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S. 981

To provide for analysis of major rules.

IN THE SENATE OF THE UNITED STATES

JUNE 27, 1997

Mr. LEVIN (for himself, Mr. THOMPSON, Mr. GLENN, Mr. ABRAHAM, Mr. ROBB, Mr. ROTH, Mr. ROCKEFELLER, and Mr. STEVENS) introduced the following bill; which was read twice and referred to the Committee on Governmental Affairs

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”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

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

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

5 (3) Cost and risk need to be considered in eval-
6 uating regulatory proposals which address health,
7 safety, or the environment. Other factors such as so-
8 cial values, distributional effects, and equity, must
9 also be considered.

10 (4) Cost-benefit analysis and risk assessment
11 should be presented with a clear statement of the
12 analytical assumptions and uncertainties including
13 an explanation of what is known and not known and
14 what the implications of alternative assumptions
15 might be.

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

22 (6) The Administrator of the Office of Informa-
23 tion and Regulatory Affairs should oversee regu-
24 latory activities to ensure consistent and valid use of

1 cost-benefit analysis and risk assessment among all
2 agencies.

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

8 **SEC. 3. REGULATORY ANALYSIS.**

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

12 “SUBCHAPTER II—REGULATORY ANALYSIS

13 “§ 621. Definitions

14 “For purposes of this subchapter the definitions
15 under section 551 shall apply and—

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

22 “(2) the term ‘cost’ means the reasonably iden-
23 tifiable significant adverse effects, quantifiable and
24 nonquantifiable, including social, health, safety, envi-
25 ronmental, economic, and distributional effects that

1 are expected to result directly or indirectly from im-
2 plementation of, or compliance with, a rule;

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

13 “(4) the term ‘Director’ means the Director of
14 the Office of Management and Budget, acting
15 through the Administrator of the Office of Informa-
16 tion and Regulatory Affairs;

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

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

1 “(A) the agency proposing the rule or the
2 Director reasonably determines is likely to have
3 an annual effect on the economy of
4 \$100,000,000 or more in reasonably quantifi-
5 able costs; or

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

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

20 “(8) the term ‘risk assessment’ means the sys-
21 tematic process of organizing hazard and exposure
22 assessments to estimate the potential for specific
23 harm to exposed individuals, populations, or natural
24 resources;

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

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

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

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

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

21 “(D) a rule relating to monetary policy
22 proposed or promulgated by the Board of Gov-
23 ernors of the Federal Reserve System or by the
24 Federal Open Market Committee;

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

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

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

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

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

19 “(I) a rule or agency action relating to the
20 public debt;

21 “(11) the term ‘screening analysis’ means an
22 analysis using simple assumptions to arrive at an es-
23 timate of upper and lower bounds of risk as appro-
24 priate; and

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

4 **“§ 622. Applicability**

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

7 **“§ 623. Regulatory analysis**

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

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

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

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

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

1 consistent with subsection (d) in the notice of proposed
2 rule making.

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

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

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

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

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

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

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

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

19 “(I) require no government action;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 **“§ 625. Peer review**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 **“§ 627. Judicial review**

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

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

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

5 “(c) 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
9 assist comparative risk analysis and risk commu-
10 nication related to both carcinogens and noncarcino-
11 gens; 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
14 providing peer review consistent with section 625
15 and opportunities for public comment and participa-
16 tion; 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 regu-
5 latory options;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 “SUBCHAPTER IV—EXECUTIVE OVERSIGHT

5 “§ 641. **Definitions**

6 “For purposes of this subchapter—

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

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

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

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

15 “(C) Notice of proposed rule making.

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

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

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

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

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

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

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

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

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

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

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

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

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

5 “(c) 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.

