

Calendar No. 117

104TH CONGRESS
1ST SESSION

S. 291

[Report No. 104-88]

A BILL

To reform the regulatory process, to make Government more efficient and effective, and for other purposes.

May 25 (legislative day, May 15), 1995

Reported with an amendment

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To reform the regulatory process, to make Government more efficient and effective, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 27 (legislative day, JANUARY 10), 1995

Mr. ROTH introduced the following bill; which was read twice and referred to the Committee on Governmental Affairs

MAY 25 (legislative day, MAY 15), 1995

Reported by Mr. ROTH, with an amendment

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

A BILL

To reform the regulatory process, to make Government more efficient and effective, and for other purposes.

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 Reform Act
5 of 1995”.

1 **SEC. 2. TABLE OF CONTENTS.**

2 The table of contents for this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of Contents.

TITLE I—REGULATORY ANALYSIS AND REVIEW

- Sec. 101. Cost/benefit analysis of agency proposals; risk assessment; regulatory review
- Sec. 102. Use of State or local requirements.
- Sec. 103. Presidential authority.

TITLE II—RISK-BASED PRIORITIES

- Sec. 201. Short title.
- Sec. 202. Purposes.
- Sec. 203. Definitions.
- Sec. 204. Department and agency program goals.
- Sec. 205. Comparative risk analysis.
- Sec. 206. Reports and recommendations to Congress and the President.
- Sec. 207. Savings provision and judicial review.

TITLE III—REGULATORY ACCOUNTING

- Sec. 301. Short title.
- Sec. 302. Accounting statement.
- Sec. 303. Associated report to Congress.
- Sec. 304. Guidance from Office of Management and Budget.
- Sec. 305. Recommendations from Congressional Budget Office.
- Sec. 306. Definitions.

TITLE IV—MARKET INCENTIVES AND ECONOMICALLY EFFICIENT REGULATION

- Sec. 401. Short title.
- Sec. 402. Program design requirements.
- Sec. 403. Agency assessment and OMB review.
- Sec. 404. Definitions.

3 **TITLE I—REGULATORY ANALYSIS AND**
 4 **REVIEW**

5 **SEC. 101. COST/BENEFIT ANALYSIS OF AGENCY PROPOS-**
 6 **ALS; RISK ASSESSMENT; REGULATORY RE-**
 7 **VIEW.**

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

1 **“Subchapter II—Analysis of Agency**
2 **Proposals**

3 **“§ 621. Definitions**

4 “For purposes of this subchapter and subchapter III
5 of this chapter:

6 “(1) The term ‘agency’ has the same meaning
7 as in section 551(1) of this title.

8 “(2) The term ‘person’ has the same meaning
9 as in section 551(2) of this title.

10 “(3) The term ‘rule’ has the same meaning as
11 in section 551(4) of this title, except that such term
12 does not include—

13 “(A) a rule of particular applicability that
14 approves or prescribes for the future rates,
15 wages, prices, services, or allowances therefor,
16 corporate or financial structures, reorganiza-
17 tions, mergers or acquisitions, or accounting
18 practices or disclosures bearing on any of the
19 foregoing;

20 “(B) a rule relating to monetary policy
21 proposed or promulgated by the Board of Gov-
22 ernors of the Federal Reserve System; or

23 “(C) a rule issued by the Federal Election
24 Commission or a rule issued by the Federal
25 Communications Commission pursuant to sec-

1 tions 315 and 312(a)(7) of the Communications
2 Act of 1934.

3 ~~“(4) The term ‘major rule’ means—~~

4 ~~“(A) a rule or a group of closely related~~
5 ~~rules that the agency, the President, or the offi-~~
6 ~~cer selected under section 624 of this title rea-~~
7 ~~sonably determines is likely to have an annual~~
8 ~~effect in the economy of \$100,000,000 or more~~
9 ~~in reasonably quantifiable direct and indirect~~
10 ~~costs, or has a significant impact on a subsector~~
11 ~~of the economy; and~~

12 ~~“(B) a rule or a group of closely related~~
13 ~~rules that is otherwise designated a major rule~~
14 ~~by the agency proposing the rule, or is so des-~~
15 ~~ignated by the President, or by the officer se-~~
16 ~~lected under section 624 of this title, on the~~
17 ~~ground that the rule is likely to result in—~~

18 ~~“(i) a substantial increase in costs or~~
19 ~~prices for wage earners, consumers, indi-~~
20 ~~vidual industries, nonprofit organizations,~~
21 ~~Federal, State, or local government agen-~~
22 ~~cies, or geographic regions; or~~

23 ~~“(ii) significant adverse effects on~~
24 ~~wages, economic growth, investment, pro-~~
25 ~~ductivity, innovation, the environment,~~

1 public health or safety, or the ability of en-
2 terprises whose principal places of business
3 are in the United States to compete in do-
4 mestic or export markets. For purposes of
5 subparagraph (A) of this paragraph, the
6 term ‘rule’ does not mean—

7 “(I) a rule that involves the in-
8 ternal revenue laws of the United
9 States;

10 “(II) a rule that authorizes the
11 introduction into commerce or recog-
12 nizes the marketable status of a prod-
13 uct, pursuant to sections 408, 409(c),
14 and 706 of the Federal Food, Drug,
15 and Cosmetic Act;

16 “(III) a rule exempt from notice
17 and public procedure pursuant to sec-
18 tion 553(a) of this title; or

19 “(IV) a rule relating to the via-
20 bility, stability, asset powers, or cat-
21 egories of accounts of, or permissible
22 interest rate ceilings applicable to, de-
23 pository institutions the deposits or
24 accounts of which are insured by the
25 Federal Deposit Insurance Corpora-

1 tion, or the Share Insurance Fund of
2 the National Credit Union Adminis-
3 tration Board.

4 “(5) The term ‘benefit’ means the reasonably
5 identifiable significant benefits and beneficial effects,
6 including social and economic benefits and effects,
7 that are expected to result directly or indirectly from
8 implementation of a rule or an alternative to a rule.

9 “(6) The term ‘cost’ means the reasonably iden-
10 tifiable significant costs and adverse effects, includ-
11 ing economic and social costs and effects, that are
12 expected to result directly or indirectly from imple-
13 mentation of a rule or an alternative to a rule.

14 **“§ 622. Regulatory cost/benefit analysis**

15 “(a) Prior to publishing notice of proposed rule-
16 making for any rule, each agency shall determine whether
17 the rule is or is not a major rule within the meaning of
18 section 621(4)(A) of this title and, if it is not, whether
19 it should be designated a major rule under section
20 621(4)(B) of this title. For the purpose of any such deter-
21 mination or designation, a group of closely related rules
22 shall be considered as one rule. Every notice of proposed
23 rulemaking shall include a succinct statement and expla-
24 nation of the agency’s determination of whether or not the
25 rule is a major rule within the meaning of section

1 621(4)(A) of this title and, if applicable, of its designation
2 as a major rule under section 621(4)(B) of this title.

3 “(b) The President or the officer selected by the
4 President under section 624 of this title may determine
5 that a rule is a major rule within the meaning of section
6 621(4)(A) of this title or may designate a rule as a major
7 rule under section 621(4)(B) of this title not later than
8 thirty days after the publication of the notice of proposed
9 rulemaking for that rule. Such determination or designa-
10 tion shall be published in the Federal Register, together
11 with a succinct statement of the basis for the determina-
12 tion or designation. The President or the officer selected
13 by the President under section 624 of this title may des-
14 ignate not more than seventy-five rules as major rules
15 under section 621(4)(B) of this title in any fiscal year.

16 “(c)(1) When the agency publishes a notice of pro-
17 posed rulemaking for a major rule, the agency shall issue
18 and place in the rulemaking file maintained under section
19 553(f) of this title a preliminary regulatory analysis and
20 shall include in such notice of proposed rulemaking a sum-
21 mary of the analysis. When the President or the officer
22 selected by the President under section 624 of this title
23 has published a determination or designation that a rule
24 is a major rule after the publication of the notice of pro-
25 posed rulemaking for that rule, the agency shall promptly

1 issue and place in the rulemaking file maintained under
2 section 553(f) of this title a preliminary regulatory analy-
3 sis for the rule and shall publish in the Federal Register
4 a summary of such analysis. Following the issuance of a
5 preliminary regulatory analysis under the preceding sen-
6 tence, the agency shall give interested persons an oppor-
7 tunity to comment thereon pursuant to section 553 of this
8 title in the same manner as if the preliminary regulatory
9 analysis had been issued with the notice of proposed rule-
10 making.

11 “(2) Each preliminary regulatory analysis shall con-
12 tain—

13 “(A) a succinct description of the benefit of the
14 proposed rule, including any beneficial effects that
15 cannot be quantified, and an explanation of how the
16 agency anticipates each benefit will be achieved by
17 the proposed rule, including a description of the per-
18 sons, classes of persons, or particular levels of Gov-
19 ernment likely to receive such benefits;

20 “(B) a succinct description of the costs of the
21 proposed rule, including any costs that cannot be
22 quantified as well as the cost-reduction effects of
23 complying with the requirements of title IV, and an
24 explanation of how the agency anticipates each such
25 cost will result from the proposed rule, including a

1 description of the persons, classes of persons, or par-
2 ticular levels of Government likely to incur such
3 costs;

4 “(C) a succinct description of reasonable alter-
5 natives for achieving the identified benefits of the
6 proposed rule, including alternatives that—

7 “(i) require no Government action;

8 “(ii) will accommodate differences between
9 geographic regions; and

10 “(iii) employ performance or other
11 marketbased standards which permit the great-
12 est flexibility in achieving the identified benefits
13 of the proposed rule and which comply with the
14 requirements of title IV;

15 “(D) in any case in which the proposed rule is
16 based on scientific evaluations or information, a de-
17 scription of action undertaken by the agency to ver-
18 ify the quality, reliability, and relevance of such sci-
19 entific evaluations or scientific information in ac-
20 cordance with the requirements of title IV; and

21 “(E) where it is not expressly or by necessary
22 implication inconsistent with the provisions of the
23 enabling statute pursuant to which the agency is
24 proposing the rule, an explanation of how the identi-
25 fied benefits of the proposed rule are likely to justify

1 the identified costs of the proposed rule, and an ex-
2 planation of how the proposed rule is likely to sub-
3 stantially achieve the rulemaking objectives in a
4 more cost-effective manner than the alternatives to
5 the proposed rule, including alternatives identified in
6 accordance with title IV.

7 “(d)(1) When the agency publishes a final major rule,
8 the agency shall also issue and place in the rulemaking
9 file maintained under section 553(f) of this title a final
10 regulatory analysis, and shall include a summary of the
11 analysis in the statement of basis and purpose required
12 by section 553(e)(6) of this title. Notwithstanding the pre-
13 ceding sentence, in any case in which an agency, under
14 section 553(b)(2) of this title, is not required to comply
15 with subsections (b) through (f) of section 553 of this title
16 prior to the adoption of a final rule, an agency is not re-
17 quired to comply with the preceding sentence prior to the
18 adoption of the final rule but shall comply with such
19 sentence when complying with section 553(b)(2)(C) of this
20 title.

21 “(2) Each final regulatory analysis shall contain—
22 “(A) a description and comparison of the bene-
23 fits and costs of the rule and of the reasonable alter-
24 natives to the rule described in the rulemaking, in-

1 including the market-based mechanisms identified pur-
2 suant to title IV; and

3 ~~“(B) where it is not expressly or by necessary~~
4 ~~implication inconsistent with the provisions of the~~
5 ~~enabling statute pursuant to which the agency is~~
6 ~~acting, a reasonable determination, based upon the~~
7 ~~rulemaking file considered as a whole, that the bene-~~
8 ~~fits of the rule justify the costs of the rule, and that~~
9 ~~the rule will substantially achieve the rulemaking ob-~~
10 ~~jectives in a more cost-effective manner than the al-~~
11 ~~ternatives described in the rulemaking, including the~~
12 ~~market-based incentives identified pursuant to title~~
13 ~~IV.~~

14 ~~“(e)(1) An agency shall describe the nature and ex-~~
15 ~~tent of the nonqualifiable benefits and costs of a proposed~~
16 ~~and a final rule pursuant to this section in as precise and~~
17 ~~succinet a manner as possible. The description of the bene-~~
18 ~~fits and costs of a proposed and a final rule required under~~
19 ~~this section shall include a quantification or numerical es-~~
20 ~~timate of the quantifiable benefits and costs. Such quan-~~
21 ~~tification or numerical estimate shall be made in the most~~
22 ~~appropriate unit of measurement and shall specify the~~
23 ~~ranges of predictions and explain the margins of error in-~~
24 ~~volved in the quantification methods and in the estimates~~
25 ~~used.~~

1 “(2) In evaluating and comparing costs and benefits,
2 the agency shall not rely on cost or benefit information
3 submitted by any person that is not accompanied by data,
4 analysis, or other supporting materials that would enable
5 the agency and other persons interested in the rulemaking
6 to assess the accuracy and reliability of such information.
7 The agency evaluations of the relationships of the benefits
8 of a proposed and final rule to its costs required by this
9 section shall be clearly articulated in accordance with the
10 provisions of this section. An agency is not required to
11 make such evaluation primarily on a mathematical or nu-
12 merical basis.

13 “(f) The preparation of the preliminary or final regu-
14 latory analysis required by this section shall only be per-
15 formed by an officer or employee of the agency. The provi-
16 sions of the preceding sentence do not preclude a person
17 outside the agency from gathering data or information to
18 be used by the agency in preparing any such regulatory
19 analysis or from providing an explanation sufficient to per-
20 mit the agency to analyze such data or information. If any
21 such data or information is gathered or explained by a
22 person outside the agency, the agency shall specifically
23 identify in the preliminary or final regulatory analysis the
24 data or information gathered or explained and the person
25 who gathered or explained it, and shall describe the ar-

1 rangement by which the information was procured by the
2 agency, including the total amount of funds expended for
3 such procurement.

4 “(g) The requirements of this section do not alter the
5 criteria for rulemaking otherwise applicable under other
6 statutes.

7 **“§ 623. Judicial review**

8 “(a) Compliance or noncompliance by an agency with
9 the provisions of this subchapter shall not be subject to
10 judicial review except according to the provisions of this
11 section.

12 “(b) Any determination by the President or by the
13 officer selected under section 624 of this title that a rule
14 is a major rule within the meaning of section 621(4)(A)
15 of this title, and any designation by the President or the
16 officer selected under section 624 of this title that a rule
17 is a major rule under section 621(4)(B) of this title, or
18 any failure to make such a designation, shall not be sub-
19 ject to judicial review in any manner.

20 “(c) The determination of an agency of whether a
21 rule is or is not a major rule within the meaning of section
22 621(4)(A) of this title shall be set aside by a reviewing
23 court only upon a clear and convincing showing that the
24 determination is erroneous in light of the information
25 available to the agency at the time it made the determina-

1 tion. Any designation by an agency that a rule is a major
2 rule under section 621(4)(B) of this title, or any failure
3 to make such a designation, shall not be subject to judicial
4 review.

5 “(d) Any regulatory analysis prepared under section
6 622 of this title shall not be subject to judicial consider-
7 ation separate or apart from review of the rule to which
8 it relates. When an action for judicial review of a rule is
9 instituted, any regulatory analysis for such rule shall con-
10 stitute part of the whole rulemaking record of agency ac-
11 tion for the purpose of judicial review of the rule and shall,
12 to the extent relevant, be considered by a court in deter-
13 mining the legality of the rule.

14 **“§ 624. Executive oversight**

15 “(a) The President shall have the authority to estab-
16 lish procedures for agency compliance with this title and
17 titles II, III, and IV of this Act. The President shall have
18 the authority to monitor, review, and ensure agency imple-
19 mentation of such procedures. The President shall report
20 annually to the Congress on agency compliance or non-
21 compliance with the requirements of this chapter.

22 “(b) Any procedures established pursuant to the au-
23 thority granted under subsection (a) of this section shall
24 be adopted after the public has been afforded an oppor-
25 tunity to comment thereon, and shall be consistent with

1 the prompt completion of rulemaking proceedings. If such
2 procedures include review of preliminary or final regu-
3 latory analyses to ensure that they comply with the proce-
4 dures established pursuant to subsection (a), the time for
5 any such review of a preliminary regulatory analysis shall
6 not exceed thirty days following the receipt of that analysis
7 by the President or by an officer to whom the authority
8 granted under subsection (a) of this section has been dele-
9 gated pursuant to subsection (c) of this section, and the
10 time for such review of a final regulatory analysis shall
11 not exceed thirty days following the receipt of that analysis
12 by the President or such officer. The times for each such
13 review may be extended for good cause by the President
14 or such officer for an additional thirty days. Notice of any
15 such extension, together with a succinct statement of the
16 reasons therefor, shall be inserted in the rulemaking file.

17 “(c) The President may delegate the authority grant-
18 ed by this Act to the Vice President or to an officer within
19 the Executive Office of the President whose appointment
20 has been subject to the advice and consent of the Senate.
21 Any such notice with respect to a delegation to the Vice
22 President shall contain a statement by the Vice President
23 that the Vice President will make every reasonable effort
24 to respond to congressional inquiries concerning the exer-
25 cise of the authority delegated under this subsection. No-

1 tice of any such delegation, or any revocation or modifica-
2 tion thereof, shall be published in the Federal Register.

3 “(d) The authority granted under subsection (a) of
4 this section and title II shall not apply to rules issued by
5 the Nuclear Regulatory Commission.

6 “(e) Any exercise of the authority granted under this
7 section, or any failure to exercise such authority, by the
8 President or by an officer to whom such authority has
9 been delegated under subsection (c) of this section, shall
10 not be subject to judicial review in any manner under this
11 Act.

12 **“Subchapter III—Risk Assessments**

13 **“§ 631. Findings, purposes, and definitions**

14 “(a) FINDINGS.—The Congress finds that:

15 “(1) Environmental, health, and safety regula-
16 tions have lead to dramatic improvements in the en-
17 vironment and have significantly reduced risks to
18 human health; however, many regulations have been
19 more costly and less effective than they could have
20 been; too often, regulatory priorities have not been
21 based upon a realistic consideration of risk, risk re-
22 duction opportunities, and costs.

23 “(2) The public and private resources available
24 to address health, safety, and environmental risks
25 are not unlimited; those resources should be allo-

1 cated to address the greatest needs in the most cost-
2 effective manner and to ensure that the incremental
3 costs of regulatory options are reasonably related to
4 the incremental benefits.

5 “(3) To provide more cost-effective protection
6 to human health and the environment, regulatory
7 priorities should be based upon realistic consider-
8 ation of risk; the priority-setting process must in-
9 clude scientifically sound, objective, and unbiased
10 risk assessments and risk management choices that
11 are grounded in cost/benefit principles.

12 “(4) Risk assessment has proved to be a useful
13 decisionmaking tool; however, improvements are
14 needed in both the quality of assessments and the
15 characterization and communication of findings; sci-
16 entific and other data must be better collected, orga-
17 nized, and evaluated; most importantly, the critical
18 information resulting from a risk assessment must
19 be effectively communicated in an objective and un-
20 biased manner to decision makers, and from decision
21 makers to the public.

22 “(5) The public stakeholders must be fully in-
23 volved in the decisionmaking process for regulating
24 risks. The public has the right to know about the
25 risks addressed by regulation, the amount of risk re-

1 duced, the quality of the science used to support de-
2 cisions, and the cost of implementing and complying
3 with regulations. This knowledge will allow for pub-
4 lic scrutiny and will promote the quality, integrity,
5 and responsiveness of agency decisions.

6 “(b) PURPOSES.—The purposes of this subchapter
7 are—

8 “(1) to present the public and executive branch
9 with the most scientifically objective and unbiased
10 information concerning the nature and magnitude of
11 health, safety, and environmental risks to promote
12 sound regulatory decisions and public education;

13 “(2) to provide for full consideration and dis-
14 cussion of relevant data and potential methodologies;

15 “(3) to require explanation of significant
16 choices in the risk assessment process that will allow
17 for better public understanding; and

18 “(4) to improve consistency within the executive
19 branch in preparing risk assessments and risk char-
20 acterizations.

21 “(c) DEFINITIONS.—For purposes of this subchapter:

22 “(1) BEST ESTIMATE.—The term ‘best esti-
23 mate’ means an estimate that, to the extent feasible
24 and scientifically appropriate, is based on one of the
25 following:

1 “(A) Central estimates of risk using the
2 most plausible assumptions.

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

6 “(C) Any other methodology designed to
7 provide the most unbiased representation of the
8 most plausible level of risk, given the current
9 scientific information available to the Federal
10 agency concerned.

11 “(2) COVERED AGENCY.—The term ‘covered
12 agency’ means each of the following:

13 “(A) The Environmental Protection Agen-
14 ey.

15 “(B) The Department of Labor.

16 “(C) The Food and Drug Administration.

17 “(D) The Consumer Product Safety Com-
18 mission.

19 “(E) The Department of Transportation.

20 “(F) The Department of Energy.

21 “(G) The Department of Agriculture.

22 “(H) The Department of the Interior.

23 “(I) The Nuclear Regulatory Commission.

1 “(3) EMERGENCY.—The term ‘emergency’
2 means an imminent and substantial endangerment
3 to public health, safety, or the environment.

4 “(4) HAZARD IDENTIFICATION.—The term
5 ‘hazard identification’ means identification of a sub-
6 stance, activity, or condition as potentially posing a
7 risk to human health or safety or the environment
8 based on empirical data, measurements, or testing
9 showing that it has caused significant adverse effects
10 at some levels of dose or exposure not necessarily
11 relevant to level of dose or exposure that are nor-
12 mally expected to occur.

13 “(5) RISK ASSESSMENT.—The term ‘risk as-
14 sessment’ means—

15 “(A) the process of identifying hazards and
16 quantifying or describing the degree of toxicity,
17 exposure, or other risk they pose for exposed
18 individuals, populations, or resources; and

19 “(B) the document containing the expla-
20 nation of how the assessment process has been
21 applied to an individual substance, activity, or
22 condition.

23 “(6) RISK CHARACTERIZATION.—The term ‘risk
24 characterization’ means—

1 “(A) the element of a risk assessment that
2 involves presentation of the degree of risk in
3 any regulatory proposal or decision, report to
4 Congress, or other document that is made avail-
5 able to the public; and

6 “(B) includes discussions of uncertainties,
7 conflicting data, estimates, extrapolations, in-
8 ferences, and opinions.

9 “(7) **SUBSTITUTION RISK.**—The term ‘substi-
10 tution risk’ means a potential increased risk to
11 human health, safety, or the environment from a
12 regulatory option designed to decrease other risks.

13 **“§ 632. Applicability**

14 “(a) **IN GENERAL.**—Except as otherwise provided in
15 subsection (b), this title shall apply to all risk assessments
16 and risk characterizations prepared by, or on behalf of,
17 or prepared by others and adopted by any covered agency
18 in connection with health, safety, and environmental risks.

19 “(b) **EXCEPTIONS.**—

20 “(1) **IN GENERAL.**—This title shall not apply to
21 risk assessments or risk characterizations performed
22 with respect to—

23 “(A) a situation that the head of the agen-
24 cy considers to be an emergency; or

1 ~~“(B)~~ a screening analysis, including a
2 screening analysis for the purposes of product
3 registration, product reregistrations, or
4 premanufacturing notices.

5 ~~“(2)~~ TREATMENT OF ANALYSIS AS SCREENING
6 ANALYSIS.—An analysis shall not be treated as a
7 screening analysis for the purposes of paragraph
8 ~~(1)(B)~~ if the result of the analysis is used—

9 ~~“(A)~~ as the basis for imposing a restriction
10 on a substance or activity; or

11 ~~“(B)~~ to characterize a positive finding of
12 risks from a substance, product, or activity in
13 any agency document or other communication
14 made available to the general public, the media,
15 or Congress.

16 ~~“(3)~~ LABELS.—This title shall not apply to any
17 food, drug, or other product label or to any risk
18 characterization appearing on any such label.

19 **~~“§ 633. Savings provisions~~**

20 ~~“Nothing in this title shall be construed to—~~

21 ~~“(1)~~ modify any statutory standard or require-
22 ment designed to protect human health, safety, or
23 the environment;

24 ~~“(2)~~ preclude the consideration of any data or
25 the calculation of any estimate to more fully describe

1 risk or provide examples of scientific uncertainty or
2 variability; or

3 ~~“(3) require the disclosure of any trade secrets~~
4 ~~or other confidential information.~~

5 **“§ 634. Requirement to prepare risk assessments**

6 ~~“Except as provided in subsection 632(b), the Presi-~~
7 ~~dent shall require that the head of each covered agency~~
8 ~~prepare for each major rule relating to human health,~~
9 ~~safety, or the environment that is proposed by the agency~~
10 ~~after the date of enactment of this title—~~

11 ~~“(1) a risk assessment in accordance with this~~
12 ~~title; and~~

13 ~~“(2) for each such proposed or final rule, an as-~~
14 ~~essment of incremental risk reduction or other ben-~~
15 ~~efits associated with each significant regulatory al-~~
16 ~~ternative considered by the agency in connection~~
17 ~~with the rule or proposed rule.~~

18 **“§ 635. Principles for risk assessment**

19 ~~“(a) IN GENERAL.—The head of each covered agency~~
20 ~~shall ensure that risk assessments and all of their compo-~~
21 ~~nents—~~

22 ~~“(1) distinguish scientific findings and best es-~~
23 ~~timates of risk from other considerations;~~

24 ~~“(2) are, to the maximum extent practicable,~~
25 ~~unbiased and inclusive of all reliable information and~~

1 employ default assumptions only if situation-specific
2 information is not reasonably available;

3 ~~“(3) rely on scientific findings of risk;~~

4 ~~“(4) result in the most plausible and realistic~~
5 ~~estimates feasible for the population, or, if only~~
6 ~~bounds can be estimated reliably, describe the range~~
7 ~~encompassed; and~~

8 ~~“(5) are tailored so that the degree of specific-~~
9 ~~ity and rigor employed is commensurate with the~~
10 ~~consequences of the decision to be made.~~

11 ~~“(b) HAZARD IDENTIFICATION AND RISK CHARAC-~~
12 ~~TERIZATION.—A risk assessment shall clearly separate~~
13 ~~hazard identification from risk characterization and make~~
14 ~~clear the relationship between the level of risk and the~~
15 ~~level of exposure to a hazard.~~

16 **“§ 636. Principles for risk characterization and risk**
17 **communication**

18 ~~“In characterizing risk in any risk assessment docu-~~
19 ~~ment, regulatory proposal or decision each covered agency~~
20 ~~shall include in the risk characterization each of the fol-~~
21 ~~lowing:~~

22 ~~“(1) ESTIMATES OF RISK.—~~

23 ~~“(A) SUBJECT.—A description of the pop-~~
24 ~~ulations or natural resources that are the sub-~~
25 ~~ject of the risk characterization.~~

1 “(B) ASSUMPTIONS, INFERENCES, AND
2 MODELS.—When a risk assessment involves a
3 choice of any significant assumption, inference,
4 or model, the covered agency or instrumentality
5 preparing the risk assessment shall—

6 “(i) present a representative list and
7 explanation of plausible and alternative as-
8 sumptions, inferences, or models;

9 “(ii) explain the basis for any choices;

10 “(iii) identify any subjective policy de-
11 cisions or value judgments; and

12 “(iv) indicate the extent to which any
13 significant model has been validated by, or
14 conflicts with, empirical data.

15 “(C) UNCERTAINTY.—The major uncer-
16 tainties in the risk assessment.

17 “(D) EXPOSURE SCENARIOS.—Information
18 about exposure scenarios used, including the
19 likelihood of those scenarios.

20 “(E) RISK RANGE.—To the extent feasible,
21 a range of risk estimates, including central esti-
22 mates, for each exposure scenario.

23 “(F) SCIENTIFIC FINDINGS AND POLICY
24 DECISIONS.—To the extent feasible, each risk

1 characterization should distinguish between sci-
2 entific findings and policy decisions.

3 ~~“(2) SUBSTITUTION RISKS.—When a covered~~
4 ~~agency provides a risk assessment or risk character-~~
5 ~~ization for a proposed or final regulatory action,~~
6 ~~such assessment or characterization shall include a~~
7 ~~statement of any significant substitution risks, when~~
8 ~~information on such risks has been provided to the~~
9 ~~agency.~~

10 ~~“(3) SUMMARIES OF OTHER RISK ESTI-~~
11 ~~MATES.—If—~~

12 ~~“(A) a covered agency provides a public~~
13 ~~comment period with respect to a risk assess-~~
14 ~~ment or regulation;~~

15 ~~“(B) a commenter provides a risk assess-~~
16 ~~ment, and a summary of results of such risk as-~~
17 ~~essment; and~~

18 ~~“(C) such risk assessment is consistent~~
19 ~~with the principles and the guidance provided~~
20 ~~under this subtitle,~~

21 the covered agency shall present such summary in
22 connection with its presentation of the risk assess-
23 ment or regulation.

1 **“§ 637. Guidelines, plan for assessing new informa-**
2 **tion, and report**

3 ~~“(a) GUIDELINES.—~~

4 ~~“(1) IN GENERAL.—~~Within fifteen months after
5 the date of enactment of this title, each covered
6 agency shall issue, after notice and public comment,
7 guidelines to implement the risk assessment and risk
8 characterization principles set forth in sections 635
9 and 636 and shall provide a format for summarizing
10 risk assessment results.

11 ~~“(2) MATTERS TO BE ADDRESSED.—~~The guide-
12 lines under paragraph (1) shall—

13 ~~“(A) include guidance on utilization of spe-~~
14 ~~cific technical methodologies and standards for~~
15 ~~acceptable quality of specific kinds of data; and~~

16 ~~“(B) address important decisional factors~~
17 ~~for the risk assessment or risk characterization~~
18 ~~at issue, such as criteria for scaling animal~~
19 ~~studies to assess risk to human health; use of~~
20 ~~different types of dose-response models; thresh-~~
21 ~~olds; definitions, use, and interpretations of the~~
22 ~~maximum tolerated dose; weighing of evidence~~
23 ~~with respect to extrapolating human health~~
24 ~~risks from sensitive species; evaluation of be-~~
25 ~~nign tumors; and evaluation of differences in~~
26 ~~human health endpoints, where relevant.~~

1 “(b) PLAN.—

2 “(1) IN GENERAL.—Within eighteen months
3 after the date of enactment of this title, the head of
4 each covered agency shall publish a plan to review
5 and revise any risk assessment published prior to
6 the expiration of such eighteen-month period if the
7 covered agency determines that significant new in-
8 formation or methodologies are available that could
9 significantly alter the results of the prior risk assess-
10 ment.

11 “(2) CONTENTS.—A plan under paragraph (1)
12 shall—

13 “(A) provide procedures for receiving and
14 considering new information and risk assess-
15 ments from the public; and

16 “(B) set priorities for review and revision
17 of risk assessments based on such factors as
18 the agency head considers appropriate.

19 “(c) REPORT.—Within three years after the enact-
20 ment of this title, each covered agency shall provide a re-
21 port to the Congress evaluating the categories of policy
22 and value judgments identified under subparagraph
23 (B)(iii) of section 636(1).

24 “(d) PUBLIC COMMENT AND CONSULTATION.—The
25 guidelines, plan and report under this section shall be de-

1 veloped after notice and opportunity for public comment,
2 and after consultation with representatives of appropriate
3 State agencies and local governments, and such other de-
4 partments and agencies, organizations, or persons as may
5 be advisable.

6 “(e) REVIEW.—The President shall review the guide-
7 lines published under this section at least every four years.

8 “(f) LIMITATION ON JUDICIAL REVIEW.—The devel-
9 opment, issuance, and publication of risk assessment and
10 risk characterization guidelines under this section shall
11 not be subject to judicial review.

12 **“§ 638. Risk management criteria**

13 “For each major rule subject to this title, the head
14 of the agency or the President shall make a determination
15 that—

16 “(1) the risk assessment under section 634(1)
17 and the analysis under section 634(2) are based on
18 a scientific evaluation of the risk addressed by the
19 major rule and are supported by the best available
20 scientific data; and

21 “(2) there is no regulatory alternative that is
22 allowed by the statute under which the regulation is
23 promulgated that would achieve an equivalent reduc-
24 tion in risk in a more cost-effective and flexible man-
25 ner.

1 **“§ 639. Interagency coordination**

2 “To promote the conduct, application, and practice
3 of risk assessment in a consistent manner and to identify
4 risk assessment data and research needs common to more
5 than one Federal agency, the Director of the Office of
6 Science and Technology Policy shall—

7 “(1) periodically survey the manner in which
8 each Federal agency involved in risk assessment is
9 conducting such risk assessment to determine the
10 scope and adequacy of risk assessment practices in
11 use by the Federal Government;

12 “(2) provide advice and recommendations to the
13 President and Congress based on the surveys con-
14 ducted and determinations made under paragraph
15 (1);

16 “(3) establish appropriate interagency mecha-
17 nisms to promote coordination among Federal agen-
18 cies conducting risk assessment with respect to the
19 conduct, application, and practice of risk assessment
20 and to promote the use of state-of-the-art risk as-
21 sessment practices throughout the Federal Govern-
22 ment;

23 “(4) establish appropriate mechanisms between
24 Federal and State agencies to communicate state-of-
25 the-art risk assessment practices; and

1 ~~“(5) periodically convene meetings with State~~
 2 ~~government representatives and Federal and other~~
 3 ~~leaders to assess the effectiveness of Federal-State~~
 4 ~~cooperation in the development and application of~~
 5 ~~risk assessment.~~

6 **~~“Subchapter IV—Regulatory Priorities and~~**
 7 **~~Review~~**

8 **~~“§ 641. Review of agency rules~~**

9 ~~“(a)(1)(A) Not later than nine months after the ef-~~
 10 ~~fective date of this section, each agency shall prepare and~~
 11 ~~publish in the Federal Register a proposed schedule for~~
 12 ~~the review, in accordance with this section, of—~~

13 ~~“(i) each rule of the agency which is in effect~~
 14 ~~on such effective date and which, if adopted on such~~
 15 ~~effective date, would be a major rule under section~~
 16 ~~621(4)(A) of this title, and~~

17 ~~“(ii) each rule of the agency in effect on such~~
 18 ~~effective date (in addition to the rules described in~~
 19 ~~clause (i)) which the agency has selected for review.~~

20 ~~“(B) Each proposed schedule required by subpara-~~
 21 ~~graph (A) shall include—~~

22 ~~“(i) a brief explanation of the reasons the agen-~~
 23 ~~cy considers each rule on the schedule to be such a~~
 24 ~~major rule under section 621(a)(4)(A) of this title or~~

1 of the reasons why the agency selected the rule for
2 review;

3 ~~“(ii) a date set by the agency, in accordance~~
4 ~~with the provisions of subsection (b)(1) of this sec-~~
5 ~~tion, for the completion of the review of each such~~
6 ~~rule; and~~

7 ~~“(iii) a statement that the agency requests com-~~
8 ~~ments from the public on the proposed schedule.~~

9 ~~“(C) The agency shall set a date to initiate review~~
10 ~~of each rule on the schedule in a manner which will ensure~~
11 ~~the simultaneous review of related items and which will~~
12 ~~achieve a reasonable distribution of reviews over the period~~
13 ~~of time covered by the schedule.~~

14 ~~“(2) At least ninety days before publishing in the~~
15 ~~Federal Register the proposed schedule required under~~
16 ~~paragraph (1), each agency shall make the proposed~~
17 ~~schedule available to the President, or to the Vice Presi-~~
18 ~~dent or other officer to whom oversight authority has been~~
19 ~~delegated under section 624(b) of this title. The President~~
20 ~~or that officer may select for review in accordance with~~
21 ~~this section any additional rule that the President or such~~
22 ~~officer determines to be a major rule under section~~
23 ~~621(4)(A) of this title.~~

24 ~~“(3) Not later than one year after the effective date~~
25 ~~of this section, each agency shall publish in the Federal~~

1 Register a final schedule for the review of the rules re-
2 ferred to in paragraphs (1) and (2) of this subsection.
3 Each agency shall publish with the final schedule the re-
4 sponse of the agency to comments received concerning the
5 proposed schedule.

6 “(b)(1) Except where explicitly provided otherwise by
7 statute, the agency shall, pursuant to subsections (c)
8 through (e) of this section, review—

9 “(A) each rule on the schedule promulgated
10 pursuant to subsection (a) of this section;

11 “(B) each major rule under section 621(4) of
12 this title promulgated, amended, or otherwise re-
13 newed by an agency after the date of the enactment
14 of this section; and

15 “(C) each rule promulgated after the date of
16 enactment of this section which the President or the
17 officer designated by the President pursuant to sub-
18 section (a)(2) of this section determines to be a
19 major rule under section 621(4) of this title.

20 Except where an extension has been granted pursuant to
21 subsection (f) of this section, the review of a rule required
22 by this section shall be completed within ten years after
23 the effective date of this section or within ten years after
24 the date on which the rule is promulgated, amended, or
25 renewed, whichever is later.

1 ~~“(2) A rule required to be reviewed under the preced-~~
2 ~~ing subsection on grounds that it is major need not be~~
3 ~~reviewed if the agency determines that such rule, if adopt-~~
4 ~~ed at the time of the planned review, would not be major~~
5 ~~under the definition previously applied to it. When the~~
6 ~~agency makes such a determination, it shall publish a no-~~
7 ~~tice and explanation of the determination in the Federal~~
8 ~~Register.~~

9 ~~“(c) An agency shall publish in the Federal Register~~
10 ~~a notice of its proposed action under this section with re-~~
11 ~~spect to a rule being reviewed. The notice shall include—~~

12 ~~“(1) an identification of the specific statutory~~
13 ~~authority under which the rule was promulgated and~~
14 ~~a statement specifying the agency’s determination of~~
15 ~~whether the rule continues to fulfill the intent of~~
16 ~~Congress in enacting that authority;~~

17 ~~“(2) an assessment of the benefits and costs of~~
18 ~~the rule during the period in which it has been in~~
19 ~~effect;~~

20 ~~“(3) an explanation of the proposed agency ac-~~
21 ~~tion with respect to the rule; and~~

22 ~~“(4) a statement that the agency seeks propos-~~
23 ~~als from the public for modifications or alternatives~~
24 ~~to the rule which may accomplish the objectives of~~
25 ~~the rule in a more effective or less burdensome man-~~

1 ner, including alternatives developed in accordance
2 with the provisions of title IV of this bill.

3 ~~“(d) If an agency proposes to repeal or amend a rule
4 under review pursuant to this section, the agency shall,
5 after issuing the notice required by subsection (c) of this
6 section, comply with the provisions of this chapter and
7 chapter 5 of this title or other applicable law. The require-
8 ments of such provisions and related requirements of law
9 shall apply to the same extent and in the same manner
10 as in the case of a proposed agency action to repeal or
11 amend a rule which is not taken pursuant to the review
12 required by this section.~~

13 ~~“(e) If an agency proposed to renew without amend-
14 ment a rule under review pursuant to this section, the
15 agency shall—~~

16 ~~“(1) give interested persons not less than sixty
17 days after the publication of the notice required by
18 subsection (c) of this section to comment on the pro-
19 posed renewal; and~~

20 ~~“(2) publish in the Federal Register notice of
21 the renewal of such rule and an explanation of the
22 continued need for the rule, and, if the renewed rule
23 is a major rule under section 621(4) of this title, in-
24 clude with such notice an explanation of the reason-
25 able determination of the agency that the rule com-~~

1 plies with the provisions of section 622(d)(2)(B) of
2 this title.

3 ~~“(f)(1) Any agency, which for good cause finds com-~~
4 ~~pliance with this section with respect to a particular rule~~
5 ~~to be impracticable during the period provided in sub-~~
6 ~~section (b) of this section, may request the President, or~~
7 ~~the officer designated by the President pursuant to sub-~~
8 ~~section (a)(2) of this section, to establish a period longer~~
9 ~~than ten years for the completion of the review of such~~
10 ~~rule. The President or that officer may extend the period~~
11 ~~for review of a rule to a total period of not more than~~
12 ~~fifteen years. Such extension shall be published in the~~
13 ~~Federal Register with an explanation of the reasons there-~~
14 ~~for.~~

15 ~~“(2) An agency may, with the concurrence of the~~
16 ~~President or the officer designated by the President pursu-~~
17 ~~ant to subsection (a)(2) of this section, or shall, at the~~
18 ~~direction of the President or that officer, alter the timing~~
19 ~~of review of rules under any schedule required by this sec-~~
20 ~~tion for the review of rules if an explanation of such alter-~~
21 ~~ation is published in the Federal Register at the time such~~
22 ~~alteration is made.~~

23 ~~“(g) In any case in which an agency has not com-~~
24 ~~pleted the review of a rule within the period prescribed~~
25 ~~by subsection (b) or (f) of this section, the agency shall~~

1 immediately publish in the Federal Register a notice pro-
2 posing to amend, repeal, or renew the rule under sub-
3 section (e) of this section, and shall complete proceedings
4 pursuant to subsection (d) or (e) of this section within
5 one hundred and eighty days of the date on which the re-
6 view was required to be completed under subsection (b)
7 or (f) of this section.

8 “(h)(1) Agency compliance or noncompliance with the
9 provisions of subsection (a) of this section shall not be
10 subject to judicial review in any manner.

11 “(2) Agency compliance or noncompliance with the
12 provisions of subsections (b), (c), (e), (f) and (g) of this
13 section shall be subject to judicial review only pursuant
14 to section 706(a)(1) of this title.

15 “(i) Nothing in this section shall relieve any agency
16 from its obligation to respond to a petition to issue,
17 amend, or repeal a rule, for an interpretation regarding
18 the meaning of a rule, or for a variance or exemption from
19 the terms of a rule, submitted pursuant to section 553(e)
20 of this title.

21 **§ 642. Regulatory agenda and calendar**

22 “(a) Each agency shall publish in the Federal Reg-
23 ister in April and October of each year an agenda of the
24 rules that the agency expects to propose, promulgate,
25 renew, or repeal in the succeeding twelve months. For

1 each such rule, the agenda shall contain, at a minimum,
2 and in addition to any other information required by
3 law—

4 “(1) a general description of the rule, including
5 a citation to the authority under which the action
6 with respect to the rule is to be taken, or a specific
7 explanation of the congressional intent to which the
8 objectives of rule respond;

9 “(2) a statement of whether or not the rule is
10 or is expected to be a major rule;

11 “(3) an approximate schedule of the significant
12 dates on which the agency will take action relating
13 to the rule, including the dates for any notice of pro-
14 posed rulemaking, hearing, and final action on the
15 rule;

16 “(4) the name, address, and telephone number
17 of an agency official responsible for answering ques-
18 tions from the public concerning the rule;

19 “(5) a statement specifying whether each rule
20 listed on the previous agenda has been published as
21 a proposed rule, has been published as a final rule,
22 has become effective, has been repealed, or is pend-
23 ing in some other status; and

1 ~~“(6) a cumulative summary of the status of the~~
2 ~~rules listed on the previous agenda in accordance~~
3 ~~with clause (5) of this subsection.~~

4 ~~“(b) The President or an officer in the Executive Of-~~
5 ~~fice of the President whose appointment has been subject~~
6 ~~to the advice and consent of the Senate shall publish in~~
7 ~~the Federal Register in May and November of each year~~
8 ~~a Calendar of Federal Regulations listing each of the~~
9 ~~major rules identified in the regulatory agendas published~~
10 ~~by agencies in the preceding month. Each rule listed in~~
11 ~~the calendar shall be accompanied by a summary of the~~
12 ~~information relating to the rule that appeared in the most~~
13 ~~recent regulatory agenda in which the rule was identified.~~

14 ~~“(c) An agency may propose or promulgate a major~~
15 ~~rule that was not listed in the regulatory agenda required~~
16 ~~by subsection (a) of this section only if the agency pub-~~
17 ~~lishes with the rule an explanation of the omission of the~~
18 ~~rule from such agenda and otherwise complies with this~~
19 ~~section with respect to that rule.~~

20 ~~“(d) Any compliance or noncompliance by the agency~~
21 ~~with the provisions of this section shall not be subject to~~
22 ~~judicial review.~~

23 ~~“§ 643. Establishment of deadlines~~

24 ~~“(a)(1) Whenever any agency publishes a notice of~~
25 ~~proposed rulemaking pursuant to section 553 of this title,~~

1 the agency shall include in such notice an announcement
2 of the date by which it intends to complete final agency
3 action on the rule.

4 “(2) If any agency announcement under this section
5 indicates that the proceeding relating to such rule will re-
6 quire more than one year to complete, the agency shall
7 also indicate in the announcement the date by which the
8 agency intends to complete each major portion of that pro-
9 ceeding. In carrying out the requirements of this sub-
10 section, the agency shall select dates for completing agen-
11 cy action which will assure the most expeditious consider-
12 ation of the rule which is possible, consistent with the in-
13 terests of fairness and other agency priorities.

14 “(3) The requirements of this subsection shall not
15 apply to any rule on which the agency intends to complete
16 action within one hundred and twenty days after providing
17 notice of the proposed action.

18 “(b) If an agency fails to complete action in a pro-
19 ceeding, or a major portion of the proceeding, by the date
20 announced pursuant to subsection (a) of this section, or,
21 in the case of a proceeding described in paragraph (3) of
22 such subsection, if an agency fails to complete action with-
23 in one hundred and twenty days after providing notice of
24 such proposed action, and the expected delay in complet-
25 ing action will exceed thirty days, the agency shall prompt-

1 ly announce the new date by which the agency intends to
 2 complete action in such proceeding and new dates by
 3 which the agency intends to complete action on each major
 4 portion of the proceeding.

5 “(c) Compliance or noncompliance by an agency with
 6 the provisions of this section shall not be subject to judi-
 7 cial review except in accordance with subsection (d).

8 “(d) In determining whether to compel agency action
 9 unreasonably delayed pursuant to section 706(a)(1) of this
 10 title, the reviewing court shall consider, in addition to any
 11 other relevant factors, the extent to which the agency has
 12 failed to comply with this section.”.

13 (b) TECHNICAL AND CONFORMING AMENDMENTS.—
 14 Part I of title 5, United States Code, is amended by strik-
 15 ing out the chapter heading and table of sections for chap-
 16 ter 6 and inserting in lieu thereof the following:

“CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS

“SUBCHAPTER I—REGULATORY ANALYSIS

“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 analyses.

“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—ANALYSIS OF AGENCY PROPOSALS

“621. Definitions.

- “622. Regulatory cost/benefit analysis.
- “623. Judicial review.
- “624. Executive oversight.

“SUBCHAPTER III—RISK ASSESSMENTS

- “631. Findings, purposes, and definitions.
- “632. Applicability.
- “633. Savings provisions.
- “634. Requirement to prepare risk assessments.
- “635. Principles for risk assessment.
- “636. Principles for risk characterization and risk communication.
- “637. Guidelines, plan for assessing new information, and report.
- “638. Risk management criteria.
- “639. Interagency coordination.

“SUBCHAPTER IV—REGULATORY PRIORITIES AND REVIEW

- “641. Review of agency rules.
- “642. Regulatory agenda and calendar.
- “643. Establishment of deadlines.”.

1 **SEC. 102. USE OF STATE OR LOCAL REQUIREMENTS.**

2 (a) IN GENERAL.—Subchapter II of chapter 5 of title
3 5, United States Code, is amended by adding at the end
4 thereof the following new section:

5 **“§ 560. Use of duplicative State or local requirements**

6 “(a) Except as otherwise provided by law, the head
7 of each Federal agency is authorized, in the administra-
8 tion of a Federal statute with respect to any State or local-
9 ity, to adopt as a Federal rule a regulation of that State
10 or local government or use as a Federal recordkeeping or
11 reporting requirement or implementation procedure a rec-
12 ordkeeping or reporting requirement or implementation
13 procedure of that State or locality if the head of the agen-
14 cy determines—

15 “(1) that such State or local government regu-
16 lation, implementation procedure, recordkeeping re-

1 requirement, or reporting requirement duplicates a
2 Federal regulation, procedure, recordkeeping re-
3 quirement, or reporting requirement; and

4 “(2) that such State or local government regu-
5 lation, implementation procedure, recordkeeping re-
6 quirement, or reporting requirement is substantively
7 equivalent to or more stringent than the Federal
8 regulation, procedure, recordkeeping requirement, or
9 reporting requirement.

10 “(b) When the head of an agency determines to use
11 a State or local recordkeeping or reporting requirement
12 or implementation procedure, as a Federal recordkeeping
13 or reporting requirement, or implementation procedure in
14 that State or locality, the head of the agency shall prepare
15 at a minimum, a written statement of the reasons for any
16 determination made under subsection (a), and shall make
17 such statement available to the public.

18 “(c) This section does not limit the authority or re-
19 sponsibility of the head of any agency to enforce Federal
20 law.”.

21 (b) RULEMAKING.—Section 551 of title 5, United
22 States Code, is amended by inserting the following be-
23 tween “rule” and the semicolon: “; or the adoption of a
24 rule pursuant to section 561 of this title”.

1 (c) TABLE OF SECTIONS.—The table of sections for
 2 chapter 5 of such title is amended by inserting after the
 3 item relating to section 559 the following new item:

“560. Use of duplicative State or local requirements.”.

4 **SEC. 103. PRESIDENTIAL AUTHORITY.**

5 Nothing in this Act (i) limits the exercise by the
 6 President of the authority and responsibility that he other-
 7 wise possesses under the Constitution and other laws of
 8 the United States with respect to regulatory policies, pro-
 9 cedures, and programs of departments, agencies, and of-
 10 fices, or (ii) alters in any manner rulemaking authority
 11 vested by law in an agency to initiate or complete a rule-
 12 making proceeding, or to issue, modify, or rescind a rule.

13 **TITLE II—RISK-BASED PRIORITIES**

14 **SEC. 201. SHORT TITLE.**

15 This title may be cited as the “Risk Reduction Prior-
 16 ities Act of 1995”.

17 **SEC. 202. PURPOSES.**

18 It is the purposes of this title to—

19 (1) encourage Federal agencies engaged in reg-
 20 ulating risks to human health, safety, and the envi-
 21 ronment to achieve the greatest risk reduction at the
 22 least cost practical;

23 (2) promote the coordination of policies and
 24 programs to reduce risks to human health, safety,
 25 and the environment; and

1 ~~(3)~~ promote open communication among Fed-
2 eral agencies, the public, the President, and Con-
3 gress regarding environmental, health, and safety
4 risks, and the prevention and management of those
5 risks.

6 **SEC. 203. DEFINITIONS.**

7 For the purposes of this title:

8 ~~(1)~~ ~~COMPARATIVE RISK ANALYSIS.~~—The term
9 “comparative risk analysis” means a process to sys-
10 tematically estimate, compare, and rank the size and
11 severity of risks to provide a common basis for eval-
12 uating strategies for reducing or preventing those
13 risks.

14 ~~(2)~~ ~~COVERED AGENCY.~~—The term “covered
15 agency” means each of the following:

16 ~~(A)~~ The Environmental Protection Agency.

17 ~~(B)~~ The Department of Labor.

18 ~~(C)~~ The Food and Drug Administration.

19 ~~(D)~~ The Consumer Product Safety Com-
20 mission.

21 ~~(E)~~ The Department of Transportation.

22 ~~(F)~~ The Department of Energy.

23 ~~(G)~~ The Department of Agriculture.

24 ~~(H)~~ The Department of the Interior.

25 ~~(I)~~ The Nuclear Regulatory Commission.

1 (3) DIRECTOR.—The term “Director” means
2 the Director of the Office of Management and Budget.
3 et.

4 (4) EFFECT.—The term “effect” means a dele-
5 terious change in the condition—

6 (A) of a human or other living thing (in-
7 cluding death, cancer, or other chronic illness,
8 decreased reproductive capacity, or disfigure-
9 ment); or

10 (B) of an inanimate thing important to
11 human welfare (including destruction, degenera-
12 tion, the loss of intended function, and in-
13 creased costs for maintenance).

14 (5) IRREVERSIBILITY.—The term “irre-
15 versibility” means the extent to which a return to
16 conditions prior to the occurrence of an effect are ei-
17 ther very slow or will never occur.

18 (6) LIKELIHOOD.—The term “likelihood”
19 means the estimated probability that an effect will
20 occur.

21 (7) MAGNITUDE.—The term “magnitude”
22 means the number of individuals or the quantity of
23 ecological resources or other resources that contrib-
24 ute to human welfare that are affected by exposure
25 to a stressor.

1 (8) SERIOUSNESS.—The term “seriousness”
2 means the intensity of effect, the likelihood, the
3 irreversibility, and the magnitude.

4 **SEC. 204. DEPARTMENT AND AGENCY PROGRAM GOALS.**

5 (a) SETTING PRIORITIES.—In exercising authority
6 under applicable laws protecting human health, safety, or
7 the environment, the head of each covered agency should
8 strive to set priorities and to use the resources available
9 under those laws to address those risks to human health,
10 safety, and the environment that—

11 (1) the covered agency determines to be the
12 most serious; and

13 (2) can be addressed in a cost-effective manner,
14 with the goal of achieving the greatest overall net re-
15 duction in risks with the public and private sector
16 resources expended.

17 (b) DETERMINING THE MOST SERIOUS RISKS.—In
18 identifying the greatest risks under subsection (a) of this
19 section, each covered agency shall consider, at a mini-
20 mum—

21 (1) the likelihood, irreversibility, and severity of
22 the effect; and

23 (2) the number and groups of individuals poten-
24 tially affected, and shall explicitly take into account

1 the results of the comparative risk analysis con-
2 ducted under section 205 of this Act.

3 ~~(c) OMB REVIEW.~~—The covered agency’s determina-
4 tions of the sources of the most serious risks for purposes
5 of setting priorities shall be reviewed and approved by the
6 Director of the Office of Management and Budget prior
7 to submission of the covered agency’s annual budget re-
8 quests to Congress.

9 ~~(d) INCORPORATING RISK-BASED PRIORITIES INTO~~
10 ~~BUDGET AND PLANNING.~~—The head of each covered
11 agency shall incorporate the priorities identified in sub-
12 section (a) of this section into the agency budget, strategic
13 planning, regulatory agenda, enforcement, and research
14 activities by—

15 (1) in the covered agency’s annual budget re-
16 quest to Congress—

17 (A) identifying which risks that the cov-
18 ered agency head has determined are the most
19 serious and can be addressed in a cost-effective
20 manner under subsection (a) and the basis for
21 that determination;

22 (B) explicitly identifying how the covered
23 agency’s requested funds will be used to reduce
24 those risks, including the amount of funds re-
25 quested to address each of those risks; and

1 (C) identifying any statutory, regulatory,
2 or administrative obstacles to allocating agency
3 resources in accordance with the mandates of
4 subsection (a);

5 (2) explicitly considering the requirements of
6 subsection (a) and the results of the comparative
7 risk analysis prepared under section 205 of this title
8 when preparing the covered agency's regulatory
9 agenda or other covered agency strategic plan and
10 explaining how the agenda or plan reflects those re-
11 quirements and the comparative risk analysis when
12 publishing any such agenda or strategic plan;

13 (3) developing an annual enforcement strategic
14 plan that targets the priority risks identified under
15 subsection (a); and

16 (4) expressly considering the priority risks de-
17 termined under subsection (a) in selecting research
18 activities.

19 (c) **EFFECTIVE DATE.**—This section shall take effect
20 twelve months from the date of enactment of this title.

21 **SEC. 205. COMPARATIVE RISK ANALYSIS.**

22 (a) **REQUIREMENT.**—Within six months of the enact-
23 ment of this title, the Director of the Office of Manage-
24 ment and Budget shall enter into appropriate arrange-
25 ments with an accredited scientific body—

1 (1) to conduct a study of the methodologies for
2 using comparative risk to rank dissimilar human
3 health, safety, and environmental risks; and

4 (2) to conduct a comparative risk analysis. The
5 comparative risk analysis shall compare and rank, to
6 the extent feasible, human health, safety, and envi-
7 ronmental risks potentially regulated across the
8 spectrum of programs administered by all covered
9 agencies.

10 The Director shall consult with the Office of Science and
11 Technology Policy regarding the scope of the study and
12 the conduct of the comparative risk analysis.

13 (b) CRITERIA.—In arranging for the comparative risk
14 analysis referred to in subsection (a), the Director shall
15 ensure that—

16 (1) the scope and specificity of the analysis are
17 sufficient to provide the President and agency heads
18 guidance in allocating resources across agencies and
19 among programs in agencies to achieve the greatest
20 degree of risk prevention and reduction for the pub-
21 lic and private resources expended;

22 (2) the analysis is conducted through an open
23 process, which may include using panels of appro-
24 priate independent experts and public stakeholders;

1 (3) The methodologies and principal scientific
2 determinations made in the analysis are subjected to
3 independent and external peer review and that the
4 conclusions of the peer review are made publicly
5 available as part of the final report required by sub-
6 section (c);

7 (4) there is an opportunity for public comment
8 on the results prior to making them final; and

9 (5) the results are presented in a manner that
10 distinguishes between the scientific conclusions and
11 any policy or value judgments embodied in the com-
12 parisons.

13 (c) REPORT.—The comparative risk analysis required
14 by subsection (a) shall be completed and a report submit-
15 ted to Congress and the President no later than three
16 years following the enactment of this Act. The compara-
17 tive risk analysis shall be reviewed and revised at least
18 every five years thereafter for a minimum of fifteen years
19 following the release of the first analysis. The Director
20 shall arrange for such review and revision with an accred-
21 ited scientific body in the same manner as provided in sub-
22 sections (a) and (b) above.

23 (d) STUDY.—The study of methodologies provided in
24 subsection (a) shall be conducted as part of the first com-
25 parative risk analysis. The goal of the study shall be to

1 develop and rigorously test methods of comparative risk
2 analysis. The study shall have sufficient scope and breadth
3 to test approaches for improving comparative risk analysis
4 and its use in setting priorities for human health, safety,
5 and environmental risk prevention and reduction. As part
6 of its analysis, the study shall review and evaluate the ex-
7 perience of the States that have conducted comparative
8 risk analyses.

9 (e) REPORT.—Within one hundred and eighty days
10 after the completion of the study, the Director shall issue
11 a report of the study to the Congress, along with results
12 of a scientific peer review of the study.

13 (f) TECHNICAL GUIDANCE.—Not later than one hun-
14 dred and eighty days after the enactment of this Act, the
15 Director, in collaboration with other heads of covered
16 agencies shall enter into a contract with the National Re-
17 search Council to provide technical guidance to agencies
18 on approaches to using comparative risk analysis in set-
19 ting human health, safety, and environmental priorities to
20 assist agencies in complying with section 204 of this title.

21 **SEC. 206. REPORTS AND RECOMMENDATIONS TO CON-**
22 **GRESS AND THE PRESIDENT.**

23 (a) IN GENERAL.—In addition to the statement sub-
24 mitted to Congress with each covered agency's annual
25 budget request required under section 204(d)(1) of this

1 title, each covered agency shall submit a report to Con-
2 gress and the President twenty-four months following the
3 enactment of this legislation, and every twenty-four
4 months thereafter—

5 (1) detailing how the agency has complied with
6 section 204;

7 (2) describing the reasons for any departure
8 from the requirement to establish priorities to
9 achieve the greatest overall net reduction in risk;
10 and

11 (3) estimating the total public and private costs
12 of regulatory and voluntary risk reduction activities
13 under programs administered by the agency that
14 year, a comparison of that estimate with the pre-
15 vious year, and a projection for the following year.

16 (b) RECOMMENDATION.—In March of each year, the
17 head of each covered agency shall submit to Congress spe-
18 cific recommendations for—

19 (1) modifying, repealing, or enacting laws to re-
20 form, eliminate, or enhance programs or mandates
21 relating to human health, safety, and the environ-
22 ment; and

23 (2) modifying or eliminating statutorily or judi-
24 cially mandated deadlines,

1 that would assist the covered agency to set priorities in
2 its activities to address the risks to human health, safety,
3 and the environment that are the most serious and can
4 be addressed in a cost-effective manner consistent with the
5 requirements of section 204(a).

6 **SEC. 207. SAVINGS PROVISION AND JUDICIAL REVIEW.**

7 (1) **IN GENERAL.**—Nothing in this title shall be con-
8 strued to modify any statutory standard or requirement
9 designed to protect human health, safety, or the environ-
10 ment.

11 (2) **JUDICIAL REVIEW.**—Compliance or noncompli-
12 ance by an agency with the provisions of this title shall
13 not be subject to judicial review.

14 (3) **AGENCY ANALYSIS.**—Any analysis prepared
15 under this title shall not be subject to judicial consider-
16 ation separate or apart from the requirement, rule, pro-
17 gram, or law to which it relates. When an action for judi-
18 cial review of a covered agency action is instituted, any
19 analysis for, or relating to, the action shall constitute part
20 of the whole record of agency action for the purpose of
21 judicial review of the action and shall, to the extent rel-
22 evant, be considered by a court in determining the legality
23 of the covered agency action.

1 **TITLE III—REGULATORY ACCOUNTING**

2 **SEC. 301. SHORT TITLE**

3 This title may be cited as the “Regulatory Accounting
4 Act of 1995”.

5 **SEC. 302. ACCOUNTING STATEMENT**

6 (a) IN GENERAL.—

7 (1) RESPONSIBILITY FOR IMPLEMENTATION.—

8 The President shall be responsible for implementing
9 and administering the requirements of this title.

10 (2) ACCOUNTING STATEMENT.—Every two

11 years, not later than June of the second year, the
12 President shall prepare and submit to Congress an
13 accounting statement that estimates the costs of
14 Federal regulatory programs and corresponding ben-
15 efits in accordance with this section.

16 (b) YEARS COVERED BY ACCOUNTING STATE-

17 MENT.—Each accounting statement shall cover, at a mini-
18 mum, the five fiscal years beginning on October 1 of the
19 year in which the report is submitted and may cover any
20 fiscal year preceding such fiscal years for purpose of revis-
21 ing previous estimates.

22 (c) TIMING AND PROCEDURES.—

23 (1) NOTICE AND COMMENT.—The President
24 shall provide notice and opportunity for comment for
25 each accounting statement. The President may dele-

1 gate to an agency the requirement to provide notice
2 and opportunity to comment for the portion of the
3 accounting statement relating to that agency.

4 (2) DEADLINES FOR FIRST STATEMENT.—The
5 President shall propose the first accounting state-
6 ment under this section not later than two years
7 after the date of the enactment of this Act and shall
8 issue the first accounting statement in final form
9 not later than three years after the date of the en-
10 actment of this Act. Such statement shall cover, at
11 a minimum, each of the eight fiscal years beginning
12 after the date of the enactment of this Act.

13 (d) CONTENT OF ACCOUNTING STATEMENT.—

14 (1) IN GENERAL.—Each accounting statement
15 shall contain estimates of costs and benefits with re-
16 spect to each fiscal year covered by the statement in
17 accordance with this subsection. For each such fiscal
18 year for which estimates were made in a previous ac-
19 counting statement, the statement shall revise those
20 estimates and state the reasons for the revisions.

21 (2) STATEMENT OF COSTS.—

22 (A) IN GENERAL.—An accounting state-
23 ment shall estimate the costs of Federal regu-
24 latory programs by setting forth, for each year
25 covered by the statement—

1 (i) the annual expenditure of national
2 economic resources for the regulatory pro-
3 gram; and

4 (ii) such other quantitative and quali-
5 tative measures of costs as the President
6 considers appropriate.

7 (B) NATIONAL ECONOMIC RESOURCES.—

8 For purposes of the estimate of costs in the ac-
9 counting statement, national economic re-
10 sources shall include, and shall be listed under,
11 at least the following categories:

12 (i) Private sector costs.

13 (ii) Federal sector administrative
14 costs.

15 (iii) Federal sector compliance costs.

16 (iv) State and local government ad-
17 ministrative costs.

18 (v) State and local government com-
19 pliance costs.

20 (3) STATEMENT OF CORRESPONDING BENE-

21 FITS.—An accounting statement shall estimate the
22 benefits of Federal regulatory programs by setting
23 forth, for each year covered by the statement, such
24 quantitative and qualitative measures of benefits as
25 the President considers appropriate. Any estimates

1 of benefits concerning reduction in human health,
2 safety, or environmental risks shall present the most
3 plausible level of risk practical, along with a state-
4 ment of the reasonable degree of scientific certainty.

5 **SEC. 303. ASSOCIATED REPORT TO CONGRESS.**

6 (a) ~~IN GENERAL.~~—At the same time as the President
7 submits an accounting statement under section 302, the
8 President, acting through the Director of the Office of
9 Management and Budget, shall submit to Congress a re-
10 port associated with the accounting statement (hereinafter
11 referred to as an “associated report”). The associated re-
12 port shall contain, in accordance with this section—

13 (1) analyses of impacts; and

14 (2) recommendations for reform.

15 (b) ~~ANALYSES OF IMPACTS.~~—The President shall in-
16 clude in the associated report the following:

17 (1) Analyses prepared by the President of the
18 cumulative impact of Federal regulatory programs
19 covered in the accounting statement on the follow-
20 ing:

21 (A) The ability of State and local govern-
22 ments to provide essential services, including
23 police, fire protection, and education.

24 (B) Small business.

25 (C) Productivity.

1 (D) Wages.

2 (E) Economic growth.

3 (F) Technological innovation.

4 (G) Consumer prices for goods and serv-
5 ices.

6 (H) Such other factors considered appro-
7 priate by the President.

8 (2) A summary of any independent analyses of
9 impacts prepared by persons commenting during the
10 comment period on the accounting statement.

11 (c) RECOMMENDATIONS FOR REFORM.—The Presi-
12 dent shall include in the associated report the following:

13 (1) A summary of recommendations of the
14 President for reform or elimination of any Federal
15 regulatory program or program element that does
16 not represent sound use of national economic re-
17 sources or otherwise is inefficient.

18 (2) A summary of any recommendations for
19 such reform or elimination of Federal regulatory
20 programs or program elements prepared by persons
21 commenting during the comment period on the ac-
22 counting statement.

1 **SEC. 304. GUIDANCE FROM OFFICE OF MANAGEMENT AND**
2 **BUDGET.**

3 The Director of the Office of Management and Budget
4 et shall, in consultation with the Council of Economic Ad-
5 visers, provide guidance to agencies—

6 (1) to standardize measures of costs and bene-
7 fits in accounting statements prepared pursuant to
8 titles I and III, including—

9 (A) detailed guidance on estimating the
10 costs and benefits of major rules;

11 (B) general guidance on estimating the
12 costs and benefits of all other rules that do not
13 meet the thresholds for major rules; and

14 (2) to standardize the format of the accounting
15 statements.

16 **SEC. 305. RECOMMENDATIONS FROM CONGRESSIONAL**
17 **BUDGET OFFICE.**

18 After each accounting statement and associated re-
19 port submitted to Congress, the Director of the Congres-
20 sional Budget Office shall make recommendations to the
21 President—

22 (1) for improving accounting statements pre-
23 pared pursuant to this title, including recommenda-
24 tions on level of detail and accuracy; and

1 (2) for improving associated reports prepared
2 pursuant to this title, including recommendations on
3 the quality of analysis.

4 **SEC. 306. DEFINITIONS.**

5 For purposes of this title, the following definitions
6 apply:

7 (1) The term “Federal regulatory program”
8 means a program carried out pursuant to a related
9 group of Federal statutes and regulations, as deter-
10 mined by the President.

11 (2) The term “regulation” means an agency
12 statement of general applicability and future effect
13 designed to implement, interpret, or prescribe law or
14 policy or describing the procedures or practice re-
15 quirements of an agency. The term does not in-
16 clude—

17 (A) administrative actions governed by sec-
18 tions 556 and 557 of title 5, United States
19 Code;

20 (B) regulations issued with respect to a
21 military or foreign affairs function of the Unit-
22 ed States; or

23 (C) regulations related to agency organiza-
24 tion, management, or personnel.

1 (3) The term “agency” means any executive de-
 2 partment, military department, Government corpora-
 3 tion, Government controlled corporation, or other es-
 4 tablishment in the executive branch of the Govern-
 5 ment (including the Executive Office of the Presi-
 6 dent), or any independent regulatory agency, but
 7 does not include—

8 (A) the General Accounting Office;

9 (B) the Federal Election Commission;

10 (C) the governments of the District of Co-
 11 lumbia and of the territories and possessions of
 12 the United States, and their various subdivi-
 13 sions; or

14 (D) Government-owned contractor-oper-
 15 ated facilities, including laboratories engaged in
 16 national defense research and production activi-
 17 ties.

18 **TITLE IV—MARKET INCENTIVES AND**

19 **ECONOMICALLY EFFICIENT REGULATION**

20 **SEC. 401. SHORT TITLE.**

21 This title maybe cited as the “Market Incentives Act
 22 of 1995”.

23 **SEC. 402. PROGRAM DESIGN REQUIREMENTS.**

24 (a) **IN GENERAL.**—To the maximum extent prac-
 25 ticable, agencies shall ensure that major rules, especially,

1 but not limited to, those that limit the emission of environ-
2 mental pollutants or otherwise govern the use of natural
3 resources, operate through the application of market-
4 based mechanisms.

5 (b) FLEXIBLE ALTERNATIVES.—Where it is not
6 practicable to rely on market-based mechanisms in design-
7 ing regulatory programs, rules, or requirements, agencies
8 shall ensure that major rules, to the maximum extent
9 practicable, are comparable to market-based mechanisms
10 with respect to (i) assuring the achievement of the regu-
11 latory objective, and (ii) affording flexibility to regulated
12 persons.

13 (c) APPLICABILITY.—Section 402 shall apply, to the
14 extent feasible, to rules in effect on the date of enactment
15 of this Act and rules that take effect after the date of
16 enactment of this Act.

17 **SEC. 403. AGENCY ASSESSMENT AND OMB REVIEW.**

18 (a) IN GENERAL.—Each agency shall include an as-
19 sessment of market-based mechanisms in each proposed
20 major rule. Each assessment shall demonstrate the extent
21 to which the major rule complies with the requirements
22 of section 402, or why section 402 is not applicable or
23 appropriate.

24 (b) OMB REVIEW.—The Office of Management and
25 Budget shall review, as part of its regulatory review and

1 oversight function, the agency assessments and statements
2 prepared in section 403(a). OMB shall determine whether
3 such assessments are detailed, thorough, and otherwise in
4 compliance with section 402.

5 ~~(c) EFFECTIVE DATE.~~—Section 403 shall take effect
6 three months after the date of enactment of this Act.

7 **SEC. 404. DEFINITIONS.**

8 For the purposes of this title:

9 (1) The term “agency” means any executive de-
10 partment, military department, Government corpora-
11 tion, Government controlled corporation, or other es-
12 tablishment in the executive branch of the Govern-
13 ment (including the Executive Office of the Presi-
14 dent), or any independent regulatory agency, but
15 does not include—

16 (A) the General Accounting Office;

17 (B) the Federal Election Commission;

18 (C) the governments of the District of Co-
19 lumbia and of the territories and possessions of
20 the United States, and their various subdivi-
21 sions; or

22 (D) Government-owned contractor-oper-
23 ated facilities, including laboratories engaged in
24 national defense research and production activi-
25 ties.

1 (2) The term “major rule” means—

2 (A) a rule or a group of closely related
3 rules that the agency or the President reason-
4 ably determines is likely to have an annual ef-
5 fect on the economy of \$100,000,000 or more
6 in reasonably quantifiable direct and indirect
7 costs, or has a significant impact on a subsector
8 of the economy; and

9 (B) a rule or a group of closely related
10 rules that is otherwise designated a major rule
11 by the agency proposing the rule, or is so des-
12 ignated by the President, on the ground that
13 the rule is likely to result in—

14 (i) a substantial increase in costs or
15 prices for wage earners, consumers, indi-
16 vidual industries, nonprofit organizations,
17 Federal, State, or local government agen-
18 cies, or geographic regions; or

19 (ii) significant adverse effects on
20 wages, economic growth, investment, pro-
21 ductivity, innovation, the environment,
22 public health or safety, or the ability of en-
23 terprises whose principal places of business
24 are in the United States to compete in do-
25 mestic or export markets. For purposes of

1 subparagraph (A) of this paragraph, the
2 term “rule” does not mean—

3 ~~(I) a rule that involves the internal revenue~~
4 ~~laws of the United States;~~

5 ~~(II) a rule that authorizes the introduction into~~
6 ~~commerce or recognizes the marketable status of a~~
7 ~~product, pursuant to sections 408, 409(c), and 706~~
8 ~~of the Federal Food, Drug, and Cosmetic Act;~~

9 ~~(III) a rule exempt from notice and public pro-~~
10 ~~cedure pursuant to section 553(a) of title 5, United~~
11 ~~States Code; or~~

12 ~~(IV) a rule relating to the viability, stability,~~
13 ~~asset powers, or categories of accounts of, or permis-~~
14 ~~sible interest rate ceilings applicable to, depository~~
15 ~~institutions the deposits or accounts of which are in-~~
16 ~~sured by the Federal Deposit Insurance Corporation,~~
17 ~~or the Share Insurance Fund of the National Credit~~
18 ~~Union Administration Board.~~

19 ~~(3) The term “market-based mechanism”~~
20 ~~means a regulatory requirement that:~~

21 ~~(A) imposes legal accountability for the~~
22 ~~achievement of an explicit regulatory objective~~
23 ~~on each regulated person;~~

24 ~~(B) affords maximum flexibility to each~~
25 ~~regulated person in complying with mandatory~~

1 regulatory objectives, which flexibility shall in-
2 clude, but not be limited to, the opportunity to
3 transfer to, or receive from, other persons, in-
4 cluding for cash or other legal consideration, in-
5 crements of compliance responsibility estab-
6 lished by the program; and

7 (C) permits regulated persons to respond
8 automatically to changes in general economic
9 conditions and in economic circumstances di-
10 rectly pertinent to the regulatory program with-
11 out affecting the achievement of the program's
12 explicit regulatory mandates.

13 (4) The term "rule" has the same meaning as
14 in section 551(4) of title 5, United States Code, ex-
15 cept that such term does not include—

16 (A) a rule of particular applicability that
17 approves or prescribes for the future rates,
18 wages, prices, services, or allowances therefor,
19 corporate or financial structures, reorganiza-
20 tions, mergers or acquisitions, or accounting
21 practices or disclosures bearing on any of the
22 foregoing.

23 (B) a rule relating to monetary policy pro-
24 posed or promulgated by the Board of Gov-
25 ernors of the Federal Reserve System; or

1 (C) a rule issued by the Federal Election
2 Commission or a rule issued by the Federal
3 Communications Commission pursuant to sec-
4 tions 315 and 312(a)(7) of the Communications
5 Act of 1934.

6 **SECTION 1. SHORT TITLE.**

7 *This Act may be cited as the “Regulatory Reform Act*
8 *of 1995”.*

9 **SEC. 2. DEFINITIONS.**

10 *Section 551 of title 5, United States Code, is amend-*
11 *ed—*

12 (1) *in paragraph (13), by striking out “; and”*
13 *and inserting in lieu thereof a semicolon;*

14 (2) *in paragraph (14), by striking out the period*
15 *and inserting in lieu thereof “; and”; and*

16 (3) *by adding at the end thereof the following*
17 *new paragraph:*

18 “(15) ‘Director’ means the Director of the Office
19 of Management and Budget.”.

20 **SEC. 3. ANALYSIS OF AGENCY RULES.**

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

1 *“SUBCHAPTER II—ANALYSIS OF AGENCY RULES*2 ***“§ 621. Definitions***

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

5 *“(1) the term ‘benefit’ means the reasonably*
6 *identifiable significant favorable effects, including so-*
7 *cial, environmental and economic benefits, that are*
8 *expected to result directly or indirectly from imple-*
9 *mentation of a rule or an alternative to a rule;*

10 *“(2) the term ‘cost’ means the reasonably identi-*
11 *fiable significant adverse effects, including social, en-*
12 *vironmental, and economic costs that are expected to*
13 *result directly or indirectly from implementation of,*
14 *or compliance with, a rule or an alternative to a rule;*

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

24 *“(4)(A) the term ‘major rule’ means—*

1 “(i) a rule or a group of closely related
2 rules that the agency proposing the rule, the Di-
3 rector, or a designee of the President reasonably
4 determines is likely to have a gross annual effect
5 on the economy of \$100,000,000 or more in rea-
6 sonably quantifiable direct and indirect costs; or

7 “(ii) a rule or a group of closely related
8 rules that is otherwise determined to be a major
9 rule by the agency proposing the rule, the Direc-
10 tor, or a designee of the President on the ground
11 that the rule is likely to result in—

12 “(I) a substantial increase in costs or
13 prices for wage earners, consumers, individ-
14 ual industries, nonprofit organizations,
15 Federal, State, local, or tribal government
16 agencies, or geographic regions;

17 “(II) significant adverse effects on
18 wages, economic growth, investment, pro-
19 ductivity, innovation, the environment,
20 public health or safety, or the ability of en-
21 terprises whose principal places of business
22 are in the United States to compete in do-
23 mestic or export markets;

1 “(III) a serious inconsistency or inter-
2 ference with an action taken or planned by
3 another agency;

4 “(IV) the material alteration of the
5 budgetary impact of entitlements, grants,
6 user fees, or loan programs, or the rights
7 and obligations of recipients thereof; or

8 “(V) a significant impact on a sector
9 of the economy, or disproportionate costs to
10 a class of persons and relatively severe eco-
11 nomic, social, and environmental con-
12 sequences for the class; and

13 “(B) the term ‘major rule’ shall not include—

14 “(i) a rule that involves the internal reve-
15 nue laws of the United States;

16 “(ii) a rule or agency action that authorizes
17 the introduction into, or removal from, com-
18 merce, or recognizes the marketable status, of a
19 product; or

20 “(iii) a rule exempt from notice and public
21 comment procedure under section 553 of this
22 title;

23 “(5) the term ‘market-based mechanism’ means a
24 regulatory program that—

1 “(A) imposes legal accountability for the
2 achievement of an explicit regulatory objective,
3 including the reduction of environmental pollut-
4 ants or of risks to human health, safety, or the
5 environment, on each regulated person;

6 “(B) affords maximum flexibility to each
7 regulated person in complying with mandatory
8 regulatory objectives, and such flexibility shall,
9 where feasible and appropriate, include the op-
10 portunity to transfer to, or receive from, other
11 persons, including for cash or other legal consid-
12 eration, increments of compliance responsibility
13 established by the program; and

14 “(C) permits regulated persons to respond
15 at their own discretion in an automatic manner,
16 consistent with subparagraph (B), to changes in
17 general economic conditions and in economic cir-
18 cumstances directly pertinent to the regulatory
19 program without affecting the achievement of the
20 program’s explicit regulatory mandates under
21 subparagraph (A);

22 “(6) the term ‘performance standard’ means a
23 requirement that imposes legal accountability for the
24 achievement of an explicit regulatory objective, such
25 as the reduction of environmental pollutants or of

1 *risks to human health, safety, or the environment, on*
2 *each regulated person;*

3 *“(7) the term ‘risk assessment’ has the same*
4 *meaning as such term is defined under section 632(5);*
5 *and*

6 *“(8) the term ‘rule’ has the same meaning as in*
7 *section 551(4) of this title, and shall not include—*

8 *“(A) a rule of particular applicability that*
9 *approves or prescribes for the future rates, wages,*
10 *prices, services, corporate or financial structures,*
11 *reorganizations, mergers, acquisitions, account-*
12 *ing practices, or disclosures bearing on any of*
13 *the foregoing;*

14 *“(B) a rule relating to monetary policy pro-*
15 *posed or promulgated by the Board of Governors*
16 *of the Federal Reserve System or by the Federal*
17 *Open Market Committee;*

18 *“(C) a rule relating to the safety or sound-*
19 *ness of federally insured depository institutions*
20 *or any affiliate of such an institution (as defined*
21 *in section 2(k) of the Bank Holding Company*
22 *Act of 1956 (12 U.S.C. 1841(k)); credit unions;*
23 *the Federal Home Loan Banks; government-*
24 *sponsored housing enterprises; a Farm Credit*
25 *System Institution; foreign banks, and their*

1 *branches, agencies, commercial lending compa-*
2 *nies or representative offices that operate in the*
3 *United States and any affiliate of such foreign*
4 *banks (as those terms are defined in the Inter-*
5 *national Banking Act of 1978 (12 U.S.C. 3101));*
6 *or a rule relating to the payments system or the*
7 *protection of deposit insurance funds or Farm*
8 *Credit Insurance Fund; or*

9 *“(D) a rule issued by the Federal Election*
10 *Commission or a rule issued by the Federal*
11 *Communications Commission pursuant to sec-*
12 *tions 312(a)(7) and 315 of the Communications*
13 *Act of 1934.*

14 **“§ 622. Rulemaking cost-benefit analysis**

15 *“(a) Before publishing notice of a proposed rulemaking*
16 *for any rule (or, in the case of a notice of a proposed rule-*
17 *making that has been published on or before the effective*
18 *date of this subchapter, no later than 30 days after such*
19 *date), each agency shall determine whether the rule is or*
20 *is not a major rule within the meaning of section*
21 *621(4)(A)(i) and, if it is not, determine whether it is a*
22 *major rule under section 621(4)(A)(ii). For the purpose of*
23 *any such determination, a group of closely related rules*
24 *shall be considered as one rule.*

1 “(b)(1) If an agency has determined that a rule is not
2 a major rule, the Director or a designee of the President
3 may, as appropriate, determine that the rule is a major
4 rule no later than 30 days after the publication of the notice
5 of proposed rulemaking for the rule (or, in the case of a
6 notice of proposed rulemaking that has been published on
7 or before the effective date of this subchapter, no later than
8 60 days after such date).

9 “(2) Such determination shall be published in the Fed-
10 eral Register, together with a succinct statement of the basis
11 for the determination.

12 “(c)(1)(A) When the agency publishes a notice of pro-
13 posed rulemaking for a major rule, the agency shall issue
14 and place in the rulemaking file an initial cost-benefit
15 analysis, and shall include a summary of such analysis in
16 the notice of proposed rulemaking.

17 “(B)(i) When the Director or a designee of the Presi-
18 dent has published a determination that a rule is a major
19 rule after the publication of the notice of proposed rule-
20 making for the rule, the agency shall promptly issue and
21 place in the rulemaking file an initial cost-benefit analysis
22 for the rule and shall publish in the Federal Register a sum-
23 mary of such analysis.

24 “(ii) Following the issuance of an initial cost-benefit
25 analysis under clause (i), the agency shall give interested

1 *persons an opportunity to comment pursuant to section 553*
2 *in the same manner as if the draft cost-benefit analysis had*
3 *been issued with the notice of proposed rulemaking.*

4 *“(2) Each initial cost-benefit analysis shall contain—*

5 *“(A) an analysis of the benefits of the proposed*
6 *rule, including any benefits that cannot be quantified,*
7 *and an explanation of how the agency anticipates*
8 *that such benefits will be achieved by the proposed*
9 *rule, including a description of the persons or classes*
10 *of persons likely to receive such benefits;*

11 *“(B) an analysis of the costs of the proposed*
12 *rule, including any costs that cannot be quantified,*
13 *and an explanation of how the agency anticipates*
14 *that such costs will result from the proposed rule, in-*
15 *cluding a description of the persons or classes of per-*
16 *sons likely to bear such costs;*

17 *“(C) an identification (including an analysis of*
18 *costs and benefits) of an appropriate number of rea-*
19 *sonable alternatives allowed under the statute grant-*
20 *ing the rulemaking authority for achieving the identi-*
21 *fied benefits of the proposed rule, including alter-*
22 *natives that—*

23 *“(i) require no government action;*

24 *“(ii) will accommodate differences among*
25 *geographic regions and among persons with dif-*

1 *fering levels of resources with which to comply;*
2 *and*

3 *“(iii) employ voluntary programs, perform-*
4 *ance standards, or market-based mechanisms*
5 *that permit greater flexibility in achieving the*
6 *identified benefits of the proposed rule and that*
7 *comply with the requirements of subparagraph*
8 *(D);*

9 *“(D) an assessment of the feasibility of establish-*
10 *ing a regulatory program that operates through the*
11 *application of market-based mechanisms;*

12 *“(E) an explanation of the extent to which the*
13 *proposed rule—*

14 *“(i) will accommodate differences among ge-*
15 *ographic regions and among persons with differ-*
16 *ing levels of resources with which to comply; and*

17 *“(ii) employs voluntary programs, perform-*
18 *ance standards, or market-based mechanisms*
19 *that permit greater flexibility in achieving the*
20 *identified benefits of the proposed rule;*

21 *“(F) a description of the quality, reliability, and*
22 *relevance of scientific or economic evaluations or in-*
23 *formation in accordance with the cost-benefit analysis*
24 *and risk assessment requirements of this chapter;*

1 “(G) if not expressly or implicitly inconsistent
2 with the statute under which the agency is proposing
3 the rule, an explanation of the extent to which the
4 identified benefits of the proposed rule justify the
5 identified costs of the proposed rule, and an expla-
6 nation of how the proposed rule is likely to substan-
7 tially achieve the rulemaking objectives in a more
8 cost-effective manner than the alternatives to the pro-
9 posed rule, including alternatives identified in ac-
10 cordance with subparagraph (C); and

11 “(H) if a major rule subject to subchapter III
12 addresses risks to human health, safety, or the envi-
13 ronment—

14 “(i) a risk assessment in accordance with
15 this chapter; and

16 “(ii) for each such proposed or final rule,
17 an assessment of incremental risk reduction or
18 other benefits associated with each significant
19 regulatory alternative considered by the agency
20 in connection with the rule or proposed rule.

21 “(d)(1) When the agency publishes a final major rule,
22 the agency shall also issue and place in the rulemaking file
23 a final cost-benefit analysis, and shall include a summary
24 of the analysis in the statement of basis and purpose.

25 “(2) Each final cost-benefit analysis shall contain—

1 “(A) a description and comparison of the bene-
2 fits and costs of the rule and of the reasonable alter-
3 natives to the rule described in the rulemaking, in-
4 cluding the market-based mechanisms identified
5 under subsection (c)(2)(C)(iii); and

6 “(B) if not expressly or implicitly inconsistent
7 with the statute under which the agency is acting, a
8 reasonable determination, based upon the rulemaking
9 file considered as a whole, whether—

10 “(i) the benefits of the rule justify the costs
11 of the rule; and

12 “(ii) the rule will achieve the rulemaking
13 objectives in a more cost-effective manner than
14 the alternatives described in the rulemaking, in-
15 cluding the market-based mechanisms identified
16 under subsection (c)(2)(C)(iii).

17 “(e)(1) The analysis of the benefits and costs of a pro-
18 posed and a final rule required under this section shall in-
19 clude, to the extent feasible, a quantification or numerical
20 estimate of the quantifiable benefits and costs. Such quan-
21 tification or numerical estimate shall be made in the most
22 appropriate units of measurement, using comparable as-
23 sumptions, including time periods, shall specify the ranges
24 of predictions, and shall explain the margins of error in-
25 volved in the quantification methods and in the estimates

1 *used. An agency shall describe the nature and extent of the*
2 *nonquantifiable benefits and costs of a final rule pursuant*
3 *to this section in as precise and succinct a manner as pos-*
4 *sible. An agency shall not be required to make such evalua-*
5 *tion primarily on a mathematical or numerical basis.*

6 “(2)(A) *In evaluating and comparing costs and bene-*
7 *fits and in evaluating the risk assessment information de-*
8 *veloped under subchapter III, the agency shall not rely on*
9 *cost, benefit, or risk assessment information that is not ac-*
10 *companied by data, analysis, or other supporting materials*
11 *that would enable the agency and other persons interested*
12 *in the rulemaking to assess the accuracy, reliability, and*
13 *uncertainty factors applicable to such information.*

14 “(B) *The agency evaluations of the relationships of the*
15 *benefits of a proposed and final rule to its costs shall be*
16 *clearly articulated in accordance with this section.*

17 “(f) *As part of the promulgation of each major rule*
18 *that addresses risks to human health, safety, or the environ-*
19 *ment, the head of the agency or the President shall make*
20 *a determination that—*

21 “(1) *the risk assessment and the analysis under*
22 *subsection (c)(2)(H) are based on a scientific evalua-*
23 *tion of the risk addressed by the major rule and that*
24 *the conclusions of such evaluation are supported by*
25 *the available information; and*

1 “(2) the regulatory alternative chosen will reduce
2 risk in a cost-effective and, to the extent feasible, flexi-
3 ble manner, taking into consideration any of the al-
4 ternatives identified under subsection (c)(2) (C) and
5 (D).

6 “(g) The preparation of the initial or final cost-benefit
7 analysis required by this section shall only be performed
8 under the direction of an officer or employee of the agency.
9 The preceding sentence shall not preclude a person outside
10 the agency from gathering data or information to be used
11 by the agency in preparing any such cost-benefit analysis
12 or from providing an explanation sufficient to permit the
13 agency to analyze such data or information. If any such
14 data or information is gathered or explained by a person
15 outside the agency, the agency shall specifically identify in
16 the initial or final cost-benefit analysis the data or infor-
17 mation gathered or explained and the person who gathered
18 or explained it, and shall describe the arrangement by
19 which the information was procured by the agency, includ-
20 ing the total amount of funds expended for such procure-
21 ment.

22 “(h) The requirements of this subchapter shall not alter
23 the criteria for rulemaking otherwise applicable under other
24 statutes.

1 **“§ 623. Judicial review**

2 “(a) Compliance or noncompliance by an agency with
3 the provisions of this subchapter and subchapter III shall
4 not be subject to judicial review except in connection with
5 review of a final agency rule and according to the provi-
6 sions of this section.

7 “(b) Any determination by a designee of the President
8 or the Director that a rule is, or is not, a major rule shall
9 not be subject to judicial review in any manner.

10 “(c) The determination by an agency that a rule is,
11 or is not, a major rule under section 621(4)(A)(i) shall be
12 set aside by a reviewing court only upon a clear and con-
13 vincing showing that the determination is erroneous in
14 light of the information available to the agency at the time
15 the agency made the determination. Any determination by
16 an agency that a rule is, or is not, a major rule under
17 section 621(4)(A)(ii) shall not be subject to judicial review
18 in any manner.

19 “(d) If the cost-benefit analysis or risk assessment re-
20 quired under this chapter has been wholly omitted for any
21 major rule, a court shall vacate the rule and remand the
22 case for further consideration. If an analysis or assessment
23 has been performed, the court shall not review to determine
24 whether the analysis or assessment conformed to the par-
25 ticular requirements of this chapter.

1 “(e) Any cost-benefit analysis or risk assessment pre-
2 pared under this chapter shall not be subject to judicial con-
3 sideration separate or apart from review of the agency ac-
4 tion to which it relates. When an action for judicial review
5 of an agency action is instituted, any regulatory analysis
6 for such agency action shall constitute part of the whole
7 administrative record of agency action for the purpose of
8 judicial review of the agency action, and shall, to the extent
9 relevant, be considered by a court in determining the legal-
10 ity of the agency action.

11 **“§ 624. Deadlines for rulemaking**

12 “(a) All deadlines in statutes that require agencies to
13 propose or promulgate any rule subject to section 622 or
14 subchapter III during the 2-year period beginning on the
15 effective date of this section shall be suspended until the ear-
16 lier of—

17 “(1) the date on which the requirements of sec-
18 tion 622 or subchapter III are satisfied; or

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

21 “(b) All deadlines imposed by any court of the United
22 States that would require an agency to propose or promul-
23 gate a rule subject to section 622 or subchapter III during
24 the 2-year period beginning on the effective date of this sec-
25 tion shall be suspended until the earlier of—

1 “(1) the date on which the requirements of sec-
2 tion 622 or subchapter III are satisfied; or

3 “(2) the date occurring 6 months after the date
4 of the applicable deadline.

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

10 “(1) the date on which the requirements of sec-
11 tion 622 or subchapter III are satisfied; or

12 “(2) the date occurring 6 months after the date
13 of the applicable deadline.

14 **“§ 625. Agency review of rules**

15 “(a)(1)(A) No later than 9 months after the effective
16 date of this section, each agency shall prepare and publish
17 in the Federal Register a proposed schedule for the review,
18 in accordance with this section, of—

19 “(i) each rule of the agency that is in effect on
20 such effective date and which, if adopted on such ef-
21 fective date, would be a major rule; and

22 “(ii) each rule of the agency in effect on the effec-
23 tive date of this section (in addition to the rules de-
24 scribed in clause (i)) that the agency has selected for
25 review.

1 “(B) Each proposed schedule required under subpara-
2 graph (A) shall be developed in consultation with—

3 “(i) the Administrator of the Office of Informa-
4 tion and Regulatory Affairs; and

5 “(ii) the classes of persons affected by the rules,
6 including members from the regulated industries,
7 small businesses, State and local governments, and or-
8 ganizations representing the interested public.

9 “(C) Each proposed schedule required under subpara-
10 graph (A) shall establish priorities for the review of rules
11 that, in the joint determination of the Administrator of the
12 Office of Information and Regulatory Affairs and the agen-
13 cy, most likely can be amended or eliminated to—

14 “(i) provide the same or greater benefits at sub-
15 stantially lower costs;

16 “(ii) achieve substantially greater benefits at the
17 same or lower costs; or

18 “(iii) replace command-and-control regulatory
19 requirements with market mechanisms or performance
20 standards that achieve substantially equivalent bene-
21 fits at lower costs or with greater flexibility.

22 “(D) Each proposed schedule required by subpara-
23 graph (A) shall include—

24 “(i) a brief explanation of the reasons the agency
25 considers each rule on the schedule to be a major rule,

1 *or the reasons why the agency selected the rule for re-*
2 *view;*

3 *“(ii) a date set by the agency, in accordance*
4 *with subsection (b), for the completion of the review*
5 *of each such rule; and*

6 *“(iii) a statement that the agency requests com-*
7 *ments from the public on the proposed schedule.*

8 *“(E) The agency shall set a date to initiate review of*
9 *each rule on the schedule in a manner that will ensure the*
10 *simultaneous review of related items and that will achieve*
11 *a reasonable distribution of reviews over the period of time*
12 *covered by the schedule.*

13 *“(2) No later than 90 days before publishing in the*
14 *Federal Register the proposed schedule required under para-*
15 *graph (1), each agency shall make the proposed schedule*
16 *available to the Director or a designee of the President. The*
17 *President or that officer may select for review in accordance*
18 *with this section any additional rule.*

19 *“(3) No later than 1 year after the effective date of*
20 *this section, each agency shall publish in the Federal Reg-*
21 *ister a final schedule for the review of the rules referred*
22 *to in paragraphs (1) and (2). Each agency shall publish*
23 *with the final schedule the response of the agency to com-*
24 *ments received concerning the proposed schedule.*

1 “(b)(1) Except as explicitly provided otherwise by stat-
2 ute, the agency shall, pursuant to subsections (c) through
3 (e), review—

4 “(A) each rule on the schedule promulgated pur-
5 suant to subsection (a);

6 “(B) each major rule promulgated, amended, or
7 otherwise continued by an agency after the effective
8 date of this section; and

9 “(C) each rule promulgated after the effective
10 date of this section that the President or the officer
11 designated by the President selects for review pursu-
12 ant to subsection (a)(2).

13 “(2) Except as provided pursuant to subsection (f), the
14 review of a rule required by this section shall be completed
15 no later than the later of—

16 “(A) 10 years after the effective date of this sec-
17 tion; or

18 “(B) 10 years after the date on which the rule
19 is—

20 “(i) promulgated; or

21 “(ii) amended or continued under this sec-
22 tion.

23 “(c) An agency shall publish in the Federal Register
24 a notice of its proposed action under this section with re-
25 spect to a rule being reviewed. The notice shall include—

1 “(1) an identification of the specific statutory
2 authority under which the rule was promulgated and
3 an explanation of whether the agency’s interpretation
4 of the statute is expressly required by the current text
5 of that statute or, if not, whether it is within the
6 range of permissible interpretations of the statute;

7 “(2) an analysis of the benefits and costs of the
8 rule during the period in which it has been in effect;

9 “(3) an explanation of the proposed agency ac-
10 tion with respect to the rule, including action to re-
11 peal or amend the rule to resolve inconsistencies or
12 conflicts with any other obligation or requirement es-
13 tablished by any Federal statute, rule, or other agency
14 statement, interpretation, or action that has the force
15 of law; and

16 “(4) a statement that the agency seeks proposals
17 from the public for modifications or alternatives to
18 the rule which may accomplish the objectives of the
19 rule in a more effective or less burdensome manner.

20 “(d) If an agency proposes to repeal or amend a rule
21 under review pursuant to this section, the agency shall,
22 after issuing the notice required by subsection (c), comply
23 with the provisions of this chapter, chapter 5, and any other
24 applicable law. The requirements of such provisions and re-
25 lated requirements shall apply to the same extent and in

1 *the same manner as in the case of a proposed agency action*
2 *to repeal or amend a rule that is not taken pursuant to*
3 *the review required by this section.*

4 “(e) *If an agency proposes to continue without amend-*
5 *ment a rule under review pursuant to this section, the agen-*
6 *cy shall—*

7 “(1) *give interested persons no less than 60 days*
8 *after the publication of the notice required by sub-*
9 *section (c) to comment on the proposed continuation;*
10 *and*

11 “(2) *publish in the Federal Register notice of the*
12 *continuation of such rule.*

13 “(f) *Any agency, which for good cause finds that com-*
14 *pliance with this section with respect to a particular rule*
15 *during the period provided in subsection (b) of this section*
16 *is contrary to an important public interest may request the*
17 *President, or the officer designated by the President pursu-*
18 *ant to subsection (a)(2), to establish a period longer than*
19 *10 years for the completion of the review of such rule. The*
20 *President or that officer may extend the period for review*
21 *of a rule to a total period of no more than 15 years. Such*
22 *extension shall be published in the Federal Register with*
23 *an explanation of the reasons therefor.*

24 “(g) *If the agency fails to comply with the require-*
25 *ments of subsection (b)(2), the rule for which rulemaking*

1 *proceedings have not been completed shall cease to be en-*
2 *forceable against any person.*

3 “(h) *Nothing in this section shall relieve any agency*
4 *from its obligation to respond to a petition to issue, amend,*
5 *or repeal a rule, for an interpretation regarding the mean-*
6 *ing of a rule, or for a variance or exemption from the terms*
7 *of a rule, submitted pursuant to any other provision of law.*

8 **“§ 626. Public participation and accountability**

9 *“In order to maximize accountability for, and public*
10 *participation in, the development and review of regulatory*
11 *actions each agency shall, consistent with chapter 5 and*
12 *other applicable law, provide the public with opportunities*
13 *for meaningful participation in the development of regu-*
14 *latory actions, including—*

15 “(1) *seeking the involvement, where practicable*
16 *and appropriate, of those who are intended to benefit*
17 *from and those who are expected to be burdened by*
18 *any regulatory action;*

19 “(2) *providing in any proposed or final rule-*
20 *making notice published in the Federal Register—*

21 “(A) *a certification of compliance with the*
22 *requirements of this chapter, or an explanation*
23 *why such certification cannot be made;*

24 “(B) *a summary of any regulatory analysis*
25 *required under this chapter, or under any other*

1 *legal requirement, and notice of the availability*
2 *of the regulatory analysis;*

3 “(C) a certification that the rule will
4 produce benefits that will justify the cost to the
5 Government and to the public of implementation
6 of, and compliance with, the rule, or an expla-
7 nation why such certification cannot be made;
8 and

9 “(D) a summary of the results of any regu-
10 latory review and the agency’s response to such
11 review, including an explanation of any signifi-
12 cant changes made to such regulatory action as
13 a consequence of regulatory review;

14 “(3) identifying, upon request, a regulatory ac-
15 tion and the date upon which such action was sub-
16 mitted to the designated officer to whom authority
17 was delegated under section 644 for review;

18 “(4) disclosure to the public, consistent with sec-
19 tion 634(3), of any information created or collected in
20 performing a regulatory analysis required under this
21 chapter, or under any other legal requirement; and

22 “(5) placing in the appropriate rulemaking
23 record all written communications received from the
24 Director, other designated officer, or other individual
25 or entity relating to regulatory review.

1 “SUBCHAPTER III—RISK ASSESSMENTS

2 **“§ 631. Findings and purposes**3 “(a) *The Congress finds that:*4 “(1) *Environmental, health, and safety regula-*
5 *tions have lead to dramatic improvements in the en-*
6 *vironment and have significantly reduced risks to*
7 *human health; except—*8 “(A) *many regulations have been more cost-*
9 *ly and less effective than necessary; and*10 “(B) *too often, regulatory priorities have*
11 *not been based upon a realistic consideration of*
12 *risk, risk reduction opportunities, and costs.*13 “(2) *The public and private resources available*
14 *to address health, safety, and environmental risks are*
15 *not unlimited. Those resources should be allocated to*
16 *address the greatest needs in the most cost-effective*
17 *manner and to ensure that the incremental costs of*
18 *regulatory options are reasonably related to the incre-*
19 *mental benefits.*20 “(3) *To provide more cost-effective protection to*
21 *human health, safety, and the environment, regu-*
22 *latory priorities should be supported by realistic and*
23 *plausible scientific risk assessments and risk manage-*
24 *ment choices that are grounded in cost-benefit prin-*
25 *ciples.*

1 “(4) Risk assessment has proved to be a useful
2 decisionmaking tool, except—

3 “(A) improvements are needed in both the
4 quality of assessments and the characterization
5 and communication of findings;

6 “(B) scientific and other data must be bet-
7 ter collected, organized, and evaluated; and

8 “(C) the critical information resulting from
9 a risk assessment must be effectively commu-
10 nicated in an objective and unbiased manner to
11 decision makers, and from decision makers to the
12 public.

13 “(5) The public stakeholders should be involved
14 in the decisionmaking process for regulating risks.
15 The public has the right to know about the risks ad-
16 dressed by regulation, the amount of risk reduced, the
17 quality of the science used to support decisions, and
18 the cost of implementing and complying with regula-
19 tions. Such knowledge will allow for public scrutiny
20 and will promote the quality, integrity, and respon-
21 siveness of agency decisions.

22 “(b) The purposes of this subchapter are to—

23 “(1) present the public and executive branch
24 with the most realistic and plausible information con-
25 cerning the nature and magnitude of health, safety,

1 *and environmental risks to promote sound regulatory*
2 *decisions and public education;*

3 *“(2) provide for full consideration and discus-*
4 *sion of relevant data and potential methodologies;*

5 *“(3) require explanation of significant choices in*
6 *the risk assessment process that will allow for better*
7 *public understanding; and*

8 *“(4) improve consistency within the executive*
9 *branch in preparing risk assessments and risk char-*
10 *acterizations.*

11 **“§ 632. Definitions**

12 *“For purposes of this subchapter, the definitions under*
13 *sections 551 and 621 shall apply and:*

14 *“(1) The term ‘covered agency’ means each of the*
15 *following:*

16 *“(A) The Environmental Protection Agency.*

17 *“(B) The Department of Labor.*

18 *“(C) The Department of Transportation.*

19 *“(D) The Food and Drug Administration.*

20 *“(E) The Department of Energy.*

21 *“(F) The Department of the Interior.*

22 *“(G) The Department of Agriculture.*

23 *“(H) The Consumer Product Safety Com-*
24 *mission.*

1 “(I) *The National Oceanic and Atmospheric*
2 *Administration.*

3 “(J) *The United States Army Corps of En-*
4 *gineers.*

5 “(K) *The Nuclear Regulatory Commission.*

6 “(L) *Any other Federal agency considered a*
7 *covered agency under section 633(b).*

8 “(2) *The term ‘emergency’ means a situation*
9 *that is immediately impending and extraordinary in*
10 *nature, demanding attention due to a condition, cir-*
11 *cumstance or practice reasonably expected to cause*
12 *death, serious illness or severe injury to humans, or*
13 *substantial endangerment to private property or the*
14 *environment if no action is taken.*

15 “(3) *The term ‘estimates of risk’ means numeri-*
16 *cal representations of the potential magnitude of*
17 *harm to populations or the probability of harm to in-*
18 *dividuals, including, as appropriate, those derived by*
19 *considering the range and distribution of estimates of*
20 *dose-response (potency) and exposure, including ap-*
21 *propriate statistical representation of the range and*
22 *most likely exposure levels, and the identification of*
23 *the populations or subpopulations addressed. When*
24 *appropriate and practicable, a description of any*
25 *populations or subpopulations that are likely to expe-*

1 *rience exposures at the upper end of the distribution*
2 *should be included.*

3 “(4) The term ‘hazard identification’ means
4 *identification of a substance, activity, or condition as*
5 *potentially causing harm to human health, safety, or*
6 *the environment.*

7 “(5) The term ‘risk assessment’ means—

8 “(A) *identifying, quantifying to the extent*
9 *feasible and appropriate, and characterizing*
10 *hazards and exposures to those hazards in order*
11 *to provide structured information on the nature*
12 *of threats to human health, safety, or the envi-*
13 *ronment; and*

14 “(B) *the document containing the expla-*
15 *nation of how the assessment process has been*
16 *applied to an individual substance, activity, or*
17 *condition.*

18 “(6) The term ‘risk characterization’ means the
19 *integration, synthesis, and organization of hazard*
20 *identification, dose-response and exposure informa-*
21 *tion that addresses the needs of decision makers and*
22 *interested parties. The term includes both the process*
23 *and specific outputs, including—*

24 “(A) *the element of a risk assessment that*
25 *involves presentation of the degree of risk in any*

1 regulatory proposal or decision, report to Con-
2 gress, or other document that is made available
3 to the public; and

4 “(B) discussions of uncertainties, conflicting
5 data, estimates of risk, extrapolations, inferences,
6 and opinions.

7 “(7) The term ‘screening analysis’ means an
8 analysis that arrives at a qualitative estimate or a
9 bounding estimate of risk that permits the risk man-
10 ager to accept or reject some management options, or
11 permits establishing priorities for agency action. Such
12 term includes an assessment performed by a regulated
13 party and submitted to an agency under a regulatory
14 requirement.

15 “(8) The term ‘substitution risk’ means a reason-
16 ably likely increased risk to human health, safety, or
17 the environment from a regulatory option designed to
18 decrease other risks.

19 **“§ 633. Applicability**

20 “(a) Except as provided in subsection (c), this sub-
21 chapter shall apply to all risk assessments and risk charac-
22 terizations prepared by, or on behalf of, or prepared by oth-
23 ers and adopted by any covered agency in connection with
24 a major rule addressing health, safety, and environmental
25 risks.

1 “(b)(1) No later than 18 months after the effective date
2 of this section, the President, acting through the Director
3 of the Office of Management and Budget, shall determine
4 whether other Federal agencies should be considered covered
5 agencies for the purposes of this subchapter. Such deter-
6 mination, with respect to a particular Federal agency, shall
7 be based on the impact of risk assessment documents and
8 risk characterization documents on—

9 “(A) regulatory programs administered by that
10 agency; and

11 “(B) the communication of risk information by
12 that agency to the public.

13 “(2) If the President makes a determination under
14 paragraph (1), the provisions of this subchapter shall apply
15 to any affected agency beginning on a date set by the Presi-
16 dent. Such date may be no later than 6 months after the
17 date of such determination.

18 “(c)(1) This subchapter shall not apply to risk assess-
19 ments or risk characterizations performed with respect to—

20 “(A) an emergency determined by the head of an
21 agency;

22 “(B) a health, safety, or environmental inspec-
23 tion or individual facility permitting action; or

24 “(C) a screening analysis.

1 “(2) This subchapter shall not apply to any food, drug,
2 or other product label, or to any risk characterization ap-
3 pearing on any such label.

4 **“§ 634. Savings provisions**

5 “Nothing in this subchapter shall be construed to—

6 “(1) modify any statutory standard or require-
7 ment designed to protect human health, safety, or the
8 environment;

9 “(2) preclude the consideration of any data or
10 the calculation of any estimate to more fully describe
11 risk or provide examples of scientific uncertainty or
12 variability; or

13 “(3) require the disclosure of any trade secret or
14 other confidential information.

15 **“§ 635. Principles for risk assessment**

16 “(a) The head of each covered agency shall ensure that
17 risk assessments and all of the components of such assess-
18 ments—

19 “(1) provide for a systematic means to structure
20 information useful to decision makers;

21 “(2) provide, to the maximum extent practicable,
22 that policy-driven default assumptions be used only
23 in the absence of relevant available information;

24 “(3) promote involvement from all stakeholders;

1 “(4) provide an opportunity for public input
2 throughout the regulatory process; and

3 “(5) are designed so that the degree of specificity
4 and rigor employed is commensurate with the con-
5 sequences of the decision to be made.

6 “(b) A risk assessment shall, to the maximum extent
7 practicable, clearly delineate hazard identification from
8 dose-response and exposure assessment and make clear the
9 relationship between the level of risk and the level of expo-
10 sure to a hazard.

11 **“§ 636. Principles for risk characterization**

12 *“In characterizing risk in any risk assessment docu-
13 ment, regulatory proposal, or decision, each covered agency
14 shall include in the risk characterization, as appropriate,
15 each of the following:*

16 “(1)(A) A description of the exposure scenarios
17 used, the natural resources or subpopulations being
18 exposed, and the likelihood of those exposure scenarios.

19 “(B) When a risk assessment involves a choice of
20 any significant assumption, inference, or model, the
21 covered agency or instrumentality preparing the risk
22 assessment shall—

23 “(i) identify the assumptions, inferences,
24 and models that materially affect the outcome;

25 “(ii) explain the basis for any choices;

1 “(iii) identify any policy decisions or pol-
2 icy-based default assumptions;

3 “(iv) indicate the extent to which any sig-
4 nificant model has been validated by, or conflicts
5 with, empirical data; and

6 “(v) describe the impact of alternative
7 choices of assumptions, default options or mathe-
8 matical models.

9 “(C) The major sources of uncertainties in the
10 hazard identification, dose-response and exposure as-
11 sessment phases of the risk assessment.

12 “(D) To the extent feasible, the range and dis-
13 tribution of exposures and risks derived from the risk
14 assessment should be included as a component of the
15 risk characterization.

16 “(2) When a covered agency provides a risk as-
17 sessment or risk characterization for a proposed or
18 final regulatory action, such assessment or character-
19 ization shall include a statement of any significant
20 substitution risks, when information on such risks has
21 been made available to the agency.

22 **“§ 637. Peer review**

23 “(a) The head of each covered agency shall develop a
24 systematic program for independent and external peer re-

1 *view required under subsection (b). Such program shall be*
2 *applicable throughout each covered agency and—*

3 *“(1) shall provide for the creation of peer review*
4 *panels that—*

5 *“(A) consist of members with expertise rel-*
6 *evant to the sciences involved in regulatory deci-*
7 *sions and who are independent of the covered*
8 *agency; and*

9 *“(B) are broadly representative and bal-*
10 *anced and, to the extent relevant and appro-*
11 *priate, may include persons affiliated with Fed-*
12 *eral, State, local, or tribal governments, small*
13 *businesses, other representatives of industry, uni-*
14 *versities, agriculture, labor consumers, conserva-*
15 *tion organizations, or other public interest*
16 *groups and organizations;*

17 *“(2) shall not exclude any person with substan-*
18 *tial and relevant expertise as a panel member on the*
19 *basis that such person represents an entity that may*
20 *have a potential interest in the outcome, if such inter-*
21 *est is fully disclosed to the agency, and in the case of*
22 *a regulatory decision affecting a single entity, no peer*
23 *reviewer representing such entity may be included on*
24 *the panel;*

1 “(3) shall provide for a timely completed peer re-
2 view, meeting agency deadlines, that contains a bal-
3 anced presentation of all considerations, including
4 minority reports and an agency response to all sig-
5 nificant peer review comments; and

6 “(4) shall provide adequate protections for con-
7 fidential business information and trade secrets, in-
8 cluding requiring panel members to enter into con-
9 fidentiality agreements.

10 “(b)(1)(A) Except as provided under subparagraph
11 (B), each covered agency shall provide for peer review in
12 accordance with this section of any risk assessment or cost-
13 benefit analysis that forms the basis of any major rule that
14 addresses risks to the environment, health, or safety.

15 “(B) Subparagraph (A) shall not apply to a rule or
16 other action taken by an agency to authorize or approve
17 any individual substance or product.

18 “(2) The Director of the Office of Management and
19 Budget may order that peer review be provided for any risk
20 assessment or cost-benefit analysis that is likely to have a
21 significant impact on public policy decisions or would es-
22 tablish an important precedent.

23 “(c) Each peer review under this section shall include
24 a report to the Federal agency concerned with respect to

1 *the scientific and technical merit of data and methods used*
2 *for the risk assessments or cost-benefit analyses.*

3 “(d) *The head of the covered agency shall provide a*
4 *written response to all significant peer review comments.*

5 “(e) *All peer review comments or conclusions and the*
6 *agency’s responses shall be made available to the public and*
7 *shall be made part of the administrative record for purposes*
8 *of judicial review of any final agency action.*

9 “(f) *No peer review shall be required under this section*
10 *for any data, method, document, or assessment, or any com-*
11 *ponent thereof, which has been previously subjected to peer*
12 *review.*

13 **“§638. Guidelines, plan for assessing new informa-**
14 **tion, and report**

15 “(a)(1)(A) *As soon as practicable and scientifically*
16 *feasible, each covered agency shall adopt, after notification*
17 *and opportunity for public comment, guidelines to imple-*
18 *ment the risk assessment and risk characterization prin-*
19 *ciples under sections 635 and 636, as well as the cost-benefit*
20 *analysis requirements under section 622, and shall provide*
21 *a format for summarizing risk assessment results.*

22 “(B) *No later than 12 months after the effective date*
23 *of this section, the head of each covered agency shall issue*
24 *a report on the status of such guidelines to the Congress.*

25 “(2) *The guidelines under paragraph (1) shall—*

1 “(A) include guidance on use of specific technical
2 methodologies and standards for acceptable quality of
3 specific kinds of data;

4 “(B) address important decisional factors for the
5 risk assessment, risk characterization, and cost-benefit
6 analysis at issue; and

7 “(C) provide procedures for the refinement and
8 replacement of policy-based default assumptions.

9 “(b) The guidelines, plan and report under this section
10 shall be developed after notice and opportunity for public
11 comment, and after consultation with representatives of ap-
12 propriate State agencies and local governments, and such
13 other departments and agencies, organizations, or persons
14 as may be advisable.

15 “(c) The President shall review the guidelines pub-
16 lished under this section at least every 4 years.

17 “(d) The development, issuance, and publication of
18 risk assessment and risk characterization guidelines under
19 this section shall not be subject to judicial review.

20 **“§ 639. Research and training in risk assessment**

21 “(a) The head of each covered agency shall regularly
22 and systematically evaluate risk assessment research and
23 training needs of the agency, including, where relevant and
24 appropriate, the following:

1 “(1) Research to reduce generic data gaps, to ad-
2 dress modelling needs (including improved model sen-
3 sitivity), and to validate default options, particularly
4 those common to multiple risk assessments.

5 “(2) Research leading to improvement of methods
6 to quantify and communicate uncertainty and varia-
7 bility among individuals, species, populations, and,
8 in the case of ecological risk assessment, ecological
9 communities.

10 “(3) Emerging and future areas of research, in-
11 cluding research on comparative risk analysis, expo-
12 sure to multiple chemicals and other stressors,
13 noncancer endpoints, biological markers of exposure
14 and effect, mechanisms of action in both mammalian
15 and nonmammalian species, dynamics and prob-
16 abilities of physiological and ecosystem exposures, and
17 prediction of ecosystem-level responses.

18 “(4) Long-term needs to adequately train indi-
19 viduals in risk assessment and risk assessment appli-
20 cation. Evaluations under this paragraph shall in-
21 clude an estimate of the resources needed to provide
22 necessary training.

23 “(b) The head of each covered agency shall develop a
24 strategy and schedule for carrying out research and train-
25 ing to meet the needs identified in subsection (a).

1 **“§ 640. Interagency coordination**

2 “(a) To promote the conduct, application, and practice
3 of risk assessment in a consistent manner and to identify
4 risk assessment data and research needs common to more
5 than 1 Federal agency, the Director of the Office of Manage-
6 ment and Budget, in consultation with the Office of Science
7 and Technology Policy, shall—

8 “(1) periodically survey the manner in which
9 each Federal agency involved in risk assessment is
10 conducting such risk assessment to determine the
11 scope and adequacy of risk assessment practices in
12 use by the Federal Government;

13 “(2) provide advice and recommendations to the
14 President and Congress based on the surveys con-
15 ducted and determinations made under paragraph
16 (1);

17 “(3) establish appropriate interagency mecha-
18 nisms to promote—

19 “(A) coordination among Federal agencies
20 conducting risk assessment with respect to the
21 conduct, application, and practice of risk assess-
22 ment; and

23 “(B) the use of state-of-the-art risk assess-
24 ment practices throughout the Federal Govern-
25 ment;

1 “(4) establish appropriate mechanisms between
2 Federal and State agencies to communicate state-of-
3 the-art risk assessment practices; and

4 “(5) periodically convene meetings with State
5 government representatives and Federal and other
6 leaders to assess the effectiveness of Federal and State
7 cooperation in the development and application of
8 risk assessment.

9 “(b) The President shall appoint National Peer Review
10 Panels to review every 3 years the risk assessment practices
11 of each covered agency for programs designed to protect
12 human health, safety, or the environment. The Panels shall
13 submit a report to the President and the Congress at least
14 every 3 years containing the results of such review.

15 **“§ 640a. Plan for review of risk assessments**

16 “(a) No later than 18 months after the effective date
17 of this section, the head of each covered agency shall publish
18 a plan to review and revise any risk assessment published
19 before the expiration of such 18-month period if the covered
20 agency determines that significant new information or
21 methodologies are available that could significantly alter
22 the results of the prior risk assessment.

23 “(b) A plan under subsection (a) shall—

1 “(1) provide procedures for receiving and consid-
2 ering new information and risk assessments from the
3 public; and

4 “(2) set priorities and criteria for review and re-
5 vision of risk assessments based on such factors as the
6 agency head considers appropriate.

7 **“§ 640b. Judicial review**

8 “The provisions of section 623 relating to judicial re-
9 view shall apply to this subchapter.

10 **“§ 640c. Deadlines for rulemaking**

11 “The provisions of section 624 relating to deadlines for
12 rulemaking shall apply to this subchapter.

13 “SUBCHAPTER IV—EXECUTIVE OVERSIGHT

14 **“§ 641. Definition**

15 “For purposes of this subchapter, the definitions under
16 sections 551 and 621 shall apply.

17 **“§ 642. Procedures**

18 “The Director or other designated officer to whom au-
19 thority is delegated under section 644 shall—

20 “(1) establish procedures for agency compliance
21 with this chapter; and

22 “(2) monitor, review, and ensure agency imple-
23 mentation of such procedures.

1 **“§ 643. Promulgation and adoption**

2 “(a) Procedures established pursuant to section 642
3 shall only be implemented after opportunity for public com-
4 ment. Any such procedures shall be consistent with the
5 prompt completion of rulemaking proceedings.

6 “(b)(1) If procedures established pursuant to section
7 642 include review of any initial or final analyses of a rule
8 required under this chapter, the time for any such review
9 of any initial analysis shall not exceed 60 days following
10 the receipt of the analysis by the Director, a designee of
11 the President, or by an officer to whom the authority grant-
12 ed under section 642 has been delegated pursuant to section
13 644.

14 “(2) The time for review of any final analysis required
15 under this chapter shall not exceed 60 days following the
16 receipt of the analysis by the Director, a designee of the
17 President, or such officer.

18 “(3)(A) The times for each such review may be ex-
19 tended for good cause by the President or such officer for
20 an additional 30 days.

21 “(B) Notice of any such extension, together with a suc-
22 cinct statement of the reasons therefor, shall be inserted in
23 the rulemaking file.

24 **“§ 644. Delegation of authority**

25 “(a) The President shall delegate the authority granted
26 by this subchapter to the Director or to another officer with-

1 *in the Executive Office of the President whose appointment*
2 *has been subject to the advice and consent of the Senate.*

3 “(b) *Notice of any delegation, or any revocation or*
4 *modification thereof shall be published in the Federal Reg-*
5 *ister.*

6 **“§ 645. Public disclosure of information**

7 *“The Director or other designated officer to whom au-*
8 *thority is delegated under section 644, in carrying out the*
9 *provisions of section 642, shall establish procedures (cover-*
10 *ing all employees of the Director or other designated officer)*
11 *to provide public and agency access to information concern-*
12 *ing regulatory review actions, including—*

13 “(1) *disclosure to the public on an ongoing basis*
14 *of information regarding the status of regulatory ac-*
15 *tions undergoing review;*

16 “(2) *disclosure to the public, no later than publi-*
17 *cation of, or other substantive notice to the public*
18 *concerning a regulatory action, of—*

19 “(A) *all written communications, regardless*
20 *of form or format, including drafts of all propos-*
21 *als and associated analyses, between the Director*
22 *or other designated officer and the regulatory*
23 *agency;*

24 “(B) *all written communications, regardless*
25 *of form or format, between the Director or other*

1 *designated officer and any person not employed*
2 *by the executive branch of the Federal Govern-*
3 *ment relating to the substance of a regulatory ac-*
4 *tion;*

5 *“(C) a record of all oral communications*
6 *relating to the substance of a regulatory action*
7 *between the Director or other designated officer*
8 *and any person not employed by the executive*
9 *branch of the Federal Government; and*

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

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

14 *“(A) all written communications between*
15 *the Director or other designated officer and any*
16 *person who is not employed by the executive*
17 *branch of the Federal Government;*

18 *“(B) a record of all oral communications,*
19 *and an invitation to participate in meetings, re-*
20 *lating to the substance of a regulatory action be-*
21 *tween the Director or other designated officer*
22 *and any person not employed by the executive*
23 *branch of the Federal Government; and*

1 “(C) a written explanation of any review
2 action taken concerning an agency regulatory
3 action.

4 **“§ 646. Judicial review**

5 “The exercise of the authority granted under this sub-
6 chapter by the Director, the President, or by an officer to
7 whom such authority has been delegated under section 644
8 shall not be subject to judicial review in any manner.”.

9 (b) REGULATORY FLEXIBILITY ANALYSIS.—

10 (1) IN GENERAL.—Section 611 of title 5, United
11 States Code, is amended to read as follows:

12 **“§ 611. Judicial review**

13 “(a)(1) Except as provided in paragraph (2), no later
14 than 1 year after the effective date of a final rule with re-
15 spect to which an agency—

16 “(A) certified, pursuant to section 605(b), that
17 such rule would not have a significant economic im-
18 pact on a substantial number of small entities; or

19 “(B) prepared a final regulatory flexibility anal-
20 ysis pursuant to section 604,

21 an affected small entity may petition for the judicial review
22 of such certification or analysis in accordance with this
23 subsection. A court having jurisdiction to review such rule
24 for compliance with section 553 of this title or under any

1 *other provision of law shall have jurisdiction to review such*
2 *certification or analysis.*

3 “(2)(A) *Except as provided in subparagraph (B), in*
4 *the case of a provision of law that requires that an action*
5 *challenging a final agency regulation be commenced before*
6 *the expiration of the 1-year period provided in paragraph*
7 *(1), such lesser period shall apply to a petition for the judi-*
8 *cial review under this subsection.*

9 “(B) *In a case in which an agency delays the issuance*
10 *of a final regulatory flexibility analysis pursuant to section*
11 *608(b), a petition for judicial review under this subsection*
12 *shall be filed no later than—*

13 “(i) *1 year; or*

14 “(ii) *in a case in which a provision of law re-*
15 *quires that an action challenging a final agency regu-*
16 *lation be commenced before the expiration of the 1-*
17 *year period provided in paragraph (1), the number of*
18 *days specified in such provision of law,*
19 *after the date the analysis is made available to the public.*

20 “(3) *For purposes of this subsection, the term ‘affected*
21 *small entity’ means a small entity that is or will be ad-*
22 *versely affected by the final rule.*

23 “(4) *Nothing in this subsection shall be construed to*
24 *affect the authority of any court to stay the effective date*

1 *of any rule or provision thereof under any other provision*
2 *of law.*

3 “(5)(A) *In a case in which an agency certifies that*
4 *such rule would not have a significant economic impact on*
5 *a substantial number of small entities, the court may order*
6 *the agency to prepare a final regulatory flexibility analysis*
7 *pursuant to section 604 if the court determines, on the basis*
8 *of the rulemaking record, that the certification was arbi-*
9 *trary, capricious, an abuse of discretion, or otherwise not*
10 *in accordance with law.*

11 “(B) *In a case in which the agency prepared a final*
12 *regulatory flexibility analysis, the court may order the*
13 *agency to take corrective action consistent with section 604*
14 *if the court determines, on the basis of the rulemaking*
15 *record, that the final regulatory flexibility analysis was*
16 *prepared by the agency without complying with section 604.*

17 “(6) *If, by the end of the 90-day period beginning on*
18 *the date of the order of the court pursuant to paragraph*
19 *(5) (or such longer period as the court may provide), the*
20 *agency fails, as appropriate—*

21 “(A) *to prepare the analysis required by section*
22 *604; or*

23 “(B) *to take corrective action consistent with sec-*
24 *tion 604 of this title,*

1 *the court may stay the rule or grant such other relief as*
2 *it deems appropriate.*

3 “(7) *In making any determination or granting any*
4 *relief authorized by this subsection, the court shall take due*
5 *account of the rule of prejudicial error.*

6 “(b) *In an action for the judicial review of a rule, any*
7 *regulatory flexibility analysis for such rule (including an*
8 *analysis prepared or corrected pursuant to subsection*
9 *(a)(5)) shall constitute part of the whole record of agency*
10 *action in connection with such review.*

11 “(c) *Nothing in this section bars judicial review of any*
12 *other impact statement or similar analysis required by any*
13 *other law if judicial review of such statement or analysis*
14 *is otherwise provided by law.”.*

15 (2) *EFFECTIVE DATE.—The amendment made by*
16 *paragraph (1) shall take effect on the effective date of*
17 *this Act, except that the judicial review authorized by*
18 *section 611(a) of title 5, United States Code (as added*
19 *by subsection (a)), shall apply only to final agency*
20 *rules issued after such effective date.*

21 (c) *PRESIDENTIAL AUTHORITY.—Nothing in this Act*
22 *shall limit the exercise by the President of the authority*
23 *and responsibility that the President otherwise possesses*
24 *under the Constitution and other laws of the United States*

1 *with respect to regulatory policies, procedures, and pro-*
 2 *grams of departments, agencies, and offices.*

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

4 (1) *Part I of title 5, United States Code, is*
 5 *amended by striking out the chapter heading and*
 6 *table of sections for chapter 6 and inserting in lieu*
 7 *thereof the following:*

8 ***“CHAPTER 6—THE ANALYSIS OF***
 9 ***REGULATORY FUNCTIONS***

“SUBCHAPTER I—REGULATORY ANALYSIS

“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—ANALYSIS OF AGENCY RULES

“621. Definitions.

“622. Rulemaking cost-benefit analysis.

“623. Judicial review.

“624. Deadlines for rulemaking.

“625. Agency review of rules.

“626. Public participation and accountability.

“SUBCHAPTER III—RISK ASSESSMENTS

“631. Findings and purposes.

“632. Definitions.

“633. Applicability.

“634. Savings provisions.

“635. Principles for risk assessment.

“636. Principles for risk characterization.

“637. Peer review.

“638. Guidelines, plan for assessing new information, and report.

“639. Research and training in risk assessment.

- “640. Interagency coordination.
 “640a. Plan for review of risk assessments.
 “640b. Judicial review.
 “640c. Deadlines for rulemaking.

“SUBCHAPTER IV—EXECUTIVE OVERSIGHT

- “641. Definition.
 “642. Procedures.
 “643. Promulgation and adoption.
 “644. Delegation of authority.
 “645. Public disclosure of information.
 “646. 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—REGULATORY ANALYSIS”.

5 **SEC. 4. CONGRESSIONAL REVIEW.**

6 (a) *IN GENERAL.*—Part I of title 5, United States
 7 Code, is amended by inserting after chapter 7 the following
 8 new chapter:

9 **“CHAPTER 8—CONGRESSIONAL REVIEW**
 10 **OF AGENCY RULEMAKING**

11 **“§ 801. Congressional review of agency rulemaking**

12 “(a) For purposes of this chapter, the term—

13 “(1) ‘major rule’ means a major rule as defined
 14 under section 621(4) of this title and as determined
 15 under section 622 of this title; and

16 “(2) ‘rule’ (except in reference to a rule of the
 17 Senate or House of Representatives) is a reference to
 18 a major rule.

1 “(b)(1) Upon the promulgation of a final major rule,
2 the agency promulgating such rule shall submit to the Con-
3 gress a copy of the rule, the statement of basis and purpose
4 for the rule, and the proposed effective date of the rule.

5 “(2) A rule submitted under paragraph (1) shall not
6 take effect as a final rule before the latest of the following:

7 “(A) The later of the date occurring 45 days
8 after the date on which—

9 “(i) the Congress receives the rule submitted
10 under paragraph (1); or

11 “(ii) the rule is published in the Federal
12 Register.

13 “(B) If the Congress passes a joint resolution of
14 disapproval described under subsection (i) relating to
15 the rule, and the President signs a veto of such resolu-
16 tion, the earlier date—

17 “(i) on which either House of Congress votes
18 and fails to override the veto of the President; or

19 “(ii) occurring 30 session days after the
20 date on which the Congress received the veto and
21 objections of the President.

22 “(C) The date the rule would have otherwise
23 taken effect, if not for this section (unless a joint reso-
24 lution of disapproval under subsection (i) is ap-
25 proved).

1 “(c) A major rule shall not take effect as a final rule
2 if the Congress passes a joint resolution of disapproval de-
3 scribed under subsection (i), which is signed by the Presi-
4 dent or is vetoed and overridden by the Congress.

5 “(d)(1) Notwithstanding any other provision of this
6 section (except subject to paragraph (2)), a major rule that
7 would not take effect by reason of this section may take ef-
8 fect if the President makes a determination and submits
9 written notice of such determination to the Congress that
10 the major rule should take effect because such major rule
11 is—

12 “(A) necessary because of an imminent threat to
13 health or safety, or other emergency;

14 “(B) necessary for the enforcement of criminal
15 laws; or

16 “(C) necessary for national security.

17 “(2) An exercise by the President of the authority
18 under this subsection shall have no effect on the procedures
19 under subsection (i) or the effect of a joint resolution of dis-
20 approval under this section.

21 “(e)(1) Subsection (i) shall apply to any major rule
22 that is promulgated as a final rule during the period begin-
23 ning on the date occurring 60 days before the date the Con-
24 gress adjourns sine die through the date on which the suc-
25 ceeding Congress first convenes.

1 “(2) For purposes of subsection (i), a major rule de-
2 scribed under paragraph (1) shall be treated as though such
3 rule were published in the Federal Register (as a rule that
4 shall take effect as a final rule) on the date the succeeding
5 Congress first convenes.

6 “(3) During the period between the date the Congress
7 adjourns sine die through the date on which the succeeding
8 Congress first convenes, a rule described under paragraph
9 (1) shall take effect as a final rule as otherwise provided
10 by law.

11 “(f) Any rule that takes effect and later is made of
12 no force or effect by the enactment of a joint resolution
13 under subsection (i) shall be treated as though such rule
14 had never taken effect.

15 “(g) If the Congress does not enact a joint resolution
16 of disapproval under subsection (i), no court or agency may
17 infer any intent of the Congress from any action or inaction
18 of the Congress with regard to such major rule, related stat-
19 ute, or joint resolution of disapproval.

20 “(h) If the agency fails to comply with the require-
21 ments of subsection (b) for any rule, the rule shall cease
22 to be enforceable against any person.

23 “(i)(1) For purposes of this subsection, the term ‘joint
24 resolution’ means only a joint resolution introduced after
25 the date on which the rule referred to in subsection (b) is

1 received by Congress the matter after the resolving clause
2 of which is as follows: ‘That Congress disapproves the rule
3 submitted by the _____ relating to
4 _____, and such rule shall have no force or ef-
5 fect.’ (The blank spaces being appropriately filled in.)

6 “(2)(A) In the Senate, a resolution described in para-
7 graph (1) shall be referred to the committees with jurisdic-
8 tion. Such a resolution shall not be reported before the
9 eighth day after its submission or publication date.

10 “(B) For purposes of this subsection, the term ‘submis-
11 sion or publication date’ means the later of the date on
12 which—

13 “(i) the Congress receives the rule submitted
14 under subsection (b)(1); or

15 “(ii) the rule is published in the Federal Reg-
16 ister.

17 “(3) In the Senate, if the committee to which a resolu-
18 tion described in paragraph (1) is referred has not reported
19 such resolution (or an identical resolution) at the end of
20 20 calendar days after its submission or publication date,
21 such committee may be discharged on a petition approved
22 by 30 Senators from further consideration of such resolution
23 and such resolution shall be placed on the Senate calendar.

24 “(4)(A) In the Senate, when the committee to which
25 a resolution is referred has reported, or when a committee

1 *is discharged (under paragraph (3)) from further consider-*
2 *ation of, a resolution described in paragraph (1), it shall*
3 *at any time thereafter be in order (even though a previous*
4 *motion to the same effect has been disagreed to) for any*
5 *Senator to move to proceed to the consideration of the reso-*
6 *lution, and all points of order against the resolution (and*
7 *against consideration of the resolution) shall be waived. The*
8 *motion shall be privileged in the Senate and shall not be*
9 *debatable. The motion shall not be subject to amendment,*
10 *or to a motion to postpone, or to a motion to proceed to*
11 *the consideration of other business. A motion to reconsider*
12 *the vote by which the motion is agreed to or disagreed to*
13 *shall not be in order. If a motion to proceed to the consider-*
14 *ation of the resolution is agreed to, the resolution shall re-*
15 *main the unfinished business of the Senate until disposed*
16 *of.*

17 “(B) *In the Senate, debate on the resolution, and on*
18 *all debatable motions and appeals in connection therewith,*
19 *shall be limited to not more than 10 hours, which shall be*
20 *divided equally between those favoring and those opposing*
21 *the resolution. A motion further to limit debate shall be in*
22 *order and shall not be debatable. An amendment to, or a*
23 *motion to postpone, or a motion to proceed to the consider-*
24 *ation of other business, or a motion to recommit the resolu-*
25 *tion shall not be in order. A motion to reconsider the vote*

1 *by which the resolution is agreed to or disagreed to shall*
2 *not be in order.*

3 “(C) *In the Senate, immediately following the conclu-*
4 *sion of the debate on a resolution described in paragraph*
5 *(1), and a single quorum call at the conclusion of the debate*
6 *if requested in accordance with the Senate rules, the vote*
7 *on final passage of the resolution shall occur.*

8 “(D) *Appeals from the decisions of the Chair relating*
9 *to the application of the rules of the Senate to the procedure*
10 *relating to a resolution described in paragraph (1) shall*
11 *be decided without debate.*

12 “(5) *If, before the passage in the Senate of a resolution*
13 *described in paragraph (1), the Senate receives from the*
14 *House of Representatives a resolution described in para-*
15 *graph (1), then the following procedures shall apply:*

16 “(A) *The resolution of the House of Representa-*
17 *tives shall not be referred to a committee.*

18 “(B) *With respect to a resolution described in*
19 *paragraph (1) of the Senate—*

20 “(i) *the procedure in the Senate shall be the*
21 *same as if no resolution had been received from*
22 *the other House; but*

23 “(ii) *the vote on final passage shall be on*
24 *the resolution of the other House.*

25 “(6) *This subsection is enacted by Congress—*

1 “(A) as an exercise of the rulemaking power of
 2 the Senate and House of Representatives, respectively,
 3 and as such it is deemed to be a part of the rules of
 4 each House, respectively, but applicable only with re-
 5 spect to the procedure to be followed in that House in
 6 the case of a resolution described in paragraph (1),
 7 and it supersedes other rules only to the extent that
 8 it is inconsistent with such rules; and

9 “(B) with full recognition of the constitutional
 10 right of either House to change the rules (so far as re-
 11 lating to the procedure of that House) at any time,
 12 in the same manner, and to the same extent as in the
 13 case of any other rule of that House.

14 “(j) No requirements under this chapter shall be subject
 15 to judicial review in any manner.”.

16 (b) *TECHNICAL AND CONFORMING AMENDMENT.*—The
 17 table of chapters for part I of title 5, United States Code,
 18 is amended by inserting after the item relating to chapter
 19 7 the following:

“8. Congressional Review of Agency Rulemaking 801”.

20 ***SEC. 5. STUDIES AND REPORTS.***

21 (a) *RISK ASSESSMENTS.*—The Administrative Con-
 22 ference of the United States shall—

23 (1) develop and carry out an ongoing study of
 24 the operation of the risk assessment requirements of

1 *subchapter III of chapter 6 of title 5, United States*
2 *Code (as added by section 3 of this Act); and*

3 *(2) submit an annual report to the Congress on*
4 *the findings of the study.*

5 *(b) ADMINISTRATIVE PROCEDURE ACT.—No later than*
6 *December 31, 1996, the Administrative Conference of the*
7 *United States shall—*

8 *(1) carry out a study of the operation of chapters*
9 *5 and 6 of title 5, United States Code (commonly re-*
10 *ferred to as the Administrative Procedure Act), as*
11 *amended by section 3 of this Act; and*

12 *(2) submit a report to the Congress on the find-*
13 *ings of the study, including proposals for revision, if*
14 *any.*

15 **SEC. 6. RISK-BASED PRIORITIES.**

16 *(a) PURPOSES.—The purposes of this section are to—*

17 *(1) encourage Federal agencies engaged in regu-*
18 *lating risks to human health, safety, and the environ-*
19 *ment to achieve the greatest risk reduction at the least*
20 *cost practical;*

21 *(2) promote the coordination of policies and pro-*
22 *grams to reduce risks to human health, safety, and*
23 *the environment; and*

24 *(3) promote open communication among Federal*
25 *agencies, the public, the President, and Congress re-*

1 *garding environmental, health, and safety risks, and*
2 *the prevention and management of those risks.*

3 *(b) DEFINITIONS.—For the purposes of this section:*

4 *(1) COMPARATIVE RISK ANALYSIS.—The term*
5 *“comparative risk analysis” means a process to sys-*
6 *tematically estimate, compare, and rank the size and*
7 *severity of risks to provide a common basis for evalu-*
8 *ating strategies for reducing or preventing those risks.*

9 *(2) COVERED AGENCY.—The term “covered agen-*
10 *cy” means each of the following:*

11 *(A) The Environmental Protection Agency.*

12 *(B) The Department of Labor.*

13 *(C) The Department of Transportation.*

14 *(D) The Food and Drug Administration.*

15 *(E) The Department of Energy.*

16 *(F) The Department of the Interior.*

17 *(G) The Department of Agriculture.*

18 *(H) The Consumer Product Safety Commis-*

19 *sion.*

20 *(I) The National Oceanic and Atmospheric*
21 *Administration.*

22 *(J) The United States Army Corps of Engi-*
23 *neers.*

24 *(K) The Nuclear Regulatory Commission.*

1 (3) *EFFECT.*—The term “effect” means a deleterious change in the condition of—

2
3 (A) a human or other living thing (including death, cancer, or other chronic illness, decreased reproductive capacity, or disfigurement);
4
5
6 or

7 (B) an inanimate thing important to human welfare (including destruction, degeneration, the loss of intended function, and increased costs for maintenance).

11 (4) *IRREVERSIBILITY.*—The term “irreversibility” means the extent to which a return to conditions before the occurrence of an effect are either very slow or will never occur.

15 (5) *LIKELIHOOD.*—The term “likelihood” means the estimated probability that an effect will occur.

17 (6) *MAGNITUDE.*—The term “magnitude” means the number of individuals or the quantity of ecological resources or other resources that contribute to human welfare that are affected by exposure to a stressor.

22 (7) *SERIOUSNESS.*—The term “seriousness” means the intensity of effect, the likelihood, the irreversibility, and the magnitude.

25 (c) *DEPARTMENT AND AGENCY PROGRAM GOALS.*—

1 (1) *SETTING PRIORITIES.*—*In exercising author-*
2 *ity under applicable laws protecting human health,*
3 *safety, or the environment, the head of each covered*
4 *agency should set priorities and use the resources*
5 *available under those laws to address those risks to*
6 *human health, safety, and the environment that—*

7 (A) *the covered agency determines to be the*
8 *most serious; and*

9 (B) *can be addressed in a cost-effective*
10 *manner, with the goal of achieving the greatest*
11 *overall net reduction in risks with the public and*
12 *private sector resources expended.*

13 (2) *DETERMINING THE MOST SERIOUS RISKS.*—
14 *In identifying the greatest risks under paragraph (1)*
15 *of this subsection, each covered agency shall consider,*
16 *at a minimum—*

17 (A) *the likelihood, irreversibility, and sever-*
18 *ity of the effect; and*

19 (B) *the number and classes of individuals*
20 *potentially affected, and shall explicitly take into*
21 *account the results of the comparative risk anal-*
22 *ysis conducted under subsection (d) of this sec-*
23 *tion.*

24 (3) *OMB REVIEW.*—*The covered agency's deter-*
25 *minations of the most serious risks for purposes of set-*

1 *ting priorities shall be reviewed and approved by the*
2 *Director of the Office of Management and Budget be-*
3 *fore submission of the covered agency's annual budget*
4 *requests to Congress.*

5 (4) *INCORPORATING RISK-BASED PRIORITIES*
6 *INTO BUDGET AND PLANNING.—The head of each cov-*
7 *ered agency shall incorporate the priorities identified*
8 *under paragraph (1) into the agency budget, strategic*
9 *planning, regulatory agenda, enforcement, and re-*
10 *search activities. When submitting its budget request*
11 *to Congress and when announcing its regulatory*
12 *agenda in the Federal Register, each covered agency*
13 *shall identify the risks that the covered agency head*
14 *has determined are the most serious and can be ad-*
15 *dressed in a cost-effective manner under paragraph*
16 *(1), the basis for that determination, and explicitly*
17 *identify how the covered agency's requested budget*
18 *and regulatory agenda reflect those priorities.*

19 (5) *EFFECTIVE DATE.—This subsection shall take*
20 *effect 12 months after the date of enactment of this*
21 *Act.*

22 (d) *COMPARATIVE RISK ANALYSIS.—*

23 (1) *REQUIREMENT.—(A)(i) No later than 6*
24 *months after the effective date of this Act, the Director*
25 *of the Office of Management and Budget shall enter*

1 *into appropriate arrangements with an accredited*
2 *scientific body—*

3 *(I) to conduct a study of the methodologies*
4 *for using comparative risk to rank dissimilar*
5 *human health, safety, and environmental risks;*
6 *and*

7 *(II) to conduct a comparative risk analysis.*

8 *(ii) The comparative risk analysis shall compare*
9 *and rank, to the extent feasible, human health, safety,*
10 *and environmental risks potentially regulated across*
11 *the spectrum of programs administered by all covered*
12 *agencies.*

13 *(B) The Director shall consult with the Office of*
14 *Science and Technology Policy regarding the scope of*
15 *the study and the conduct of the comparative risk*
16 *analysis.*

17 *(2) CRITERIA.—In arranging for the compara-*
18 *tive risk analysis referred to in paragraph (1) of this*
19 *subsection, the Director shall ensure that—*

20 *(A) the scope and specificity of the analysis*
21 *are sufficient to provide the President and agen-*
22 *cy heads guidance in allocating resources across*
23 *agencies and among programs in agencies to*
24 *achieve the greatest degree of risk prevention and*

1 *reduction for the public and private resources ex-*
2 *pended;*

3 *(B) the analysis is conducted through an*
4 *open process, by individuals with relevant exper-*
5 *tise, including toxicologists, biologists, engineers*
6 *and experts in medicine, industrial hygiene and*
7 *environmental effects;*

8 *(C) the analysis is conducted, to the extent*
9 *feasible, consistent with the risk assessment and*
10 *risk characterization principles in sections 635*
11 *and 636 of this title;*

12 *(D) the methodologies and principal sci-*
13 *entific determinations made in the analysis are*
14 *subjected to independent and external peer re-*
15 *view consistent with section 637, and the conclu-*
16 *sions of the peer review are made publicly avail-*
17 *able as part of the final report required under*
18 *subsection (e);*

19 *(E) there is an opportunity for public com-*
20 *ment on the results before making them final;*
21 *and*

22 *(F) the results are presented in a manner*
23 *that distinguishes between the scientific conclu-*
24 *sions and any policy or value judgments em-*
25 *bodied in the comparisons.*

1 (3) *COMPLETION AND REVIEW.*—No later than 3
2 years after the effective date of this Act, the compara-
3 tive risk analysis required under paragraph (1) shall
4 be completed. The comparative risk analysis shall be
5 reviewed and revised at least every 5 years thereafter
6 for a minimum of 15 years following the release of the
7 first analysis. The Director shall arrange for such re-
8 view and revision with an accredited scientific body
9 in the same manner as provided under paragraphs
10 (1) and (2).

11 (4) *STUDY.*—The study of methodologies pro-
12 vided under paragraph (1) shall be conducted as part
13 of the first comparative risk analysis and shall be
14 completed no later than 180 days after the completion
15 of that analysis. The goal of the study shall be to de-
16 velop and rigorously test methods of comparative risk
17 analysis. The study shall have sufficient scope and
18 breadth to test approaches for improving comparative
19 risk analysis and its use in setting priorities for
20 human health, safety, and environmental risk preven-
21 tion and reduction.

22 (5) *TECHNICAL GUIDANCE.*—No later than 180
23 days after the effective date of this Act, the Director,
24 in collaboration with other heads of covered agencies
25 shall enter into a contract with the National Research

1 *Council to provide technical guidance to agencies on*
2 *approaches to using comparative risk analysis in set-*
3 *ting human health, safety, and environmental prior-*
4 *ities to assist agencies in complying with subsection*
5 *(c) of this section.*

6 *(e) REPORTS AND RECOMMENDATIONS TO CONGRESS*
7 *AND THE PRESIDENT.—No later than 24 months after the*
8 *effective date of this Act, each covered agency shall submit*
9 *a report to Congress and the President—*

10 *(1) detailing how the agency has complied with*
11 *subsection (c) and describing the reasons for any de-*
12 *parture from the requirement to establish priorities to*
13 *achieve the greatest overall net reduction in risk;*

14 *(2) recommending—*

15 *(A) modification, repeal, or enactment of*
16 *laws to reform, eliminate, or enhance programs*
17 *or mandates relating to human health, safety, or*
18 *the environment; and*

19 *(B) modification or elimination of statu-*
20 *torily or judicially mandated deadlines,*

21 *that would assist the covered agency to set priorities*
22 *in activities to address the risks to human health,*
23 *safety, or the environment in a manner consistent*
24 *with the requirements of subsection (c)(1);*

1 (3) *evaluating the categories of policy and value*
2 *judgments used in risk assessment, risk characteriza-*
3 *tion, or cost-benefit analysis; and*

4 (4) *discussing risk assessment research and*
5 *training needs, and the agency's strategy and schedule*
6 *for meeting those needs.*

7 (f) *SAVINGS PROVISION AND JUDICIAL REVIEW.—*

8 (1) *IN GENERAL.—Nothing in this section shall*
9 *be construed to modify any statutory standard or re-*
10 *quirement designed to protect human health, safety,*
11 *or the environment.*

12 (2) *JUDICIAL REVIEW.—Compliance or non-*
13 *compliance by an agency with the provisions of this*
14 *section shall not be subject to judicial review.*

15 (3) *AGENCY ANALYSIS.—Any analysis prepared*
16 *under this section shall not be subject to judicial con-*
17 *sideration separate or apart from the requirement,*
18 *rule, program, or law to which it relates. When an*
19 *action for judicial review of a covered agency action*
20 *is instituted, any analysis for, or relating to, the ac-*
21 *tion shall constitute part of the whole record of agency*
22 *action for the purpose of judicial review of the action*
23 *and shall, to the extent relevant, be considered by a*
24 *court in determining the legality of the covered agen-*
25 *cy action.*

1 **SEC. 7. REGULATORY ACCOUNTING.**

2 (a) *DEFINITIONS.*—For purposes of this section, the
3 following definitions apply:

4 (1) *AGENCY.*—The term “agency” means any ex-
5 ecutive department, military department, Government
6 corporation, Government controlled corporation, or
7 other establishment in the executive branch of the
8 Government (including the Executive Office of the
9 President), or any independent regulatory agency, but
10 shall not include—

11 (A) the General Accounting Office;

12 (B) the Federal Election Commission;

13 (C) the governments of the District of Co-
14 lumbia and of the territories and possessions of
15 the United States, and their various subdivi-
16 sions; or

17 (D) government-owned contractor-operated
18 facilities, including laboratories engaged in na-
19 tional defense research and production activities.

20 (2) *REGULATION.*—The term “regulation” means
21 an agency statement of general applicability and fu-
22 ture effect designed to implement, interpret, or pre-
23 scribe law or policy or describing the procedures or
24 practice requirements of an agency. The term shall
25 not include—

1 (A) *administrative actions governed by sec-*
2 *tions 556 and 557 of title 5, United States Code;*

3 (B) *regulations issued with respect to a*
4 *military or foreign affairs function of the United*
5 *States; or*

6 (C) *regulations related to agency organiza-*
7 *tion, management, or personnel.*

8 (b) *ACCOUNTING STATEMENT.—*

9 (1) *IN GENERAL.—(A) The President shall be re-*
10 *sponsible for implementing and administering the re-*
11 *quirements of this section.*

12 (B) *Every 2 years, no later than June of the sec-*
13 *ond year, the President shall prepare and submit to*
14 *Congress an accounting statement that estimates the*
15 *annual costs of Federal regulatory programs and cor-*
16 *responding benefits in accordance with this sub-*
17 *section.*

18 (2) *YEARS COVERED BY ACCOUNTING STATE-*
19 *MENT.—Each accounting statement shall cover, at a*
20 *minimum, the 5 fiscal years beginning on October 1*
21 *of the year in which the report is submitted and may*
22 *cover any fiscal year preceding such fiscal years for*
23 *purpose of revising previous estimates.*

24 (3) *TIMING AND PROCEDURES.—(A) The Presi-*
25 *dent shall provide notice and opportunity for com-*

1 *ment for each accounting statement. The President*
2 *may delegate to an agency the requirement to provide*
3 *notice and opportunity to comment for the portion of*
4 *the accounting statement relating to that agency.*

5 *(B) The President shall propose the first ac-*
6 *counting statement under this subsection no later*
7 *than 2 years after the effective date of this Act and*
8 *shall issue the first accounting statement in final*
9 *form no later than 3 years after such effective date.*
10 *Such statement shall cover, at a minimum, each of*
11 *the fiscal years beginning after the effective date of*
12 *this Act.*

13 *(4) CONTENT OF ACCOUNTING STATEMENT.—(A)*
14 *Each accounting statement shall contain estimates of*
15 *costs and benefits with respect to each fiscal year cov-*
16 *ered by the statement in accordance with this para-*
17 *graph. For each such fiscal year for which estimates*
18 *were made in a previous accounting statement, the*
19 *statement shall revise those estimates and state the*
20 *reasons for the revisions.*

21 *(B)(i) An accounting statement shall estimate*
22 *the costs of Federal regulatory programs by setting*
23 *forth, for each year covered by the statement—*

1 (I) the annual expenditure of national eco-
2 nomic resources for each regulatory program;
3 and

4 (II) such other quantitative and qualitative
5 measures of costs as the President considers ap-
6 propriate.

7 (ii) For purposes of the estimate of costs in the
8 accounting statement, national economic resources
9 shall include, and shall be listed under, at least the
10 following categories:

11 (I) Private sector costs.

12 (II) Federal sector costs.

13 (III) State and local government costs.

14 (C) An accounting statement shall estimate the
15 benefits of Federal regulatory programs by setting
16 forth, for each year covered by the statement, such
17 quantitative and qualitative measures of benefits as
18 the President considers appropriate. Any estimates of
19 benefits concerning reduction in human health, safety,
20 or environmental risks shall present the most plau-
21 sible level of risk practical, along with a statement of
22 the reasonable degree of scientific certainty.

23 (c) ASSOCIATED REPORT TO CONGRESS.—

24 (1) IN GENERAL.—At the same time as the Presi-
25 dent submits an accounting statement under sub-

1 *section (b), the President, acting through the Director*
2 *of the Office of Management and Budget, shall submit*
3 *to Congress a report associated with the accounting*
4 *statement (hereinafter referred to as an “associated*
5 *report”). The associated report shall contain, in ac-*
6 *cordance with this subsection—*

7 *(A) analyses of impacts; and*

8 *(B) recommendations for reform.*

9 *(2) ANALYSES OF IMPACTS.—The President shall*
10 *include in the associated report the following:*

11 *(A) The cumulative impact on the economy*
12 *of Federal regulatory programs covered in the*
13 *accounting statement. Factors to be considered in*
14 *such report shall include impacts on the follow-*
15 *ing:*

16 *(i) The ability of State and local gov-*
17 *ernments to provide essential services, in-*
18 *cluding police, fire protection, and edu-*
19 *cation.*

20 *(ii) Small business.*

21 *(iii) Productivity.*

22 *(iv) Wages.*

23 *(v) Economic growth.*

24 *(vi) Technological innovation.*

1 (vii) *Consumer prices for goods and*
2 *services.*

3 (viii) *Such other factors considered ap-*
4 *propriate by the President.*

5 (B) *A summary of any independent analy-*
6 *ses of impacts prepared by persons commenting*
7 *during the comment period on the accounting*
8 *statement.*

9 (3) *RECOMMENDATIONS FOR REFORM.*—*The*
10 *President shall include in the associated report the*
11 *following:*

12 (A) *A summary of recommendations of the*
13 *President for reform or elimination of any Fed-*
14 *eral regulatory program or program element that*
15 *does not represent sound use of national eco-*
16 *nomical resources or otherwise is inefficient.*

17 (B) *A summary of any recommendations*
18 *for such reform or elimination of Federal regu-*
19 *latory programs or program elements prepared*
20 *by persons commenting during the comment pe-*
21 *riod on the accounting statement.*

22 (d) *GUIDANCE FROM OFFICE OF MANAGEMENT AND*
23 *BUDGET.*—*The Director of the Office of Management and*
24 *Budget shall, in consultation with the Council of Economic*

1 *Advisers and the agencies, develop guidance for the agen-*
2 *cies—*

3 (1) *to standardize measures of costs and benefits*
4 *in accounting statements prepared pursuant to this*
5 *section and section 3 of this Act, including—*

6 (A) *detailed guidance on estimating the*
7 *costs and benefits of major rules; and*

8 (B) *general guidance on estimating the costs*
9 *and benefits of all other rules that do not meet*
10 *the thresholds for major rules; and*

11 (2) *to standardize the format of the accounting*
12 *statements.*

13 (e) *RECOMMENDATIONS FROM CONGRESSIONAL BUDG-*
14 *ET OFFICE.—After each accounting statement and associ-*
15 *ated report submitted to Congress, the Director of the Con-*
16 *gressional Budget Office shall make recommendations to the*
17 *President—*

18 (1) *for improving accounting statements pre-*
19 *pared pursuant to this section, including rec-*
20 *ommendations on level of detail and accuracy; and*

21 (2) *for improving associated reports prepared*
22 *pursuant to this section, including recommendations*
23 *on the quality of analysis.*

24 (f) *JUDICIAL REVIEW.—No requirements under this*
25 *section shall be subject to judicial review in any manner.*

1 **SEC. 8. EFFECTIVE DATE.**

2 *Except as otherwise provided in this Act, this Act shall*
3 *take effect 180 days after the date of the enactment of this*
4 *Act.*

S 291 RS—2

S 291 RS—3

S 291 RS—4

S 291 RS—5

S 291 RS—6

S 291 RS—7

S 291 RS—8

S 291 RS—9

S 291 RS—10