

Calendar No. 364

105TH CONGRESS
2^D 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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105TH CONGRESS
2D SESSION**S. 981****[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 *italie*]**A BILL**

To provide for analysis of major rules.

- 1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*
 3 **SECTION 1. SHORT TITLE.**
 4 This Act may be cited as the “Regulatory Improve-
 5 ment Act of 1997”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) Current regulatory programs can be im-
4 proved by being more firmly rooted in sound eco-
5 nomic and scientific analysis.

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

10 (3) Cost and risk need to be considered in eval-
11 uating regulatory proposals which address health,
12 safety, or the environment. Other factors such as so-
13 cial values, distributional effects, and equity, must
14 also be considered.

15 (4) Cost-benefit analysis and risk assessment
16 should be presented with a clear statement of the
17 analytical assumptions and uncertainties including
18 an explanation of what is known and not known and
19 what the implications of alternative assumptions
20 might be.

21 (5) The public has a right to know about the
22 costs and benefits of regulations, the risks ad-
23 dressed, the amount of risk reduced, and the quality
24 of scientific and economic analysis used to support
25 decisions. Such knowledge will promote the quality,
26 integrity and responsiveness of agency actions.

1 (6) The Administrator of the Office of Informa-
 2 tion and Regulatory Affairs should oversee regu-
 3 latory activities to ensure consistent and valid use of
 4 cost-benefit analysis and risk assessment among all
 5 agencies.

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

11 **SEC. 3. REGULATORY ANALYSIS.**

12 (a) IN GENERAL.—Chapter 6 of title 5, United
 13 States Code, is amended by adding at the end the follow-
 14 ing:

15 “SUBCHAPTER II—REGULATORY ANALYSIS

16 “§ 621. Definitions

17 “For purposes of this subchapter the definitions
 18 under section 551 shall apply and—

19 “(1) the term ‘benefit’ means the reasonably
 20 identifiable significant favorable effects, quantifiable
 21 and nonquantifiable, including social, health, safety,
 22 environmental, economic, and distributional effects,
 23 that are expected to result directly or indirectly from
 24 implementation of, or compliance with, a rule;

1 “(2) the term ‘cost’ means the reasonably iden-
2 tifiable significant adverse effects, quantifiable and
3 nonquantifiable, including social, health, safety, envi-
4 ronmental, economic, and distributional effects that
5 are expected to result directly or indirectly from im-
6 plementation of, or compliance with, a rule;

7 “(3) the term ‘cost-benefit analysis’ means an
8 evaluation of the costs and benefits of a rule, quan-
9 tified to the extent feasible and appropriate and oth-
10 erwise qualitatively described, that is prepared in ac-
11 cordance with the requirements of this subchapter at
12 the level of detail appropriate and practicable for
13 reasoned decisionmaking on the matter involved,
14 taking into consideration uncertainties, the signifi-
15 cance and complexity of the decision, and the need
16 to adequately inform the public;

17 “(4) the term ‘Director’ means the Director of
18 the Office of Management and Budget, acting
19 through the Administrator of the Office of Informa-
20 tion and Regulatory Affairs;

21 “(5) the term ‘flexible regulatory options’
22 means regulatory options that permit flexibility to
23 regulated persons in achieving the objective of the
24 statute as addressed by the rule making, including
25 regulatory options that use market-based mecha-

1 nisms, outcome oriented performance-based stand-
2 ards, or other options that promote flexibility;

3 “(6) the term ‘major rule’ means a rule or a
4 group of closely related rules that—

5 “(A) the agency proposing the rule or the
6 Director reasonably determines is likely to have
7 an annual effect on the economy of
8 \$100,000,000 or more in reasonably quantifi-
9 able costs; or

10 “(B) is otherwise designated a major rule
11 by the Director on the ground that the rule is
12 likely to adversely affect, in a material way, the
13 economy, a sector of the economy, including
14 small business, productivity, competition, jobs,
15 the environment, public health or safety, or
16 State, local or tribal governments, or commu-
17 nities;

18 “(7) the term ‘reasonable alternative’ means a
19 reasonable regulatory option that would achieve the
20 objective of the statute as addressed by the rule
21 making and that the agency has authority to adopt
22 under the statute granting rule making authority,
23 including flexible regulatory options;

24 “(8) the term ‘risk assessment’ means the sys-
25 tematic process of organizing hazard and exposure

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

4 “(9) the term ‘risk characterization’ means the
 5 presentation of risk assessment results including, to
 6 the extent feasible, a characterization of the dis-
 7 tribution of risk as well as an analysis of uncertain-
 8 ties, variabilities, conflicting information, and infer-
 9 ences and assumptions in the assessment;

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

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

14 “(B) a rule that involves the internal reve-
 15 nue laws of the United States, or the assess-
 16 ment and collection of taxes, duties, or other
 17 revenue or receipts;

18 “(C) a rule of particular applicability that
 19 approves or prescribes for the future rates,
 20 wages, prices, services, corporate or financial
 21 structures, reorganizations, mergers, acquisi-
 22 tions, accounting practices, or disclosures bear-
 23 ing on any of the foregoing;

24 “(D) a rule relating to monetary policy
 25 proposed or promulgated by the Board of Gov-

1 errors of the Federal Reserve System or by the
2 Federal Open Market Committee;

3 “(E) a rule relating to the safety or sound-
4 ness of federally insured depository institutions
5 or any affiliate of such an institution (as de-
6 fined in section 2(k) of the Bank Holding Com-
7 pany Act of 1956 (12 U.S.C. 1841(k)); credit
8 unions; the Federal Home Loan Banks; govern-
9 ment-sponsored housing enterprises; a Farm
10 Credit System Institution; foreign banks; and
11 their branches, agencies, commercial lending
12 companies or representative offices that operate
13 in the United States and any affiliate of such
14 foreign banks (as those terms are defined in the
15 International Banking Act of 1978 (12 U.S.C.
16 3101)); or a rule relating to the payments sys-
17 tem or the protection of deposit insurance funds
18 or Farm Credit Insurance Fund;

19 “(F) a rule or order relating to the finan-
20 cial responsibility, recordkeeping, or reporting
21 of brokers and dealers (including Government
22 securities brokers and dealers) or futures com-
23 mission merchants; the safeguarding of investor
24 securities and funds or commodity future or op-
25 tions customer securities and funds; the clear-

1 ance and settlement of securities, futures, or
 2 options transactions, or the suspension of trad-
 3 ing under the Securities Exchange Act of 1934
 4 (15 U.S.C. 78a et seq.) or emergency action
 5 taken under the Commodity Exchange Act (7
 6 U.S.C. 1 et seq.), or a rule relating to the pro-
 7 tection of the Securities Investor Protection
 8 Corporation, that is promulgated under the Se-
 9 curities Investor Protection Act of 1970 (15
 10 U.S.C. 78aaa et seq.), or a rule relating to the
 11 custody of Government securities by depository
 12 institutions under section 3121 or 9110 of
 13 title 31;

14 “(G) a rule issued by the Federal Election
 15 Commission or a rule issued by the Federal
 16 Communications Commission under sections
 17 312(a)(7) and 315 of the Communications Act
 18 of 1934 (47 U.S.C. 312(a)(7) and 315);

19 “(H) a rule required to be promulgated at
 20 least annually pursuant to statute; or

21 “(I) a rule or agency action relating to the
 22 public debt;

23 “(11) the term ‘screening analysis’ means an
 24 analysis using simple assumptions to arrive at an es-

1 estimate of upper and lower bounds of risk as appropriate; and

3 “(12) the term ‘substitution risk’ means an increased risk to health, safety, or the environment

4 reasonably likely to result from a regulatory option.

6 **“§ 622. Applicability**

7 “Except as provided in section 623(c), this sub-

8 chapter shall apply to all proposed and final major rules.

9 **“§ 623. Regulatory analysis**

10 “(a)(1) Before publishing a notice of a proposed rule

11 making for any rule, each agency shall determine whether

12 the rule is or is not a major rule covered by this sub-

13 chapter.

14 “(2) The Director may designate any rule to be a

15 major rule under section 621(6)(B), if the Director—

16 “(A) makes such designation no later than 30

17 days after the close of the comment period for the

18 rule; and

19 “(B) publishes such determination in the Fed-

20 eral Register together with a succinct statement of

21 the basis for the determination within 30 days after

22 such determination.

23 “(b)(1)(A) When an agency publishes a notice of pro-

24 posed rule making for a major rule, the agency shall pre-

25 pare and place in the rule making file an initial regulatory

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

4 “(B)(i) When the Director has published a deter-
 5 mination that a rule is a major rule after the publication
 6 of the notice of proposed rule making for the rule, the
 7 agency shall promptly prepare and place in the rule mak-
 8 ing file an initial regulatory analysis for the rule and shall
 9 publish in the Federal Register a summary of such analy-
 10 sis consistent with subsection (d).

11 “(ii) Following the issuance of an initial regulatory
 12 analysis under clause (i), the agency shall give interested
 13 persons an opportunity to comment under section 552 in
 14 the same manner as if the initial regulatory analysis had
 15 been issued with the notice of proposed rule making.

16 “(2) Each initial regulatory analysis shall contain—

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

19 “(i) an analysis of the benefits of the pro-
 20 posed rule, including any benefits that cannot
 21 be quantified, and an explanation of how the
 22 agency anticipates that such benefits will be
 23 achieved by the proposed rule, including a de-
 24 scription of the persons or classes of persons
 25 likely to receive such benefits;

1 “(ii) an analysis of the costs of the pro-
2 posed rule, including any costs that cannot be
3 quantified, and an explanation of how the agen-
4 cy anticipates that such costs will result from
5 the proposed rule, including a description of the
6 persons or classes of persons likely to bear such
7 costs; and

8 “(iii) an evaluation of the relationship of
9 the benefits of the proposed rule to its costs, in-
10 cluding the determinations required under sub-
11 section (c)(3), taking into account the results of
12 any risk assessment;

13 “(iv) an evaluation of the benefits and
14 costs of a reasonable number of reasonable al-
15 ternatives reflecting the range of regulatory op-
16 tions that would achieve the objective of the
17 statute as addressed by the rule making, includ-
18 ing, where feasible, alternatives that—

19 “(I) require no government action;

20 “(II) accommodate differences among
21 geographic regions and among persons
22 with differing levels of resources with
23 which to comply; or

24 “(III) employ flexible regulatory op-
25 tions;

1 “(v) a description of the scientific or eco-
 2 nomic evaluations or information upon which
 3 the agency substantially relied in the cost-bene-
 4 fit analysis and risk assessment required under
 5 this subchapter, and an explanation of how the
 6 agency reached the determinations under sub-
 7 section (c)(3); and

8 “(B) if required, the risk assessment in accord-
 9 ance with section 624.

10 “(c)(1) When the agency publishes a final major rule,
 11 the agency shall also prepare and place in the rule making
 12 file a final regulatory analysis, and shall prepare a sum-
 13 mary of the analysis consistent with subsection (d).

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

17 “(A) any material changes made to the pro-
 18 posed rule by the agency after publication of the no-
 19 tice of proposed rule making;

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

22 “(C) agency consideration of significant com-
 23 ments received regarding the proposed rule and the
 24 initial regulatory analysis, including regulatory re-
 25 view communications under subchapter IV.

1 “(3)(A) The agency shall include in the statement of
2 basis and purpose for the rule a reasonable determination,
3 based upon the rule making record considered as a
4 whole—

5 “(i) whether the rule is likely to provide bene-
6 fits that justify the costs of the rule; and

7 “(ii) whether the rule is likely to substantially
8 achieve the rule making objective in a more cost-ef-
9 fective manner, or with greater net benefits, than
10 the other reasonable alternatives considered by the
11 agency.

12 “(B) If the agency head cannot reasonably determine
13 that the final rule is likely to provide benefits that justify
14 the costs of the rule and substantially achieve the rule
15 making objective in a more cost-effective manner or with
16 greater net benefits than the other reasonable alternatives
17 considered by the agency, the agency head shall—

18 “(i) explain why such determinations cannot be
19 made;

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

22 “(iii) describe a reasonable alternative consid-
23 ered by the agency, if feasible, that would allow the
24 agency to determine that the benefits justify the
25 costs and that the rule making objective would be

1 achieved in a more cost-effective manner or with
 2 greater net benefits than the other reasonable alter-
 3 natives considered by the agency.

4 “(d) Each agency shall include an executive summary
 5 of the regulatory analysis, including any risk assessment,
 6 in the regulatory analysis and in the statement of basis
 7 and purpose for the rule. Such executive summary shall
 8 include a succinct presentation of—

9 “(1) the benefits and costs expected to result
 10 from the rule and any determinations required under
 11 subsection (e)(3);

12 “(2) if applicable, the risk addressed by the
 13 rule, including the most plausible estimate of the
 14 risk and the results of any risk assessment;

15 “(3) the benefits and costs of reasonable alter-
 16 natives considered by the agency; and

17 “(4) the key assumptions and scientific or eco-
 18 nomic information upon which the agency relied.

19 “(e)(1) A major rule may be adopted without prior
 20 compliance with this subchapter if—

21 “(A) the agency for good cause finds that con-
 22 ducting the regulatory analysis under this sub-
 23 chapter is contrary to the public interest due to an
 24 emergency, or an imminent threat to health or safe-

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

3 ~~“(B) the agency publishes in the Federal Reg-~~
4 ~~ister, together with such finding, a succinct state-~~
5 ~~ment of the basis for the finding.~~

6 ~~“(2) If a major rule is adopted under paragraph (1),~~
7 ~~the agency shall comply with this subchapter as promptly~~
8 ~~as possible unless compliance would be unreasonable be-~~
9 ~~cause the rule is, or soon will be, no longer in effect.~~

10 **~~“§ 624. Principles for risk assessments~~**

11 ~~“(a)(1) Subject to paragraph (2), each agency shall~~
12 ~~design and conduct risk assessments in accordance with~~
13 ~~this subchapter for each proposed and final major rule the~~
14 ~~primary purpose of which is to address health, safety, or~~
15 ~~environmental risk, or which results in a significant sub-~~
16 ~~stitution risk, in a manner that promotes rational and in-~~
17 ~~formed risk management decisions and informed public~~
18 ~~input into and understanding of the process of making~~
19 ~~agency decisions.~~

20 ~~“(2) If a risk assessment under this subchapter is~~
21 ~~otherwise required by this section, but the agency deter-~~
22 ~~mines that—~~

23 ~~“(A) a final rule subject to this subchapter is~~
24 ~~substantially similar to the proposed rule with re-~~
25 ~~spect to the risk being addressed;~~

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

4 “(C) a new risk assessment for the final rule is
5 not required in order to respond to comments re-
6 ceived during the period for comment on the pro-
7 posed rule;
8 the agency may publish such determination along with the
9 final rule in lieu of preparing a new risk assessment for
10 the final rule.

11 “(b) Each agency shall consider in each risk assess-
12 ment reliable and reasonably available scientific informa-
13 tion and shall describe the basis for selecting such sci-
14 entific information.

15 “(c)(1) Each agency may use reasonable assumptions
16 to the extent that relevant and reliable scientific informa-
17 tion, including site-specific or substance-specific informa-
18 tion, is not reasonably available.

19 “(2) When a risk assessment involves a choice of as-
20 sumptions, the agency shall—

21 “(A) identify the assumption and its scientific
22 or policy basis, including the extent to which the as-
23 sumption has been validated by, or conflicts with,
24 empirical data;

1 “(B) explain the basis for any choices among
2 assumptions and, where applicable, the basis for
3 combining multiple assumptions; and

4 “(C) describe reasonable alternative assump-
5 tions that were considered but not selected by the
6 agency for use in the risk assessment, how such al-
7 ternative assumptions would have changed the con-
8 clusions of the risk assessment, and the rationale for
9 not using such alternatives.

10 “(d) Each agency shall provide appropriate oppor-
11 tunity for public comment and participation during the de-
12 velopment of a risk assessment.

13 “(e) Each risk assessment supporting a major rule
14 under this subchapter shall include, as appropriate, each
15 of the following:

16 “(1) A description of the hazard of concern.

17 “(2) A description of the populations or natural
18 resources that are the subject of the risk assess-
19 ment.

20 “(3) An explanation of the exposure scenarios
21 used in the risk assessment, including an estimate of
22 the corresponding population at risk and the likeli-
23 hood of such exposure scenarios.

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

4 “(5) A description of the major uncertainties in
5 each component of the risk assessment and their in-
6 fluence on the results of the assessment.

7 “(f) To the extent scientifically appropriate, each
8 agency shall—

9 “(1) express the overall estimate of risk as a
10 reasonable range or probability distribution that re-
11 flects variabilities, uncertainties, and lack of data in
12 the analysis;

13 “(2) provide the range and distribution of risks
14 and the corresponding exposure scenarios, identify-
15 ing the range and distribution and likelihood of risk
16 to the general population and, as appropriate, to
17 more highly exposed or sensitive subpopulations; in-
18 cluding the most plausible estimates of the risks;
19 and

20 “(3) where quantitative estimates are not avail-
21 able, describe the qualitative factors influencing the
22 range, distribution, and likelihood of possible risks.

23 “(g) When scientific information that permits rel-
24 evant comparisons of risk is reasonably available, each
25 agency shall use the information to place the nature and

1 magnitude of a risk to health, safety, or the environment
 2 being analyzed in relationship to other reasonably com-
 3 parable risks familiar to and routinely encountered by the
 4 general public. Such comparisons should consider relevant
 5 distinctions among risks, such as the voluntary or involun-
 6 tary nature of risks.

7 “(h) When scientifically appropriate information on
 8 significant substitution risks to health, safety, or the envi-
 9 ronment is reasonably available to the agency, the agency
 10 shall describe such risks in the risk assessment.

11 **“§ 625. Peer review**

12 “(a) Each agency shall provide for peer review in ac-
 13 cordance with this section of any cost benefit analysis and
 14 risk assessment required by this subchapter that forms the
 15 basis of any major rule covered by this subchapter.

16 “(b)(1) Peer review required under subsection (a)
 17 shall—

18 “(A) provide for the creation or utilization of
 19 peer review panels, expert bodies, or other formal or
 20 informal devices that are broadly representative and
 21 balanced and that consist of panel members or par-
 22 ticipants with expertise relevant to the sciences in-
 23 volved in the regulatory decisions and who are inde-
 24 pendent of the agency program;

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

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

7 “(D) contain a balanced presentation of all con-
8 siderations, including minority reports and an agen-
9 cy response to all significant peer review comments;
10 and

11 “(E) provide adequate protections for confiden-
12 tial business information and trade secrets, including
13 requiring panel members or participants to enter
14 into confidentiality agreements.

15 “(2) All peer review written comments or conclusions
16 and the agency’s written responses to significant peer re-
17 view comments shall be made available to the public and
18 shall be made part of the rule making record for purposes
19 of judicial review of any final agency action.

20 “(3) If the head of an agency, with the concurrence
21 of the Director, publishes a determination that a cost-ben-
22 efit analysis or risk assessment, or any component thereof,
23 has been previously subjected to adequate peer review, no
24 further peer review shall be required under this section
25 for such analysis, assessment, or component.

1 **“§ 626. Deadlines for rule making**

2 “(a) All deadlines in statutes or imposed by a court
3 of the United States, that require an agency to propose
4 or promulgate any major rule during the 2-year period be-
5 ginning on the effective date of this section shall be sus-
6 pended until the earlier of—

7 “(1) the date on which the requirements of this
8 subchapter are satisfied; or

9 “(2) the date occurring 6 months after the date
10 of the applicable deadline.

11 “(b) In any case in which the failure to promulgate
12 a major rule by a deadline occurring during the 2-year
13 period beginning on the effective date of this section would
14 create an obligation to regulate through individual adju-
15 dications, the deadline shall be suspended until the earlier
16 of—

17 “(1) the date on which the requirements of this
18 subchapter are satisfied; or

19 “(2) the date occurring 6 months after the date
20 of the applicable deadline.

21 **“§ 627. Judicial review**

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

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

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

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

9 “(d) The cost-benefit analysis and any risk assess-
10 ment required under this subchapter shall not be subject
11 to judicial review separate from review of the final rule
12 to which they apply. The cost-benefit analysis, cost-benefit
13 determination under section 623(c)(3), and any risk as-
14 sessment shall be part of the whole rule making record
15 for purposes of judicial review of the rule and shall be
16 considered by a court in determining whether the final rule
17 is arbitrary or capricious unless the agency can dem-
18 onstrate that the analysis or assessment would not be ma-
19 terial to the outcome of the rule.

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

1 **“§ 628. Guidelines, interagency coordination, and re-**
 2 **search**

3 “(a)(1) No later than 9 months after the date of en-
 4 actment of this section, the Director, in consultation with
 5 the Director of the Office of Science and Technology Pol-
 6 icy and the relevant agency heads, shall develop guidelines
 7 for cost-benefit analyses and risk assessments required by
 8 this subchapter or with significant implications for public
 9 policy. To the extent feasible such guidelines shall apply
 10 the principles of sections 623 and 624. The Director shall
 11 oversee and periodically revise such guidelines as appro-
 12 priate.

13 “(2) As soon as practicable and no later than 18
 14 months after the date of enactment of this section, each
 15 relevant agency shall adopt detailed guidelines for risk as-
 16 sessments required by this subchapter or with significant
 17 implications for public policy. Such guidelines shall be con-
 18 sistent with the guidance issued under paragraph (1).
 19 Each agency shall periodically revise such agency guide-
 20 lines as appropriate.

21 “(3) The guidelines under this subsection shall be de-
 22 veloped following notice and public comment. The develop-
 23 ment and issuance of the guidelines shall not be subject
 24 to judicial review, except in accordance with section
 25 706(1) of this title.

1 “(b) To promote the use of cost-benefit analysis and
2 assessment in a consistent manner and to identify agency
3 research and training needs, the Director, in consultation
4 with the Director of the Office of Science and Technology
5 Policy, shall—

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

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

11 “(3) establish appropriate interagency mecha-
12 nisms to improve the consistency and quality of cost-
13 benefit analysis and risk assessment among Federal
14 agencies; and

15 “(4) establish appropriate mechanisms between
16 Federal and State agencies to improve cooperation
17 in the development and application of cost-benefit
18 analysis and risk assessment.

19 “(c)(1) The head of each agency, in consultation with
20 the Director and the Director of the Office of Science and
21 Technology Policy, shall regularly evaluate and develop a
22 strategy to meet agency needs for research and training
23 in cost-benefit analysis and risk assessment, including re-
24 search on modelling, the development of generic data, use

1 of assumptions and the identification and quantification
 2 of uncertainty and variability.

3 “(2)(A) No later than 6 months from the date of en-
 4 actment of this section, the Director, in consultation with
 5 the Director of the Office of Science and Technology Pol-
 6 icy, shall enter into appropriate arrangements with an ac-
 7 credited scientific institution to conduct research to—

8 “(i) identify and evaluate a common basis to as-
 9 sist comparative risk analysis and risk communica-
 10 tion related to both carcinogens and noncarcinogens;
 11 and

12 “(ii) appropriately incorporate risk assessments
 13 into related cost-benefit analyses.

14 “(B) The results of the research conducted under this
 15 paragraph shall be submitted to the Director and Con-
 16 gress no later than 18 months after the date of enactment
 17 of this section.

18 **“§ 629. Comparative risk analysis study**

19 “(a) No later than 180 days after the effective date
 20 of this section, the Director, in consultation with the Di-
 21 rector of the Office of Science and Technology Policy, shall
 22 enter into a contract with an accredited scientific institu-
 23 tion to conduct a study that provides—

24 “(1) a systematic comparison of the extent and
 25 severity of significant risks to human health, safety,

1 or the environment (hereafter referred to as a com-
2 parative risk analysis);

3 “(2) a study of methodologies for using com-
4 parative risk analysis to compare dissimilar risks to
5 human health, safety, or the environment; and

6 “(3) technical guidance and recommendations
7 on the use of comparative risk analysis to assist in
8 allocating resources within and across agencies to
9 set priorities for the reduction of risks to human
10 health, safety, or the environment.

11 “(b) The Director shall ensure that the study re-
12 quired under subsection (a) is—

13 “(1) conducted through an open process provid-
14 ing peer review consistent with section 625 and op-
15 portunities for public comment and participation;
16 and

17 “(2) completed and submitted to Congress and
18 the President no later than 3 years after the effec-
19 tive date of this section.

20 “(c) No later than 5 years after the effective date
21 of this section, and periodically thereafter, the President
22 shall submit a report to Congress recommending legisla-
23 tive changes to assist in setting priorities to more effec-
24 tively and efficiently reduce risks to human health, safety,
25 or the environment.

1 “SUBCHAPTER III—REVIEW OF RULES

2 **“§ 631. Definitions**

3 “For purposes of this subchapter the definitions
4 under sections 551 and 621 shall apply.

5 **“§ 632. Advisory committee on regulations**

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

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

15 “(2) The head of an agency described under para-
16 graph (1) may establish panels under its advisory commit-
17 tee.

18 “(b)(1) Each such agency head shall appoint a rea-
19 sonable number of members to serve on the agency’s advi-
20 sory committee and shall designate a chairman from the
21 members of the committee. Membership on the committee
22 shall represent a balanced cross-section of public and pri-
23 vate interests affected by the regulations of the agency,
24 including small businesses, small governments, and public
25 interest groups. No employee of the agency establishing

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

3 ~~“(2) Each member shall be appointed for the life of~~
4 ~~the advisory committee. The advisory committee shall ter-~~
5 ~~minate 1 year after the date on which the committee is~~
6 ~~established.~~

7 ~~“(3) A vacancy on a committee shall be filled in the~~
8 ~~same manner as the original appointment.~~

9 ~~“(4) Each committee shall solicit public comments~~
10 ~~and may solicit public participation through appropriate~~
11 ~~means including hearings, written comments, public meet-~~
12 ~~ings, and electronic mail.~~

13 ~~“(5) Members of each committee shall receive travel~~
14 ~~expenses, including per diem in lieu of subsistence, in ac-~~
15 ~~cordance with sections 5702 and 5703.~~

16 ~~“(6) Each committee shall be subject to the provi-~~
17 ~~sions of the Federal Advisory Committee Act (5 U.S.C.~~
18 ~~App.).~~

19 **~~“§ 633. Agency regulatory review~~**

20 ~~“(a) Each advisory committee appointed under sec-~~
21 ~~tion 632 shall develop a list of rules promulgated by the~~
22 ~~agency that the committee serves, which the committee de-~~
23 ~~termines should be reviewed by the agency and can reason-~~
24 ~~ably be reviewed by the agency within a 5-year period. In~~

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

3 ~~“(1) a rule could be revised to substantially in-~~
4 ~~crease net benefits, including through flexible regula-~~
5 ~~tory options;~~

6 ~~“(2) the rule is important relative to other rules~~
7 ~~being considered for review; and~~

8 ~~“(3) the agency has discretion under the statute~~
9 ~~authorizing the rule to modify or repeal the rule.~~

10 ~~“(b) In developing the list required under subsection~~
11 ~~(a), each advisory committee shall obtain comments and~~
12 ~~suggestions from the public.~~

13 ~~“(c) No later than 1 year after an advisory committee~~
14 ~~is established, such committee shall deliver to the agency~~
15 ~~the committee’s recommended list of rules to be reviewed~~
16 ~~in order of priority. The agency shall immediately publish~~
17 ~~the list in the Federal Register and forward a copy of the~~
18 ~~list to the appropriate committees of jurisdiction in the~~
19 ~~House of Representatives and the Senate.~~

20 ~~“(d)(1) No later than 60 days after receiving and re-~~
21 ~~viewing the list of rules from its committee, the agency~~
22 ~~shall publish in the Federal Register a preliminary sched-~~
23 ~~ule for review of rules based on such list.~~

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

1 nation of each modification to the list provided by the ad-
 2 visory committee and shall invite public comment on the
 3 preliminary schedule for a period of no less than 60 days.

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

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

11 “(2) The schedule shall establish a deadline for com-
 12 pletion of the review of each rule listed on the schedule.
 13 Each deadline shall occur no later than 5 years from the
 14 date of publication of the final schedule.

15 “(g) In preparing the preliminary and final schedule,
 16 the agency shall give deference to the recommendations
 17 of its advisory committee but may modify the list of rules
 18 to be reviewed, taking into account the factors contained
 19 in subsection (a) and the resource constraints of the agen-
 20 cy.

21 “(h)(1) For each rule on the schedule under sub-
 22 section (e), the agency shall—

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

1 er the rule should be continued, amended, or re-
2 pealed;

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

6 “(i) addresses public comments generated
7 by the notice in subparagraph (A);

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

11 “(iii) contains a preliminary determination
12 whether the rule should be continued, amended,
13 or repealed; and

14 “(iv) solicits public comment on the pre-
15 liminary determination for the rule; and

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

19 “(i) addresses public comments generated
20 by the notice in subsection (c);

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

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

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

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

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

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

22 “(l) A court may remand a determination under sub-
 23 section (h)(2) only upon a clear and convincing showing
 24 that the agency could have adopted a reasonable alter-
 25 native that would substantially increase net benefits, in-

1 eluding through flexible regulatory options, while meeting
 2 the objectives of the statute as addressed by the rule mak-
 3 ing.

4 “SUBCHAPTER IV—EXECUTIVE OVERSIGHT

5 “§ 641. Definitions

6 “For purposes of this subchapter—

7 “(1) the definitions under sections 551 and 621
 8 shall apply; and

9 “(2) the term ‘regulatory action’ means any one
 10 of the following:

11 “(A) An agenda or schedule for rule mak-
 12 ings.

13 “(B) Advance notice of proposed rule mak-
 14 ing.

15 “(C) Notice of proposed rule making.

16 “(D) Final rule making, including interim
 17 final rule making.

18 “§ 642. Presidential regulatory review

19 “(a) The President shall establish a process for the
 20 review and coordination of Federal agency regulatory ac-
 21 tions. Such process shall be the responsibility of the Direc-
 22 tor.

23 “(b) For the purpose of carrying out the review es-
 24 tablished under subsection (a), the Director shall—

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

5 “(2) develop policies and procedures for the re-
6 view of regulatory actions by the Director; and

7 “(3) develop and oversee an annual govern-
8 mentwide regulatory planning process that shall in-
9 clude review of planned agency major rules and
10 other significant regulatory actions and publication
11 of—

12 “(A) a summary of and schedule for pro-
13 mulgation of planned agency major rules;

14 “(B) agency specific schedules for review
15 of existing rules under subchapter III;

16 “(C) a summary of regulatory review ac-
17 tions undertaken in the prior year;

18 “(D) a list of major rules promulgated in
19 the prior year for which an agency could not
20 make the determinations that the benefits of a
21 rule justify the costs under section 623(c)(3);

22 “(E) identification of significant agency
23 noncompliance with this chapter in the prior
24 year; and

1 ~~“(F) recommendations for improving com-~~
 2 ~~pliance with this chapter and increasing the ef-~~
 3 ~~iciency and effectiveness of the regulatory~~
 4 ~~process.~~

5 ~~“(e) The review established under subsection (a) shall~~
 6 ~~be conducted as expeditiously as practicable and the Di-~~
 7 ~~rector’s review of any regulatory action shall be limited~~
 8 ~~to no more than 90 days, unless extended for an additional~~
 9 ~~30 days at the written request of the rule making agency~~
 10 ~~or the Director.~~

11 **~~“§ 643. Public disclosure of information~~**

12 ~~“(a) The Director, in carrying out the provisions of~~
 13 ~~section 642, shall establish procedures to provide public~~
 14 ~~and agency access to information concerning regulatory~~
 15 ~~review actions, including—~~

16 ~~“(1) disclosure to the public on an ongoing~~
 17 ~~basis of information regarding the status of regu-~~
 18 ~~latory actions undergoing review;~~

19 ~~“(2) disclosure to the public, no later than pub-~~
 20 ~~lication of a regulatory action, of—~~

21 ~~“(A) all written communications relating~~
 22 ~~to the substance of a regulatory action includ-~~
 23 ~~ing drafts of all proposals and associated analy-~~
 24 ~~ses, between the Director or employees of the~~
 25 ~~Director and the regulatory agency;~~

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

6 “(C) a list identifying the dates, names of
7 individuals involved, and subject matter dis-
8 cussed in substantive meetings and telephone
9 conversations relating to the substance of a reg-
10 ulatory action between the Director or employ-
11 ees of the Director and any person not em-
12 ployed by the executive branch of the Federal
13 Government; and

14 “(D) a written explanation of any review
15 action and the date of such action; and

16 “(3) disclosure to the regulatory agency, on a
17 timely basis, of—

18 “(A) all written communications relating
19 to the substance of a regulatory action between
20 the Director or employees of the Director and
21 any person who is not employed by the execu-
22 tive branch of the Federal Government;

23 “(B) a list identifying the dates, names of
24 individuals involved, and subject matter dis-
25 cussed in substantive meetings and telephone

1 conversations, and an invitation to participate
2 in meetings, relating to the substance of a regu-
3 latory action between the Director or employees
4 of the Director and any person not employed
5 by the executive branch of the Federal Govern-
6 ment; and

7 “(C) a written explanation of any review
8 action taken concerning an agency regulatory
9 action.

10 “(b) Prior to the publication of any proposed or final
11 rule, the agency shall include in the rule making record—

12 “(1) a document identifying in a complete,
13 clear, and simple manner, the substantive changes
14 between the draft submitted to the Director for re-
15 view and the rule subsequently announced;

16 “(2) a document identifying those changes in
17 the rule that were made at the suggestion or rec-
18 ommendation of the Director; and

19 “(3) all written communications exchanged be-
20 tween the Director and the agency during the review
21 of the rule, including drafts of all proposals and as-
22 sociated analyses.

1 **“§ 644. Judicial review**

2 “The exercise of the authority granted under this
3 subchapter by the Director or the President shall not be
4 subject to judicial review in any manner.”.

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

11 (c) **TECHNICAL AND CONFORMING AMENDMENTS.**—

12 (1) Part I of title 5, United States Code, is
13 amended by striking the chapter heading and table
14 of sections for chapter 6 and inserting the following:

15 **“CHAPTER 6—THE ANALYSIS OF**
16 **REGULATORY FUNCTIONS**

“SUBCHAPTER I—ANALYSIS OF REGULATORY FLEXIBILITY

“Sec.

“601. Definitions.

“602. Regulatory agenda.

“603. Initial regulatory flexibility analysis.

“604. Final regulatory flexibility analysis.

“605. Avoidance of duplicative or unnecessary analyses.

“606. Effect on other law.

“607. Preparation of analysis.

“608. Procedure for waiver or delay of completion.

“609. Procedures for gathering comments.

“610. Periodic review of rules.

“611. Judicial review.

“612. Reports and intervention rights.

“SUBCHAPTER II—REGULATORY ANALYSIS

“621. Definitions.

“622. Applicability.

“623. Regulatory analysis.

“631. Definitions.
“632. Advisory committee on regulations.
“633. Agency regulatory review.

“641. Definitions:
“642. Presidential regulatory review:
“643. Public disclosure of information:
“644. Judicial review.”.

4 ~~“SUBCHAPTER I—ANALYSIS OF REGULATORY~~
5 ~~FLEXIBILITY”;~~

7 Except as otherwise provided in this Act, this Act
8 shall take effect 180 days after the date of enactment of
9 this Act, but shall not apply to any agency rule for which
10 a notice of proposed rulemaking is published on or before
11 August 1, 1997.

13 *This Act may be cited as the “Regulatory Improvement*
14 *Act of 1998”.*

16 *Congress finds the following:*

1 (1) *Effective regulatory programs provide impor-*
2 *tant benefits to the public, including improving the*
3 *environment, worker safety, and public health. Regu-*
4 *latory programs also impose significant costs on the*
5 *public, including individuals, businesses, and State,*
6 *local, and tribal governments.*

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

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

15 (4) *The evaluation of costs and benefits must in-*
16 *volve the consideration of the relevant information,*
17 *whether expressed in quantitative or qualitative*
18 *terms, including factors such as social values, dis-*
19 *tributional effects, and equity.*

20 (5) *Cost-benefit analysis and risk assessment*
21 *should be presented with a clear statement of the ana-*
22 *lytical assumptions and uncertainties, including an*
23 *explanation of what is known and not known and*
24 *what the implications of alternative assumptions*
25 *might be.*

1 (6) *The public has a right to know about the*
 2 *costs and benefits of regulations, the risks addressed,*
 3 *the risks reduced, and the quality of scientific and*
 4 *economic analysis used to support decisions. Such*
 5 *knowledge will promote the quality, integrity and re-*
 6 *sponsiveness of agency actions.*

7 (7) *The Administrator of the Office of Informa-*
 8 *tion and Regulatory Affairs should oversee regulatory*
 9 *activities to raise the quality and consistency of cost-*
 10 *benefit analysis and risk assessment among all agen-*
 11 *cies.*

12 (8) *The Federal Government should develop a*
 13 *better understanding of the strengths, weaknesses, and*
 14 *uncertainties of cost-benefit analysis and risk assess-*
 15 *ment and conduct the research needed to improve*
 16 *these analytical tools.*

17 **SEC. 3. REGULATORY ANALYSIS.**

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

20 “SUBCHAPTER II—REGULATORY ANALYSIS

21 “§ 621. **Definitions**

22 “*For purposes of this subchapter the definitions under*
 23 *section 551 shall apply and—*

1 “(1) the term ‘Administrator’ means the Admin-
 2 istrator of the Office of Information and Regulatory
 3 Affairs of the Office of Management and Budget;

4 “(2) the term ‘benefit’ means the reasonably
 5 identifiable significant favorable effects, quantifiable
 6 and nonquantifiable, including social, health, safety,
 7 environmental, economic, and distributional effects,
 8 that are expected to result from implementation of, or
 9 compliance with, a rule;

10 “(3) the term ‘cost’ means the reasonably identi-
 11 fiable significant adverse effects, quantifiable and
 12 nonquantifiable, including social, health, safety, envi-
 13 ronmental, economic, and distributional effects, that
 14 are expected to result from implementation of, or
 15 compliance with, a rule;

16 “(4) the term ‘cost-benefit analysis’ means an
 17 evaluation of the costs and benefits of a rule, quan-
 18 tified to the extent feasible and appropriate and oth-
 19 erwise qualitatively described, that is prepared in ac-
 20 cordance with the requirements of this subchapter at
 21 the level of detail appropriate and practicable for rea-
 22 soned decisionmaking on the matter involved, taking
 23 into consideration uncertainties, the significance and
 24 complexity of the decision, and the need to adequately
 25 inform the public;

1 “(5) the term ‘Director’ means the Director of the
2 Office of Management and Budget, acting through the
3 Administrator of the Office of Information and Regu-
4 latory Affairs;

5 “(6) the term ‘flexible regulatory options’ means
6 regulatory options that permit flexibility to regulated
7 persons in achieving the objective of the statute as ad-
8 dressed by the rule making, including regulatory op-
9 tions that use market-based mechanisms, outcome ori-
10 ented performance-based standards, or other options
11 that promote flexibility;

12 “(7) the term ‘major rule’ means a rule that—

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

17 “(B) is otherwise designated a major rule
18 by the Director on the ground that the rule is
19 likely to adversely affect, in a material way, the
20 economy, a sector of the economy, including
21 small business, productivity, competition, jobs,
22 the environment, public health or safety, or
23 State, local or tribal governments, or commu-
24 nities;

1 “(8) the term ‘reasonable alternative’ means a
2 reasonable regulatory option that would achieve the
3 objective of the statute as addressed by the rule mak-
4 ing and that the agency has authority to adopt under
5 the statute granting rule making authority, including
6 flexible regulatory options;

7 “(9) the term ‘risk assessment’ means the system-
8 atic, objective process of organizing hazard and expo-
9 sure information, based on a careful analysis of the
10 weight of the scientific evidence, to estimate the poten-
11 tial for specific harm to an exposed population, sub-
12 population, or natural resource including, to the ex-
13 tent feasible, a characterization of the distribution of
14 risk as well as an analysis of uncertainties,
15 variabilities, conflicting information, and inferences
16 and assumptions;

17 “(10) the term ‘rule’ has the same meaning as in
18 section 551(4), and shall not include—

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

21 “(B) a rule that involves the internal reve-
22 nue laws of the United States, or the assessment
23 or collection of taxes, duties, or other debts, reve-
24 nue, or receipts;

1 “(C) a rule of particular applicability that
2 approves or prescribes for the future rates, wages,
3 prices, services, corporate or financial structures,
4 reorganizations, mergers, acquisitions, account-
5 ing practices, or disclosures bearing on any of
6 the foregoing;

7 “(D) a rule relating to monetary policy
8 proposed or promulgated by the Board of Gov-
9 ernors of the Federal Reserve System or by the
10 Federal Open Market Committee;

11 “(E) a rule relating to the operations, safe-
12 ty, or soundness of federally insured depository
13 institutions or any affiliate of such an institu-
14 tion (as defined in section 2(k) of the Bank
15 Holding Company Act of 1956 (12 U.S.C.
16 1841(k)); credit unions; the Federal Home Loan
17 Banks; government-sponsored housing enter-
18 prises; a Farm Credit System Institution; for-
19 eign banks, and their branches, agencies, com-
20 mercial lending companies or representative of-
21 fices that operate in the United States and any
22 affiliate of such foreign banks (as those terms are
23 defined in the International Banking Act of
24 1978 (12 U.S.C. 3101)); or a rule relating to the

1 *payments system or the protection of deposit in-*
 2 *surance funds or Farm Credit Insurance Fund;*

3 *“(F) a rule relating to the integrity of the*
 4 *securities or commodities futures markets or to*
 5 *the protection of investors in those markets;*

6 *“(G) a rule issued by the Federal Election*
 7 *Commission or a rule issued by the Federal*
 8 *Communications Commission under sections*
 9 *312(a)(7) and 315 of the Communications Act of*
 10 *1934 (47 U.S.C. 312(a)(7) and 315);*

11 *“(H) a rule required to be promulgated at*
 12 *least annually pursuant to statute;*

13 *“(I) a rule or agency action relating to the*
 14 *public debt or fiscal policy of the United States;*
 15 *or*

16 *“(J) a rule or agency action that authorizes*
 17 *the introduction into commerce, or recognizes the*
 18 *marketable status of, a product; and*

19 *“(11) the term ‘substitution risk’ means a sig-*
 20 *nificant increased risk to health, safety, or the envi-*
 21 *ronment reasonably likely to result from a regulatory*
 22 *option.*

23 **“§ 622. Applicability and effect**

24 *“(a) Except as provided in section 623(f), this sub-*
 25 *chapter shall apply to all proposed and final major rules.*

1 “(b) *Nothing in this subchapter shall be construed to*
 2 *alter or modify the substantive standards otherwise applica-*
 3 *ble to a rule making under other statutes or opportunity*
 4 *for judicial review made applicable under other statutes.*

5 **“§ 623. *Regulatory analysis***

6 “(a)(1) *Before publishing a notice of a proposed rule*
 7 *making for any rule, each agency shall determine whether*
 8 *the rule is or is not a major rule covered by this subchapter.*

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

11 “(A) *makes such designation no later than 30*
 12 *days after the close of the comment period for the rule;*
 13 *and*

14 “(B) *publishes such designation in the Federal*
 15 *Register, together with a succinct statement of the*
 16 *basis for the designation, within 30 days after such*
 17 *designation.*

18 “(b)(1)(A) *When an agency publishes a notice of pro-*
 19 *posed rule making for a major rule, the agency shall pre-*
 20 *pare and place in the rule making file an initial regulatory*
 21 *analysis, and shall include a summary of such analysis*
 22 *consistent with subsection (e) in the notice of proposed rule*
 23 *making.*

24 “(B)(i) *When the Director has published a designation*
 25 *that a rule is a major rule after the publication of the notice*

1 of proposed rule making for the rule, the agency shall
2 promptly prepare and place in the rule making file an ini-
3 tial regulatory analysis for the rule and shall publish in
4 the Federal Register a summary of such analysis consistent
5 with subsection (e).

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

11 “(2) Each initial regulatory analysis shall contain—

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

14 “(i) an analysis of the benefits of the pro-
15 posed rule, including any benefits that cannot be
16 quantified, and an explanation of how the agen-
17 cy anticipates that such benefits will be achieved
18 by the proposed rule, including a description of
19 the persons or classes of persons likely to receive
20 such benefits;

21 “(ii) an analysis of the costs of the proposed
22 rule, including any costs that cannot be quan-
23 tified, and an explanation of how the agency an-
24 ticipates that such costs will result from the pro-

1 *posed rule, including a description of the persons*
2 *or classes of persons likely to bear such costs;*

3 *“(iii) an evaluation of the relationship of*
4 *the benefits of the proposed rule to its costs, in-*
5 *cluding the determinations required under sub-*
6 *section (d), taking into account the results of any*
7 *risk assessment;*

8 *“(iv) an evaluation of the benefits and costs*
9 *of a reasonable number of reasonable alternatives*
10 *reflecting the range of regulatory options that*
11 *would achieve the objective of the statute as ad-*
12 *dressed by the rule making, including, where fea-*
13 *sible, alternatives that—*

14 *“(I) require no government action or*
15 *utilize voluntary programs;*

16 *“(II) provide flexibility for small enti-*
17 *ties under subchapter I and for State, local,*
18 *or tribal government agencies delegated to*
19 *administer a Federal program;*

20 *“(III) employ flexible regulatory op-*
21 *tions; and*

22 *“(IV) assure protection of sensitive*
23 *subpopulations, or populations exposed to*
24 *multiple and cumulative risks; and*

1 “(v) a description of the scientific or eco-
 2 nomic evaluations or information upon which
 3 the agency substantially relied in the cost-benefit
 4 analysis and risk assessment required under this
 5 subchapter, and an explanation of how the agen-
 6 cy reached the determinations under subsection
 7 (d);

8 “(B) if required, the risk assessment in accord-
 9 ance with section 624; and

10 “(C) when scientific information on substitution
 11 risks to health, safety, or the environment is reason-
 12 ably available to the agency, an identification and
 13 evaluation of such risks.

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

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

20 “(A) any material changes made to the proposed
 21 rule by the agency after publication of the notice of
 22 proposed rule making;

23 “(B) any material changes made to the cost-ben-
 24 efit analysis or risk assessment; and

1 “(C) agency consideration of significant com-
 2 ments received regarding the proposed rule and the
 3 initial regulatory analysis, including regulatory re-
 4 view communications under subchapter IV.

5 “(d)(1) The agency shall include in the statement of
 6 basis and purpose for a proposed or final major rule a rea-
 7 sonable determination, based upon the rule making record
 8 considered as a whole—

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

11 “(B) whether the rule is likely to substantially
 12 achieve the rule making objective in a more cost-effec-
 13 tive manner, or with greater net benefits, than the
 14 other reasonable alternatives considered by the agen-
 15 cy; and

16 “(C) whether the rule adopts a flexible regulatory
 17 option.

18 “(2) If the agency head determines that the rule is not
 19 likely to provide benefits that justify the costs of the rule
 20 or is not likely to substantially achieve the rule making ob-
 21 jective in a more cost-effective manner, or with greater net
 22 benefits, than the other reasonable alternatives considered
 23 by the agency, the agency head shall—

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

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

3 *“(B) describe any reasonable alternative consid-*
 4 *ered by the agency that would be likely to provide*
 5 *benefits that justify the costs of the rule and be likely*
 6 *to substantially achieve the rule making objective in*
 7 *a more cost-effective manner, or with greater net bene-*
 8 *fits, than the alternative selected by the agency; and*

9 *“(C) describe any flexible regulatory option con-*
 10 *sidered by the agency and explain why that option*
 11 *was not adopted by the agency if that option was not*
 12 *adopted.*

13 *“(e) Each agency shall include an executive summary*
 14 *of the regulatory analysis, including any risk assessment,*
 15 *in the regulatory analysis and in the statement of basis and*
 16 *purpose for the proposed and final major rule. Such execu-*
 17 *tive summary shall include a succinct presentation of—*

18 *“(1) the benefits and costs expected to result from*
 19 *the rule and any determinations required under sub-*
 20 *section (d);*

21 *“(2) if applicable, the risk addressed by the rule*
 22 *and the results of any risk assessment;*

23 *“(3) the benefits and costs of reasonable alter-*
 24 *natives considered by the agency; and*

1 “(4) the key assumptions and scientific or eco-
2 nomic information upon which the agency relied.

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

5 “(A) the agency for good cause finds that con-
6 ducting the regulatory analysis under this subchapter
7 before the rule becomes effective is impracticable or
8 contrary to an important public interest; and

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

12 “(2) If a major rule is adopted under paragraph (1),
13 the agency shall comply with this subchapter as promptly
14 as possible unless compliance would be unreasonable be-
15 cause the rule is, or soon will be, no longer in effect.

16 “(g) Each agency shall develop an effective process to
17 permit elected officers of State, local, and tribal govern-
18 ments (or their designated employees with authority to act
19 on their behalf) to provide meaningful and timely input
20 in the development of regulatory proposals that contain sig-
21 nificant Federal intergovernmental mandates. The process
22 developed under this subsection shall be consistent with sec-
23 tion 204 of the Unfunded Mandates Reform Act of 1995
24 (2 U.S.C. 1534).

1 **“§ 624. Principles for risk assessments**

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

5 “(i) each proposed and final major rule the pri-
6 mary purpose of which is to address health, safety, or
7 environmental risk; or

8 “(ii) any risk assessment that is not the basis of
9 a rule making that the Director reasonably deter-
10 mines is anticipated to have a substantial impact on
11 a significant public policy or on the economy.

12 “(B)(i) Risk assessments conducted under this sub-
13 chapter shall be conducted in a manner that promotes ra-
14 tional and informed risk management decisions and in-
15 formed public input into and understanding of the process
16 of making agency decisions.

17 “(ii) The scope and level of analysis of such a risk as-
18 sessment shall be commensurate with the significance and
19 complexity of the decision and the need to adequately in-
20 form the public, consistent with any need for expedition,
21 and designed for the nature of the risk being assessed.

22 “(2) If a risk assessment under this subchapter is oth-
23 erwise required by this section, but the agency determines
24 that—

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

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

7 “(C) a new risk assessment for the final rule is
8 not required in order to respond to comments received
9 during the period for comment on the proposed rule,
10 the agency may publish such determination along with the
11 final rule in lieu of preparing a new risk assessment for
12 the final rule.

13 “(b) Each agency shall consider in each risk assess-
14 ment all relevant, reliable, and reasonably available sci-
15 entific information and shall describe the basis for selecting
16 such scientific information.

17 “(c)(1) When a risk assessment involves a choice of as-
18 sumptions, the agency shall, with respect to significant as-
19 sumptions—

20 “(A) identify the assumption and its scientific
21 and policy basis, including the extent to which the as-
22 sumption has been validated by, or conflicts with, em-
23 pirical data;

1 “(B) explain the basis for any choices among as-
 2 sumptions and, where applicable, the basis for com-
 3 bining multiple assumptions; and

4 “(C) describe reasonable alternative assumptions
 5 that—

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

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

10 “(2) As relevant and reliable scientific information be-
 11 comes reasonably available, each agency shall revise its sig-
 12 nificant assumptions to incorporate such information.

13 “(d) The agency shall notify the public of the agency’s
 14 intent to conduct a risk assessment and, to the extent prac-
 15 ticable, shall solicit relevant and reliable data from the pub-
 16 lic. The agency shall consider such data in conducting the
 17 risk assessment.

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

20 “(1) A description of the hazard of concern.

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

23 “(3) An explanation of the exposure scenarios
 24 used in the risk assessment, including an estimate of

1 *the corresponding population or natural resource at*
2 *risk and the likelihood of such exposure scenarios.*

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

6 “(5) *A description of the major uncertainties in*
7 *each component of the risk assessment and their influ-*
8 *ence on the results of the assessment.*

9 “(f) *To the extent scientifically appropriate, each agen-*
10 *cy shall—*

11 “(1) *express the estimate of risk as 1 or more*
12 *reasonable ranges and, if feasible, probability dis-*
13 *tributions that reflects variabilities, uncertainties,*
14 *and lack of data in the analysis;*

15 “(2) *provide the ranges and distributions of*
16 *risks, including central and high end estimates of the*
17 *risks, and their corresponding exposure scenarios for*
18 *the potentially exposed population and, as appro-*
19 *priate, for more highly exposed or sensitive sub-*
20 *populations; and*

21 “(3) *describe the qualitative factors influencing*
22 *the ranges, distributions, and likelihood of possible*
23 *risks.*

24 “(g) *When scientific information that permits relevant*
25 *comparisons of risk is reasonably available, each agency*

1 *shall use the information to place the nature and magnitude*
 2 *of a risk to health, safety, or the environment being ana-*
 3 *lyzed in relationship to other reasonably comparable risks*
 4 *familiar to and routinely encountered by the general public.*
 5 *Such comparisons should consider relevant distinctions*
 6 *among risks, such as the voluntary or involuntary nature*
 7 *of risks, well understood or newly discovered risks, and re-*
 8 *versible or irreversible risks.*

9 **“§ 625. Peer review**

10 “(a) *Each agency shall provide for an independent*
 11 *peer review in accordance with this section of the cost-bene-*
 12 *fit analysis and risk assessment required by this subchapter.*

13 “(b)(1) *Peer review required under subsection (a)*
 14 *shall—*

15 “(A) *be conducted through panels, expert bodies,*
 16 *or other formal or informal devices that are broadly*
 17 *representative and involve participants—*

18 “(i) *with expertise relevant to the sciences,*
 19 *or analyses involved in the regulatory decisions;*
 20 *and*

21 “(ii) *who are independent of the agency;*

22 “(B) *be governed by agency standards and prac-*
 23 *tices governing conflicts of interest of nongovern-*
 24 *mental agency advisors;*

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

3 “(D) contain a balanced presentation of all con-
4 siderations, including minority reports and an agen-
5 cy response to all significant peer review comments;
6 and

7 “(E) provide adequate protections for confiden-
8 tial business information and trade secrets, including
9 requiring panel members or participants to enter into
10 confidentiality agreements.

11 “(2) Each agency shall provide a written response to
12 all significant peer review comments. All peer review com-
13 ments and any responses shall be made—

14 “(A) available to the public; and

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

17 “(3) If the head of an agency, with the concurrence
18 of the Director, publishes a determination in the rule mak-
19 ing file that a cost-benefit analysis or risk assessment, or
20 any component thereof, has been previously subjected to ade-
21 quate peer review, no further peer review shall be required
22 under this section for such analysis, assessment, or compo-
23 nent.

24 “(c) For each peer review conducted by an agency
25 under this section, the agency head shall include in the rule

1 *making record a statement by a Federal officer or employee*
 2 *who is not an employee of the agency rule making office*
 3 *or program—*

4 “(1) *whether the peer review participants reflect*
 5 *the independence and expertise required under sub-*
 6 *section (b)(1)(A); and*

7 “(2) *whether the agency has adequately re-*
 8 *sponded to the peer review comments as required*
 9 *under subsection (b)(2).*

10 “(d) *The peer review required by this section shall not*
 11 *be subject to the Federal Advisory Committee Act (5 U.S.C.*
 12 *App.).*

13 **“§ 626. Deadlines for rule making**

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

18 “(1) *the date on which the requirements of this*
 19 *subchapter are satisfied; or*

20 “(2) *the date occurring 6 months after the date*
 21 *of the applicable deadline.*

22 “(b) *In any proceeding involving a deadline imposed*
 23 *by a court of the United States that requires an agency*
 24 *to propose or promulgate any major rule during the 2-year*
 25 *period beginning on the effective date of this section, the*

1 *United States shall request, and the court may grant, an*
 2 *extension of such deadline until the earlier of—*

3 “(1) *the date on which the requirements of this*
 4 *subchapter are satisfied; or*

5 “(2) *the date occurring 6 months after the date*
 6 *of the applicable deadline.*

7 “(c) *In any case in which the failure to promulgate*
 8 *a major rule by a deadline occurring during the 2-year pe-*
 9 *riod beginning on the effective date of this section would*
 10 *create an obligation to regulate through individual adju-*
 11 *dications, the deadline shall be suspended until the earlier*
 12 *of—*

13 “(1) *the date on which the requirements of this*
 14 *subchapter are satisfied; or*

15 “(2) *the date occurring 6 months after the date*
 16 *of the applicable deadline.*

17 **“§ 627. Judicial review**

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

20 “(1) *in connection with review of final agency*
 21 *action;*

22 “(2) *in accordance with this section; and*

23 “(3) *in accordance with the limitations on tim-*
 24 *ing, venue, and scope of review imposed by the statute*
 25 *authorizing judicial review.*

1 “(b) *Any determination of an agency whether a rule*
2 *is a major rule under section 621(7)(A) shall be set aside*
3 *by a reviewing court only upon a showing that the deter-*
4 *mination is arbitrary or capricious.*

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

8 “(d) *The cost-benefit analysis, cost-benefit determina-*
9 *tion under section 623(d), and any risk assessment required*
10 *under this subchapter shall not be subject to judicial review*
11 *separate from review of the final rule to which such analysis*
12 *or assessment applies. The cost-benefit analysis, cost-benefit*
13 *determination under section 623(d), and any risk assess-*
14 *ment shall be part of the rule making record and shall be*
15 *considered by a court to the extent relevant, only in deter-*
16 *mining whether the final rule is arbitrary, capricious, an*
17 *abuse of discretion, or is unsupported by substantial evi-*
18 *dence where that standard is otherwise provided by law.*

19 “(e) *If an agency fails to perform the cost-benefit anal-*
20 *ysis, cost-benefit determination, or risk assessment, or to*
21 *provide for peer review, a court shall remand or invalidate*
22 *the rule.*

1 **“§ 628. Guidelines, interagency coordination, and re-**
 2 **search**

3 “(a)(1) *No later than 9 months after the date of enact-*
 4 *ment of this section, the Director, in consultation with the*
 5 *Council of Economic Advisors, the Director of the Office of*
 6 *Science and Technology Policy, and relevant agency heads,*
 7 *shall issue guidelines for cost-benefit analyses, risk assess-*
 8 *ments, and peer reviews as required by this subchapter. The*
 9 *Director shall oversee and periodically revise such guide-*
 10 *lines as appropriate.*

11 “(2) *As soon as practicable and no later than 18*
 12 *months after issuance of the guidelines required under para-*
 13 *graph (1), each agency subject to section 624 shall adopt*
 14 *detailed guidelines for risk assessments as required by this*
 15 *subchapter. Such guidelines shall be consistent with the*
 16 *guidelines issued under paragraph (1). Each agency shall*
 17 *periodically revise such agency guidelines as appropriate.*

18 “(3) *The guidelines under this subsection shall be de-*
 19 *veloped following notice and public comment. The develop-*
 20 *ment and issuance of the guidelines shall not be subject to*
 21 *judicial review, except in accordance with section 706(1)*
 22 *of this title.*

23 “(b) *To promote the use of cost-benefit analysis and*
 24 *risk assessment in a consistent manner and to identify*
 25 *agency research and training needs, the Director, in con-*
 26 *sultation with the Council of Economic Advisors and the*

1 *Director of the Office of Science and Technology Policy,*
 2 *shall—*

3 “(1) *oversee periodic evaluations of Federal*
 4 *agency cost-benefit analysis and risk assessment;*

5 “(2) *provide advice and recommendations to the*
 6 *President and Congress to improve agency use of cost-*
 7 *benefit analysis and risk assessment;*

8 “(3) *utilize appropriate interagency mechanisms*
 9 *to improve the consistency and quality of cost-benefit*
 10 *analysis and risk assessment among Federal agencies;*
 11 *and*

12 “(4) *utilize appropriate mechanisms between*
 13 *Federal and State agencies to improve cooperation in*
 14 *the development and application of cost-benefit analy-*
 15 *sis and risk assessment.*

16 “(c)(1) *The Director, in consultation with the head of*
 17 *each agency, the Council of Economic Advisors, and the Di-*
 18 *rector of the Office of Science and Technology Policy, shall*
 19 *periodically evaluate and develop a strategy to meet agency*
 20 *needs for research and training in cost-benefit analysis and*
 21 *risk assessment, including research on modelling, the devel-*
 22 *opment of generic data, use of assumptions and the identi-*
 23 *fication and quantification of uncertainty and variability.*

24 “(2)(A) *No later than 6 months after the date of enact-*
 25 *ment of this section, the Director, in consultation with the*

1 *Director of the Office of Science and Technology Policy,*
 2 *shall enter a contract with an accredited scientific institu-*
 3 *tion to conduct research to—*

4 “(i) *develop a common basis to assist risk com-*
 5 *munication related to both carcinogens and non-*
 6 *carcinogens; and*

7 “(ii) *develop methods to appropriately incor-*
 8 *porate risk assessments into related cost-benefit analy-*
 9 *ses.*

10 “(B) *No later than 24 months after the date of enact-*
 11 *ment of this section, the results of the research conducted*
 12 *under this paragraph shall be submitted to the Director and*
 13 *Congress.*

14 **“§ 629. Risk based priorities study**

15 “(a) *No later than 1 year after the date of enactment*
 16 *of this section, the Director, in consultation with the Direc-*
 17 *tor of the Office of Science and Technology Policy, shall*
 18 *enter into a contract with an accredited scientific institu-*
 19 *tion to conduct a study that provides—*

20 “(1) *a systematic comparison of the extent and*
 21 *severity of significant risks to human health, safety,*
 22 *or the environment (hereafter referred to as a com-*
 23 *parative risk analysis);*

24 “(2) *a study of methodologies for using compara-*
 25 *tive risk analysis to compare dissimilar risks to*

1 *human health, safety, or the environment, including*
2 *development of a common basis to assist comparative*
3 *risk analysis related to both carcinogens and non-*
4 *carcinogens; and*

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

8 *“(b) The Director shall ensure that the study required*
9 *under subsection (a) is—*

10 *“(1) conducted through an open process provid-*
11 *ing peer review consistent with section 625 and op-*
12 *portunities for public comment and participation;*
13 *and*

14 *“(2) no later than 3 years after the date of enact-*
15 *ment of this section, completed and submitted to Con-*
16 *gress and the President.*

17 *“(c) No later than 4 years after the date of enactment*
18 *of this section, each relevant agency shall, as appropriate,*
19 *use the results of the study required under subsection (a)*
20 *to inform the agency in the preparation of the agency’s an-*
21 *nual budget and strategic plan and performance plan under*
22 *section 306 of this title and sections 1115, 1116, 1117, 1118,*
23 *and 1119 of title 31.*

24 *“(d) No later than 5 years after the date of enactment*
25 *of this section, and periodically thereafter, the President*

1 *shall submit a report to Congress recommending legislative*
 2 *changes to assist in setting priorities to more effectively and*
 3 *efficiently reduce risks to human health, safety, or the envi-*
 4 *ronment.*

5 **“SUBCHAPTER III—REVIEW OF RULES**

6 **“§ 631. Definitions**

7 *“For purposes of this subchapter—*

8 *“(1) the definitions under section 551 shall*
 9 *apply; and*

10 *“(2) the term ‘economically significant rule’*
 11 *means a rule that—*

12 *“(A) is likely to have an annual effect on*
 13 *the economy of \$100,000,000 or more in reason-*
 14 *ably quantifiable costs; or*

15 *“(B) is likely to adversely affect, in a mate-*
 16 *rial way, the economy, a sector of the economy,*
 17 *including small business, productivity, competi-*
 18 *tion, jobs, the environment, public health or safe-*
 19 *ty, or State, local or tribal governments, or com-*
 20 *munities.*

21 **“§ 632. Review of rules**

22 *“(a)(1) No later than 1 year after the date of enact-*
 23 *ment of this section (and no later than every 5th year fol-*
 24 *lowing the year in which this section takes effect) each agen-*
 25 *cy shall publish in the Federal Register a preliminary*

1 *schedule for the review of economically significant rules pre-*
 2 *viously promulgated by the agency. The preliminary sched-*
 3 *ule shall be subject to public comment for 60 days after the*
 4 *date of publication. Within 120 days after the close of the*
 5 *public comment period, each agency shall publish a final*
 6 *schedule in the Federal Register.*

7 “(2) *In selecting which economically significant rules*
 8 *it shall review, each agency shall consider the extent to*
 9 *which—*

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

13 “(B) *the rule is important relative to other rules*
 14 *being considered for review; and*

15 “(C) *the agency has discretion under the statute*
 16 *authorizing the rule to modify or repeal the rule.*

17 “(3) *Each preliminary and final schedule shall in-*
 18 *clude—*

19 “(A) *a brief description of each rule selected for*
 20 *review;*

21 “(B) *a brief explanation of the reasons for the se-*
 22 *lection of each such rule for review; and*

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

1 5 years after the date of publication of the final
2 schedule.

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

8 “(5)(A) If an agency makes a determination to amend
9 or repeal a rule, the agency shall complete final agency ac-
10 tion with regard to such rule no later than 2 years after
11 the deadline established for such rule under paragraph (3).

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

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

16 “(ii) publishes in the Federal Register such find-
17 ing and a succinct explanation of the reasons for the
18 finding.

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

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

4 “(2) *Consultation with representatives of State, local,*
 5 *and tribal governments shall be governed by the process es-*
 6 *tablished under section 204 of the Unfunded Mandates Re-*
 7 *form Act of 1995 (2 U.S.C. 1534).*

8 “SUBCHAPTER IV—EXECUTIVE OVERSIGHT

9 “§ 641. **Definitions**

10 “*For purposes of this subchapter—*

11 “(1) *the definitions under sections 551 and 621*
 12 *shall apply; and*

13 “(2) *the term ‘regulatory action’ means any one*
 14 *of the following:*

15 “(A) *Advance notice of proposed rule mak-*
 16 *ing.*

17 “(B) *Notice of proposed rule making.*

18 “(C) *Final rule making, including interim*
 19 *final rule making.*

20 “§ 642. **Presidential regulatory review**

21 “(a) *The President shall establish a process for the re-*
 22 *view and coordination of Federal agency regulatory actions.*
 23 *Such process shall be the responsibility of the Director.*

24 “(b) *For the purpose of carrying out subsection (a),*
 25 *the Director shall—*

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

5 “(2) develop policies and procedures for the re-
6 view of regulatory actions by the Director; and

7 “(3) develop and oversee an annual government-
8 wide regulatory planning process that shall include
9 review of planned significant regulatory actions and
10 publication of—

11 “(A) a summary of and schedule for pro-
12 mulgation of planned agency major rules;

13 “(B) agency specific schedules for review of
14 existing rules under subchapter III and section
15 610;

16 “(C) a summary of regulatory review ac-
17 tions undertaken in the prior year;

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

22 “(E) identification of significant agency
23 noncompliance with this chapter in the prior
24 year; and

1 “(F) recommendations for improving com-
 2 pliance with this chapter and increasing the effi-
 3 ciency and effectiveness of the regulatory process.

4 “(c)(1) The review established under subsection (a)
 5 shall be conducted as expeditiously as practicable and shall
 6 be limited to no more than 90 days.

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

12 **“§ 643. Public disclosure of information**

13 “(a) The Director, in carrying out the provisions of
 14 section 642, shall establish procedures to provide public and
 15 agency access to information concerning review of regu-
 16 latory actions under this subchapter, including—

17 “(1) disclosure to the public on an ongoing basis
 18 of information regarding the status of regulatory ac-
 19 tions undergoing review;

20 “(2) disclosure to the public, no later than publi-
 21 cation of a regulatory action, of—

22 “(A) all written communications relating to
 23 the substance of a regulatory action, including
 24 drafts of all proposals and associated analyses,

1 *between the Administrator or employees of the*
2 *Administrator and the regulatory agency;*

3 “(B) *all written communications relating to*
4 *the substance of a regulatory action between the*
5 *Administrator or employees of the Administrator*
6 *and any person not employed by the executive*
7 *branch of the Federal Government;*

8 “(C) *a list identifying the dates, names of*
9 *individuals involved, and subject matter dis-*
10 *cussed in substantive meetings and telephone*
11 *conversations relating to the substance of a regu-*
12 *latory action between the Administrator or em-*
13 *ployees of the Administrator and any person not*
14 *employed by the executive branch of the Federal*
15 *Government; and*

16 “(D) *a written explanation of any review*
17 *action and the date of such action; and*

18 “(3) *disclosure to the regulatory agency, on a*
19 *timely basis, of—*

20 “(A) *all written communications relating to*
21 *the substance of a regulatory action between the*
22 *Administrator or employees of the Administrator*
23 *and any person not employed by the executive*
24 *branch of the Federal Government;*

1 “(B) a list identifying the dates, names of
2 individuals involved, and subject matter dis-
3 cussed in substantive meetings and telephone
4 conversations, relating to the substance of a regu-
5 latory action between the Administrator or em-
6 ployees of the Administrator and any person not
7 employed by the executive branch of the Federal
8 Government; and

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

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

14 “(1) a document identifying in a complete, clear,
15 and simple manner, the substantive changes between
16 the draft submitted to the Administrator for review
17 and the rule subsequently announced;

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

23 “(3) all written communications relating to the
24 substance of a regulatory action between the Adminis-
25 trator and the agency during the review of the rule,

1 including drafts of all proposals and associated anal-
 2 yses.

3 “(c) *In any meeting relating to the substance of a regu-*
 4 *latory action under review between the Administrator or*
 5 *employees of the Administrator and any person not em-*
 6 *ployed by the executive branch of the Federal Government,*
 7 *a representative of the agency submitting the regulatory ac-*
 8 *tion shall be invited.*

9 **“§ 644. Judicial review**

10 *“The exercise of the authority granted under this sub-*
 11 *chapter by the President, the Director, or the Administrator*
 12 *shall not be subject to judicial review in any manner.”.*

13 (b) *PERIODIC REVIEW OF RULES.—Section 610 of title*
 14 *5, United States Code, is amended—*

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

17 “(a)(1)(A) *No later than 60 days after the effective*
 18 *date of this section (and every fifth year following the year*
 19 *in which this section takes effect) each agency shall submit*
 20 *to the Administrator of the Office of Information and Regu-*
 21 *latory Affairs and the Chief Counsel for Advocacy of the*
 22 *Small Business Administration a proposed plan describing*
 23 *the procedures and timetables for the periodic review of*
 24 *rules issued by the agency that have or will have a signifi-*
 25 *cant economic impact on a substantial number of small en-*

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

6 “(B) *No later than 120 days after the publication of*
 7 *the plan under subparagraph (A), each agency shall submit*
 8 *a final plan to the Administrator and the Chief Counsel.*
 9 *No later than 60 days after the date of such submission*
 10 *of the plan to the Administrator and Chief Counsel, each*
 11 *agency shall publish the agency’s final plan in the Federal*
 12 *Register.*

13 “(C) *Each agency’s plan shall provide for the review*
 14 *of such rules no later than 5 years after publication of the*
 15 *final plan.*

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

19 “(B) *The publication of the list under subparagraph*
 20 *(A) shall include—*

21 “(i) *a brief description of each rule and the basis*
 22 *for the agency’s determination that the rule has or*
 23 *will have a significant economic impact on a substan-*
 24 *tial number of small entities;*

1 “(ii) *the need for and legal basis of each rule;*
2 *and*

3 “(iii) *an invitation for public comment on each*
4 *rule.*

5 “(3)(A) *Each agency shall conduct a review of each*
6 *rule on the list published under paragraph (2) in accord-*
7 *ance with the plan maintained under paragraph (1) and*
8 *pursuant to the factors under subsection (b). After the com-*
9 *pletion of the review, the agency shall determine whether*
10 *the rule should be continued without change, or should be*
11 *amended or rescinded, consistent with the stated objectives*
12 *of the applicable statutes, to minimize any significant eco-*
13 *nomie impact of the rule upon a substantial number of*
14 *small entities.*

15 “(B) *No later than 18 months after the date of the pub-*
16 *lication of the list of rules referred to under paragraph*
17 *(2)(A), each agency shall publish in the Federal Register*
18 *the determinations made with respect to such rules under*
19 *subparagraph (A) and an explanation for each determina-*
20 *tion.*

21 “(4) *If the head of an agency determines that the com-*
22 *pletion of a review of a rule under this subsection is not*
23 *feasible within the period described under paragraph*
24 *(1)(C), the head of the agency—*

1 “(A) shall certify such determination in a state-
2 ment published in the Federal Register; and

3 “(B) may extend the completion date of the re-
4 view by 1 year at a time for a total of not more than
5 2 years.”; and

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

8 “(c) The Administrator and the Chief Counsel shall
9 work with small entities to achieve the objectives of this sec-
10 tion.”.

11 (c) *PRESIDENTIAL AUTHORITY.*—Nothing in this Act
12 shall limit the exercise by the President of the authority
13 and responsibility that the President otherwise possesses
14 under the Constitution and other laws of the United States
15 with respect to regulatory policies, procedures, and pro-
16 grams of departments, agencies, and offices.

17 (d) *TECHNICAL AND CONFORMING AMENDMENTS.*—

18 (1) Part I of title 5, United States Code, is
19 amended by striking the chapter heading and table of
20 sections for chapter 6 and inserting the following:

21 **“CHAPTER 6—THE ANALYSIS OF**
22 **REGULATORY FUNCTIONS**

 “SUBCHAPTER I—ANALYSIS OF REGULATORY FLEXIBILITY

 “Sec.

 “601. Definitions.

 “602. Regulatory agenda.

 “603. Initial regulatory flexibility analysis.

 “604. Final regulatory flexibility analysis.

- “605. *Avoidance of duplicative or unnecessary analyses.*
- “606. *Effect on other law.*
- “607. *Preparation of analysis.*
- “608. *Procedure for waiver or delay of completion.*
- “609. *Procedures for gathering comments.*
- “610. *Periodic review of rules.*
- “611. *Judicial review.*
- “612. *Reports and intervention rights.*

“SUBCHAPTER II—REGULATORY ANALYSIS

- “621. *Definitions.*
- “622. *Applicability and effect.*
- “623. *Regulatory analysis.*
- “624. *Principles for risk assessments.*
- “625. *Peer review.*
- “626. *Deadlines for rule making.*
- “627. *Judicial review.*
- “628. *Guidelines, interagency coordination, and research.*
- “629. *Risk based priorities study.*

“SUBCHAPTER III—REVIEW OF RULES

- “631. *Definitions.*
- “632. *Review of rules.*

“SUBCHAPTER IV—EXECUTIVE OVERSIGHT

- “641. *Definitions.*
- “642. *Presidential regulatory review.*
- “643. *Public disclosure of information.*
- “644. *Judicial review.”.*

1 (2) *Chapter 6 of title 5, United States Code, is*
 2 *amended by inserting immediately before section 601,*
 3 *the following subchapter heading:*

4 “*SUBCHAPTER I—ANALYSIS OF REGULATORY*
 5 *FLEXIBILITY”.*

6 **SEC. 4. COMPLIANCE WITH THE UNFUNDED MANDATES RE-**
 7 **FORM ACT OF 1995.**

8 *Compliance with the requirements of subchapter II of*
 9 *chapter 6 of title 5, United States Code (as added by section*
 10 *3 of this Act), shall constitute compliance with the require-*
 11 *ments pertaining to the costs and benefits of a Federal man-*

1 *date to the private sector in sections 202, 205(a)(2), and*
2 *208 of the Unfunded Mandates Reform Act of 1995 (2*
3 *U.S.C. 1532, 1535(a)(2), and 1538).*

4 **SEC. 5. EFFECTIVE DATE.**

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