

104TH CONGRESS  
1ST SESSION

# S. 291

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

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## IN THE SENATE OF THE UNITED STATES

JANUARY 27 (legislative day, JANUARY 10), 1995

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

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## A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Regulatory Reform Act  
5 of 1995”.

6 **SEC. 2. TABLE OF CONTENTS.**

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

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

### TITLE I—REGULATORY ANALYSIS AND REVIEW

- Sec. 101. Cost/benefit analysis of agency proposals; risk assessment; regulatory review





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

3 “(4) The term ‘major rule’ means—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

7 “(i) require no Government action;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 **“§ 623. Judicial review**

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

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

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

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

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

14 **“§ 624. Executive oversight**

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

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

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

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

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

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

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

## 12 **“Subchapter III—Risk Assessments**

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15           “(B) The Department of Labor.

16           “(C) The Food and Drug Administration.

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

19           “(E) The Department of Transportation.

20           “(F) The Department of Energy.

21           “(G) The Department of Agriculture.

22           “(H) The Department of the Interior.

23           “(I) The Nuclear Regulatory Commission.

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

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

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

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

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

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

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

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

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

13 **“§ 632. Applicability**

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

19           “(b) EXCEPTIONS.—

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

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

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

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

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

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

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

19 **“§ 633. Savings provisions**

20           “Nothing in this title shall be construed to—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 “(1) ESTIMATES OF RISK.—

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(a) GUIDELINES.—

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

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

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

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

1 “(b) PLAN.—

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

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

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

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

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

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

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

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

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

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

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

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

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

1 **“§ 639. Interagency coordination**

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

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

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

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

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



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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

“CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS

“SUBCHAPTER I—REGULATORY ANALYSIS

“Sec.

“601. Definitions.

“602. Regulatory agenda.

“603. Initial regulatory flexibility analysis.

“604. Final regulatory flexibility analysis.

“605. Avoidance of duplicative or unnecessary analyses.

“606. Effect on other law.

“607. Preparation of analyses.

“608. Procedure for waiver or delay of completion.

“609. Procedures for gathering comments.

“610. Periodic review of rules.

“611. Judicial review.

“612. Reports and intervention rights.

“SUBCHAPTER II—ANALYSIS OF AGENCY PROPOSALS

“621. Definitions.

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

“SUBCHAPTER III—RISK ASSESSMENTS

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

“SUBCHAPTER IV—REGULATORY PRIORITIES AND REVIEW

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 **TITLE II—RISK-BASED PRIORITIES**

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

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

17 **SEC. 202. PURPOSES.**

18 It is the purposes of this title to—

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

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

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

6 **SEC. 203. DEFINITIONS.**

7           For the purposes of this title:

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

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

16                (A) The Environmental Protection Agency.

17                (B) The Department of Labor.

18                (C) The Food and Drug Administration.

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

21                (E) The Department of Transportation.

22                (F) The Department of Energy.

23                (G) The Department of Agriculture.

24                (H) The Department of the Interior.

25                (I) The Nuclear Regulatory Commission.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1     **TITLE III—REGULATORY ACCOUNTING**

2     **SEC. 301. SHORT TITLE**

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

5     **SEC. 302. ACCOUNTING STATEMENT**

6         (a) IN GENERAL.—

7             (1) RESPONSIBILITY FOR IMPLEMENTATION.—

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

10            (2) ACCOUNTING STATEMENT.—Every two

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

16            (b) YEARS COVERED BY ACCOUNTING STATE-

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

22            (c) TIMING AND PROCEDURES.—

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

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

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

13 (d) CONTENT OF ACCOUNTING STATEMENT.—

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

21 (2) STATEMENT OF COSTS.—

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



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

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

7 (B) NATIONAL ECONOMIC RESOURCES.—  
8 For purposes of the estimate of costs in the ac-  
9 counting statement, national economic re-  
10 sources shall include, and shall be listed under,  
11 at least the following categories:

12 (i) Private sector costs.

13 (ii) Federal sector administrative  
14 costs.

15 (iii) Federal sector compliance costs.

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

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

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

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

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

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

- 13 (1) analyses of impacts; and  
14 (2) recommendations for reform.

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

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

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

24 (B) Small business.

25 (C) Productivity.

1 (D) Wages.

2 (E) Economic growth.

3 (F) Technological innovation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 **SEC. 306. DEFINITIONS.**

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

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

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

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

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

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

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

8                   (A) the General Accounting Office;

9                   (B) the Federal Election Commission;

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

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

## 18           **TITLE IV—MARKET INCENTIVES AND**

## 19           **ECONOMICALLY EFFICIENT REGULATION**

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

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

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

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

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

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

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

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

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

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

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

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

7 **SEC. 404. DEFINITIONS.**

8 For the purposes of this title:

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

16 (A) the General Accounting Office;

17 (B) the Federal Election Commission;

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

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



1 (2) The term “major rule” means—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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