

Calendar No. 364

105<sup>TH</sup> CONGRESS  
2D SESSION

**S. 981**

[Report No. 105-188]

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**A BILL**

To provide for analysis of major rules.

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MAY 11, 1998

Reported with an amendment

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## IN THE SENATE OF THE UNITED STATES

JUNE 27, 1997

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

MAY 11, 1998

Reported by Mr. THOMPSON, with an amendment

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

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## A BILL

To provide for analysis of major rules.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Regulatory Improve-  
5 ment Act of 1997”.

★(Star Print)

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

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

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

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

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

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

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

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

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

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

15          “SUBCHAPTER II—REGULATORY ANALYSIS

16          “§ 621. **Definitions**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 estimate of upper and lower bounds of risk as appro-  
 2 priate; and

3 “(12) the term ‘substitution risk’ means an in-  
 4 creased risk to health, safety, or the environment  
 5 reasonably likely to result from a regulatory option.

6 **“§ 622. Applicability**

7 “Except as provided in section 623(c), this sub-  
 8 chapter shall apply to all proposed and final major rules.

9 **“§ 623. Regulatory analysis**

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

14 “(2) The Director may designate any rule to be a  
 15 major rule under section 621(6)(B), if the Director—

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

19 “(B) publishes such determination in the Fed-  
 20 eral Register together with a succinct statement of  
 21 the basis for the determination within 30 days after  
 22 such determination.

23 “(b)(1)(A) When an agency publishes a notice of pro-  
 24 posed rule making for a major rule, the agency shall pre-  
 25 pare and place in the rule making file an initial regulatory

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

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

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

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

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

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

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

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

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

19                   “(I) require no government action;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4           ~~“(C) a new risk assessment for the final rule is~~  
5           ~~not required in order to respond to comments re-~~  
6           ~~ceived during the period for comment on the pro-~~  
7           ~~posed rule;~~

8           ~~the agency may publish such determination along with the~~  
9           ~~final rule in lieu of preparing a new risk assessment for~~  
10          ~~the final rule.~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 **“§ 625. Peer review**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 **“§ 627. Judicial review**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## 1           “SUBCHAPTER III—REVIEW OF RULES

2   **“§ 631. Definitions**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 “SUBCHAPTER IV—EXECUTIVE OVERSIGHT

5 “§ 641. **Definitions**

6 “For purposes of this subchapter—

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

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

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

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

15 “(C) Notice of proposed rule making.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 **“§ 644. Judicial review**

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

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

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

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

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

**“SUBCHAPTER I—ANALYSIS OF REGULATORY FLEXIBILITY**

“Sec.

“601. Definitions.

“602. Regulatory agenda.

“603. Initial regulatory flexibility analysis.

“604. Final regulatory flexibility analysis.

“605. Avoidance of duplicative or unnecessary analyses.

“606. Effect on other law.

“607. Preparation of analysis.

“608. Procedure for waiver or delay of completion.

“609. Procedures for gathering comments.

“610. Periodic review of rules.

“611. Judicial review.

“612. Reports and intervention rights.

**“SUBCHAPTER II—REGULATORY ANALYSIS**

“621. Definitions.

“622. Applicability.

“623. Regulatory analysis.



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

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

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

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

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

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

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

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

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

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

20           “*SUBCHAPTER II—REGULATORY ANALYSIS*

21           “**§ 621. Definitions**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5       **“§ 623. Regulatory analysis**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 **“§ 625. Peer review**

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

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

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

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

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

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

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

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

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

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

14                 “(A) available to the public; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 **“§ 627. Judicial review**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 **“SUBCHAPTER III—REVIEW OF RULES**

6 **“§ 631. Definitions**

7 *“For purposes of this subchapter—*

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

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

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

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

21 **“§ 632. Review of rules**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8       “**SUBCHAPTER IV—EXECUTIVE OVERSIGHT**

9       “**§ 641. Definitions**

10       “*For purposes of this subchapter—*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9        **“§ 644. Judicial review**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

                              “SUBCHAPTER I—ANALYSIS OF REGULATORY FLEXIBILITY

                              “Sec.

                              “601. Definitions.

                              “602. Regulatory agenda.

                              “603. Initial regulatory flexibility analysis.

                              “604. Final regulatory flexibility analysis.



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

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

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