the Office of Information and Regulatory Affairs and the Chief Counsel for Advocacy of the Small Business Administration a proposed plan describing the procedures and timetables for the periodic review of rules issued by the agency that have or will have a significant economic impact on a substantial number of small en-

tities. No later than 60 days after the submission of the proposed plan to the Administrator and the Chief Counsel, such plan shall be published in the Federal Register and shall be subject to public comment for 60 days after the date of publication.

"(B) No later than 120 days after the publication of the plan under subparagraph (A), each agency shall submit a final plan to the Administrator and the Chief Counsel. No later than 60 days after the date of such submission of the plan to the Administrator and Chief Counsel, each agency shall publish the agency's final plan in the Federal Register.

"(C) Each agency's plan shall provide for the review of such rules no later than 5 years after publication of the final plan.

"(2)(A) Each year, each agency shall publish in the Federal Register a list of rules that will be reviewed under the plan during the succeeding fiscal year.

"(B) The publication of the list under subparagraph (A) shall include—

"(i) a brief description of each rule and the basis for the agency's determination that the rule has or will have a significant economic impact on a substantial number of small entities;

"(ii) the need for and legal basis of each rule; and

"(iii) an invitation for public comment on each rule.

"(3)(A) Each agency shall conduct a review of each rule on the list published under paragraph (2) in accordance with the plan maintained under paragraph (1) and pursuant to the factors under subsection (b). After the completion of the review, the agency shall determine whether the rule should be continued without change, or should be amended or rescinded, consistent with the stated objectives of the applicable statutes, to minimize any significant economic impact of the rule upon a substantial number of small entities.

"(B) No later than 18 months after the date of the publication of the list of rules referred to under paragraph (2)(A), each agency shall publish in the Federal Register the determinations made with respect to such rules under subparagraph (A) and an explanation for each determination.

"(4) If the head of an agency determines that the completion of a review of a rule under this subsection is not feasible within the period described under paragraph (1)(C), the head of the agency—

"(A) shall certify such determination in a statement published in the Federal Register; and

"(B) may extend the completion date of the review by 1 year at a time for a total of not more than 2 years."; and

(2) by striking subsection (c) and inserting the following:

"(c) The Administrator and the Chief Counsel shall work with small entities to achieve the objectives of this section.".

(c) 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.

(d) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) 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

(2) 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 man-

date 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.