

Calendar No. 219

106TH CONGRESS
1ST Session

S. 746

[Report No. 106-110]

A BILL

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

JULY 20, 1999

Reported with amendments

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

IN THE SENATE OF THE UNITED STATES

MARCH 25, 1999

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

JULY 20, 1999

Reported by Mr. THOMPSON, with amendments

[Omit the part struck through and insert the part printed in italic]

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Regulatory Improve-
3 ment Act of 1999”.

4 **SEC. 2. FINDINGS.**

5 Congress finds the following:

6 (1) Effective regulatory programs provide im-
7 portant benefits to the public, including improving
8 the environment, worker safety, and public health.
9 Regulatory programs also impose significant costs
10 on the public, including individuals, businesses, and
11 State, local, and tribal governments.

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

16 (3) Cost-benefit analysis and risk assessment
17 are useful tools to better inform agencies in devel-
18 oping regulations, although such analyses and as-
19 sessments do not replace the need for good judgment
20 and consideration of values.

21 (4) The evaluation of costs and benefits must
22 involve the consideration of the relevant information,
23 whether expressed in quantitative or qualitative
24 terms, including factors such as social values, dis-
25 tributional effects, and equity.

1 (5) Cost-benefit analysis and risk assessment
2 should be presented with a clear statement of the
3 analytical assumptions and uncertainties, including
4 an explanation of what is known and not known and
5 what the implications of alternative assumptions
6 might be.

7 (6) The public has a right to know about the
8 costs and benefits of regulations, the risks ad-
9 dressed, the risks reduced, and the quality of sci-
10 entific and economic analysis used to support deci-
11 sions. Such knowledge will promote the quality, in-
12 tegrity and responsiveness of agency actions.

13 (7) The Administrator of the Office of Informa-
14 tion and Regulatory Affairs should oversee regu-
15 latory activities to raise the quality and consistency
16 of cost-benefit analysis and risk assessment among
17 all agencies.

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

1 **SEC. 3. REGULATORY ANALYSIS.**

2 (a) IN GENERAL.—Chapter 6 of title 5, United
3 States Code, is amended by adding at the end the fol-
4 lowing:

5 “SUBCHAPTER II—REGULATORY ANALYSIS

6 “§ 621. Definitions

7 “For purposes of this subchapter the definitions
8 under section 551 shall apply and—

9 “(1) the term ‘Administrator’ means the Ad-
10 ministrator of the Office of Information and Regu-
11 latory Affairs of the Office of Management and
12 Budget;

13 “(2) the term ‘benefit’ means the reasonably
14 identifiable significant favorable effects, quantifiable
15 and nonquantifiable, including social, health, safety,
16 environmental, economic, and distributional effects,
17 that are expected to result from implementation of,
18 or compliance with, a rule;

19 “(3) the term ‘cost’ means the reasonably iden-
20 tifiable significant adverse effects, quantifiable and
21 nonquantifiable, including social, health, safety, envi-
22 ronmental, economic, and distributional effects, that
23 are expected to result from implementation of, or
24 compliance with, a rule;

25 “(4) the term ‘cost-benefit analysis’ means an
26 evaluation of the costs and benefits of a rule, quan-

1 tified to the extent feasible and appropriate and oth-
2 erwise qualitatively described, that is prepared in ac-
3 cordance with the requirements of this subchapter at
4 the level of detail appropriate and practicable for
5 reasoned decisionmaking on the matter involved,
6 taking into consideration uncertainties, the signifi-
7 cance and complexity of the decision, and the need
8 to adequately inform the public;

9 “(5) the term ‘Director’ means the Director of
10 the Office of Management and Budget, acting
11 through the Administrator of the Office of Informa-
12 tion and Regulatory Affairs;

13 “(6) the term ‘flexible regulatory options’
14 means regulatory options that permit flexibility to
15 regulated persons in achieving the objective of the
16 statute as addressed by the rule making, including
17 regulatory options that use market-based mecha-
18 nisms, outcome oriented performance-based stand-
19 ards, or other options that promote flexibility;

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

21 “(A) the agency proposing the rule or the
22 Director reasonably determines is likely to have
23 an annual effect on the economy of
24 \$100,000,000 or more in reasonably quantifi-
25 able costs; or

1 “(B) is otherwise designated a major rule
2 by the Director on the ground that the rule is
3 likely to adversely affect, in a material way, the
4 economy, a sector of the economy, including
5 small business, productivity, competition, jobs,
6 the environment, public health or safety, or
7 State, local or tribal governments, or commu-
8 nities;

9 “(8) the term ‘reasonable alternative’ means a
10 reasonable regulatory option that would achieve the
11 objective of the statute as addressed by the rule
12 making and that the agency has authority to adopt
13 under the statute granting rule making authority,
14 including flexible regulatory options;

15 “(9) the term ‘risk assessment’ means the sys-
16 tematic, objective process of organizing hazard and
17 exposure information, based on a careful analysis of
18 the weight of the scientific evidence, to estimate the
19 potential for specific harm to an exposed population,
20 subpopulation, or natural resource including, to the
21 extent feasible, a characterization of the distribution
22 of risk as well as an analysis of uncertainties,
23 variabilities, conflicting information, and inferences
24 and assumptions;

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

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

5 “(B) a rule that involves the internal rev-
6 enue laws of the United States, or the assess-
7 ment or collection of taxes, duties, or other
8 debts, revenue, or receipts;

9 “(C) a rule of particular applicability that
10 approves or prescribes for the future rates,
11 wages, prices, services, corporate or financial
12 structures, reorganizations, mergers, acquisi-
13 tions, accounting practices, or disclosures bear-
14 ing on any of the foregoing;

15 “(D) a rule relating to monetary policy
16 proposed or promulgated by the Board of Gov-
17 ernors of the Federal Reserve System or by the
18 Federal Open Market Committee;

19 “(E) a rule relating to the operations, safe-
20 ty, or soundness of federally insured depository
21 institutions or any affiliate of such an institu-
22 tion (as defined in section 2(k) of the Bank
23 Holding Company Act of 1956 (12 U.S.C.
24 1841(k)); credit unions; the Federal Home
25 Loan Banks; government-sponsored housing en-

1 terprises; a Farm Credit System Institution;
 2 foreign banks, and their branches, agencies,
 3 commercial lending companies or representative
 4 offices that operate in the United States and
 5 any affiliate of such foreign banks (as those
 6 terms are defined in the International Banking
 7 Act of 1978 (12 U.S.C. 3101)); or a rule relat-
 8 ing to the payments system or the protection of
 9 deposit insurance funds or Farm Credit Insur-
 10 ance Fund;

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

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

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

21 “(I) a rule or agency action relating to the
 22 public debt or fiscal policy of the United States;
 23 or

24 “(J) a rule or agency action that author-
 25 izes or bars the introduction into or removal

from commerce, or recognizes or cancels recognition of the marketable status, of a product under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.); and

“(11) the term ‘substitution risk’—

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

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

§ 622. Applicability and effect

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

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

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

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

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

1 “(3) any opportunity for judicial review made
2 applicable under other statutes.

3 **“§ 623. Regulatory analysis**

4 “(a)(1) Before publishing a notice of a proposed rule
5 making for any rule, each agency shall determine whether
6 the rule is or is not a major rule covered by this sub-
7 chapter.

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

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

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

17 “(b)(1)(A) When an agency publishes a notice of pro-
18 posed rule making for a major rule, the agency shall—

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

21 “(ii) include a summary of such analysis con-
22 sistent with subsection (e) in the notice of proposed
23 rule making.

24 “(B)(i) When the Director has published a designa-
25 tion that a rule is a major rule after the publication of

1 the notice of proposed rule making for the rule, the agency
2 shall—

3 “(I) promptly prepare and place in the rule
4 making file an initial regulatory analysis for the
5 rule; and

6 “(II) publish in the Federal Register a sum-
7 mary of such analysis consistent with subsection (e).

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

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

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

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

23 “(ii) an analysis of the costs of the pro-
24 posed rule, including any costs that cannot be
25 quantified, and an explanation of how the agen-

1 cy anticipates that such costs will result from
2 the proposed rule, including a description of the
3 persons or classes of persons likely to bear such
4 costs;

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

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

16 “(I) require no government action or
17 utilize voluntary programs;

18 “(II) provide flexibility for small enti-
19 ties under subchapter I and for State,
20 local, or tribal government agencies dele-
21 gated to administer a Federal program;

22 “(III) employ flexible regulatory op-
23 tions; and

1 “(IV) assure protection of sensitive
2 subpopulations, or populations exposed to
3 multiple and cumulative risks; and

4 “(v) a description of the scientific or eco-
5 nomic evaluations or information upon which
6 the agency substantially relied in the cost-ben-
7 efit analysis and risk assessment required under
8 this subchapter, and an explanation of how the
9 agency reached the determinations under sub-
10 section (d);

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

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

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

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

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

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

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

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

11 “(i) whether the rule is likely to provide bene-
12 fits that justify the costs of the rule;

13 “(ii) whether the rule is likely to substantially
14 achieve the rule making objective in a more cost-ef-
15 fective manner, or with greater net benefits, than
16 the other reasonable alternatives considered by the
17 agency; and

18 “(iii) whether the rule adopts a flexible regu-
19 latory option.

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

23 “(2) If the agency head determines that the rule is
24 not likely to provide benefits that justify the costs of the
25 rule or is not likely to substantially achieve the rule mak-

1 ing objective in a more cost-effective manner, or with
2 greater net benefits, than the other reasonable alternatives
3 considered by the agency, the agency head shall—

4 “(A) explain the reasons for selecting the rule
5 notwithstanding such determination, including iden-
6 tifying any statutory provision that required the
7 agency to select such rule;

8 “(B) describe any reasonable alternative consid-
9 ered by the agency that would be likely to provide
10 benefits that justify the costs of the rule and be like-
11 ly to substantially achieve the rule making objective
12 in a more cost-effective manner, or with greater net
13 benefits, than the alternative selected by the agency;
14 and

15 “(C) describe any flexible regulatory option con-
16 sidered by the agency and explain why that option
17 was not adopted by the agency if that option was
18 not adopted.

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

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

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

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

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

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

12 “(A) the agency for good cause finds that con-
13 ducting the regulatory analysis under this sub-
14 chapter before the rule becomes effective is impracti-
15 cable or contrary to an important public interest;
16 and

17 “(B) the agency publishes the rule in the Fed-
18 eral Register with such finding and a succinct expla-
19 nation of the reasons for the finding.

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

24 “(g) Each agency shall develop an effective process
25 to permit elected officers of State, local, and tribal govern-

1 ments (or their designated employees with authority to act
 2 on their behalf) to provide meaningful and timely input
 3 in the development of regulatory proposals that contain
 4 significant Federal intergovernmental mandates. The
 5 process developed under this subsection shall be consistent
 6 with section 204 of the Unfunded Mandates Reform Act
 7 of 1995 (2 U.S.C. 1534).

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

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

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

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

17 “(I) reasonably anticipates is likely to have
 18 an annual effect on the economy of
 19 \$100,000,000 or more in reasonably quantifi-
 20 able costs; and

21 “(II) determines shall be subject to the re-
 22 quirements of this section.

23 “(B)(i) Risk assessments conducted under this sub-
 24 chapter shall be conducted in a manner that promotes ra-
 25 tional and informed risk management decisions and in-

1 formed public input into and understanding of the process
 2 of making agency decisions.

3 “(ii) The scope and level of analysis of such a risk
 4 assessment shall be commensurate with the significance
 5 and complexity of the decision and the need to adequately
 6 inform the public, consistent with any need for expedition,
 7 and designed for the nature of the risk being assessed.

8 “(2) If a risk assessment under this subchapter is
 9 otherwise required by this section, but the agency deter-
 10 mines that—

11 “(A) a final rule subject to this subchapter is
 12 substantially similar to the proposed rule with re-
 13 spect to the risk being addressed;

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

17 “(C) a new risk assessment for the final rule is
 18 not required in order to respond to comments re-
 19 ceived during the period for comment on the pro-
 20 posed rule,

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

24 “(b) Each agency shall consider in each risk assess-
 25 ment all relevant, reliable, and reasonably available sci-

1 entific information and shall describe the basis for select-
 2 ing such scientific information.

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

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

10 “(B) explain the basis for any choices among
 11 assumptions and, where applicable, the basis for
 12 combining multiple assumptions; and

13 “(C) describe reasonable alternative assump-
 14 tions that—

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

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

19 “(2) Significant assumptions used in a risk assess-
 20 ment shall incorporate all reasonably available, relevant,
 21 and reliable scientific information.

22 “(d) The agency shall inform the public when the
 23 agency is conducting a risk assessment subject to this sec-
 24 tion and, to the extent practicable, shall solicit relevant

1 and reliable data from the public. The agency shall con-
2 sider such data in conducting the risk assessment.

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

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

6 “(2) A description of the populations or natural
7 resources that are the subject of the risk assess-
8 ment.

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

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

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

19 “(f) To the extent scientifically appropriate, each
20 agency shall—

21 “(1) express the estimate of risk as 1 or more
22 reasonable ranges and, if feasible, probability dis-
23 tributions that reflect variabilities, uncertainties, and
24 lack of data in the analysis;

1 “(2) provide the ranges and distributions of
2 risks, including central and high end estimates of
3 the risks, and their corresponding exposure scenarios
4 for the potentially exposed population and, as appro-
5 priate, for more highly exposed or sensitive sub-
6 populations; and

7 “(3) describe the qualitative factors influencing
8 the ranges, distributions, and likelihood of possible
9 risks.

10 “(g) When scientific information that permits rel-
11 evant comparisons of risk is reasonably available, each
12 agency shall use the information to place the nature and
13 magnitude of a risk to health, safety, or the environment
14 being analyzed in relationship to other reasonably com-
15 parable risks familiar to and routinely encountered by the
16 general public. Such comparisons should consider relevant
17 distinctions among risks, such as the voluntary or involun-
18 tary nature of risks, well understood or newly discovered
19 risks, and reversible or irreversible risks.

20 **“§ 625. Peer review**

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

23 “(1) a cost-benefit analysis of a major rule that
24 the agency or Director reasonably anticipates is like-

1 ly to have an annual effect on the economy of
2 \$500,000,000 in reasonably quantifiable costs; and

3 “(2) a risk assessment required by this sub-
4 chapter.

5 “(b)(1) Peer review required under subsection (a)
6 shall—

7 “(A) be conducted through panels, expert bod-
8 ies, or other formal or informal devices that are
9 broadly representative and involve participants—

10 “(i) with expertise relevant to the sciences,
11 or analyses involved in the regulatory decisions;
12 and

13 “(ii) who are independent of the agency;

14 “(B) be governed by agency standards and
15 practices governing conflicts of interest of non-
16 governmental agency advisors;

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

19 “(D) contain a balanced presentation of all con-
20 siderations, including minority reports and an agen-
21 cy response to all significant peer review comments;
22 and

23 “(E) provide adequate protections for confiden-
24 tial business information and trade secrets, including

1 requiring panel members or participants to enter
2 into confidentiality agreements.

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

6 “(A) available to the public; and

7 “(B) part of the rule making record for pur-
8 poses of judicial review of any final agency action.

9 “(3) If the head of an agency, with the concurrence
10 of the Director, publishes a determination in the rule mak-
11 ing file that a cost-benefit analysis or risk assessment, or
12 any component thereof, has been previously subjected to
13 adequate peer review, no further peer review shall be re-
14 quired under this section for such analysis, assessment,
15 or component.

16 “(c) For each peer review conducted by an agency
17 under this section, the agency head shall include in the
18 rule making record a statement by a Federal officer or
19 employee who is not an employee of the agency rule mak-
20 ing office or program—

21 “(1) whether the peer review participants re-
22 flect the independence and expertise required under
23 subsection (b)(1)(A); and

1 “(2) whether the agency has adequately re-
2 sponded to the peer review comments as required
3 under subsection (b)(2).

4 “(d) The formality of the peer review conducted
5 under this section shall be commensurate with the signifi-
6 cance and complexity of the subject matter.

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

10 “(f) A member of an agency advisory board (or com-
11 parable organization) established by statute shall be con-
12 sidered independent of the agency for purposes of sub-
13 section (b)(1)(A)(ii).

14 “(g) The status of a person as a contractor or grantee
15 of the agency conducting the peer review shall not, in and
16 of itself, exclude such person from serving as a peer re-
17 viewer for such agency because of the requirement of sub-
18 section (b)(1)(A)(ii).

19 “(h) Nothing in this section shall require more than
20 one peer review of a cost-benefit analysis or a risk assess-
21 ment during a rule making. A peer review required by this
22 section shall occur to the extent feasible before the notice
23 of proposed rule making.

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

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

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

8 “(2) the date occurring 180 days after the date
9 of the applicable deadline.

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

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

18 “(2) the date occurring 180 days after the date
19 of the applicable deadline.

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

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

3 “(2) the date occurring 180 days after the date
4 of the applicable deadline.

5 **“§ 627. Judicial review**

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

8 “(1) in connection with review of final agency
9 action;

10 “(2) in accordance with this section; and

11 “(3) in accordance with the limitations on tim-
12 ing, venue, and scope of review imposed by the stat-
13 ute authorizing judicial review.

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

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

21 “(d) The cost-benefit analysis, cost-benefit deter-
22 mination under section 623(d), and any risk assessment
23 required under this subchapter shall not be subject to judi-
24 cial review separate from review of the final rule to which
25 such analysis or assessment applies. The cost-benefit anal-

1 ysis, cost-benefit determination under section 623(d), and
 2 any risk assessment shall be part of the rule making
 3 record and shall be considered by a court to the extent
 4 relevant, only in determining under the statute granting
 5 the rule making authority whether the final rule is arbi-
 6 trary, capricious, an abuse of discretion, or is unsupported
 7 by substantial evidence where that standard is otherwise
 8 provided by law.

9 “(e) If an agency fails to perform the cost-benefit
 10 analysis, cost-benefit determination, or risk assessment, or
 11 to provide for peer review, a court may, giving due regard
 12 to prejudicial error, remand or invalidate the rule. The
 13 adequacy of compliance with the specific requirements of
 14 this subchapter shall not otherwise be grounds for re-
 15 manding or invalidating a rule under this subchapter. If
 16 the court allows the rule to take effect, the court shall
 17 order the agency to promptly perform such analysis, deter-
 18 mination, or assessment or provide for such peer review.

19 **“§ 628. Guidelines, interagency coordination, and re-**
 20 **search**

21 “(a)(1) Not later than 270 days after the date of en-
 22 actment of this section, the Director, in consultation with
 23 the Council of Economic Advisors, the Director of the Of-
 24 fice of Science and Technology Policy, and relevant agency
 25 heads, shall issue guidelines for cost-benefit analyses, risk

1 assessments, and peer reviews as required by this sub-
2 chapter. The Director shall oversee and periodically revise
3 such guidelines as appropriate.

4 “(2) As soon as practicable and not later than 18
5 months after issuance of the guidelines required under
6 paragraph (1), each agency subject to section 624 shall
7 adopt detailed guidelines for risk assessments as required
8 by this subchapter. Such guidelines shall be consistent
9 with the guidelines issued under paragraph (1). Each
10 agency shall periodically revise such agency guidelines as
11 appropriate.

12 “(3) The guidelines under this subsection shall be de-
13 veloped following notice and public comment. The develop-
14 ment and issuance of the guidelines shall not be subject
15 to judicial review, except in accordance with section
16 706(1).

17 “(b) To promote the use of cost-benefit analysis and
18 risk assessment in a consistent manner and to identify
19 agency research and training needs, the Director, in con-
20 sultation with the Council of Economic Advisors and the
21 Director of the Office of Science and Technology Policy,
22 shall—

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

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

4 “(3) utilize appropriate interagency mechanisms
5 to improve the consistency and quality of cost-ben-
6 efit analysis and risk assessment among Federal
7 agencies; and

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

12 “(c)(1) The Director, in consultation with the head
13 of each agency, the Council of Economic Advisors, and the
14 Director of the Office of Science and Technology Policy,
15 shall periodically evaluate and develop a strategy to meet
16 agency needs for research and training in cost-benefit
17 analysis and risk assessment, including research on model-
18 ling, the development of generic data, use of assumptions
19 and the identification and quantification of uncertainty
20 and variability.

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

1 “(i) develop a common basis to assist risk com-
 2 munication related to both carcinogens and non-
 3 carcinogens; and

4 “(ii) develop methods to appropriately incor-
 5 porate risk assessments into related cost-benefit
 6 analyses.

7 “(B) Not later than 2 years after the date of enact-
 8 ment of this section, the results of the research conducted
 9 under this paragraph shall be submitted to the Director
 10 and Congress.

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

12 “(a) Not later than 1 year after the date of enact-
 13 ment of this section, the Director, in consultation with the
 14 Director of the Office of Science and Technology Policy,
 15 shall enter into a contract with an accredited scientific in-
 16 stitution to conduct a study that provides—

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

21 “(2) a study of methodologies for using com-
 22 parative risk analysis to compare dissimilar risks to
 23 human health, safety, or the environment, including
 24 development of a common basis to assist compara-

1 tive risk analysis related to both carcinogens and
2 noncarcinogens; and

3 “(3) recommendations on the use of compara-
4 tive risk analysis in setting priorities for the reduc-
5 tion of risks to human health, safety, or the environ-
6 ment.

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

9 “(1) conducted through an open process pro-
10 viding peer review consistent with section 625 and
11 opportunities for public comment and participation;
12 and

13 “(2) not later than 3 years after the date of en-
14 actment of this section, completed and submitted to
15 Congress and the President.

16 “(c) Not later than 4 years after the date of enact-
17 ment of this section, each relevant agency shall, as appro-
18 priate, use the results of the study required under sub-
19 section (a) to inform the agency in the preparation of the
20 agency’s annual budget and strategic plan and perform-
21 ance plan under section 306 of this title and sections
22 1115, 1116, 1117, 1118, and 1119 of title 31.

23 “(d) Not later than 5 years after the date of enact-
24 ment of this section, and periodically thereafter, the Presi-
25 dent shall submit a report to Congress recommending leg-

1 islative changes to assist in setting priorities to more effec-
 2 tively and efficiently reduce risks to human health, safety,
 3 or the environment.

4 “SUBCHAPTER III—EXECUTIVE OVERSIGHT

5 “§ 631. Definitions

6 “For purposes of this subchapter—

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

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

11 “(A) Advance notice of proposed rule mak-
 12 ing.

13 “(B) Notice of proposed rule making.

14 “(C) Final rule making, including interim
 15 final rule making.

16 “§ 632. Presidential regulatory review

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

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

24 “(c) For the purpose of carrying out subsection
 25 ~~(e)~~(b), the Director shall—

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

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

7 “(3) develop and oversee an annual govern-
8 mentwide regulatory planning process that shall in-
9 clude review of planned significant regulatory ac-
10 tions and publication of—

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

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

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

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

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

24 “(F) recommendations for improving com-
25 pliance with this chapter and increasing the ef-

1 ficiency and effectiveness of the regulatory
2 process.

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

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

11 **“§ 633. Public disclosure of information**

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

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

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

21 “(A) all written correspondence relating to
22 the substance of a regulatory action, including
23 drafts of all proposals and associated analyses,
24 between the Administrator or employees of the
25 Administrator and the regulatory agency;

1 “(B) all written correspondence relating to
2 the substance of a regulatory action between
3 the Administrator or employees of the Adminis-
4 trator and any person not employed by the ex-
5 ecutive branch of the Federal Government; and

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

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

16 “(A) all written correspondence relating to
17 the substance of a regulatory action between
18 the Administrator or employees of the Adminis-
19 trator and any person not employed by the ex-
20 ecutive branch of the Federal Government; and

21 “(B) a list identifying the dates, names of
22 individuals involved, and subject matter dis-
23 cussed in significant meetings and telephone
24 conversations relating to the substance of a reg-
25 ulatory action between the Administrator or

1 employees of the Administrator and any person
2 not employed by the executive branch of the
3 Federal Government.

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

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

10 “(2) a document identifying and describing
11 those substantive changes in the rule that were
12 made as a result of the regulatory review and a
13 statement if the Administrator suggested or rec-
14 ommended no changes; and

15 “(3) all written correspondence relating to the
16 substance of a regulatory action between the Admin-
17 istrator and the agency during the review of the
18 rule, including drafts of all proposals and associated
19 analyses.

20 “(c) In any meeting relating to the substance of a
21 regulatory action under review between the Administrator
22 or employees of the Administrator and any person not em-
23 ployed by the executive branch of the Federal Government,
24 a representative of the agency submitting the regulatory
25 action shall be invited.

1 **“§ 634. Judicial review**

2 “The exercise of the authority granted under this
3 subchapter by the President, the Director, or the Adminis-
4 trator shall not be subject to judicial review in any man-
5 ner.”.

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

12 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

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

17 **“CHAPTER 6—THE ANALYSIS OF**
18 **REGULATORY FUNCTIONS**

“SUBCHAPTER I—ANALYSIS OF REGULATORY FLEXIBILITY

“Sec.

“601. Definitions.

“602. Regulatory agenda.

“603. Initial regulatory flexibility analysis.

“604. Final regulatory flexibility analysis.

“605. Avoidance of duplicative or unnecessary analyses.

“606. Effect on other law.

“607. Preparation of analysis.

“608. Procedure for waiver or delay of completion.

“609. Procedures for gathering comments.

“610. Periodic review of rules.

“611. Judicial review.

“612. Reports and intervention rights.

- ## SUBCHAPTER III—EXECUTIVE OVERSIGHT

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

5 “SUBCHAPTER I—ANALYSIS OF REGULATORY
6 FLEXIBILITY”.

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

•S 746 RS

1 **SEC. 5. REPORT TO CONGRESS.**

2 *Not later than February 5, 2002, the President, acting*
3 *through the Director of the Office of Management and Budg-*
4 *et, shall prepare and submit to Congress an accounting*
5 *statement and report containing an estimate of the total*
6 *annual incremental benefits and costs of complying with*
7 *the provisions of subchapter II of chapter 6 of title 5, United*
8 *States Code (as added by this Act) for each agency.*

9 **SEC. ~~5~~. 6. EFFECTIVE DATE.**

10 Except as otherwise provided in this Act, this Act
11 shall take effect 180 days after the date of enactment of
12 this Act, but shall not apply to any agency rule for which
13 a notice of proposed rule making is published on or before
14 60 days before the date of enactment of this Act.