

Calendar No. 219

106<sup>TH</sup> CONGRESS  
1<sup>ST</sup> 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

# Calendar No. 219

106<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 746

[Report No. 106-110]

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

1 from commerce, or recognizes or cancels rec-  
2 ognition of the marketable status, of a product  
3 under the Federal Food, Drug and Cosmetic  
4 Act (21 U.S.C. 301 et seq.); and

5 “(11) the term ‘substitution risk’—

6 “(A) means a reasonably identifiable sig-  
7 nificant increased risk to health, safety, or the  
8 environment expected to result from a regu-  
9 latory option; and

10 “(B) shall not include risks attributable to  
11 the effect of an option on the income of individ-  
12 uals.

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

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

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

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

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

23 “(B) the deference otherwise accorded to the  
24 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.



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.