

S.343

"COMPREHENSIVE REGULATORY REFORM ACT OF 1995"
SECTION BY SECTION ANALYSIS

Section 3. Rulemaking

This section of the bill substantially rewrites Section 553 of the Administrative Procedure Act (Title 5, U.S.C.). This section of the APA governs agency rulemaking procedures that are not required by the organic statute "to be on the record" (and thus require "adjudicatory" or "trial type" procedures such as live witnesses and cross-examination).

New § 553(a) states that this section applies to all such rulemaking except (1) matter pertaining to military or foreign affairs, (2) matter relating to agency management or personnel, (3) interpretation rules (etc.), and (4) rules relating to agency property. The statutory language as to (1), (2) and (3) is the same as in the current APA, except that additional language has been added to (3) to guard against an agency's trying to evade rulemaking requirements. Item (4) is new. All of the changes made were in S.1080.

New § 553(b)(1) deals with notice of a proposed rulemaking. It is based on the present APA provision, but the items that must be in the notice are expanded. The new items are, for the most part, taken from S.1080.

New § 553(b)(2) provides an exception from the procedural requirements where the agency for good cause finds that providing prior notice and affording public comment would be (1) contrary to an important public interest or (2) unnecessary due to the insignificant impact of the rule. This exemption tracks the existing APA procedure except that (1) is new and (2) unnecessary "has been tied to "insignificant impact."

New § 553(b)(3) provides for supplemental notice where the agency changes its mind and is considering a new alternative not described in the first notice. This was in first S.1080.

New § 553(c)(1). This provision amends the current APA provision to require 60 days for public comment, as compared to 30 days now indirectly required.

New § 553(c)(2) sets forth a number of additional procedures the agency may afford in this rulemaking. The procedures were mentioned in S.1080, but in that bill some were mandated. Here they are discretionary. The agency's decisions here are not subject to judicial review.

New § 553(c)(3) compliments (c)(2) by allowing an agency to "establish reasonable procedures" to regulate any informal hearings. It is taken from S.1080.

New § 553(c)(4) governs the agency's statement of basis and purpose, which must accompany the "final" (adopted) rule. The section is based on S.1080.

New § 553(c)(5) states that the requirements of Section 556 and 557 of the APA, rather than those in Section 553, apply to rule makings "on the record." This is what the present APA provides.

New § 553(d)(1) provides that the final (adopted) rule must be published in the Federal Register at least 60 days before its effective date. The present APA requirement is 30 days.

New § 553(e)(1) reiterates the current APA right to petition an agency to issue, amend or repeal a rule but does so only in the context of a "major rule." It also adopts changes that S.1080 would have made generally for all rules. Thus the new section gives his agency a 180 day deadline for action in the petition and requires it to respond in writing. Denial of the petition is appealable. The agency must grant the petition if this petitioner raises [a substantial question] that the rule is likely to be a "major rule". [Note: It would also be helpful to add the deadline and the written response requirement to the current APA right for all rules and to afford it to "any interested person"].

New § 553(f)(1) requires an agency to maintain a rulemaking file and provides that this constitutes the record for judicial review. It was taken from S.1080.

New § 553(f)(2) specifies what must be in the rulemaking file. It is based on S.1080.

New § 553(g) is a provision that "conforms" other statutes. that contain provisions exempting the agency from the APA and instead provide equivalent procedures, to the changes made in § 553. The need for such a provision was addressed when S.1080 was passed.

New § 553(h) prohibits payment of attorney's fees to participants or intervenors. This was a provision in S.1080.

Section 1. Title

Comprehensive Regulatory Reform Act of 1995

Section 2. Analysis of Agency Proposals

SUBCHAPTER II - ANALYSIS OF AGENCY PROPOSALS

621. Definitions.

"Agency", "person", and "rule" have the same meaning as in section 551 of the title

"Major Rule" \$50 Million; also includes those that would substantially increase costs of prices, or cause substantial adverse effects on competition or employment; a group of closely related rules is considered on rule for purposes of this definition.

"Benefits" are defined to include "social" benefits as well as economic benefits

"Costs" include "social" cost, reduced consumer choice, substitution effects, and impeded technological advancement, in addition to economic costs

"Market-based mechanism" is a regulatory program that (a) imposes legal accountability for the achievement of an explicit regulatory objective on each regulated person; (b) affords maximum flexibility to each regulated person in complying with mandatory regulatory objectives, which flexibility shall, where feasible and appropriate, include, but not be limited to, the opportunity to transfer to, or receive from, other persons, including for cash or other legal consideration, increments of compliance responsibility established by the program and (c) permits regulated persons to respond automatically to changes in general economic conditions and in economic circumstances directly pertinent to the regulatory program without affecting the achievement of the program's explicit regulatory mandates.

622. Rulemaking cost-benefit analysis.

Agencies must prepare, and include in the administrative record, a draft cost-benefit analysis when they publish a notice of proposed rulemaking for a

major rule; the public must be provided with notice and an opportunity to comment on the draft analysis; the final analysis must be issued with the final rule.

The cost-benefit analysis must include analysis and comparison of reasonable alternatives, including a "no-action" alternative; the agency must analyze whether the benefits of the rule would "outweigh" the costs of the rule, and "whether the rule will provide greater net benefits to society than any of the alternatives."

Non-quantifiable benefits and costs must be described "in as precise and succinct a manner as possible."

Where practicable, benefits and costs must be described on an "industry by industry basis."

Risk assessment results must be included in the cost-benefit analysis.

624 Decisional criteria.

A key requirement is that an agency may not issue a final rule unless its benefits "outweigh" its costs and it will provide greater new benefits to society than any of the reasonable alternatives identified by the agency.

These criteria apply to all statutes unless the "statute contains explicit textual language prohibiting the consideration of the [cost-benefit] criteria"; where the agency finds that cost-benefit consideration is prohibited, it must transmit this finding to Congress together with the final cost-benefit analysis required by Section 622.

625 Judicial review.

Determinations that a rule is or is not a "major rule" may be set aside by a reviewing court only.

If a court decides that rule should have been designated as a major rule, the rule has no force until the bill's requirements are met; challenges must be brought within 30 days after the publication indicating that the rule was not designated "major."

A court may set aside rules that fail to satisfy the cost-benefit decisional criteria, applying the standard of review applicable to the statute under which the agency conducted the rulemaking.

623 Petition for cost-benefit analysis.

Any person "subject to a major rule" may petition for the performance of a cost-benefit analysis for rules already in effect when S. 343 is enacted, even if an earlier version of cost-benefit analysis had been performed, provided that there is a reasonable likelihood that the rule does not provide net benefits.

The existing rule must be amended or revoked to comply with S. 343's criteria.

"Agency guidance" and "general statements of policy" are also subject to this "look back" provision.

626. Effective date or final regulations.

Statutory and judicial deadlines are suspended until the bill's requirements are satisfied.

Agencies must transmit copies of major rules and their cost-benefit analyses to Congress; no rule may take effect for at least 45 days after the transmittal to Congress.

Procedures are provided for the possibility that Congress could pass a joint resolution of disapproval of the regulation stating that it shall have no force or effect.

Another key provision of the bill would provide that Agency interpretations of their enabling statutes shall be upheld if the reviewing court "finds that the [agency's] interpretation is clearly the interpretation of the statute intended by Congress."

Where the agency has discretion, its interpretation should be affirmed if the court finds that (a) the

agency has identified the range of permissible statutory constructions, (b) the interpretation chosen by the agency is one within that range, and (c) "the agency has engaged in reasoned decisionmaking in determining that [its] interpretation, rather than other permissible constructions of the statute, is the one that maximizes net benefits to society."

SUBCHAPTER III - RISK ASSESSMENTS

631. Definitions.

Risk assessments must be prepared for all major rules relating to human health, safety, or natural resources; they are to be used in developing the required cost-benefit analysis; and are part of the administrative record for judicial review.

632. Applicability.

Risk assessments need not be performed in connection with emergency situations, "screening" assessments, or for a rule that "authorizes the introduction into commerce, or recognizes the marketable status of a product."

"Screening" assessments do not include any analyses that "characterize a positive finding of risk from a substance or activity in any agency document or other communication made available to the public, the media or Congress"; however, FIFRA and TSCA analyses may be considered to be "screening" analyses.

633. Rule of construction.

Nothing shall preclude the consideration of any data or the calculation of any estimate to more fully describe risk or provide examples of scientific uncertainty or variability or require the disclosure of any trade secret or other confidential information

634. Requirement to prepare risk assessments.

The bill provides considerable detail regarding the conduct of risk assessments for major rules relating to human health, safety, or natural resources that are proposed by the agency after the date of enactment, pending on the date of enactment or subject to a granted petition. The risk assessment shall be a component of and used to develop the cost-benefit analysis.

635. Principles for risk assessments.

Principles for risk assessment are set forth, including a preference for human over animal data; policy judgments and assumptions must be spelled out; the risk characterization must set forth the "best estimate" of risk, and may set forth plausible upper bound risks if plausible lower bound risks are also set forth.

636. Principles for risk characterization and communication.

The degree of health risk must be placed in context to the extent possible by comparison with more familiar risks.

637. Regulations; plan for assessing new information.

Within, one year, the President must issue a final regulation implementing the bill's risk assessment and risk characterization principles; the regulation must ensure consistency across agencies.

638. Decisional criteria.

Agency heads must determine, subject to review by the President, that a risk assessment is based on unbiased scientific evaluation, realistic exposure scenarios, and the best available scientific evidence.

The agency head must also determine that "there is no alternative that is allowed by the statute under which the major rule is promulgated that would provide greater net benefits or that would provide greater benefits or that would achieve an equivalent reduction in risk in a more cost-effective and flexible manner."

639. Establishment of program.

The President is directed to establish a uniform program for peer review; peer reviewers representing potentially interested parties shall not be excluded if their interests are fully disclosed.

Peer review results are part of the administrative record for judicial review.

SUBCHAPTER IV - EXECUTIVE OVERSIGHT

651. Procedures.

The President is authorized to establish review procedures in the Executive Office of the President to oversee compliance with the bill's provisions.

652. Promulgation and adoption.

If the procedures established under section 651 include review of preliminary or final regulatory analyses to ensure that they comply with subchapters II and III, it will be done within 30 day following the receipt of the analysis by the President. The review period may be extended for an additional 30 days for good cause (to be included in rulemaking file).

653. Delegation of authority.

President may delegate authority to VP or officer within the Executive Office of the President (provided they have been confirmed by the Senate). Notice of delegation must be printed in the Federal Register.

654. Applicability.

The authority granted under this subchapter shall not apply to rules issued by the Nuclear Regulatory Commission.

655. Judicial review.

There is not judicial review of this Executive oversight.

The bill provides judicial review with respect to determinations of how many small business entities would be affected by a rule as required under the Regulatory Flexibility Act.

AMENDMENT NO. ____

Calendar No. ____

Purpose: To provide a substitute.

IN THE SENATE OF THE UNITED STATES—104th Cong., 1st Sess.**S. 343**

To reform the regulatory process, and for other purposes.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. GRASSLEY

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Comprehensive Regu-
5 latory Reform Act of 1995”.

6 **SEC. 2. DEFINITIONS.**

7 Section 551 of title 5, United States Code, is amend-
8 ed—

9 (1) in the matter preceding paragraph (1), by
10 striking “this subchapter” and inserting “chapters
11 5, 6, 7, and 8 of this title”; and

1 (2) in paragraph (13), by striking “; and” and
2 inserting a semicolon;

3 (3) in paragraph (14), by striking the period at
4 the end and inserting “; and”; and

5 (4) by adding at the end the following new
6 paragraph:

7 “(15) ‘Director’ means the Director of the Of-
8 fice of Management and Budget.”.

9 **SEC. 3. RULEMAKING.**

10 Section 553 of title 5, United States Code, is amend-
11 ed to read as follows:

12 **“§ 553. Rulemaking**

13 “(a) This section applies to every rulemaking, accord-
14 ing to the provisions thereof, except to the extent that
15 there is involved—

16 “(1) a matter pertaining to a military or for-
17 eign affairs function of the United States;

18 “(2) a matter relating to the management and
19 personnel practices of an agency;

20 “(3) an interpretive rule, general statement of
21 policy or guidance, or rule of agency organization,
22 procedure, or practice that is not generally applica-
23 ble or does not alter or create rights or obligations
24 of persons outside the agency; or

1 “(4) a rule relating to the acquisition, manage-
2 ment, or disposal by an agency of real or personal
3 property, or of services, that is promulgated in com-
4 pliance with criteria and procedures established by
5 the Administrator of General Services.

6 “(b)(1) General notice of proposed rulemaking shall
7 be published in the Federal Register, unless all persons
8 subject thereto are named and either personally served or
9 otherwise have actual notice of the proposed rulemaking
10 in accordance with law. Each notice of proposed rule-
11 making shall include—

12 “(A) a statement of the time, place, and nature
13 of public rulemaking proceedings;

14 “(B) a succinct explanation of the need for and
15 specific objectives of the proposed rule, including an
16 explanation of the agency’s determination of whether
17 or not the rule is a major rule within the meaning
18 of section 621(2);

19 “(C) an explanation of the specific statutory in-
20 terpretation under which a rule is proposed, includ-
21 ing an explanation of—

22 “(i) whether the interpretation is expressly
23 required by the text of the statute; or

24 “(ii) if the interpretation is not expressly
25 required by the text of the statute, an expla-

1 nation that the interpretation is within the
2 range of permissible interpretations of the statute as identified by the agency, and an explanation why the interpretation selected by the
3 agency is the agency's preferred interpretation;
4
5

6 “(D) the proposed provisions of the rule;

7 “(E) a summary of any initial analysis of the
8 proposed rule required to be prepared or issued pursuant to chapter 6 of this title;
9

10 “(F) a statement that the agency seeks proposals from the public and from State and local governments for alternative methods to accomplish the objectives of the rulemaking that are more effective or
11 less burdensome than the approach used in the proposed rule;
12
13
14
15

16 “(G) a description of any data, methodologies, reports, studies, scientific evaluations, or other similar information available to the agency for the rulemaking, including an identification of each author or
17 source of such information and the purposes for which the agency plans to rely on such information;
18
19
20
21
22 and

23 “(H) a statement specifying where the file of
24 the rulemaking proceeding maintained pursuant to

1 subsection (f) may be inspected and how copies of
2 the items in the file may be obtained.

3 “(2) Except when notice or hearing is required by
4 statute, a final rule may be adopted and may become ef-
5 fective without prior compliance with this subsection and
6 subsections (c) and (f) if—

7 “(A) the agency for good cause finds that pro-
8 viding notice and public procedure thereon before
9 the rule becomes effective is contrary to an impor-
10 tant public interest or unnecessary due to the insig-
11 nificant impact of the rule;

12 “(B) the agency publishes the rule in the Fed-
13 eral Register with such finding and a succinct expla-
14 nation of the reasons therefor; and

15 “(C) the agency complies with this subsection
16 and subsections (c) and (f) to the maximum extent
17 feasible prior to the promulgation of the final rule,
18 and fully complies with such provisions as soon as
19 reasonably practicable after the promulgation of the
20 rule.

21 “(3) Whenever the provisions of a final rule that an
22 agency plans to adopt are so different from the provisions
23 of the proposed rule that the original notice of proposed
24 rulemaking did not fairly apprise the public of the issues
25 ultimately to be resolved in the rulemaking or of the sub-

1 stance of the rule, the agency shall publish in the Federal
2 Register a notice of the final rule the agency plans to
3 adopt, together with the information relevant to such rule
4 that is required by the applicable provisions of this section
5 and that has not previously been published in the Federal
6 Register. The agency shall allow a reasonable period for
7 comment on such final rule.

8 “(c)(1) After providing the notice required by this
9 section, the agency shall give interested persons not less
10 than 60 days to participate in the rulemaking through the
11 submission of written data, views, or arguments.

12 “(2)(A) To collect relevant information, and to iden-
13 tify and elicit full and representative public comment on
14 the significant issues of a particular rulemaking, the agen-
15 cy may use such other procedures as the agency deter-
16 mines are appropriate, including—

17 “(i) the publication of an advance notice of pro-
18 posed rulemaking;

19 “(ii) the provision of notice, in forms which are
20 more direct than notice published in the Federal
21 Register, to persons who would be substantially af-
22 fected by the proposed rule, but who are unlikely to
23 receive notice of the proposed rulemaking through
24 the Federal Register;

1 “(iii) the provision of opportunities for oral
2 presentation of data, views, information, or rebuttal
3 arguments at informal public hearings, which may
4 be held in the District of Columbia and other loca-
5 tions;

6 “(iv) the provision of summaries, explanatory
7 materials, or other technical information in response
8 to public inquiries concerning the issues involved in
9 the rulemaking; and

10 “(v) the adoption or modification of agency pro-
11 cedural rules to reduce the cost or complexity of par-
12 ticipation in a rulemaking.

13 “(B) The decision of an agency to use or not to use
14 such other procedures in a rulemaking pursuant to this
15 paragraph shall not be subject to judicial review.

16 “(3) To ensure an orderly and expeditious proceed-
17 ing, an agency may establish reasonable procedures to reg-
18 ulate the course of informal public hearings under para-
19 graphs (2) and (3), including the designation of represent-
20 atives to make oral presentations or engage in direct or
21 cross-examination on behalf of several parties with a com-
22 mon interest in a rulemaking. Transcripts shall be made
23 of all such public hearings.

24 “(4) An agency shall publish any final rule it adopts
25 in the Federal Register, together with a concise statement

1 supported in the rulemaking file maintained pursu-
2 ant to subsection (f); and

3 “(E) a summary of any final analysis of the
4 rule required to be prepared or issued pursuant to
5 chapter 6 of this title.

6 “(5) The provisions of sections 556 and 557 shall
7 apply in lieu of this subsection in the case of rules that
8 are required by statute to be made on the record after
9 opportunity for an agency hearing.

10 “(d) An agency shall publish the final rule in the Fed-
11 eral Register not less than 60 days before the effective
12 date of such rule. An agency may make a rule effective
13 in less than 60 days after publication in the Federal Reg-
14 ister if the rule grants or recognizes an exemption, relieves
15 a restriction, or if the agency for good cause finds that
16 such a delay in the effective date would be contrary to
17 an important public interest and publishes such finding
18 and an explanation of the reasons therefor, with the final
19 rule.

20 “(e)(1) Each agency shall give an interested person
21 the right to petition for the issuance, amendment, or re-
22 peal of a rule.

23 “(2) Each person subject to a major rule may peti-
24 tion—

1 “(A) for the issuance, amendment, or repeal of
2 such rule;

3 “(B) for the amendment or repeal of an inter-
4 pretive rule or general statement of policy or guid-
5 ance;

6 “(C) for an interpretation regarding the mean-
7 ing of the rule; and

8 “(D) for a variance or exemption from the
9 terms of the rule.

10 “(2) Any person subject to a rule may petition an
11 agency for the performance of any analysis provided under
12 chapter 6 of this title if such person presents a reasonable
13 likelihood that the rule is a major rule within the meaning
14 of section 621(2). The agency shall grant the petition and
15 promptly conduct the analysis sought if the agency deter-
16 mines that the rule is a rule for which an analysis is re-
17 quired under chapter 6. If the rule does not satisfy the
18 decisional criteria set forth in section 624, then the agency
19 shall take immediate action to either revoke or amend the
20 rule to conform the rule to the requirements of chapter
21 6 and the decisional criteria under section 624.

22 “(3) The agency shall grant or deny a petition made
23 pursuant to this subsection, and give written notice of its
24 determination to the petitioner, with reasonable prompt-
25 ness, but in no event later than 180 days after the petition

1 was received by the agency. The written notice of the
2 agency's determination shall include an explanation of the
3 determination and a response to each factual and legal
4 claim that forms the basis of the petition. A decision to
5 deny a petition shall be subject to judicial review imme-
6 diately upon denial as final agency action under the stat-
7 ute granting the agency authority to carry out its action.

8 “(f)(1) The agency shall maintain a file for each rule-
9 making proceeding conducted pursuant to this section and
10 shall maintain a current index to such file. The file and
11 the material excluded from the file pursuant to paragraph
12 (4) shall constitute the rulemaking record for purposes of
13 judicial review. Except as provided in paragraph (4), the
14 file shall be made available to the public beginning on the
15 date on which the agency makes an initial publication con-
16 cerning the rule.

17 “(2) The rulemaking file shall include—

18 “(A) the notice of proposed rulemaking, any
19 supplement to, or modification or revision of, such
20 notice, and any advance notice of proposed rule-
21 making;

22 “(B) copies of all written comments received on
23 the proposed rule;

24 “(C) a transcript of any public hearing con-
25 ducted on the rulemaking;

1 “(D) copies, or an identification of the place at
2 which copies may be obtained, of all material de-
3 scribed by the agency pursuant to subsection
4 (b)(1)(G) and of other factual and methodological
5 material not described by the agency pursuant to
6 such subsection that pertains directly to the rule-
7 making and that was available to the agency in con-
8 nection with the rulemaking, or that was submitted
9 to or prepared by or for the agency in connection
10 with the rulemaking; and

11 “(E) any statement, description, analysis, or
12 any other material that the agency is required to
13 prepare or issue in connection with the rulemaking,
14 including any analysis prepared or issued pursuant
15 to chapter 6 of this title.

16 “(3) The agency shall place the materials described
17 in paragraph (2) in the file as soon as practicable after
18 such materials become available to the agency.

19 “(4) The file required by paragraph (1) need not in-
20 clude any material that need not be made available to the
21 public under section 552(b)(4) if the agency includes in
22 such file a statement that notes the existence of such ma-
23 terial and the basis upon which the material is exempt
24 from public disclosure under such section. The agency may
25 not substantially rely on any such material in formulating

1 a rule unless it makes the substance of such material
2 available for adequate comment by interested persons. The
3 agency may use summaries, aggregations of data, or other
4 appropriate mechanisms to protect the confidentiality of
5 such material to the maximum extent possible.

6 “(5) No court shall hold unlawful or set aside an
7 agency rule because of a violation of this subsection unless
8 the court finds that such violation has precluded fair pub-
9 lic consideration of a material issue of the rulemaking
10 taken as a whole. Judicial review of compliance or non-
11 compliance with this subsection shall be limited to review
12 of action or inaction on the part of an agency.

13 “(g) Notwithstanding any other provision of law, sub-
14 sections (b)(1)(C), (c)(4)(D), and (e) shall apply to and
15 supplement the procedures governing rulemaking under
16 statutes that are not generally subject to this section.

17 “(h) Nothing in this section authorizes the use of ap-
18 propriated funds available to any agency to pay the attor-
19 ney’s fees or other expenses of persons participating or
20 intervening in agency proceedings.”.

21 **SEC. 4. ANALYSIS OF AGENCY RULES.**

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

1 “(ii) a rule or a group of closely related
2 rules that is otherwise designated a major rule
3 by the agency proposing the rule, the Director,
4 or a designee of the President on the ground
5 that the rule is likely to result in—

6 “(I) a substantial increase in costs or
7 prices for wage earners, consumers, indi-
8 vidual industries, nonprofit organizations,
9 Federal, State, or local government agen-
10 cies, or geographic regions;

11 “(II) significant adverse effects on
12 competition, employment, investment, pro-
13 ductivity, innovation, the environment,
14 public health or safety, or the ability of en-
15 terprises whose principal places of business
16 are in the United States to compete in do-
17 mestic or export markets;

18 “(III) a serious inconsistency or inter-
19 ference with an action taken or planned by
20 another agency;

21 “(IV) the material alteration of the
22 budgetary impact of entitlements, grants,
23 user fees, or loan programs, or the rights
24 and obligations of recipients thereof; or

1 “(V) disproportionate costs to a class
2 of persons within the regulated sector, and
3 relatively severe economic consequences for
4 the class;

5 “(B) the term ‘major rule’ does not include—

6 “(i) a rule that involves the internal reve-
7 nue laws of the United States; or

8 “(ii) a rule or agency action that author-
9 izes the introduction into, or removal from,
10 commerce, or recognizes the marketable status,
11 of a product pursuant to sections 408, 409(c),
12 and 706 of the Federal Food, Drug, and Cos-
13 metic Act;

14 “(3) the term ‘benefit’ means the reasonably
15 identifiable significant benefits, including social and
16 economic benefits, that are expected to result di-
17 rectly or indirectly from implementation of a rule or
18 an alternative to a rule;

19 “(4) the term ‘cost’ means the reasonably iden-
20 tifiable significant costs and adverse effects, includ-
21 ing social and economic costs, reduced consumer
22 choice, substitution effects, and impeded techno-
23 logical advancement, that are expected to result di-
24 rectly or indirectly from implementation of, or com-
25 pliance with, a rule or an alternative to a rule;

1 “(5) the term ‘market-based mechanism’ means
2 a regulatory program that—

3 “(A) imposes legal accountability for the
4 achievement of an explicit regulatory objective
5 on each regulated person;

6 “(B) affords maximum flexibility to each
7 regulated person in complying with mandatory
8 regulatory objectives, which flexibility shall,
9 where feasible and appropriate, include, but not
10 be limited to, the opportunity to transfer to, or
11 receive from, other persons, including for cash
12 or other legal consideration, increments of com-
13 pliance responsibility established by the pro-
14 gram; and

15 “(C) permits regulated persons to respond
16 automatically to changes in general economic
17 conditions and in economic circumstances di-
18 rectly pertinent to the regulatory program with-
19 out affecting the achievement of the program’s
20 explicit regulatory mandates; and

21 “(6) the term ‘cost-benefit analysis’ means an
22 evaluation of the costs and benefits of a rule, quan-
23 tified to the extent feasible and appropriate and oth-
24 erwise qualitatively described, that is prepared in ac-
25 cordance with the requirements of this subchapter at

1 the level of detail appropriate and practicable for
2 reasoned decisionmaking on the matter involved,
3 taking into consideration the significance and com-
4 plexity of the decision and any need for expedition.

5 **“§ 622. Rulemaking cost-benefit analysis**

6 “(a) Prior to publishing notice of a proposed rule-
7 making for any rule (or, in the case of a notice of a pro-
8 posed rulemaking that has been published on or before the
9 date of enactment of this subchapter, not later than 30
10 days after such date of enactment), each agency shall de-
11 termine whether the rule is or is not a major rule within
12 the meaning of section 621(2)(A)(i) and, if it is not,
13 whether it should be designated a major rule under section
14 621(2)(A)(ii). For the purpose of any such determination
15 or designation, a group of closely related rules shall be
16 considered as one rule.

17 “(b)(1) If an agency has determined that a rule is
18 not a major rule within the meaning of section
19 621(2)(A)(i) and has not designated the rule a major rule
20 within the meaning of section 621(2)(A)(ii), the Director
21 or a designee of the President may, as appropriate, deter-
22 mine that the rule is a major rule or designate the rule
23 a major rule not later than 30 days after the publication
24 of the notice of proposed rulemaking for the rule (or, in
25 the case of a notice of proposed rulemaking that has been

1 published on or before the date of enactment of this sub-
2 chapter, not later than 60 days after such date of enact-
3 ment).

4 “(2) Such determination or designation shall be pub-
5 lished in the Federal Register, together with a succinct
6 statement of the basis for the determination or designa-
7 tion.

8 “(c)(1)(A) When the agency publishes a notice of pro-
9 posed rulemaking for a major rule, the agency shall issue
10 and place in the rulemaking file an initial cost-benefit
11 analysis, and shall include a summary of such analysis in
12 the notice of proposed rulemaking.

13 “(B)(i) When the Director or a designee of the Presi-
14 dent has published a determination or designation that a
15 rule is a major rule after the publication of the notice of
16 proposed rulemaking for the rule, the agency shall prompt-
17 ly issue and place in the rulemaking file an initial cost-
18 benefit analysis for the rule and shall publish in the Fed-
19 eral Register a summary of such analysis.

20 “(ii) Following the issuance of an initial cost-benefit
21 analysis under clause (i), the agency shall give interested
22 persons an opportunity to comment pursuant to section
23 553 in the same manner as if the draft cost-benefit analy-
24 sis had been issued with the notice of proposed rule-
25 making.

1 “(2) Each initial cost-benefit analysis shall contain—

2 “(A) an analysis of the benefits of the proposed
3 rule, and an explanation of how the agency antici-
4 pates each benefit will be achieved by the proposed
5 rule, including a description of the persons or classes
6 of persons likely to receive such benefits;

7 “(B) an analysis of the costs of the proposed
8 rule, and an explanation of how the agency antici-
9 pates each such cost will result from the proposed
10 rule, including a description of the persons or groups
11 of persons likely to bear such costs;

12 “(C) an identification (including an analysis of
13 the costs and benefits) of reasonable alternatives au-
14 thorized under the statute granting the rulemaking
15 authority for achieving the identified benefits of the
16 proposed rule, including alternatives that—

17 “(i) require no government action;

18 “(ii) will accommodate differences among
19 geographic regions and among persons with dif-
20 fering levels of resources with which to comply;
21 and

22 “(iii) employ voluntary, performance, or
23 other market-based standards that permit the
24 greatest flexibility in achieving the identified

1 benefits of the proposed rule and that comply
2 with the requirements of subparagraph (D);

3 “(D) an assessment of the feasibility of estab-
4 lishing a regulatory program that operates through
5 the application of market-based mechanisms;

6 “(E) in any case in which the proposed rule is
7 based on one or more scientific evaluations or infor-
8 mation or is subject to the risk assessment require-
9 ments of subchapter III, a description of actions un-
10 dertaken by the agency to verify the quality, reliabil-
11 ity, and relevance of such scientific evaluations or
12 scientific information in accordance with the risk as-
13 sessment requirements of subchapter III;

14 “(F) an analysis, to the extent practicable, of
15 the effect of the rule on—

16 “(i) the cumulative burden of compliance
17 with the rule and other existing regulations on
18 persons complying with it; and

19 “(ii) the net effect on small businesses
20 with fewer than 100 employees, including em-
21 ployment in such businesses;

22 “(G) an analysis of whether the identified bene-
23 fits of the proposed rule justify the identified costs
24 of the proposed rule, and an analysis of whether the
25 proposed rule will achieve greater net benefits to so-

1 ciety than any of the alternatives to the proposed
2 rule, including alternatives identified in accordance
3 with subparagraph (C).

4 “(d)(1) When the agency publishes a final major rule,
5 the agency shall also issue and place in the rulemaking
6 file a final cost-benefit analysis, and shall include a sum-
7 mary of the analysis in the statement of basis and pur-
8 pose.

9 “(2) Each final cost-benefit analysis shall contain—

10 “(A) a description and comparison of the bene-
11 fits and costs of the rule and of the reasonable alter-
12 natives to the rule described in the rulemaking, in-
13 cluding the market-based mechanisms identified pur-
14 suant to subsection (c)(2)(D); and

15 “(B) an analysis, based upon the rulemaking
16 record considered as a whole, of—

17 “(i) whether the benefits of the rule justify
18 the costs of the rule; and

19 “(ii) whether the rule will achieve greater
20 net benefits to society than any of the reason-
21 able alternatives described in the rulemaking,
22 including the market-based incentives identified
23 pursuant to subsection (c)(2)(D).

24 “(e)(1)(A) The analysis of the benefits and costs of
25 a proposed and a final rule required under this section

1 shall include, to the extent feasible, a quantification or nu-
2 merical estimate of the quantifiable benefits and costs.
3 Such quantification or numerical estimate shall be made
4 in the most appropriate unit of measurement, using com-
5 parable assumptions, including time periods, shall specify
6 the ranges of predictions, and shall explain the margins
7 of error involved in the quantification methods and in the
8 estimates used. An agency shall describe the nature and
9 extent of the nonquantifiable benefits and costs of a final
10 rule pursuant to this section in as precise and succinct
11 a manner as possible. An agency shall not be required to
12 make such evaluation primarily on a mathematical or nu-
13 merical basis.

14 “(B) Where practicable, the description of the bene-
15 fits and costs of a proposed and final rule required under
16 this section shall describe such benefits and costs on an
17 industry by industry basis.

18 “(2)(A) In evaluating and comparing costs and bene-
19 fits and in evaluating the risk assessment information de-
20 veloped pursuant to subchapter III, the agency shall not
21 rely on cost, benefit, or risk assessment information that
22 is not accompanied by data, analysis, or other supporting
23 materials that would enable the agency and other persons
24 interested in the rulemaking to assess the accuracy, reli-

1 ability, and uncertainty factors applicable to such informa-
2 tion.

3 “(B) The agency evaluations of the relationships of
4 the benefits of a proposed and final rule to its costs shall
5 be clearly articulated in accordance with this section.

6 “(f) The preparation of the initial or final cost-benefit
7 analysis required by this section shall only be performed
8 by an officer or employee of the agency. The preceding
9 sentence shall not preclude a person outside the agency
10 from gathering data or information to be used by the
11 agency in preparing any such cost-benefit analysis or from
12 providing an explanation sufficient to permit the agency
13 to analyze such data or information. If any such data or
14 information is gathered or explained by a person outside
15 the agency, the agency shall specifically identify in the ini-
16 tial or final cost-benefit analysis the data or information
17 gathered or explained and the person who gathered or ex-
18 plained it, and shall describe the arrangement by which
19 the information was procured by the agency, including the
20 total amount of funds expended for such procurement.

21 **“§ 623. Petition for cost-benefit analysis**

22 “(a)(1) Any person subject to a major rule may peti-
23 tion the relevant agency, the Director, or a designee of
24 the President to perform a cost-benefit analysis under this
25 subchapter for the major rule, including a major rule in

1 effect on the date of enactment of this subchapter for
2 which a cost-benefit analysis pursuant to such subchapter
3 has not been performed, regardless of whether a cost-bene-
4 fit analysis was previously performed to meet require-
5 ments imposed before the date of enactment of this sub-
6 chapter.

7 “(2) The petition shall identify with reasonable speci-
8 ficity the major rule to be reviewed.

9 “(3) The agency, the Director, or a designee of the
10 President shall grant the petition if the petition shows that
11 there is a reasonable likelihood that the costs of the major
12 rule outweigh the benefits, or that reasonable questions
13 exist as to whether the rule provides greater net benefits
14 to society than any reasonable alternative to the rule that
15 may be more clearly resolved through examination pursu-
16 ant to this subchapter and subchapter III.

17 “(4) A decision to grant or deny a petition under this
18 subsection shall be made not later than 180 days after
19 submittal. A decision to deny a petition shall be subject
20 to judicial review immediately upon denial as final agency
21 action under the statute granting the agency authority to
22 conduct the rulemaking.

23 “(b) For each major rule for which a petition has
24 been granted under subsection (a), the agency shall con-
25 duct a cost-benefit analysis in accordance with this sub-

1 chapter, and shall determine whether the rule satisfies the
2 decisional criteria set forth in section 624. If the rule does
3 not satisfy the decisional criteria, then the agency shall
4 take immediate action to either revoke or amend the rule
5 to conform the rule to the requirements of this subchapter
6 and the decisional criteria under section 624.

7 “(c) For purposes of this section, the term ‘major
8 rule’ means any major rule or portion thereof.

9 “(d)(1) Any person may petition the relevant agency
10 to withdraw, as contrary to this subchapter, any agency
11 guidance or general statement of policy that would be a
12 major rule if the guidance or general statement of policy
13 had been adopted as a rule.

14 “(2) The petition shall identify with reasonable speci-
15 ficity why the guidance or general statement of policy
16 would be major if adopted as a rule.

17 “(3) The agency shall grant the petition if the peti-
18 tion shows that there is a reasonable likelihood that the
19 guidance or general statement of policy would be major
20 if adopted as a rule.

21 “(4) A decision to grant or deny a petition under this
22 subsection shall be made not later than 180 days after
23 the petition is submitted. If the agency fails to act by
24 such date, the petition shall be deemed to have been grant-
25 ed. A decision to deny a petition shall be subject to judicial

1 chapter, and shall determine whether the rule satisfies the
2 decisional criteria set forth in section 624. If the rule does
3 not satisfy the decisional criteria, then the agency shall
4 take immediate action to either revoke or amend the rule
5 to conform the rule to the requirements of this subchapter
6 and the decisional criteria under section 624.

7 “(c) For purposes of this section, the term ‘major
8 rule’ means any major rule or portion thereof.

9 “(d)(1) Any person may petition the relevant agency
10 to withdraw, as contrary to this subchapter, any agency
11 guidance or general statement of policy that would be a
12 major rule if the guidance or general statement of policy
13 had been adopted as a rule.

14 “(2) The petition shall identify with reasonable speci-
15 ficity why the guidance or general statement of policy
16 would be major if adopted as a rule.

17 “(3) The agency shall grant the petition if the peti-
18 tion shows that there is a reasonable likelihood that the
19 guidance or general statement of policy would be major
20 if adopted as a rule.

21 “(4) A decision to grant or deny a petition under this
22 subsection shall be made not later than 180 days after
23 the petition is submitted. If the agency fails to act by
24 such date, the petition shall be deemed to have been grant-
25 ed. A decision to deny a petition shall be subject to judicial

1 review immediately upon denial as final agency action
2 under the statute under which the agency has issued the
3 guidance or general statement of policy.

4 **“§ 624. Decisional criteria**

5 “(a) Subject to subsection (b), no final rule subject
6 to this subchapter shall be promulgated unless the agency
7 finds that—

8 “(1) the potential benefits to society from the
9 rule justify the potential costs of the rule to society,
10 as determined by the analysis required by section
11 622(d)(2)(B); and

12 “(2) the rule will achieve greater net benefits to
13 society than any of the reasonable alternatives iden-
14 tified pursuant to section 622(d)(2)(B).

15 Subject to the provisions of subsection (b), the require-
16 ments of this section shall supplement any other decisional
17 criteria otherwise provided by law.

18 “(b)(1) If the text of a statute expressly requires that
19 a rule shall be promulgated without regard to whether the
20 rule satisfies the criterion provided in subsection (a)(1),
21 the rule must satisfy the criterion provided in subsection
22 (a)(2).

23 “(2) If the text of a statute expressly requires that
24 a rule shall be promulgated without regard to whether the
25 rule satisfies both criteria provided in subsection (a), the

1 rule must impose lower net costs to society than any of
2 the reasonable alternatives identified pursuant to section
3 622(d)(2)(B).

4 “(c) If an agency determines that the text of a statute
5 expressly requires a rule to be promulgated that does not
6 satisfy the criterion of subsection (a)(1) or the criteria of
7 both subsections (a)(1) and (a)(2), the agency shall—

8 “(1) include a written explanation of such de-
9 termination in the initial and final cost-benefit anal-
10 ysis required by section 622; and

11 “(2) transmit the final cost-benefit analysis to
12 Congress when the final rule is promulgated.

13 **“§ 625. Judicial review**

14 “(a) Each court with jurisdiction to review final agen-
15 cy action under the statute granting the agency authority
16 to conduct the rulemaking shall have jurisdiction to review
17 final action under this subchapter.

18 “(b) Any cost-benefit analysis of, or risk assessment
19 concerning, a rule shall constitute part of the whole rule-
20 making record of agency action for the purpose of judicial
21 review of the rule, and shall be considered by a court in
22 determining the legality of the rule. The court shall apply
23 the same standards of judicial review that govern the re-
24 view of agency findings under the statute granting the
25 agency authority to conduct the rulemaking. The court

1 shall set aside agency action that fails to satisfy the
2 decisional criteria of section 624.

3 **“§ 626. Deadlines for rulemaking**

4 “(a) Beginning on the date of enactment of this sec-
5 tion, all deadlines in statutes that require agencies to pro-
6 pose or promulgate any rule subject to this subchapter
7 shall be suspended until such time as the requirements
8 of this subchapter are satisfied.

9 “(b) Beginning on the date of enactment of this sec-
10 tion, the jurisdiction of any court of the United States
11 to enforce any deadline that would require an agency to
12 propose or promulgate a rule subject to this chapter shall
13 be suspended until such time as the requirements of this
14 subchapter are satisfied.

15 “(c) In any case in which the failure to promulgate
16 a rule by a deadline would create an obligation to regulate
17 through individual adjudications, the deadline shall be sus-
18 pended to allow the requirements of this subchapter to be
19 satisfied.

20 **“§ 627. Agency review of rules**

21 “(a)(1)(A) Not later than 9 months after the date
22 of enactment of this section, each agency shall prepare and
23 publish in the Federal Register a proposed schedule for
24 the review, in accordance with this section, of—

1 “(i) each rule of the agency that is in effect on
2 such effective date and which, if adopted on such ef-
3 fective date, would be a major rule under section
4 621(2)(A);

5 “(ii) each rule of the agency that is inconsistent
6 or in conflict with any other obligation or require-
7 ment established by any Federal statute, rule, or
8 other agency statement, interpretation, or action
9 that has the force of law; and

10 “(iii) each rule of the agency in effect on the
11 date of enactment of this section (in addition to the
12 rules described in clauses (i) and (ii)) that the agen-
13 cy has selected for review.

14 “(B) Each proposed schedule required by subpara-
15 graph (A) shall include—

16 “(i) a brief explanation of the reasons the agen-
17 cy considers each rule on the schedule to be a major
18 rule under section 621(2)(A), or the reasons why the
19 agency selected the rule for review;

20 “(ii) a date set by the agency, in accordance
21 with subsection (b)(1), for the completion of the re-
22 view of each such rule; and

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

1 “(C) The agency shall set a date to initiate review
2 of each rule on the schedule in a manner that will ensure
3 the simultaneous review of related items and that will
4 achieve a reasonable distribution of reviews over the period
5 of time covered by the schedule.

6 “(2) Not later than 90 days before publishing in the
7 Federal Register the proposed schedule required under
8 paragraph (1), each agency shall make the proposed
9 schedule available to the Director or a designee of the
10 President, or to the Vice President or other officer to
11 whom oversight authority has been delegated under sec-
12 tion 643. The President or that officer may select for re-
13 view in accordance with this section any additional rule.

14 “(3) Not later than 1 year after the date of enact-
15 ment of this section, each agency shall publish in the Fed-
16 eral Register a final schedule for the review of the rules
17 referred to in paragraphs (1) and (2). Each agency shall
18 publish with the final schedule the response of the agency
19 to comments received concerning the proposed schedule.

20 “(b)(1) Except as explicitly provided otherwise by
21 statute, the agency shall, pursuant to subsections (c)
22 through (e), review—

23 “(A) each rule on the schedule promulgated
24 pursuant to subsection (a);

1 “(B) each major rule under section 621(2) pro-
2 mulgated, amended, or otherwise renewed by an
3 agency after the date of the enactment of this sec-
4 tion; and

5 “(C) each rule promulgated after the date of
6 enactment of this section that the President or the
7 officer designated by the President selects for review
8 pursuant to subsection (a)(2).

9 “(2) Except as provided pursuant to subsection (f),
10 the review of a rule required by this section shall be com-
11 pleted not later than 10 years after the date of enactment
12 of this section or 10 years after the date on which the
13 rule is promulgated, amended, or renewed, whichever is
14 earlier.

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

18 “(1) an identification of the specific statutory
19 authority under which the rule was promulgated and
20 an explanation of whether the agency’s interpreta-
21 tion of the statute is expressly required by the cur-
22 rent text of that statute or, if not, whether it is
23 within the range of permissible interpretations of the
24 statute;

1 “(2) an analysis of the benefits and costs of the
2 rule during the period in which it has been in effect;

3 “(3) an explanation of the proposed agency ac-
4 tion with respect to the rule, including action to re-
5 peal or amend the rule to resolve inconsistencies or
6 conflicts with any other obligation or requirement es-
7 tablished by any Federal statute, rule, or other
8 agency statement, interpretation, or action that has
9 the force of law; and

10 “(4) a statement that the agency seeks propos-
11 als from the public for modifications or alternatives
12 to the rule which may accomplish the objectives of
13 the rule in a more effective or less burdensome man-
14 ner.

15 “(d) If an agency proposes to repeal or amend a rule
16 under review pursuant to this section, the agency shall,
17 after issuing the notice required by subsection (c), comply
18 with the provisions of this chapter, chapter 5, and any
19 other applicable law. The requirements of such provisions
20 and related requirements shall apply to the same extent
21 and in the same manner as in the case of a proposed agen-
22 cy action to repeal or amend a rule that is not taken pur-
23 suant to the review required by this section.

1 “(e) If an agency proposes to renew without amend-
2 ment a rule under review pursuant to this section, the
3 agency shall—

4 “(1) give interested persons not less than 60
5 days after the publication of the notice required by
6 subsection (c) to comment on the proposed renewal;
7 and

8 “(2) publish in the Federal Register notice of
9 the renewal of such rule, an explanation of the con-
10 tinued need for the rule, and, if the renewed rule is
11 a major rule under section 621(2), an explanation of
12 the reasonable determination of the agency that the
13 rule complies with section 624.

14 “(f) Any agency, which for good cause finds that
15 compliance with this section with respect to a particular
16 rule during the period provided in subsection (b) of this
17 section is contrary to an important public interest may
18 request the President, or the officer designated by the
19 President pursuant to subsection (a)(2), to establish a pe-
20 riod longer than 10 years for the completion of the review
21 of such rule. The President or that officer may extend the
22 period for review of a rule to a total period of not more
23 than 15 years. Such extension shall be published in the
24 Federal Register with an explanation of the reasons there-
25 for.

1 “(g) In any case in which an agency has not com-
2 pleted the review of a rule within the period prescribed
3 by subsection (b) or (f) of this section, the agency shall
4 immediately publish in the Federal Register a notice pro-
5 posing to amend, repeal, or renew the rule under sub-
6 section (c), and shall complete proceedings pursuant to
7 subsection (d) or (e) not later than 180 days after the
8 date on which the review was required to be completed
9 under subsection (b) or (f).

10 “(h) Nothing in this section shall relieve any agency
11 from its obligation to respond to a petition to issue,
12 amend, or repeal a rule, for an interpretation regarding
13 the meaning of a rule, or for a variance or exemption from
14 the terms of a rule, submitted pursuant to any other provi-
15 sion of law.

16 “SUBCHAPTER III—RISK ASSESSMENTS

17 “§ 631. Definitions

18 “For purposes of this subchapter—

19 “(1) the term ‘best estimate’ means an estimate
20 that, to the extent feasible and scientifically appro-
21 priate, is based on—

22 “(A) central estimates of risk using the
23 most plausible assumptions;

1 “(B) an approach that combines multiple
2 estimates based on different scenarios and
3 weighs the probability of each scenario; and

4 “(C) any other methodology designed to
5 provide the most unbiased representation of the
6 most plausible level of risk, given the current
7 scientific information available to the agency
8 concerned;

9 “(2) the term ‘emergency’ means an imminent
10 and substantial endangerment to public health or
11 the environment;

12 “(3) the term ‘hazard identification’ means
13 identification of a substance, activity, or condition as
14 potentially posing a risk to human health or safety
15 or the environment based on empirical data, meas-
16 urements, or testing showing that it has caused sig-
17 nificant adverse effects at some levels of dose or ex-
18 posure not necessarily relevant to level of dose or ex-
19 posure that are normally expected to occur;

20 “(4) the term ‘negative data’ means data indi-
21 cating that under certain conditions a given sub-
22 stance or activity did not induce an adverse effect;

23 “(5) the term ‘risk assessment’ means—

24 “(A) the iterative process of identifying
25 hazards, and quantifying (to the maximum ex-

1 tent practicable) or describing the degree of
2 toxicity, exposure, or other risk the hazards
3 pose for exposed individuals, populations, or re-
4 sources; and

5 “(B) the document containing the expla-
6 nation of how the assessment process has been
7 applied to an individual substance, activity, or
8 condition;

9 “(6) the term ‘risk characterization’—

10 “(A) means the element of a risk assess-
11 ment that involves presentation of the degree of
12 risk to individuals and populations expected to
13 be protected, as presented in any regulatory
14 proposal or decision, report to Congress, or
15 other document that is made available to the
16 public; and

17 “(B) includes discussions of uncertainties,
18 conflicting data, estimates, extrapolations, in-
19 ferences, and opinions; and

20 “(7) the term ‘substitution risk’ means a poten-
21 tial increased risk to human health, safety, or the
22 environment resulting from market substitutions, a
23 reduced standard of living, or a regulatory alter-
24 native designed to decrease other risks.

1 **“§ 632. Applicability**

2 “(a) Except as provided in subsection (b), this sub-
3 chapter shall apply to all risk assessments and risk charac-
4 terizations prepared by, or on behalf of, or prepared by
5 others and adopted by, any Federal agency in connection
6 with health, safety, and environmental risks.

7 “(b)(1) This subchapter shall not apply to risk as-
8 sessments or risk characterizations performed with respect
9 to—

10 “(A) a situation that the head of the agency
11 finds to be an emergency;

12 “(B) a rule or agency action that authorizes the
13 introduction into, or removal from, commerce, or
14 recognizes the marketable status of a product;

15 “(C) a health, safety, or environmental inspec-
16 tion or individual facility permitting action; or

17 “(F) a screening analysis clearly identified as
18 such.

19 “(2)(A) An analysis shall not be treated as a screen-
20 ing analysis for the purposes of paragraph (1)(D) if the
21 result of the analysis is used—

22 “(i) as the basis for imposing a restriction on
23 a substance, product, or activity; or

24 “(ii) to characterize a positive finding of risks
25 from a substance or activity in any agency document

1 or other communication made available to the public,
2 the media, or Congress.

3 “(B) Among the analyses that may be treated as a
4 screening analyses for the purposes of paragraph (1)(D)
5 are product registrations, reregistrations, tolerance set-
6 tings, and reviews of premanufacture notices and existing
7 chemicals under the Federal Insecticide, Fungicide, and
8 Rodenticide Act (7 U.S.C. 136 et seq.) and the Toxic Sub-
9 stances Control Act (15 U.S.C. 2601 et seq.).

10 “(3) This subchapter shall not apply to any food,
11 drug, or other product label or to any risk characterization
12 appearing on any such label.

13 **“§ 633. Rule of construction**

14 “Nothing in this subchapter shall be construed to—

15 “(1) preclude the consideration of any data or
16 the calculation of any estimate to more fully describe
17 risk or provide examples of scientific uncertainty or
18 variability; or

19 “(2) require the disclosure of any trade secret
20 or other confidential information.

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

22 “(a) Except as provided in section 632, the head of
23 each agency shall prepare for each major rule relating to
24 human health, safety, or the environment that is proposed
25 by the agency after the date of enactment of this sub-

1 chapter, is pending on the date of enactment of this sub-
2 chapter, or is subject to a granted petition for review pur-
3 suant to section 553(e) or 622(g)—

4 “(1) a risk assessment in accordance with this
5 subchapter;

6 “(2) for each such proposed or final rule, an as-
7 sessment, quantified to the extent feasible, of incre-
8 mental risk reduction or other benefits associated
9 with each significant regulatory alternative to the
10 rule or proposed rule; and

11 “(3) for each such proposed or final rule, quan-
12 tified to the extent feasible, a comparison of any
13 human health, safety, or environmental risks ad-
14 dressed by the regulatory alternatives to other rel-
15 evant risks chosen by the head of the agency, includ-
16 ing at least 3 other risks regulated by the agency
17 and to at least 3 other risks with which the public
18 is familiar.

19 “(b) A risk assessment prepared pursuant to this
20 subchapter shall be a component of and used to develop
21 the cost-benefit analysis required by subchapter II, and
22 shall be made part of the administrative record for judicial
23 review of any final agency action.

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

2 “(a)(1) The head of each agency shall apply the prin-
3 ciples set forth in subsection (b) when preparing any risk
4 assessment, whether or not required by section 634, to en-
5 sure that the risk assessment and all of its components—

6 “(A) distinguish scientific findings and best es-
7 timates of risk from other considerations;

8 “(B) are, to the maximum extent practicable
9 scientifically objective, unbiased and inclusive of all
10 relevant data; and

11 “(C) rely, to the extent available and prac-
12 ticable, on scientific findings.

13 “(2) An agency shall not be required to repeat discus-
14 sions or explanations required under this section in each
15 risk assessment document if there is a reference to the
16 relevant discussion or explanation in another agency docu-
17 ment.

18 “(b) The principles to be applied when preparing risk
19 assessments are as follows:

20 “(1)(A) When assessing human health risks, a
21 risk assessment shall consider and discuss both the
22 most important laboratory and epidemiological data
23 and summarize the remaining data that finds, or
24 fails to find, a correlation between a health risk and
25 a potential toxin or activity.

1 “(B) When conflicts among such data appear to
2 exist, or when animal data are used as a basis to as-
3 sess human health, the assessment shall include a
4 discussion of possible reconciliation of conflicting in-
5 formation, and, as appropriate, differences in study
6 designs, mechanisms of action, comparative physiolo-
7 gy, routes of exposure, bioavailability,
8 pharmacokinetics, and any other relevant factor, in-
9 cluding the availability of raw data for review.
10 Greatest emphasis shall be placed on data that indi-
11 cates the biological basis of the resulting harm in
12 humans. Animal data shall be reviewed with regard
13 to relevancy to humans.

14 “(2) When a risk assessment involves a choice
15 of any significant assumption (including the use of
16 safety factors and default assumptions), inference,
17 or model, the agencies or instrumentality preparing
18 the assessment shall—

19 “(A) present a representative description
20 and explicit explanation of plausible and alter-
21 native similar assumptions, inferences, or mod-
22 els (including the assumptions incorporated into
23 the model) and the sensitivity of the conclusions
24 to them;

25 “(B) explain the basis for any choices;

1 “(C) identify any science policy or value
2 judgments;

3 “(D) describe any model used in the risk-
4 assessment and make explicit the assumptions
5 incorporated into the model; and

6 “(E) indicate the extent to which any sig-
7 nificant model has been validated by, or con-
8 flicts with, empirical data.

9 “(3) A risk assessment shall clearly separate
10 hazard identification from risk characterization and
11 make clear the relationship between the level of risk
12 and the level of exposure to a potential hazard.

13 “(4) A risk assessment shall be prepared at the
14 level of detail appropriate and practicable for rea-
15 soned decisionmaking on the matter involved, taking
16 into consideration the significance and complexity of
17 the decision and any need for expedition.

18 **“§ 636. Principles for risk characterization and com-**
19 **munication**

20 “In characterizing risk in any risk assessment docu-
21 ment, regulatory proposal or decision, report to Congress,
22 or other document that is made available to the public,
23 each agency characterizing the risk shall comply with each
24 of the following:

1 “(1)(A) The head of the agency shall describe
2 the populations or natural resources that are the
3 subject of the risk characterization.

4 “(B) If a numerical estimate of risk is provided,
5 the head of the agency, to the extent feasible and
6 scientifically appropriate—

7 “(i) shall provide—

8 “(I) the best estimate or estimates for
9 the specific populations or natural re-
10 sources that are the subject of the charac-
11 terization (based on the information avail-
12 able to the department, agency, or instru-
13 mentality) or, in lieu of a single best esti-
14 mate, an array of multiple estimates
15 (showing the distribution of estimates and
16 the best estimate) based on assumptions,
17 inferences, or models which are equally
18 reasonably plausible, given current sci-
19 entific understanding;

20 “(II) a statement of the reasonable
21 range of scientific uncertainties; and

22 “(III) descriptions of the distribution
23 and probability of risk estimates to reflect
24 differences in exposure variability in popu-
25 lations and uncertainties;

1 “(ii) in addition to a best estimate or esti-
2 mates, may present plausible upper-bound or
3 conservative estimates, but only in conjunction
4 with equally plausible lower-bound estimates;
5 and

6 “(iii) shall ensure that, where a safety fac-
7 tor, as distinguished from an inherent quan-
8 titative uncertainty factor, is used, such factor
9 shall reflect safety factors commonly used to
10 ensure human safety in other human activities.

11 “(2) The head of the agency shall explain the
12 exposure scenarios used in any risk assessment, and,
13 to the extent feasible, provide a statement of the size
14 of the corresponding population at risk and the like-
15 lihood of such exposure scenarios.

16 “(3) To the extent feasible, the head of the
17 agency shall provide a statement that places the na-
18 ture and magnitude of individual and population
19 risks to human health in context.

20 “(4) When a Federal agency provides a risk as-
21 sessment or risk characterization for a proposed or
22 final regulatory action, such assessment or charac-
23 terization shall include a statement of any signifi-
24 cant substitution risks to human health identified by

1 the agency or contained in information provided to
2 the agency by a commentator.

3 “(5) An agency shall present a summary in
4 connection with the presentation of the agency’s risk
5 assessment or the regulation if—

6 “(A) the agency provides a public comment
7 period with respect to a risk assessment or reg-
8 ulation;

9 “(B) a commentator provides a risk assess-
10 ment, and a summary of results of such risk as-
11 sessment; and

12 “(C) such risk assessment is reasonably
13 consistent with the principles and the guidance
14 provided under this subtitle.

15 **“§ 637. Regulations; plan for assessing new informa-**
16 **tion**

17 “(a)(1) Not later than 1 year after the date of enact-
18 ment of this subchapter, the Director or a designee of the
19 President shall—

20 “(A) issue a final regulation that has been sub-
21 ject to notice and comment under section 553 that
22 directs agencies to implement the risk assessment
23 and characterization principles set forth in sections
24 635 and 636; and

1 “(B) provide a format for summarizing risk as-
2 essment results.

3 “(2) The regulation under paragraph (1) shall be suf-
4 ficiently specific to ensure that risk assessments are con-
5 ducted consistently by the various agencies.

6 “(b)(1) Review of the risk assessment for any major
7 rule shall be conducted by the head of the agency on the
8 written petition of a person showing a reasonable likeli-
9 hood that—

10 “(A) the risk assessment is inconsistent with
11 the principles set forth in sections 635 and 636;

12 “(B) the risk assessment produces substantially
13 different results;

14 “(C) the risk assessment is inconsistent with a
15 rule issued under subsection (a); or

16 “(D) the risk assessment does not take into ac-
17 count material significant new scientific data or sci-
18 entific understanding.

19 “(2) Not later than 90 days after receiving a petition
20 under paragraph (1), the head of the agency shall respond
21 to the petition by agreeing or declining to review the risk
22 assessment referred to in the petition, and shall state the
23 basis for the decision.

24 “(3) If the head of the agency agrees to review the
25 petition, the agency shall complete its review not later

1 than 180 days after the decision made under paragraph
2 (2), unless the Director agrees in writing with an agency
3 determination that an extension is necessary in view of
4 limitations on agency resources.

5 “(4) Denial of a petition by the agency head shall
6 be subject to judicial review in accordance with chapter
7 7.

8 “(5) A risk assessment completed pursuant to a peti-
9 tion may be the basis for initiating a regulatory review
10 pursuant to section 622(g).

11 “(c) The regulations under this section shall be devel-
12 oped after notice and opportunity for public comment, and
13 after consultation with representatives of appropriate
14 State agencies and local governments, and such other de-
15 partments, agencies, offices, organizations, or persons as
16 may be advisable.

17 “(d) At least every 4 years, the Director or a designee
18 of the President shall review, and when appropriate, re-
19 vise, the regulations published under this section.

20 **“§ 638. Decisional criteria**

21 “(a) For each major rule subject to this subchapter,
22 the head of the agency, subject to review by the Director
23 or a designee of the President, shall make a determination
24 that—

1 “(1) the risk assessment under section 634 is
2 based on a scientific and unbiased evaluation, re-
3 flecting reasonable exposure scenarios, of the risk
4 addressed by the major rule and are supported by
5 the best available scientific data, as determined by
6 a peer review panel in accordance with section 639;
7 and

8 “(2) there is no alternative that is allowed by
9 the statute under which the major rule is promul-
10 gated that would provide greater net benefits or that
11 would achieve an equivalent reduction in risk in a
12 more cost-effective and flexible manner.

13 “(b) Notwithstanding any other provision of law, no
14 covered agency shall prohibit or refuse to approve a sub-
15 stance or product on the basis of safety where the sub-
16 stance or product presents an insignificant human risk
17 under the intended conditions of use.

18 **“§ 639. Establishment of program**

19 “(a) The Director of the Office of Science and Tech-
20 nology shall develop a systematic program for the peer re-
21 view of work products covered by subsection (c), which
22 program shall be used uniformly across the agencies.

23 “(b) The program under subsection (a)—

24 “(1) shall provide for the creation of peer re-
25 view panels consisting of independent and external

1 experts who are broadly representative and balanced
2 to the extent feasible;

3 “(2) shall not exclude peer reviewers merely be-
4 cause they represent entities that may have a poten-
5 tial interest in the outcome, if that interest is fully
6 disclosed;

7 “(3) shall exclude, to the maximum extent prac-
8 ticable, any peer reviewer who has been involved in
9 any previous analysis of the tests and evidence pre-
10 sented for certification by the peer review panel; and

11 “(4) shall provide for a timely completed peer
12 review, meeting agency deadlines, which contains a
13 balanced presentation of all considerations, including
14 minority reports and an agency response to all sig-
15 nificant peer review comments.

16 “(c) The draft peer review and the agency’s responses
17 shall be made available to the public for comment and
18 shall be made part of the administrative record of the final
19 peer review for purposes of judicial review of any final
20 agency action.

21 “(d) The proceedings of peer review panels under this
22 section shall be subject to the applicable provisions of the
23 Federal Advisory Committee Act (5 U.S.C. App.).

1 “SUBCHAPTER IV—EXECUTIVE OVERSIGHT

2 **“§ 641. Procedures**

3 “The Director or a designee of the President shall—

4 “(1) establish procedures for agency compliance
5 with this chapter; and

6 “(2) monitor, review, and ensure agency imple-
7 mentation of such procedures.

8 **“§ 642. Promulgation and adoption**

9 “(a) Procedures established pursuant to section 641
10 shall only be implemented after opportunity for public
11 comment. Any such procedures shall be consistent with the
12 prompt completion of rulemaking proceedings.

13 “(b)(1) If procedures established pursuant to section
14 641 include review of any initial or final analyses of a rule
15 required under chapter 6, the time for any such review
16 of any initial analysis shall not exceed 30 days following
17 the receipt of the analysis by the Director, a designee of
18 the President, or by an officer to whom the authority
19 granted under section 641 has been delegated pursuant
20 to section 643.

21 “(2) The time for review of any final analysis re-
22 quired under chapter 6 shall not exceed 30 days following
23 the receipt of the analysis by the Director, a designee of
24 the President, or such officer.

1 “(3)(A) The times for each such review may be ex-
2 tended for good cause by the President or such officer for
3 an additional 30 days.

4 “(B) Notice of any such extension, together with a
5 succinct statement of the reasons therefor, shall be in-
6 serted in the rulemaking file.

7 **“§ 643. Delegation of authority**

8 “(a) The President may delegate the authority grant-
9 ed by this subchapter to the Vice President or to an officer
10 within the Executive Office of the President whose ap-
11 pointment has been subject to the advice and consent of
12 the Senate.

13 “(b)(1) Notice of any delegation, or any revocation
14 or modification thereof shall be published in the Federal
15 Register.

16 “(2) Any notice with respect to a delegation to the
17 Vice President shall contain a statement by the Vice Presi-
18 dent that the Vice President will make every reasonable
19 effort to respond to congressional inquiries concerning the
20 exercise of the authority delegated under this section.

21 **“§ 644. Judicial review**

22 “The exercise of the authority granted under this
23 subchapter by the Director, the President, or by an officer
24 to whom such authority has been delegated under section

1 643 shall not be subject to judicial review in any manner
2 under this chapter.”.

3 (b) REGULATORY FLEXIBILITY ANALYSIS.—(1) Sec-
4 tion 611 of title 5, United States Code, is amended to
5 read as follows:

6 **“§ 611. Judicial review**

7 “(a)(1) Except as provided in paragraph (2), not
8 later than 2 years after the effective date of a final rule
9 with respect to which an agency—

10 “(A) certified, pursuant to section 605(b), that
11 such rule would not have a significant economic im-
12 pact on a substantial number of small entities;

13 “(B) prepared a final regulatory flexibility anal-
14 ysis pursuant to section 604; or

15 “(C) did not prepare an initial regulatory flexi-
16 bility analysis pursuant to section 603 or a final reg-
17 ulatory flexibility analysis pursuant to section 604
18 except as permitted by sections 605 and 608,

19 an affected small entity may petition for the judicial re-
20 view of such certification, analysis, or lack of analysis, in
21 accordance with this subsection. A court having jurisdic-
22 tion to review such rule for compliance with section 553
23 or under any other provision of law shall have jurisdiction
24 to review such certification or analysis.

1 “(2)(A) Notwithstanding any other provision of law,
2 an affected small entity shall have 2 years to challenge
3 such certification, analysis or lack of analysis.

4 “(B) If an agency delays the issuance of a final regu-
5 latory flexibility analysis pursuant to section 608(b), a pe-
6 tition for judicial review under this subsection shall be
7 filed not later than 2 years after the date the analysis is
8 made available to the public.

9 “(3) For purposes of this subsection, the term ‘af-
10 fected small entity’ means a small entity that is or will
11 be adversely affected by the final rule.

12 “(4) Nothing in this subsection shall be construed to
13 affect the authority of any court to stay the effective date
14 of any rule or provision thereof under any other provision
15 of law.

16 “(5)(A) Notwithstanding section 605, if the court de-
17 termines, on the basis of the rulemaking record, that there
18 is substantial evidence to conclude that the rule would
19 have a significant economic impact on a substantial num-
20 ber of small entities, the court shall order the agency to
21 prepare a final regulatory flexibility analysis pursuant to
22 section 604.

23 “(B) If the agency prepared a final regulatory flexi-
24 bility analysis, the court may order the agency to take cor-
25 rective action consistent with section 604 if the court de-

1 terminates, on the basis of the rulemaking record, that the
2 final regulatory flexibility analysis was prepared by the
3 agency without complying with section 604.

4 “(6) The court may stay the rule or grant such other
5 relief as it deems appropriate if, by the end of the 90-
6 day period beginning on the date of the order of the court
7 pursuant to paragraph (5) (or such longer period as the
8 court may provide), the agency fails, as appropriate—

9 “(A) to prepare the analysis required by section
10 604; or

11 “(B) to take corrective action consistent with
12 section 604.

13 “(7) In making any determination or granting any
14 relief authorized by this subsection, the court shall take
15 due account of the rule of prejudicial error.

16 “(b) In an action for the judicial review of a rule,
17 any regulatory flexibility analysis for such rule (including
18 an analysis prepared or corrected pursuant to subsection
19 (a)(5)) shall constitute part of the whole record of agency
20 action in connection with such review.

21 “(c) Nothing in this section bars judicial review of
22 any other impact statement or similar analysis required
23 by any other law if judicial review of such statement or
24 analysis is otherwise provided by law.”.

1 (2) EFFECTIVE DATE.—The amendment made by
2 paragraph (1) shall take effect on the date of enactment
3 of this Act, except that the judicial review authorized by
4 section 611(a) of title 5, United States Code (as added
5 by subsection (a)), shall apply only to final agency rules
6 issued after the date of enactment of this Act.

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

13 (d) TECHNICAL AND CONFORMING AMENDMENTS.—

14 (1) Part I of title 5, United States Code, is
15 amended by striking out the chapter heading and
16 table of sections for chapter 6 and inserting in lieu
17 thereof the following:

18 **“CHAPTER 6—THE ANALYSIS OF**
19 **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 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—ANALYSIS OF AGENCY RULES

"621. Definitions.

"622. Rulemaking cost-benefit analysis.

"623. Petition for cost-benefit analysis.

"624. Decisional criteria.

"625. Judicial review.

"626. Deadlines for rulemaking.

"627. Agency review of rules.

"SUBCHAPTER III—RISK ASSESSMENTS

"631. Definitions.

"632. Applicability.

"633. Rule of construction.

"634. Requirement to prepare risk assessments.

"635. Principles for risk assessment.

"636. Principles for risk characterization and communication.

"637. Regulations; plan for assessing new information.

"638. Decisional criteria.

"639. Establishment of program.

"SUBCHAPTER IV—EXECUTIVE OVERSIGHT

"641. Procedures.

"642. Promulgation and adoption.

"643. Delegation of authority.

"644. Judicial review."

1 (2) Chapter 6 of title 5, United States Code, is
2 amended by inserting immediately before section
3 601, the following subchapter heading:

4 "SUBCHAPTER I—REGULATORY ANALYSIS".

5 **SEC. 5. JUDICIAL REVIEW.**

6 (a) DEFINITIONS.—Section 701(b)(2) of title 5, Unit-
7 ed States Code, is amended by inserting before the period
8 at the end the following: " , except that 'agency action'
9 does not include action or inaction alleged to constitute
10 a breach of contract or to cause an inability to perform,
11 or to frustrate the purpose of a contract, where jurisdic-
12 tion over a claim raising such an allegation would be prop-

1 er under section 1346(a)(2) or 1491(a)(1) of title 28,
2 United States Code”.

3 (b) RIGHT OF REVIEW.—Section 702 of title 5, Unit-
4 ed States Code, is amended—

5 (1) in the second sentence by striking “seeking
6 relief other than money damages and”; and

7 (2) in the last sentence by striking “or
8 impliedly”.

9 (c) ACTIONS REVIEWABLE.—Section 704 of title 5,
10 United States Code, is amended in the first sentence by
11 inserting “other than the Court of Federal Claims” after
12 “court”.

13 (d) SCOPE OF REVIEW.—Section 706 of title 5, Unit-
14 ed States Code, is amended to read as follows:

15 **“§ 706. Scope of Review**

16 “(a) To the extent necessary to reach a decision and
17 when presented, the reviewing court shall decide all rel-
18 evant questions of law, interpret constitutional and statu-
19 tory provisions, and determine the meaning or applicabil-
20 ity of the terms of an agency action. The reviewing court
21 shall—

22 “(1) compel agency action unlawfully withheld
23 or unreasonably delayed; and

24 “(2) hold unlawful and set aside agency action,
25 findings and conclusions found to be—

1 “(A) arbitrary, capricious, an abuse of dis-
2 cretion, or otherwise not in accordance with
3 law;

4 “(B) contrary to constitutional right,
5 power, privilege, or immunity;

6 “(C) in excess of statutory jurisdiction, au-
7 thority, or limitations, or short of statutory
8 right;

9 “(D) without observance of procedure re-
10 quired by law;

11 “(E) unsupported by substantial evidence
12 in a proceeding subject to sections 556 and 557
13 or otherwise reviewed on the record;

14 “(F) without substantial support in the
15 rulemaking file, viewed as a whole, for the as-
16 serted or necessary factual basis, as distin-
17 guished from the policy or legal basis, of a rule
18 adopted in a proceeding subject to section 553;
19 and

20 “(G) unwarranted by the facts to the ex-
21 tent that the facts are subject to trial de novo
22 by the reviewing court; and

23 “(3) award monetary relief, including money
24 damages, where appropriate.

1 “(b) In making the foregoing determinations, the
2 court shall review the whole record or those parts of it
3 cited by a party, and due account shall be taken of the
4 rule of prejudicial error.

5 “(c) In reviewing an agency interpretation of a stat-
6 ute governing the authority for an agency action, including
7 agency action taken pursuant to a statute that provides
8 for review of final agency action, the reviewing court
9 shall—

10 “(1) hold erroneous and unlawful—

11 “(A) an agency interpretation that is other
12 than the interpretation of the statute clearly in-
13 tended by Congress; or

14 “(B) an agency interpretation that is out-
15 side the range of permissible interpretations of
16 the statute; and

17 “(2) hold arbitrary, capricious, or an abuse of
18 discretion—

19 “(A) an agency action as to which the
20 agency—

21 “(i) has improperly classified an inter-
22 pretation as being within or outside the
23 range of permissible interpretations; or

24 “(ii) has not explained in a reasoned
25 analysis why it selected the interpretation

1 and why it rejected other permissible inter-
2 pretations of the statute; or

3 “(B) in the case of agency action subject
4 to chapter 6 of this title, an interpretation that
5 does not give the agency the broadest discretion
6 to develop rules that will satisfy the decisional
7 criteria of section 624.

8 “(d) Notwithstanding any other provision of law, the
9 provisions of this subsection shall apply to, and supple-
10 ment, the requirements contained in any statute for the
11 review of final agency action which is not otherwise subject
12 to this subsection.”.

13 (e) COURT OF FEDERAL CLAIMS.—

14 (1) IN GENERAL.—Section 1491(a) of title 28,
15 United States Code, is amended—

16 (A) in paragraph (1), by amending the
17 first sentence to read as follows: “The United
18 States Court of Federal Claims shall have juris-
19 diction to render judgment upon any claim
20 against the United States for monetary relief
21 founded either upon the Constitution or any
22 Act of Congress or any regulation of an execu-
23 tive department, or upon any expressed or im-
24 plied contract with the United States, in cases
25 not sounding in tort, or for invalidation of any

1 Act of Congress or any regulation of an execu-
2 tive department that adversely affects private
3 property rights in violation of the fifth amend-
4 ment of the United States Constitution.”;

5 (B) in paragraph (2), by inserting before
6 the first sentence the following: “In any case
7 within its jurisdiction, the Court of Federal
8 Claims shall have the power to grant injunctive
9 and declaratory relief when appropriate.”; and

10 (C) by adding at the end the following new
11 paragraphs:

12 “(4) In cases otherwise within its jurisdiction, the
13 Court of Federal Claims shall also have ancillary jurisdic-
14 tion, concurrent with the courts designated in section
15 1346(b), to render judgment upon any related tort claim
16 authorized under section 2674.

17 “(5) In proceedings within the jurisdiction of the
18 Court of Federal Claims which constitute judicial review
19 of agency action (rather than de novo proceedings), the
20 provisions of section 706 of title 5 shall apply.”.

21 (2) PENDENCY OF CLAIMS IN OTHER
22 COURTS.—Section 1500 of title 28, United States
23 Code, is repealed.

24 (f) CONSENT DECREES.—

1 (1) IN GENERAL.—Chapter 7 of title 5, United
2 State Code, is amended by adding at the end the fol-
3 lowing new section:

4 **“§ 707. Consent Decrees**

5 “In interpreting any consent decree in effect on or
6 after the date of enactment of this section that imposes
7 on an agency an obligation to initiate, continue, or com-
8 plete rulemaking proceedings, the court shall not enforce
9 the decree in a way that divests the agency of discretion
10 granted to it by the Congress or the Constitution to re-
11 spond to changing circumstances, make policy or manage-
12 rial choices, or protect the rights of third parties.”.

13 (2) TECHNICAL AMENDMENT.—The analysis for
14 chapter 7 of title 5, United States Code, is amended
15 by adding at the end the following new item:

“707. Consent decrees.”.

16 **SEC. 6. CONGRESSIONAL REVIEW.**

17 (a) IN GENERAL.—Title 5, United States Code, is
18 amended by inserting immediately after chapter 7 the fol-
19 lowing new chapter:

20 **“CHAPTER 8—CONGRESSIONAL REVIEW**
21 **OF AGENCY RULEMAKING**

22 **“§ 801. Congressional review of agency rulemaking**

23 “(a)(1) Before a rule takes effect as a final rule, the
24 agency promulgating such rule shall submit to the Con-
25 gress a report containing a copy of the rule, the notice

1 of proposed rulemaking, and the statement of basis and
2 purpose for the rule, including a complete copy of any
3 analysis required under chapter 6 of this title, and the
4 proposed effective date of the rule. In the case of a rule
5 that is not a major rule within the meaning of section
6 621(2), summary of the rulemaking proceedings shall be
7 submitted.

8 “(2) A rule relating to a report submitted under
9 paragraph (1) shall take effect as a final rule, the latest
10 of the following:

11 “(A) The later of the date occurring 45 days
12 after the date on which—

13 “(i) the Congress receives the report sub-
14 mitted under paragraph (1); or

15 “(ii) the rule is published in the Federal
16 Register.

17 “(B) If the Congress passes a joint resolution
18 of disapproval described under subsection (g) relat-
19 ing to the rule, and the President signs a veto of
20 such resolution, the earlier date—

21 “(i) on which either House of Congress
22 votes and fails to override the veto of the Presi-
23 dent; or

1 “(ii) occurring 30 session days after the
2 date on which the Congress received the veto
3 and objections of the President.

4 “(C) The date the rule would have otherwise
5 taken effect, if not for this section (unless a joint
6 resolution of disapproval under subsection (g) is ap-
7 proved).

8 “(b) A rule shall not take effect as a final rule if the
9 Congress passes a joint resolution of disapproval described
10 under subsection (g), which is signed by the President or
11 is vetoed and overridden by the Congress.

12 “(c)(1) Notwithstanding any other provision of this
13 section (except subject to paragraph (3)), a rule that
14 would not take effect by reason of this section may take
15 effect if the President makes a determination under para-
16 graph (2) and submits written notice of such determina-
17 tion to the Congress.

18 “(2) Paragraph (1) applies to a determination made
19 by the President by Executive order that the rule should
20 take effect because such rule is—

21 “(A) necessary because of an imminent threat
22 to health or safety or other emergency;

23 “(B) necessary for the enforcement of criminal
24 laws; or

25 “(C) necessary for national security.

1 “(3) An exercise by the President of the authority
2 under this subsection shall have no effect on the proce-
3 dures under subsection (g) or the effect of a joint resolu-
4 tion of disapproval under this section.

5 “(4) This subsection and an Executive order issued
6 by the President under paragraph (2) shall not be subject
7 to judicial review by a court of the United States.

8 “(d)(1) Subsection (g) shall apply to any rule that
9 is published in the Federal Register (as a rule that shall
10 take effect as a final rule) during the period beginning
11 on the date occurring 60 days before the date the Con-
12 gress adjourns sine die through the date on which the suc-
13 ceeding Congress first convenes.

14 “(2) For purposes of subsection (g), a rule described
15 under paragraph (1) shall be treated as though such rule
16 were published in the Federal Register (as a rule that shall
17 take effect as a final rule) on the date the succeeding Con-
18 gress first convenes.

19 “(3) During the period between the date the Congress
20 adjourns sine die through the date on which the succeed-
21 ing Congress first convenes, a rule described under para-
22 graph (1) shall take effect as a final rule as otherwise pro-
23 vided by law.

24 “(e) Any rule that takes effect and later is made of
25 no force or effect by the enactment of a joint resolution

1 under subsection (g) shall be treated as though such rule
2 had never taken effect.

3 “(f) If the Congress does not enact a joint resolution
4 of disapproval under subsection (g), no court or agency
5 may infer any intent of the Congress from any action or
6 inaction of the Congress with regard to such rule, related
7 statute, or joint resolution of disapproval.

8 “(g)(1) For purposes of this subsection, the term
9 ‘joint resolution’ means only a joint resolution introduced
10 after the date on which the report referred to in subsection
11 (a) is received by Congress the matter after the resolving
12 clause of which is as follows: ‘That Congress disapproves
13 the rule submitted by the _____ relating to
14 _____, and such rule shall have no force or ef-
15 fect.’ (The blank spaces being appropriately filled in.)

16 “(2)(A) A resolution described in paragraph (1) shall
17 be referred to the committees in each House of Congress
18 with jurisdiction. Such a resolution shall not be reported
19 before the eighth day after its submission or publication
20 date.

21 “(B) For purposes of this subsection the term ‘sub-
22 mission or publication date’ means the later of the date
23 on which—

24 “(i) the Congress receives the report submitted
25 under subsection (a)(1); or

1 “(ii) the rule is published in the Federal Reg-
2 ister.

3 “(3) If the committee to which a resolution described
4 in paragraph (1) is referred has not reported such resolu-
5 tion (or an identical resolution) at the end of 20 calendar
6 days after its submission or publication date, such com-
7 mittee may be discharged by the Majority Leader of the
8 Senate or the Majority Leader of the House of Represent-
9 atives, as the case may be, from further consideration of
10 such resolution and such resolution shall be placed on the
11 appropriate calendar of the House involved.

12 “(4)(A) When the committee to which a resolution
13 is referred has reported, or when a committee is dis-
14 charged (under paragraph (3)) from further consideration
15 of, a resolution described in paragraph (1), it shall at any
16 time thereafter be in order (even though a previous motion
17 to the same effect has been disagreed to) for any Member
18 of the respective House to move to proceed to the consider-
19 ation of the resolution, and all points of order against the
20 resolution (and against consideration of the resolution)
21 shall be waived. The motion shall be highly privileged in
22 the House of Representatives and shall be privileged in
23 the Senate and shall not be debatable. The motion shall
24 not be subject to amendment, or to a motion to postpone,
25 or to a motion to proceed to the consideration of other

1 business. A motion to reconsider the vote by which the
2 motion is agreed to or disagreed to shall not be in order.
3 If a motion to proceed to the consideration of the resolu-
4 tion is agreed to, the resolution shall remain the unfin-
5 ished business of the respective House until disposed of.

6 “(B) Debate on the resolution, and on all debatable
7 motions and appeals in connection therewith, shall be lim-
8 ited to not more than 10 hours, which shall be divided
9 equally between those favoring and those opposing the res-
10 olution. A motion further to limit debate shall be in order
11 and shall not be debatable. An amendment to, or a motion
12 to postpone, or a motion to proceed to the consideration
13 of other business, or a motion to recommit the resolution
14 shall not be in order. A motion to reconsider the vote by
15 which the resolution is agreed to or disagreed to shall not
16 be in order.

17 “(C) Immediately following the conclusion of the de-
18 bate on a resolution described in paragraph (1), and a sin-
19 gle quorum call at the conclusion of the debate if re-
20 quested in accordance with the rules of the appropriate
21 House, the vote on final passage of the resolution shall
22 occur.

23 “(D) Appeals from the decisions of the Chair relating
24 to the application of the rules of the Senate or the House
25 of Representatives, as the case may be, to the procedure

1 relating to a resolution described in paragraph (1) shall
2 be decided without debate.

3 “(5) If, before the passage by one House of a resolu-
4 tion of that House described in paragraph (1), that House
5 receives from the other House a resolution described in
6 paragraph (1), then the following procedures shall apply:

7 “(A) The resolution of the other House shall
8 not be referred to a committee.

9 “(B) With respect to a resolution described in
10 paragraph (1) of the House receiving the resolu-
11 tion—

12 “(i) the procedure in that House shall be
13 the same as if no resolution had been received
14 from the other House; but

15 “(ii) the vote on final passage shall be on
16 the resolution of the other House.

17 “(6) This subsection is enacted by Congress—

18 “(A) as an exercise of the rulemaking power of
19 the Senate and House of Representatives, respec-
20 tively, and as such it is deemed to be a part of the
21 rules of each House, respectively, but applicable only
22 with respect to the procedure to be followed in that
23 House in the case of a resolution described in para-
24 graph (1), and it supersedes other rules only to the
25 extent that it is inconsistent with such rules; and

1 “(B) with full recognition of the constitutional
2 right of either House to change the rules (so far as
3 relating to the procedure of that House) at any time,
4 in the same manner, and to the same extent as in
5 the case of any other rule of that House.”.

6 (b) The table of chapters for part I of title 5, United
7 States Code, is amended by inserting immediately after
8 the item relating to chapter 7 the following:

“8. Congressional Review of Agency Rulemaking 801”.

9 **SEC. 7. STUDIES AND REPORTS.**

10 (a) **RISK ASSESSMENTS.**—The Administrative Con-
11 ference of the United States shall—

12 (1) develop and carry out an ongoing study of
13 the operation of the risk assessment requirements of
14 subchapter III of chapter 6 of title 5, United States
15 Code (as added by section 4 of this Act); and

16 (2) submit an annual report to the Congress on
17 the findings of the study.

18 (b) **ADMINISTRATIVE PROCEDURE ACT.**—Not later
19 than December 31, 1996, the Administrative Conference
20 of the United States shall—

21 (1) carry out a study of the operation of the
22 Administrative Procedure Act (as amended by sec-
23 tion 3 of this Act); and

- 1 (2) submit a report to the Congress on the find-
- 2 ings of the study, including proposals for revision, if
- 3 any.

AMENDMENT NO. ____

Calendar No. ____

Purpose: To provide a substitute.

IN THE SENATE OF THE UNITED STATES—104th Cong., 1st Sess.

S. 343

To reform the regulatory process, and for other purposes.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. GRASSLEY

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Comprehensive Regu-
5 latory Reform Act of 1995”.

6 **SEC. 2. DEFINITIONS.**

7 Section 551 of title 5, United States Code, is amend-
8 ed—

9 (1) in the matter preceding paragraph (1), by
10 striking “this subchapter” and inserting “chapters
11 5, 6, 7, and 8 of this title”; and

1 (2) in paragraph (13), by striking “; and” and
2 inserting a semicolon;

3 (3) in paragraph (14), by striking the period at
4 the end and inserting “; and”; and

5 (4) by adding at the end the following new
6 paragraph:

7 “(15) ‘Director’ means the Director of the Of-
8 fice of Management and Budget.”.

9 **SEC. 3. RULEMAKING.**

10 Section 553 of title 5, United States Code, is amend-
11 ed to read as follows:

12 **“§ 553. Rulemaking**

13 “(a) This section applies to every rulemaking, accord-
14 ing to the provisions thereof, except to the extent that
15 there is involved—

16 “(1) a matter pertaining to a military or for-
17 eign affairs function of the United States;

18 “(2) a matter relating to the management and
19 personnel practices of an agency;

20 “(3) an interpretive rule, general statement of
21 policy, or rule of agency organization, procedure, or
22 practice that is not generally applicable or does not
23 alter or create rights or obligations of persons out-
24 side the agency; or

1 “(4) a rule relating to the acquisition, manage-
2 ment, or disposal by an agency of real or personal
3 property, or of services, that is promulgated in com-
4 pliance with criteria and procedures established by
5 the Administrator of General Services.

6 “(b)(1) General notice of proposed rulemaking shall
7 be published in the Federal Register, unless all persons
8 subject thereto are named and either personally served or
9 otherwise have actual notice of the proposed rulemaking
10 in accordance with law. Each notice of proposed rule-
11 making shall include—

12 “(A) a statement of the time, place, and nature
13 of public rulemaking proceedings;

14 “(B) a succinct explanation of the need for and
15 specific objectives of the proposed rule, including an
16 explanation of the agency’s determination of whether
17 or not the rule is a major rule within the meaning
18 of section 621(2);

19 “(C) an explanation of the specific statutory in-
20 terpretation under which the rule is proposed, in-
21 cluding an explanation of—

22 “(i) whether the interpretation is expressly
23 required by the text of the statute; or

24 “(ii) if the interpretation is not expressly
25 required by the text of the statute, whether

1 such interpretation is within the range of per-
2 missible interpretations of the statute, and why
3 the agency selected that interpretation;

4 “(D) the proposed provisions of the rule;

5 “(E) a summary of any initial analysis of the
6 proposed rule required to be prepared or issued pur-
7 suant to chapter 6 of this title;

8 “(F) a statement that the agency seeks propos-
9 als from the public and from State and local govern-
10 ments for alternative methods to accomplish the ob-
11 jectives of the rulemaking that are more effective or
12 less burdensome than the approach used in the pro-
13 posed rule;

14 “(G) a description of any data, methodologies,
15 reports, studies, scientific evaluations, or other simi-
16 lar information available to the agency for the rule-
17 making, including an identification of each author or
18 source of such information and the purposes for
19 which the agency plans to rely on such information;
20 and

21 “(H) a statement specifying where the file of
22 the rulemaking proceeding maintained pursuant to
23 subsection (f) may be inspected and how copies of
24 the items in the file may be obtained.

1 “(2) Except when notice or hearing is required by
2 statute, a final rule may be adopted and may become ef-
3 fective without prior compliance with this subsection and
4 subsections (c) and (f) if—

5 “(A) the agency for good cause finds that pro-
6 viding notice and public procedure thereon before
7 the rule becomes effective is contrary to an impor-
8 tant public interest or unnecessary due to the insig-
9 nificant impact of the rule;

10 “(B) the agency publishes the rule in the Fed-
11 eral Register with such finding and a succinct expla-
12 nation of the reasons therefor; and

13 “(C) the agency complies with this subsection
14 and subsections (c) and (f) to the maximum extent
15 feasible prior to the promulgation of the final rule,
16 and fully complies with such provisions as soon as
17 reasonably practicable after the promulgation of the
18 rule.

19 “(3) Whenever the provisions of a final rule that an
20 agency plans to adopt are so different from the provisions
21 of the proposed rule that the original notice of proposed
22 rulemaking did not fairly apprise the public of the issues
23 ultimately to be resolved in the rulemaking or of the sub-
24 stance of the rule, the agency shall publish in the Federal
25 Register a notice of the final rule the agency plans to

1 adopt, together with the information relevant to such rule
2 that is required by the applicable provisions of this section
3 and ~~that~~ has not previously been published in the Federal
4 Register. The agency shall allow a reasonable period for
5 comment on such final rule.

6 “(c)(1) After providing the notice required by this
7 section, the agency shall give interested persons not less
8 than 60 days to participate in the rulemaking through the
9 submission of written data, views, or arguments.

10 “(2)(A) To collect relevant information, and to iden-
11 tify and elicit full and representative public comment on
12 the significant issues of a particular rulemaking, the agen-
13 cy may use such other procedures as the agency deter-
14 mines are appropriate, including—

15 “(i) the publication of an advance notice of pro-
16 posed rulemaking;

17 “(ii) the provision of notice, in forms which are
18 more direct than notice published in the Federal
19 Register, to persons who would be substantially af-
20 fected by the proposed rule, but who are unlikely to
21 receive notice of the proposed rulemaking through
22 the Federal Register;

23 “(iii) the provision of opportunities for oral
24 presentation of data, views, information, or rebuttal
25 arguments at informal public hearings, which may

1 be held in the District of Columbia and other loca-
2 tions;

3 “(iv) the provision of summaries, explanatory
4 materials, or other technical information in response
5 to public inquiries concerning the issues involved in
6 the rulemaking; and

7 “(v) the adoption or modification of agency pro-
8 cedural rules to reduce the cost or complexity of par-
9 ticipation in a rulemaking.

10 “(B) The decision of an agency to use or not to use
11 such other procedures in a rulemaking pursuant to this
12 paragraph shall not be subject to judicial review.

13 “(3) To ensure an orderly and expeditious proceed-
14 ing, an agency may establish reasonable procedures to reg-
15 ulate the course of informal public hearings under para-
16 graphs (2) and (3), including the designation of represent-
17 atives to make oral presentations or engage in direct or
18 cross-examination on behalf of several parties with a com-
19 mon interest in a rulemaking. Transcripts shall be made
20 of all such public hearings.

21 “(4) An agency shall publish any final rule it adopts
22 in the Federal Register, together with a concise statement
23 of the basis and purpose of the rule and a statement of
24 when the rule may become effective. The statement of
25 basis and purpose shall include—

1 “(A) an explanation of the need for, objectives
2 of, and specific statutory authority for, the rule;

3 “(B) a discussion of, and response to, any sig-
4 nificant factual or legal issues raised by the com-
5 ments on the proposed rule prior to its promulga-
6 tion, including a description of the reasonable alter-
7 natives to the rule proposed by the agency and by
8 interested persons, and the reasons why each such
9 alternative was rejected;

10 “(C) an explanation of how the factual conclu-
11 sions upon which the rule is based are substantially
12 supported in the rulemaking file maintained pursu-
13 ant to subsection (f); and

14 “(D) a summary of any final analysis of the
15 rule required to be prepared or issued pursuant to
16 chapter 6 of this title.

17 “(5) The provisions of sections 556 and 557 shall
18 apply in lieu of this subsection in the case of rules that
19 are required by statute to be made on the record after
20 opportunity for an agency hearing.

21 “(d)(1) An agency shall publish the final rule in the
22 Federal Register not less than 60 days before the effective
23 date of such rule. An agency may make a rule effective
24 in less than 60 days after publication in the Federal Reg-
25 ister if the rule grants or recognizes an exemption, relieves

1 a restriction, or if the agency for good cause finds that
2 such a delay in the effective date would be contrary to
3 an important public interest and publishes such finding
4 and an explanation of the reasons therefor, with the final
5 rule.

6 “(2) In promulgating a final rule, an agency may not
7 substantially rely on any material that was not identified
8 in the notice of proposed rulemaking. Notwithstanding the
9 preceding sentence, an agency may rely on such mate-
10 rial—

11 “(A) if such material was placed in the rule-
12 making file promptly upon its receipt by the agency
13 and, if such material is of central relevance to the
14 rulemaking, the agency provided a reasonable oppor-
15 tunity for interested persons to comment thereon;

16 “(B) if such material is material referred to in
17 subsection (f)(3) of this section and the agency has
18 complied with the requirements of that subsection;
19 or

20 “(C) if, in the case of material developed by or
21 for the agency, such material was placed in the rule-
22 making file promptly upon its completion and, if
23 such material is of central relevance to the rule-
24 making, was made available in time for interested

1 persons to have an adequate opportunity to comment
2 thereon.

3 “(e)(1) Each person subject to a major rule may peti-
4 tion—

5 “(A) for the issuance, amendment, or repeal of
6 such rule;

7 “(B) for the amendment or repeal of an inter-
8 pretive rule or general statement of policy;

9 “(C) for an interpretation regarding the mean-
10 ing of the rule; and

11 “(D) for a variance or exemption from the
12 terms of the rule.

13 “(2) Each person subject to a rule may petition an
14 agency for the performance of any analysis provided under
15 chapter 6 of this title if such person presents a substantial
16 question that the rule is a major rule within the meaning
17 of section 621(2). The agency shall grant the petition and
18 promptly conduct the analysis sought if the agency deter-
19 mines that the rule is a rule for which an analysis is re-
20 quired under chapter 6. If the rule does not satisfy the
21 decisional criteria set forth in section 623, then the agency
22 shall take immediate action to either revoke or amend the
23 rule to conform the rule to the requirements of chapter
24 6 and the decisional criteria under section 623.

1 “(3) The agency shall grant or deny a petition made
2 pursuant to this subsection, and give written notice of its
3 determination to the petitioner, with reasonable prompt-
4 ness, but in no event later than 180 days after the petition
5 was received by the agency. The written notice of the
6 agency’s determination shall include an explanation of the
7 determination and a response to each factual and legal
8 claim that forms the basis of the petition. Such notice
9 shall constitute final agency action for purposes of appeal.

10 “(f)(1) The agency shall maintain a file for each rule-
11 making proceeding conducted pursuant to this section and
12 shall maintain a current index to such file. The file and
13 the material excluded from the file pursuant to paragraph
14 (3) shall constitute the rulemaking record for purposes of
15 judicial review. Except as provided in paragraph (3), the
16 file shall be made available to the public beginning on the
17 date on which the agency makes an initial publication con-
18 cerning the rule.

19 “(2) The rulemaking file shall include—

20 “(A) the notice of proposed rulemaking, any
21 supplement to, or modification or revision of, such
22 notice, and any advance notice of proposed rule-
23 making;

24 “(B) copies of all written comments received on
25 the proposed rule;

1 “(C) a transcript of any public hearing con-
2 ~~ducted~~ on the rulemaking;

3 “(D) copies, or an identification of the place at
4 which copies may be obtained, of all material de-
5 scribed by the agency pursuant to subsection
6 (b)(1)(G) and of other factual and methodological
7 ~~material~~ not described by the agency pursuant to
8 ~~such~~ subsection that pertains directly to the rule-
9 ~~making~~ and that was available to the agency in con-
10 ~~nection~~ with the rulemaking, or that was submitted
11 to or prepared by or for the agency in connection
12 ~~with~~ the rulemaking; and

13 “(E) any statement, description, analysis, or
14 ~~any~~ other material that the agency is required to
15 prepare or issue in connection with the rulemaking,
16 ~~including~~ any analysis prepared or issued pursuant
17 to chapter 6 of this title.

18 “(3) The agency shall place the materials described
19 in paragraph (2) in the file as soon as practicable after
20 such ~~materials~~ become available to the agency.

21 “(4) The file required by paragraph (1) need not in-
22 clude ~~any~~ material that need not be made available to the
23 public under section 552(b)(4) if the agency includes in
24 such ~~file~~ a statement that notes the existence of such ma-
25 terial ~~and~~ the basis upon which the material is exempt

1 from public disclosure under such section. The agency may
2 not substantially rely on any such material in formulating
3 a rule unless it makes the substance of such material
4 available for adequate comment by interested persons. The
5 agency may use summaries, aggregations of data, or other
6 appropriate mechanisms to protect the confidentiality of
7 such material to the maximum extent possible.

8 “(5) No court shall hold unlawful or set aside an
9 agency rule because of a violation of this subsection unless
10 the court finds that such violation has precluded fair pub-
11 lic consideration of a material issue of the rulemaking
12 taken as a whole. Judicial review of compliance or non-
13 compliance with this subsection shall be limited to review
14 of action or inaction on the part of an agency.

15 “(g) Notwithstanding any other provision of law, ex-
16 cept as otherwise provided in this section, subsections
17 (b)(1)(C), (c)(4)(D), and (e) shall supplement, and not
18 supplant, any other law or regulation governing rule-
19 making procedures.

20 “(h) Nothing in this section authorizes the use of ap-
21 propriated funds available to any agency to pay the attor-
22 ney’s fees or other expenses of persons participating or
23 intervening in agency proceedings.”.

1 **SEC. 4. ANALYSIS OF AGENCY RULES.**

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

5 “SUBCHAPTER II—ANALYSIS OF AGENCY
6 RULES

7 “§ 621. Definitions

8 “For purposes of this subchapter and subchapter
9 III—

10 “(1) the term ‘rule’ has the same meaning as
11 in section 551(4) of this title, and—

12 “(A) includes any statement of general ap-
13 plicability that alters or creates rights or obliga-
14 tions of persons outside the agency; and

15 “(B) does not include a rule of particular
16 applicability that approves or prescribes the fu-
17 ture rates, wages, prices, services, corporate or
18 financial structures, reorganizations, mergers,
19 acquisitions, accounting practices, or disclosures
20 bearing on any of the foregoing;

21 “(2)(A) the term ‘major rule’ means—

22 “(i) a rule or a group of closely related
23 rules that the agency proposing the rule, the
24 Director, or a designee of the President reason-
25 ably determines is likely to have a gross annual
26 effect on the economy of \$50,000,000 or more

1 in reasonably quantifiable increased direct and
2 indirect costs, or has a significant impact on a
3 sector of the economy; or

4 “(ii) a rule or a group of closely related
5 rules that is otherwise designated a major rule
6 by the agency proposing the rule, the Director,
7 or a designee of the President on the ground
8 that the rule is likely to result in—

9 “(I) a substantial increase in costs or
10 prices for wage earners, consumers, indi-
11 vidual industries, nonprofit organizations,
12 Federal, State, or local government agen-
13 cies, or geographic regions; or

14 “(II) significant adverse effects on
15 competition, employment, investment, pro-
16 ductivity, innovation, the environment,
17 public health or safety, or the ability of en-
18 terprises whose principal places of business
19 are in the United States to compete in do-
20 mestic or export markets;

21 “(B) the term ‘major rule’ does not include—

22 “(i) a rule that involves the internal reve-
23 nue laws of the United States; or

24 “(ii) a rule or agency action that author-
25 izes the introduction into, or removal from,

1 commerce, or recognizes the marketable status,
2 of a product pursuant to sections 408, 409(c),
3 and 706 of the Federal Food, Drug, and Cos-
4 metic Act;

5 “(3) the term ‘benefit’ means the reasonably
6 identifiable significant benefits, including social and
7 economic benefits, that are expected to result di-
8 rectly or indirectly from implementation of a rule or
9 an alternative to a rule;

10 “(4) the term ‘cost’ means the reasonably iden-
11 tifiable significant costs and adverse effects, includ-
12 ing social and economic costs, reduced consumer
13 choice, substitution effects, and impeded techno-
14 logical advancement, that are expected to result di-
15 rectly or indirectly from implementation of, or com-
16 pliance with, a rule or an alternative to a rule;

17 “(5) the term ‘market-based mechanism’ means
18 a regulatory program that—

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

22 “(B) affords maximum flexibility to each
23 regulated person in complying with mandatory
24 regulatory objectives, which flexibility shall,
25 where feasible and appropriate, include, but not

1 be limited to, the opportunity to transfer to, or
2 receive from, other persons, including for cash
3 or other legal consideration, increments of com-
4 pliance responsibility established by the pro-
5 gram; and

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

12 “(6) the term ‘cost-benefit analysis’ means an
13 evaluation of the costs and benefits of a rule, quan-
14 tified to the extent feasible and appropriate and oth-
15 erwise qualitatively described, that is prepared in ac-
16 cordance with the requirements of this subchapter at
17 the level of detail appropriate and practicable for
18 reasoned decisionmaking on the matter involved,
19 taking into consideration the significance and com-
20 plexity of the decision and any need for expedition.

21 **“§ 622. Rulemaking cost-benefit analysis**

22 “(a) Prior to publishing notice of a proposed rule-
23 making for any rule (or, in the case of a notice of a pro-
24 posed rulemaking that has been published on or before the
25 date of enactment of this subchapter, not later than 30

1 days after such date of enactment), each agency shall de-
2 termine whether the rule is or is not a major rule within
3 the meaning of section 621(2)(A)(i) and, if it is not,
4 whether it should be designated a major rule under section
5 621(2)(A)(ii). For the purpose of any such determination
6 or designation, a group of closely related rules shall be
7 considered as one rule.

8 “(b)(1) If an agency has determined that a rule is
9 not a major rule within the meaning of section
10 621(2)(A)(i) and has not designated the rule a major rule
11 within the meaning of section 621(2)(A)(ii), the Director
12 or a designee of the President may, as appropriate, deter-
13 mine that the rule is a major rule or designate the rule
14 a major rule not later than 30 days after the publication
15 of the notice of proposed rulemaking for the rule (or, in
16 the case of a notice of proposed rulemaking that has been
17 published on or before the date of enactment of this sub-
18 chapter, not later than 60 days after such date of enact-
19 ment).

20 “(2) Such determination or designation shall be pub-
21 lished in the Federal Register, together with a succinct
22 statement of the basis for the determination or designa-
23 tion.

24 “(c)(1)(A) When the agency publishes a notice of pro-
25 posed rulemaking for a major rule, the agency shall issue

1 and place in the rulemaking file an initial cost-benefit
2 analysis, and shall include a summary of such analysis in
3 the notice of proposed rulemaking.

4 “(B)(i) When the Director or a designee of the Presi-
5 dent has published a determination or designation that a
6 rule is a major rule after the publication of the notice of
7 proposed rulemaking for the rule, the agency shall prompt-
8 ly issue and place in the rulemaking file an initial cost-
9 benefit analysis for the rule and shall publish in the Fed-
10 eral Register a summary of such analysis.

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

17 “(2) Each initial cost-benefit analysis shall contain—

18 “(A) an analysis of the benefits of the proposed
19 rule, and an explanation of how the agency antici-
20 pates each benefit will be achieved by the proposed
21 rule, including a description of the persons or classes
22 of persons likely to receive such benefits;

23 “(B) an analysis of the costs of the proposed
24 rule, and an explanation of how the agency antici-
25 pates each such cost will result from the proposed

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

3 “(C) an identification (including an analysis of
4 the costs and benefits) of reasonable alternatives au-
5 thorized under the statute granting the rulemaking
6 authority for achieving the identified benefits of the
7 proposed rule, including alternatives that—

8 “(i) require no government action;

9 “(ii) will accommodate differences among
10 geographic regions and among persons with dif-
11 fering levels of resources with which to comply;
12 and

13 “(iii) employ voluntary, performance, or
14 other market-based standards that permit the
15 greatest flexibility in achieving the identified
16 benefits of the proposed rule and that comply
17 with the requirements of subparagraph (D);

18 “(D) an assessment of the feasibility of estab-
19 lishing a regulatory program that operates through
20 the application of market-based mechanisms;

21 “(E) in any case in which the proposed rule is
22 based on one or more scientific evaluations or infor-
23 mation or is subject to the risk assessment require-
24 ments of subchapter III, a description of actions un-
25 dertaken by the agency to verify the quality, reliabil-

1 ity, and relevance of such scientific evaluations or
2 scientific information in accordance with the risk as-
3 sessment requirements of subchapter III;

4 “(F) an analysis, to the extent practicable, of
5 the effect of the rule on—

6 “(i) the cumulative burden of compliance
7 with the rule and other existing regulations on
8 persons complying with it; and

9 “(ii) the net effect on small businesses
10 with fewer than 100 employees, including em-
11 ployment in such businesses;

12 “(G) an analysis of whether the identified bene-
13 fits of the proposed rule justify the identified costs
14 of the proposed rule, and an analysis of whether the
15 proposed rule will provide greater net benefits to so-
16 ciety than any of the alternatives to the proposed
17 rule, including alternatives identified in accordance
18 with subparagraph (C).

19 “(d)(1) When the agency publishes a final major rule,
20 the agency shall also issue and place in the rulemaking
21 file a final cost-benefit analysis, and shall include a sum-
22 mary of the analysis in the statement of basis and pur-
23 pose.

24 “(2) Each final cost-benefit analysis shall contain—

1 “(A) a description and comparison of the bene-
2 ~~fits~~ and costs of the rule and of the reasonable alter-
3 ~~natives~~ to the rule described in the rulemaking, in-
4 ~~cluding~~ the market-based mechanisms identified pur-
5 ~~suant~~ to subsection (c)(2)(D); and

6 “(B) an analysis, based upon the rulemaking
7 ~~record~~ considered as a whole, of—

8 “(i) whether the benefits of the rule justify
9 the costs of the rule; and

10 “(ii) whether the rule will provide greater
11 net benefits to society than any of the reason-
12 able alternatives described in the rulemaking,
13 including the market-based incentives identified
14 pursuant to subsection (c)(2)(D).

15 “(e)(1)(A) The analysis of the benefits and costs of
16 a ~~proposed~~ and a final rule required under this section
17 shall ~~include~~, to the extent feasible, a quantification or nu-
18 merical estimate of the quantifiable benefits and costs.
19 Such ~~quantification~~ or numerical estimate shall be made
20 in the ~~most~~ appropriate unit of measurement, using com-
21 parable assumptions, including time periods, shall specify
22 the ~~ranges~~ of predictions, and shall explain the margins
23 of error involved in the quantification methods and in the
24 ~~estimates~~ used. An agency shall describe the nature and
25 extent of the nonquantifiable benefits and costs of a final

1 rule pursuant to this section in as precise and succinct
2 a manner as possible. An agency shall not be required to
3 make such evaluation primarily on a mathematical or nu-
4 merical basis.

5 “(B) Where practicable, the description of the bene-
6 fits and costs of a proposed and final rule required under
7 this section shall describe such benefits and costs on an
8 industry by industry basis.

9 “(2)(A) In evaluating and comparing costs and bene-
10 fits and in evaluating the risk assessment information de-
11 veloped pursuant to subchapter III, the agency shall not
12 rely on cost, benefit, or risk assessment information that
13 is not accompanied by data, analysis, or other supporting
14 materials that would enable the agency and other persons
15 interested in the rulemaking to assess the accuracy, reli-
16 ability, and uncertainty factors applicable to such informa-
17 tion.

18 “(B) The agency evaluations of the relationships of
19 the benefits of a proposed and final rule to its costs shall
20 be clearly articulated in accordance with this section.

21 “(f) The preparation of the initial or final cost-benefit
22 analysis required by this section shall only be performed
23 by an officer or employee of the agency. The preceding
24 sentence shall not preclude a person outside the agency
25 from gathering data or information to be used by the

1 agency in preparing any such cost-benefit analysis or from
2 providing an explanation sufficient to permit the agency
3 to analyze such data or information. If any such data or
4 information is gathered or explained by a person outside
5 the agency, the agency shall specifically identify in the ini-
6 tial or final cost-benefit analysis the data or information
7 gathered or explained and the person who gathered or ex-
8 plained it, and shall describe the arrangement by which
9 the information was procured by the agency, including the
10 total amount of funds expended for such procurement.

11 “(g)(1) Each person subject to a major rule may peti-
12 tion for the issuance of a cost-benefit analysis for the rule,
13 including a major rule in effect on the date of enactment
14 of this subchapter for which a cost-benefit analysis meet-
15 ing the requirements of this subchapter has not been per-
16 formed.

17 “(2) The agency shall grant the petition and prompt-
18 ly conduct the analysis sought if the agency determines
19 that the rule is a rule for which a cost-benefit analysis
20 is required under this subchapter. If the rule does not sat-
21 isfy the decisional criteria set forth in section 623, then
22 the agency shall take immediate action to either revoke
23 or amend the rule to conform the rule to the requirements
24 of this subchapter and the decisional criteria under section
25 623.

1 “(3) The agency shall grant or deny a petition made
2 pursuant to this subsection, and give written notice of its
3 determination to the petitioner, with reasonable prompt-
4 ness, but in no event later than 180 days after the petition
5 was received by the agency. The written notice of the
6 agency’s determination shall include an explanation of the
7 determination and a response to each factual and legal
8 claim that forms the basis of the petition.

9 **“§ 623. Decisional criteria**

10 “(a) Subject to subsection (b), no final rule subject
11 to this subchapter shall be promulgated unless the agency
12 finds that—

13 “(1) the potential benefits to society from the
14 rule justify the potential costs of the rule to society,
15 as determined by the analysis required by section
16 622(d)(2)(B); and

17 “(2) the rule will substantially achieve greater
18 net benefits to society than any of the reasonable al-
19 ternatives identified pursuant to section
20 622(d)(2)(B).

21 Subject to the provisions of subsection (b), the require-
22 ments of this section shall supplement any other decisional
23 criteria otherwise provided by law.

24 “(b)(1) If the text of a statute expressly requires that
25 a rule shall be promulgated without regard to whether the

1 rule satisfies the criterion provided in subsection (a)(1),
2 the rule must satisfy the criterion provided in subsection
3 (a)(2).

4 “(2) If the text of a statute expressly requires that
5 a rule shall be promulgated even if the rule does not sat-
6 isfy both criteria provided in subsection (a), the rule must
7 impose lower net costs to society than any of the reason-
8 able alternatives identified pursuant to section
9 622(d)(2)(B).

10 “(c) If an agency determines that the text of a statute
11 expressly requires a rule to be promulgated even if the
12 rule does satisfy the criterion of subsection (a)(1) or the
13 criteria of both subsections (a)(1) and (a)(2), the agency
14 shall—

15 “(1) include a written explanation of such de-
16 termination in the initial and final cost-benefit anal-
17 ysis required by section 622; and

18 “(2) transmit the final cost-benefit analysis to
19 Congress when the final rule is promulgated.

20 **“§ 624. Judicial review**

21 “Any cost-benefit analysis of, or risk assessment con-
22 cerning, a rule shall constitute part of the whole rule-
23 making record of agency action for the purpose of judicial
24 review of the rule, and shall be considered by a court in
25 determining the legality of the rule. The court shall apply

1 the same standards of judicial review that govern the re-
2 view of agency findings under the statute granting the
3 agency authority to conduct the rulemaking. The court
4 shall set aside agency action that fails to satisfy the
5 decisional criteria of section 623.

6 **“§ 625. Deadlines for rulemaking**

7 “(a) Beginning on the date of enactment of this sec-
8 tion, all deadlines in statutes that require agencies to pro-
9 pose or promulgate any rule subject to this subchapter
10 shall be suspended until such time as the requirements
11 of this subchapter are satisfied.

12 “(b) Beginning on the date of enactment of this sec-
13 tion, the jurisdiction of any court of the United States
14 to enforce any deadline that would require an agency to
15 propose or promulgate a rule subject to this chapter shall
16 be suspended until such time as the requirements of this
17 subchapter are satisfied.

18 “(c) In any case in which the failure to promulgate
19 a rule by a deadline would create an obligation to regulate
20 through individual adjudications, the deadline shall be sus-
21 pended to allow the requirements of this subchapter to be
22 satisfied.

23 **“§ 626. Agency review of rules**

24 “(a)(1)(A) Not later than 9 months after the date
25 of enactment of this section, each agency shall prepare and

1 publish in the Federal Register a proposed schedule for
2 the review, in accordance with this section, of—

3 “(i) each rule of the agency that is in effect on
4 such effective date and which, if adopted on such ef-
5 fective date, would be a major rule under section
6 621(2)(A);

7 “(ii) each rule of the agency that is inconsistent
8 or in conflict with any other obligation or require-
9 ment established by any Federal statute, rule, or
10 other agency statement, interpretation, or action
11 that has the force of law; and

12 “(iii) each rule of the agency in effect on the
13 date of enactment of this section (in addition to the
14 rules described in clauses (i) and (ii)) that the agen-
15 cy has selected for review.

16 “(B) Each proposed schedule required by subpara-
17 graph (A) shall include—

18 “(i) a brief explanation of the reasons the agen-
19 cy considers each rule on the schedule to be a major
20 rule under section 621(2)(A), or the reasons why the
21 agency selected the rule for review;

22 “(ii) a date set by the agency, in accordance
23 with subsection (b)(1), for the completion of the re-
24 view of each such rule; and

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

3 “(C) The agency shall set a date to initiate review
4 of each rule on the schedule in a manner that will ensure
5 the simultaneous review of related items and that will
6 achieve a reasonable distribution of reviews over the period
7 of time covered by the schedule.

8 “(2) Not later than 90 days before publishing in the
9 Federal Register the proposed schedule required under
10 paragraph (1), each agency shall make the proposed
11 schedule available to the Director or a designee of the
12 President, or to the Vice President or other officer to
13 whom oversight authority has been delegated under sec-
14 tion 643. The President or that officer may select for re-
15 view in accordance with this section any additional rule.

16 “(3) Not later than 1 year after the date of enact-
17 ment of this section, each agency shall publish in the Fed-
18 eral Register a final schedule for the review of the rules
19 referred to in paragraphs (1) and (2). Each agency shall
20 publish with the final schedule the response of the agency
21 to comments received concerning the proposed schedule.

22 “(b)(1) Except as explicitly provided otherwise by
23 statute, the agency shall, pursuant to subsections (c)
24 through (e), review—

1 “(A) each rule on the schedule promulgated
2 pursuant to subsection (a);

3 “(B) each major rule under section 621(2) pro-
4 mulgated, amended, or otherwise renewed by an
5 agency after the date of the enactment of this sec-
6 tion; and

7 “(C) each rule promulgated after the date of
8 enactment of this section that the President or the
9 officer designated by the President selects for review
10 pursuant to subsection (a)(2).

11 “(2) Except as provided pursuant to subsection (f),
12 the review of a rule required by this section shall be com-
13 pleted not later than 10 years after the date of enactment
14 of this section or 10 years after the date on which the
15 rule is promulgated, amended, or renewed, whichever is
16 earlier.

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

20 “(1) an identification of the specific statutory
21 authority under which the rule was promulgated and
22 an explanation of whether the agency’s interpreta-
23 tion of the statute is expressly required by the cur-
24 rent text of that statute or, if not, whether it is

1 within the range of permissible interpretations of the
2 statute;

3 “(2) an analysis of the benefits and costs of the
4 rule during the period in which it has been in effect;

5 “(3) an explanation of the proposed agency ac-
6 tion with respect to the rule, including action to re-
7 peal or amend the rule to resolve inconsistencies or
8 conflicts with any other obligation or requirement es-
9 tablished by any Federal statute, rule, or other
10 agency statement, interpretation, or action that has
11 the force of law; and

12 “(4) a statement that the agency seeks propos-
13 als from the public for modifications or alternatives
14 to the rule which may accomplish the objectives of
15 the rule in a more effective or less burdensome man-
16 ner.

17 “(d) If an agency proposes to repeal or amend a rule
18 under review pursuant to this section, the agency shall,
19 after issuing the notice required by subsection (c), comply
20 with the provisions of this chapter, chapter 5, and any
21 other applicable law. The requirements of such provisions
22 and related requirements shall apply to the same extent
23 and in the same manner as in the case of a proposed agen-
24 cy action to repeal or amend a rule that is not taken pur-
25 suant to the review required by this section.

1 “(e) If an agency proposes to renew without amend-
2 ment a rule under review pursuant to this section, the
3 agency shall—

4 “(1) give interested persons not less than 60
5 days after the publication of the notice required by
6 subsection (c) to comment on the proposed renewal;
7 and

8 “(2) publish in the Federal Register notice of
9 the renewal of such rule, an explanation of the con-
10 tinued need for the rule, and, if the renewed rule is
11 a major rule under section 621(2), an explanation of
12 the reasonable determination of the agency that the
13 rule complies with section 623.

14 “(f) Any agency, which for good cause finds that
15 compliance with this section with respect to a particular
16 rule during the period provided in subsection (b) of this
17 section is contrary to an important public interest may
18 request the President, or the officer designated by the
19 President pursuant to subsection (a)(2), to establish a pe-
20 riod longer than 10 years for the completion of the review
21 of such rule. The President or that officer may extend the
22 period for review of a rule to a total period of not more
23 than 15 years. Such extension shall be published in the
24 Federal Register with an explanation of the reasons there-
25 for.

1 “(g) In any case in which an agency has not com-
2 pleted the review of a rule within the period prescribed
3 by subsection (b) or (f) of this section, the agency shall
4 immediately publish in the Federal Register a notice pro-
5 posing to amend, repeal, or renew the rule under sub-
6 section (c), and shall complete proceedings pursuant to
7 subsection (d) or (e) not later than 180 days after the
8 date on which the review was required to be completed
9 under subsection (b) or (f).

10 “(h) Nothing in this section shall relieve any agency
11 from its obligation to respond to a petition to issue,
12 amend, or repeal a rule, for an interpretation regarding
13 the meaning of a rule, or for a variance or exemption from
14 the terms of a rule, submitted pursuant to section 553(e).

15 “SUBCHAPTER III—RISK ASSESSMENTS

16 “§ 631. Definitions

17 “For purposes of this subchapter—

18 “(1) the term ‘best estimate’ means an estimate
19 that, to the extent feasible and scientifically appro-
20 priate, is based on—

21 “(A) central estimates of risk using the
22 most plausible assumptions;

23 “(B) an approach that combines multiple
24 estimates based on different scenarios and
25 weighs the probability of each scenario; and

1 “(C) any other methodology designed to
2 provide the most unbiased representation of the
3 most plausible level of risk, given the current
4 scientific information available to the agency
5 concerned;

6 “(2) the term ‘emergency’ means a clearly im-
7 minent and substantial endangerment to public
8 health or the environment;

9 “(3) the term ‘hazard identification’ means
10 identification of a substance, activity, or condition as
11 potentially posing a risk to human health or safety
12 or the environment based on empirical data, meas-
13 urements, or testing showing that it has caused sig-
14 nificant adverse effects at some levels of dose or ex-
15 posure not necessarily relevant to level of dose or ex-
16 posure that are normally expected to occur;

17 “(4) the term ‘negative data’ means data indi-
18 cating that under certain conditions a given sub-
19 stance or activity did not induce an adverse effect;

20 “(5) the term ‘risk assessment’ means—

21 “(A) the iterative process of identifying
22 hazards, and quantifying (to the maximum ex-
23 tent practicable) or describing the degree of
24 toxicity, exposure, or other risk the hazards

1 pose for exposed individuals, populations, or re-
2 sources; and

3 “(B) the document containing the expla-
4 nation of how the assessment process has been
5 applied to an individual substance, activity, or
6 condition;

7 “(6) the term ‘risk characterization’—

8 “(A) means the element of a risk assess-
9 ment that involves presentation of the degree of
10 risk to individuals and populations expected to
11 be protected, as presented in any regulatory
12 proposal or decision, report to Congress, or
13 other document that is made available to the
14 public; and

15 “(B) includes discussions of uncertainties,
16 conflicting data, estimates, extrapolations, in-
17 ferences, and opinions; and

18 “(7) the term ‘substitution risk’ means a poten-
19 tial increased risk to human health, safety, or the
20 environment resulting from market substitutions, a
21 reduced standard of living, or a regulatory alter-
22 native designed to decrease other risks.

23 **“§ 632. Applicability**

24 “(a) Except as provided in subsection (b), this sub-
25 chapter shall apply to all risk assessments and risk charac-

1 terizations prepared by, or on behalf of, or prepared by
2 others and adopted by, any Federal agency in connection
3 with health, safety, and environmental risks.

4 “(b)(1) This subchapter shall not apply to risk as-
5 sessments or risk characterizations performed with respect
6 to—

7 “(A) a situation that the head of the agency
8 finds to be an emergency;

9 “(B) a rule or agency action that authorizes the
10 introduction into, or removal from, commerce, or
11 recognizes the marketable status of a product;

12 “(C) a health, safety, or environmental inspec-
13 tion or individual facility permitting action; or

14 “(D) a screening analysis clearly identified as
15 such.

16 “(2)(A) An analysis shall not be treated as a screen-
17 ing analysis for the purposes of paragraph (1)(D) if the
18 result of the analysis is used—

19 “(i) as the basis for imposing a restriction on
20 a substance, product, or activity; or

21 “(ii) to characterize a positive finding of risks
22 from a substance or activity in any agency document
23 or other communication made available to the public,
24 the media, or Congress.

1 “(B) Among the analyses that may be treated as a
2 screening analyses for the purposes of paragraph (1)(D)
3 are product registrations, reregistrations, tolerance set-
4 tings, and reviews of premanufacture notices and existing
5 chemicals under the Federal Insecticide, Fungicide, and
6 Rodenticide Act (7 U.S.C. 136 et seq.) and the Toxic Sub-
7 stances Control Act (15 U.S.C. 2601 et seq.).

8 “(3) This subchapter shall not apply to any food,
9 drug, or other product label or to any risk characterization
10 appearing on any such label.

11 **“§ 633. Rule of construction**

12 “Nothing in this subchapter shall be construed to—

13 “(1) preclude the consideration of any data or
14 the calculation of any estimate to more fully describe
15 risk or provide examples of scientific uncertainty or
16 variability; or

17 “(2) require the disclosure of any trade secret
18 or other confidential information.

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

20 “(a) Except as provided in section 632, the head of
21 each agency shall prepare for each major rule relating to
22 human health, safety, or the environment that is proposed
23 by the agency after the date of enactment of this sub-
24 chapter, is pending on the date of enactment of this sub-

1 chapter, or is subject to a granted petition for review pur-
2 suant to section 553(e) or 622(g)—

3 “(1) a risk assessment in accordance with this
4 subchapter;

5 “(2) for each such proposed or final rule, an as-
6 sessment, quantified to the extent feasible, of incre-
7 mental risk reduction or other benefits associated
8 with each significant regulatory alternative to the
9 rule or proposed rule; and

10 “(3) for each such proposed or final rule, quan-
11 tified to the extent feasible, a comparison of any
12 human health, safety, or environmental risks ad-
13 dressed by the regulatory alternatives to other rel-
14 evant risks chosen by the head of the agency, includ-
15 ing at least 3 other risks regulated by the agency
16 and to at least 3 other risks with which the public
17 is familiar.

18 “(b) A risk assessment prepared pursuant to this
19 subchapter shall be a component of and used to develop
20 the cost-benefit analysis required by subchapter II, and
21 shall be made part of the administrative record for judicial
22 review of any final agency action.

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

24 “(a)(1) The head of each agency shall apply the prin-
25 ciples set forth in subsection (b) when preparing any risk

1 assessment, whether or not required by section 634, to en-
2 sure that the risk assessment and all of its components—

3 “(A) distinguish scientific findings and best es-
4 timates of risk from other considerations;

5 “(B) are, to the maximum extent practicable
6 scientifically objective, unbiased and inclusive of all
7 relevant data; and

8 “(C) rely, to the extent available and prac-
9 ticable, on scientific findings:

10 “(2) An agency shall not be required to repeat discus-
11 sions or explanations required under this section in each
12 risk assessment document if there is a reference to the
13 relevant discussion or explanation in another agency docu-
14 ment.

15 “(b) The principles to be applied when preparing risk
16 assessments are as follows:

17 “(1)(A) When assessing human health risks, a
18 risk assessment shall consider and discuss both the
19 most important laboratory and epidemiological data
20 and summarize the remaining data that finds, or
21 fails to find, a correlation between a health risk and
22 a potential toxin or activity.

23 “(B) When conflicts among such data appear to
24 exist, or when animal data are used as a basis to as-
25 sess human health, the assessment shall include a

1 discussion of possible reconciliation of conflicting in-
2 formation, and, as appropriate, differences in study
3 designs, mechanisms of action, comparative physiol-
4 ogy, routes of exposure, bioavailability,
5 pharmacokinetics, and any other relevant factor, in-
6 cluding the availability of raw data for review.
7 Greatest emphasis shall be placed on data that indi-
8 cates the biological basis of the resulting harm in
9 humans. Animal data shall be reviewed with regard
10 to relevancy to humans.

11 “(2) When a risk assessment involves a choice
12 of any significant assumption (including the use of
13 safety factors and default assumptions), inference,
14 or model, the agencies or instrumentality preparing
15 the assessment shall—

16 “(A) present a representative description
17 and explicit explanation of plausible and alter-
18 native similar assumptions, inferences, or mod-
19 els (including the assumptions incorporated into
20 the model) and the sensitivity of the conclusions
21 to them;

22 “(B) explain the basis for any choices;

23 “(C) identify any science policy or value
24 judgments;

1 “(D) describe any model used in the risk-
2 assessment and make explicit the assumptions
3 incorporated into the model; and

4 “(E) indicate the extent to which any sig-
5 nificant model has been validated by, or con-
6 flicts with, empirical data.

7 “(3) A risk assessment shall clearly separate
8 hazard identification from risk characterization and
9 make clear the relationship between the level of risk
10 and the level of exposure to a potential hazard.

11 “(4) A risk assessment shall be prepared at the
12 level of detail appropriate and practicable for rea-
13 soned decisionmaking on the matter involved, taking
14 into consideration the significance and complexity of
15 the decision and any need for expedition.

16 **“§ 636. Principles for risk characterization and com-**
17 **munication**

18 “In characterizing risk in any risk assessment docu-
19 ment, regulatory proposal or decision, report to Congress,
20 or other document that is made available to the public,
21 each agency characterizing the risk shall comply with each
22 of the following:

23 “(1)(A) The head of the agency shall describe
24 the populations or natural resources that are the
25 subject of the risk characterization.

1 “(B) If a numerical estimate of risk is provided,
2 ~~the~~ head of the agency, to the extent feasible and
3 ~~scientifically~~ appropriate—

4 “(i) shall provide—

5 “(I) the best estimate or estimates for
6 the specific populations or natural re-
7 sources that are the subject of the charac-
8 terization (based on the information avail-
9 able to the department, agency, or instru-
10 mentality) or, in lieu of a single best esti-
11 mate, an array of multiple estimates
12 (showing the distribution of estimates and
13 the best estimate) based on assumptions,
14 inferences, or models which are equally
15 reasonably plausible, given current sci-
16 entific understanding;

17 “(II) a statement of the reasonable
18 range of scientific uncertainties; and

19 “(III) descriptions of the distribution
20 and probability of risk estimates to reflect
21 differences in exposure variability in popu-
22 lations and uncertainties;

23 “(ii) in addition to a best estimate or esti-
24 mates, may present plausible upper-bound or
25 conservative estimates, but only in conjunction

1 with equally plausible lower-bound estimates;
2 and

3 “(iii) shall ensure that, where a safety fac-
4 tor, as distinguished from an inherent quan-
5 titative uncertainty factor, is used, such factor
6 shall reflect safety factors commonly used to
7 ensure human safety in other human activities.

8 “(2) The head of the agency shall explain the
9 exposure scenarios used in any risk assessment, and,
10 to the extent feasible, provide a statement of the size
11 of the corresponding population at risk and the like-
12 lihood of such exposure scenarios.

13 “(3) To the extent feasible, the head of the
14 agency shall provide a statement that places the na-
15 ture and magnitude of individual and population
16 risks to human health in context.

17 “(4) When a Federal agency provides a risk as-
18 sessment or risk characterization for a proposed or
19 final regulatory action, such assessment or charac-
20 terization shall include a statement of any signifi-
21 cant substitution risks to human health identified by
22 the agency or contained in information provided to
23 the agency by a commentator.

1 “(5) An agency shall present a summary in
2 connection with the presentation of the agency’s risk
3 assessment or the regulation if—

4 “(A) the agency provides a public comment
5 period with respect to a risk assessment or reg-
6 ulation;

7 “(B) a commentator provides a risk assess-
8 ment, and a summary of results of such risk as-
9 sessment; and

10 “(C) such risk assessment is reasonably
11 consistent with the principles and the guidance
12 provided under this subtitle,

13 **“§ 637. Regulations; plan for assessing new informa-**
14 **tion**

15 “(a)(1) Not later than 1 year after the date of enact-
16 ment of this subchapter, the Director or a designee of the
17 President shall—

18 “(A) issue a final regulation that has been sub-
19 ject to notice and comment under section 553 that
20 directs agencies to implement the risk assessment
21 and characterization principles set forth in sections
22 635 and 636; and

23 “(B) provide a format for summarizing risk as-
24 sessment results.

1 “(2) The regulation under paragraph (1) shall be suf-
2 ficiently specific to ensure that risk assessments are con-
3 ducted consistently by the various agencies.

4 “(b)(1) Review of the risk assessment for any major
5 rule shall be conducted by the head of the agency on the
6 written petition of a person showing a reasonable likeli-
7 hood that—

8 “(A) the risk assessment is inconsistent with
9 the principles set forth in sections 635 and 636;

10 “(B) the risk assessment produces substantially
11 different results;

12 “(C) the risk assessment is inconsistent with a
13 rule issued under subsection (a); or

14 “(D) the risk assessment does not take into ac-
15 count material significant new scientific data or sci-
16 entific understanding.

17 “(2) Not later than 90 days after receiving a petition
18 under paragraph (1), the head of the agency shall respond
19 to the petition by agreeing or declining to review the risk
20 assessment referred to in the petition, and shall state the
21 basis for the decision.

22 “(3) If the head of the agency agrees to review the
23 petition, the agency shall complete its review not later
24 than 180 days after the decision made under paragraph
25 (2), unless the Director agrees in writing with an agency

1 determination that an extension is necessary in view of
2 limitations on agency resources.

3 “(4) Denial of a petition by the agency head shall
4 be subject to judicial review in accordance with chapter
5 7.

6 “(5) A risk assessment completed pursuant to a peti-
7 tion may be the basis for initiating a regulatory review
8 pursuant to section 622(g).

9 “(e) The regulations under this section shall be devel-
10 oped after notice and opportunity for public comment, and
11 after consultation with representatives of appropriate
12 State agencies and local governments, and such other de-
13 partments, agencies, offices, organizations, or persons as
14 may be advisable.

15 “(d) At least every 4 years, the Director or a designee
16 of the President shall review, and when appropriate, re-
17 vise, the regulations published under this section.

18 **“§ 638. Decisional criteria**

19 “For each major rule subject to this subchapter, the
20 head of the agency, subject to review by the Director or
21 a designee of the President, shall make a determination
22 that—

23 “(1) the risk assessment under section 634 is
24 based on a scientific and unbiased evaluation, re-
25 flecting realistic exposure scenarios, of the risk ad-

1 dressed by the major rule and are supported by the
2 best available scientific data, as determined by a
3 peer review panel in accordance with section 639;
4 and

5 “(2) there is no alternative that is allowed by
6 the statute under which the major rule is promul-
7 gated that would provide greater net benefits or that
8 would achieve an equivalent reduction in risk in a
9 more cost-effective and flexible manner.

10 **“§ 639. Establishment of program**

11 “(a) The Director of the Office of Science and Tech-
12 nology shall develop a systematic program for the peer re-
13 view of work products covered by subsection (c), which
14 program shall be used uniformly across the agencies.

15 “(b) The program under subsection (a)—

16 “(1) shall provide for the creation of peer re-
17 view panels consisting of independent and external
18 experts who are broadly representative and balanced
19 to the extent feasible;

20 “(2) shall not exclude peer reviewers merely be-
21 cause they represent entities that may have a poten-
22 tial interest in the outcome, if that interest is fully
23 disclosed;

24 “(3) shall exclude, to the maximum extent prac-
25 ticable, any peer reviewer who has been involved in

1 any previous analysis of the tests and evidence pre-
2 sented for certification by the peer review panel; and

3 “(4) shall provide for a timely completed peer
4 review, meeting agency deadlines, which contains a
5 balanced presentation of all considerations, including
6 minority reports and an agency response to all sig-
7 nificant peer review comments.

8 “(c) The draft peer review and the agency’s responses
9 shall be made available to the public for comment and
10 shall be made part of the administrative record of the final
11 peer review for purposes of judicial review of any final
12 agency action.

13 “(d) The proceedings of peer review panels under this
14 section shall be subject to the applicable provisions of the
15 Federal Advisory Committee Act (5 U.S.C. App.).

16 “SUBCHAPTER IV—EXECUTIVE OVERSIGHT

17 “§ 641. Procedures

18 “The Director or a designee of the President shall—

19 “(1) establish procedures for agency compliance
20 with this chapter; and

21 “(2) monitor, review, and ensure agency imple-
22 mentation of such procedures.

23 “§ 642. Promulgation and adoption

24 “(a) Procedures established pursuant to section 641
25 shall only be implemented after opportunity for public

1 comment. Any such procedures shall be consistent with the
2 prompt completion of rulemaking proceedings.

3 “(b)(1) If procedures established pursuant to section
4 641 include review of any initial or final analyses of a rule
5 required under chapter 6, the time for any such review
6 of any initial analysis shall not exceed 30 days following
7 the receipt of the analysis by the Director, a designee of
8 the President, or by an officer to whom the authority
9 granted under section 641 has been delegated pursuant
10 to section 643.

11 “(2) The time for review of any final analysis re-
12 quired under chapter 6 shall not exceed 30 days following
13 the receipt of the analysis by the Director, a designee of
14 the President, or such officer.

15 “(3)(A) The times for each such review may be ex-
16 tended for good cause by the President or such officer for
17 an additional 30 days.

18 “(B) Notice of any such extension, together with a
19 succinct statement of the reasons therefor, shall be in-
20 serted in the rulemaking file.

21 **“§ 643. Delegation of authority**

22 “(a) The President may delegate the authority grant-
23 ed by this subchapter to the Vice President or to an officer
24 within the Executive Office of the President whose ap-

1 pointment has been subject to the advice and consent of
2 the Senate.

3 “(b)(1) Notice of any delegation, or any revocation
4 or modification thereof shall be published in the Federal
5 Register.

6 “(2) Any notice with respect to a delegation to the
7 Vice President shall contain a statement by the Vice Presi-
8 dent that the Vice President will make every reasonable
9 effort to respond to congressional inquiries concerning the
10 exercise of the authority delegated under this section.

11 **“§ 644. Judicial review**

12 “The exercise of the authority granted under this
13 subchapter by the Director, the President, or by an officer
14 to whom such authority has been delegated under section
15 643 shall not be subject to judicial review in any manner
16 under this chapter.”.

17 (b) REGULATORY FLEXIBILITY ANALYSIS.—(1) Sec-
18 tion 611 of title 5, United States Code, is amended to
19 read as follows:

20 **“§ 611. Judicial review**

21 “(a)(1) Except as provided in paragraph (2), not
22 later than 2 years after the effective date of a final rule
23 with respect to which an agency—

1 “(A) certified, pursuant to section 605(b), that
2 such rule would not have a significant economic im-
3 pact on a substantial number of small entities;

4 “(B) prepared a final regulatory flexibility anal-
5 ysis pursuant to section 604; or

6 “(C) did not prepare an initial regulatory flexi-
7 bility analysis pursuant to section 603 or a final reg-
8 ulatory flexibility analysis pursuant to section 604
9 except as permitted by sections 605 and 608,
10 an affected small entity may petition for the judicial re-
11 view of such certification, analysis, or lack of analysis, in
12 accordance with this subsection. A court having jurisdic-
13 tion to review such rule for compliance with section 553
14 or under any other provision of law shall have jurisdiction
15 to review such certification or analysis.

16 “(2)(A) Notwithstanding any other provision of law,
17 an affected small entity shall have 2 years to challenge
18 such certification, analysis or lack of analysis.

19 “(B) If an agency delays the issuance of a final regu-
20 latory flexibility analysis pursuant to section 608(b), a pe-
21 tition for judicial review under this subsection shall be
22 filed not later than 2 years after the date the analysis is
23 made available to the public.

1 “(3) For purposes of this subsection, the term ‘af-
2 fected small entity’ means a small entity that is or will
3 be adversely affected by the final rule.

4 “(4) Nothing in this subsection shall be construed to
5 affect the authority of any court to stay the effective date
6 of any rule or provision thereof under any other provision
7 of law.

8 “(5)(A) Notwithstanding section 605, if the court de-
9 termines, on the basis of the rulemaking record, that there
10 is substantial evidence to conclude that the rule would
11 have a significant economic impact on a substantial num-
12 ber of small entities, the court shall order the agency to
13 prepare a final regulatory flexibility analysis pursuant to
14 section 604.

15 “(B) If the agency prepared a final regulatory flexi-
16 bility analysis, the court may order the agency to take cor-
17 rective action consistent with section 604 if the court de-
18 termines, on the basis of the rulemaking record, that the
19 final regulatory flexibility analysis was prepared by the
20 agency without complying with section 604.

21 “(6) The court may stay the rule or grant such other
22 relief as it deems appropriate if, by the end of the 90-
23 day period beginning on the date of the order of the court
24 pursuant to paragraph (5) (or such longer period as the
25 court may provide), the agency fails, as appropriate—

1 “(A) to prepare the analysis required by section
2 604; or

3 “(B) to take corrective action consistent with
4 section 604.

5 “(7) In making any determination or granting any
6 relief authorized by this subsection, the court shall take
7 due account of the rule of prejudicial error.

8 “(b) In an action for the judicial review of a rule,
9 any regulatory flexibility analysis for such rule (including
10 an analysis prepared or corrected pursuant to subsection
11 (a)(5)) shall constitute part of the whole record of agency
12 action in connection with such review.

13 “(c) Nothing in this section bars judicial review of
14 any other impact statement or similar analysis required
15 by any other law if judicial review of such statement or
16 analysis is otherwise provided by law.”.

17 (2) EFFECTIVE DATE.—The amendment made by
18 paragraph (1) shall take effect on the date of enactment
19 of this Act, except that the judicial review authorized by
20 section 611(a) of title 5, United States Code (as added
21 by subsection (a)), shall apply only to final agency rules
22 issued after the date of enactment of this Act.

23 (c) PRESIDENTIAL AUTHORITY.—Nothing in this Act
24 shall limit the exercise by the President of the authority
25 and responsibility that the President otherwise possesses

1 under the Constitution and other laws of the United
2 States with respect to regulatory policies, procedures, and
3 programs of departments, agencies, and offices.

4 (d) TECHNICAL AND CONFORMING AMENDMENTS.—

5 (1) Part I of title 5, United States Code, is
6 amended by striking out the chapter heading and
7 table of sections for chapter 6 and inserting in lieu
8 thereof the following:

9 **“CHAPTER 6—THE ANALYSIS OF**
10 **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 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—ANALYSIS OF AGENCY RULES

“621. Definitions.

“622. Rulemaking cost-benefit analysis.

“623. Decisional criteria.

“624. Judicial review.

“625. Deadlines for rulemaking.

“626. Agency review of rules.

“SUBCHAPTER III—RISK ASSESSMENTS

“631. Definitions.

“632. Applicability.

“633. Rule of construction.

“634. Requirement to prepare risk assessments.

“635. Principles for risk assessment.

“636. Principles for risk characterization and communication.

“637. Regulations; plan for assessing new information.

"638. Decisional criteria.

"639. Establishment of program.

"SUBCHAPTER IV—EXECUTIVE OVERSIGHT

"641. Procedures.

"642. Promulgation and adoption.

"643. Delegation of authority.

"644. Judicial review."

1 (2) Chapter 6 of title 5, United States Code, is
2 amended by inserting immediately before section
3 601, the following subchapter heading:

4 "SUBCHAPTER I—REGULATORY ANALYSIS".

5 **SEC. 5. JUDICIAL REVIEW.**

6 (a) DEFINITIONS.—Section 701(b)(2) of title 5, Unit-
7 ed States Code, is amended by inserting before the period
8 at the end the following: ", except that 'agency action'
9 does not include action or inaction alleged to constitute
10 a breach of contract or to cause an inability to perform,
11 or to frustrate the purpose of a contract, where jurisdic-
12 tion over a claim raising such an allegation would be prop-
13 er under section 1346(a)(2) or 1491(a)(1) of title 28,
14 United States Code".

15 (b) RIGHT OF REVIEW.—Section 702 of title 5, Unit-
16 ed States Code, is amended—

17 (1) in the second sentence by striking "seeking
18 relief other than money damages and"; and

19 (2) in the last sentence by striking "or
20 impliedly".

1 (c) ACTIONS REVIEWABLE.—Section 704 of title 5,
2 United States Code, is amended in the first sentence by
3 inserting “other than the Court of Federal Claims” after
4 “court”.

5 (d) SCOPE OF REVIEW.—Section 706 of title 5, Unit-
6 ed States Code, is amended to read as follows:

7 **“§ 706. Scope of Review**

8 “(a) To the extent necessary to decision and when
9 presented, the reviewing court shall decide all relevant
10 questions of law, interpret constitutional and statutory
11 provisions, and determine the meaning or applicability of
12 the terms of an agency action. The reviewing court shall—

13 “(1) compel agency action unlawfully withheld
14 or unreasonably delayed; and

15 “(2) hold unlawful and set aside agency action,
16 findings and conclusions found to be—

17 “(A) arbitrary, capricious, an abuse of dis-
18 cretion, or otherwise not in accordance with
19 law;

20 “(B) contrary to constitutional right,
21 power, privilege, or immunity;

22 “(C) in excess of statutory jurisdiction, au-
23 thority, or limitations, or short of statutory
24 right;

1 “(D) without observance of procedure re-
2 quired by law;

3 “(E) unsupported by substantial evidence
4 in a proceeding subject to sections 556 and 557
5 or otherwise reviewed on the record;

6 “(F) without substantial support in the
7 rulemaking file, viewed as a whole, for the as-
8 serted or necessary factual basis, as distin-
9 guished from the policy or legal basis, of a rule
10 adopted in a proceeding subject to section 553;
11 and

12 “(G) unwarranted by the facts to the ex-
13 tent that the facts are subject to trial de novo
14 by the reviewing court; and

15 “(3) award monetary relief, including money
16 damages, where appropriate.

17 “(b) In making the foregoing determinations, the
18 court shall review the whole record or those parts of it
19 cited by a party, and due account shall be taken of the
20 rule of prejudicial error.

21 “(c) In reviewing an agency interpretation of a stat-
22 ute governing the authority for an agency action, including
23 agency action taken pursuant to a statute that provides
24 for review of final agency action, the reviewing court
25 shall—

1 “(1) hold erroneous and unlawful—

2 “(A) an agency interpretation that is other
3 than the interpretation of the statute clearly in-
4 tended by Congress; or

5 “(B) an agency interpretation that is out-
6 side the range of permissible interpretations of
7 the statute; and

8 “(2) hold arbitrary, capricious, or an abuse of
9 discretion—

10 “(A) an agency action as to which the
11 agency has not explained in a reasoned analysis
12 why it selected the interpretation, rather than
13 other permissible interpretations of the statute;
14 or

15 “(B) in the case of agency action subject
16 to chapter 6 of this title, an interpretation that
17 does not give the agency the broadest discretion
18 to develop rules that will satisfy the decisional
19 criteria of section 623.

20 “(d) Notwithstanding any other provision of law, the
21 provisions of this subsection shall apply to, and supple-
22 ment, the requirements contained in any statute for the
23 review of final agency action which is not otherwise subject
24 to this subsection.”.

25 (e) COURT OF FEDERAL CLAIMS.—

1 (1) IN GENERAL.—Section 1491(a) of title 28,
2 United States Code, is amended—

3 (A) in paragraph (1), by amending the
4 first sentence to read as follows: “The United
5 States Court of Federal Claims shall have juris-
6 diction to render judgment upon any claim
7 against the United States for monetary relief
8 founded either upon the Constitution or any
9 Act of Congress or any regulation of an execu-
10 tive department, or upon any expressed or im-
11 plied contract with the United States, in cases
12 not sounding in tort, or for invalidation of any
13 Act of Congress or any regulation of an execu-
14 tive department that adversely affects private
15 property rights in violation of the fifth amend-
16 ment of the United States Constitution.”;

17 (B) in paragraph (2), by inserting before
18 the first sentence the following: “In any case
19 within its jurisdiction, the Court of Federal
20 Claims shall have the power to grant injunctive
21 and declaratory relief when appropriate.”; and

22 (C) by adding at the end the following new
23 paragraphs:

24 “(4) In cases otherwise within its jurisdiction, the
25 Court of Federal Claims shall also have ancillary jurisdic-

1 tion, concurrent with the courts designated in section
2 1346(b), to render judgment upon any related tort claim
3 authorized under section 2674.

4 “(5) In proceedings within the jurisdiction of the
5 Court of Federal Claims which constitute judicial review
6 of agency action (rather than de novo proceedings), the
7 provisions of section 706 of title 5 shall apply.”.

8 (2) PENDENCY OF CLAIMS IN OTHER
9 COURTS.—Section 1500 of title 28, United States
10 Code, is repealed.

11 **SEC. 6. CONGRESSIONAL REVIEW.**

12 (a) IN GENERAL.—Title 5, United States Code, is
13 amended by inserting immediately after chapter 7 the fol-
14 lowing new chapter:

15 **“CHAPTER 8—CONGRESSIONAL REVIEW**
16 **OF AGENCY RULEMAKING**

17 **“§ 801. Congressional review of agency rulemaking**

18 “(a)(1) Before a rule takes effect as a final rule, the
19 agency promulgating such rule shall submit to the Con-
20 gress a report containing a copy of the rule, the notice
21 of proposed rulemaking, and the statement of basis and
22 purpose for the rule, including a complete copy of any
23 analysis required under chapter 6 of this title, and the
24 proposed effective date of the rule. In the case of a rule
25 that is not a major rule within the meaning of section

1 621(2), summary of the rulemaking proceedings shall be
2 submitted.

3 “(2) A rule relating to a report submitted under
4 paragraph (1) shall take effect as a final rule, the latest
5 of the following:

6 “(A) The later of the date occurring 45 days
7 after the date on which—

8 “(i) the Congress receives the report sub-
9 mitted under paragraph (1); or

10 “(ii) the rule is published in the Federal
11 Register.

12 “(B) If the Congress passes a joint resolution
13 of disapproval described under subsection (g) relat-
14 ing to the rule, and the President signs a veto of
15 such resolution, the earlier date—

16 “(i) on which either House of Congress
17 votes and fails to override the veto of the Presi-
18 dent; or

19 “(ii) occurring 30 session days after the
20 date on which the Congress received the veto
21 and objections of the President.

22 “(C) The date the rule would have otherwise
23 taken effect, if not for this section (unless a joint
24 resolution of disapproval under subsection (g) is ap-
25 proved).

1 “(b) A rule shall not take effect as a final rule if the
2 Congress passes a joint resolution of disapproval described
3 under subsection (g).

4 “(c)(1) Notwithstanding any other provision of this
5 section (except subject to paragraph (3)), a rule that
6 would not take effect by reason of this section may take
7 effect if the President makes a determination under para-
8 graph (2) and submits written notice of such determina-
9 tion to the Congress.

10 “(2) Paragraph (1) applies to a determination made
11 by the President by Executive order that the rule should
12 take effect because such rule is—

13 “(A) necessary because of an imminent threat
14 to health or safety or other emergency;

15 “(B) necessary for the enforcement of criminal
16 laws; or

17 “(C) necessary for national security.

18 “(3) An exercise by the President of the authority
19 under this subsection shall have no effect on the proce-
20 dures under subsection (g) or the effect of a joint resolu-
21 tion of disapproval under this section.

22 “(4) This subsection and an Executive order issued
23 by the President under paragraph (2) shall not be subject
24 to judicial review by a court of the United States.

1 “(d)(1) Subsection (g) shall apply to any rule that
2 is published in the Federal Register (as a rule that shall
3 take effect as a final rule) during the period beginning
4 on the date occurring 60 days before the date the Con-
5 gress adjourns sine die through the date on which the suc-
6 ceeding Congress first convenes.

7 “(2) For purposes of subsection (g), a rule described
8 under paragraph (1) shall be treated as though such rule
9 were published in the Federal Register (as a rule that shall
10 take effect as a final rule) on the date the succeeding Con-
11 gress first convenes.

12 “(3) During the period between the date the Congress
13 adjourns sine die through the date on which the succeed-
14 ing Congress first convenes, a rule described under para-
15 graph (1) shall take effect as a final rule as otherwise pro-
16 vided by law.

17 “(e) Any rule that takes effect and later is made of
18 no force or effect by the enactment of a joint resolution
19 under subsection (g) shall be treated as though such rule
20 had never taken effect.

21 “(f) If the Congress does not enact a joint resolution
22 of disapproval under subsection (g), no court or agency
23 may infer any intent of the Congress from any action or
24 inaction of the Congress with regard to such rule, related
25 statute, or joint resolution of disapproval.

1 “(g)(1) For purposes of this subsection, the term
2 ‘joint resolution’ means only a joint resolution introduced
3 after the date on which the report referred to in subsection
4 (a) is received by Congress the matter after the resolving
5 clause of which is as follows: ‘That Congress disapproves
6 the rule submitted by the _____ relating to
7 _____, and such rule shall have no force or ef-
8 fect.’ (The blank spaces being appropriately filled in.)

9 “(2)(A) A resolution described in paragraph (1) shall
10 be referred to the committees in each House of Congress
11 with jurisdiction. Such a resolution shall not be reported
12 before the eighth day after its submission or publication
13 date.

14 “(B) For purposes of this subsection the term ‘sub-
15 mission or publication date’ means the later of the date
16 on which—

17 “(i) the Congress receives the report submitted
18 under subsection (a)(1); or

19 “(ii) the rule is published in the Federal Reg-
20 ister.

21 “(3) If the committee to which a resolution described
22 in paragraph (1) is referred has not reported such resolu-
23 tion (or an identical resolution) at the end of 20 calendar
24 days after its submission or publication date, such com-
25 mittee may be discharged by the Majority Leader of the

1 Senate or the Majority Leader of the House of Represent-
2 atives, as the case may be, from further consideration of
3 such resolution and such resolution shall be placed on the
4 appropriate calendar of the House involved.

5 “(4)(A) When the committee to which a resolution
6 is referred has reported, or when a committee is dis-
7 charged (under paragraph (3)) from further consideration
8 of, a resolution described in paragraph (1), it shall at any
9 time thereafter be in order (even though a previous motion
10 to the same effect has been disagreed to) for any Member
11 of the respective House to move to proceed to the consider-
12 ation of the resolution, and all points of order against the
13 resolution (and against consideration of the resolution)
14 shall be waived. The motion shall be highly privileged in
15 the House of Representatives and shall be privileged in
16 the Senate and shall not be debatable. The motion shall
17 not be subject to amendment, or to a motion to postpone,
18 or to a motion to proceed to the consideration of other
19 business. A motion to reconsider the vote by which the
20 motion is agreed to or disagreed to shall not be in order.
21 If a motion to proceed to the consideration of the resolu-
22 tion is agreed to, the resolution shall remain the unfin-
23 ished business of the respective House until disposed of.

24 “(B) Debate on the resolution, and on all debatable
25 motions and appeals in connection therewith, shall be lim-

1 ited to not more than 10 hours, which shall be divided
2 equally between those favoring and those opposing the res-
3 olution. A motion further to limit debate shall be in order
4 and shall not be debatable. An amendment to, or a motion
5 to postpone, or a motion to proceed to the consideration
6 of other business, or a motion to recommit the resolution
7 shall ~~not~~ be in order. A motion to reconsider the vote by
8 which ~~the~~ the resolution is agreed to or disagreed to shall not
9 be in order.

10 “(C) Immediately following the conclusion of the de-
11 bate on a resolution described in paragraph (1), and a sin-
12 gle quorum call at the conclusion of the debate if re-
13 quested in accordance with the rules of the appropriate
14 House, the vote on final passage of the resolution shall
15 occur.

16 “(D) Appeals from the decisions of the Chair relating
17 to the application of the rules of the Senate or the House
18 of Representatives, as the case may be, to the procedure
19 relating to a resolution described in paragraph (1) shall
20 be decided without debate.

21 “(5) If, before the passage by one House of a resolu-
22 tion of that House described in paragraph (1), that House
23 receives from the other House a resolution described in
24 paragraph (1), then the following procedures shall apply:

1 “(A) The resolution of the other House shall
2 not be referred to a committee.

3 “(B) With respect to a resolution described in
4 paragraph (1) of the House receiving the resolu-
5 tion—

6 “(i) the procedure in that House shall be
7 the same as if no resolution had been received
8 from the other House; but

9 “(ii) the vote on final passage shall be on
10 the resolution of the other House.

11 “(6) This subsection is enacted by Congress—

12 “(A) as an exercise of the rulemaking power of
13 the Senate and House of Representatives, respec-
14 tively, and as such it is deemed to be a part of the
15 rules of each House, respectively, but applicable only
16 with respect to the procedure to be followed in that
17 House in the case of a resolution described in para-
18 graph (1), and it supersedes other rules only to the
19 extent that it is inconsistent with such rules; and

20 “(B) with full recognition of the constitutional
21 right of either House to change the rules (so far as
22 relating to the procedure of that House) at any time,
23 in the same manner, and to the same extent as in
24 the case of any other rule of that House.”.

1 (b) The table of chapters for part I of title 5, United
2 States Code, is amended by inserting immediately after
3 the item relating to chapter 7 the following:

“8. Congressional Review of Agency Rulemaking 801”.

4 **SEC. 7. STUDIES AND REPORTS.**

5 (a) RISK ASSESSMENTS.—The Administrative Con-
6 ference of the United States shall—

7 (1) develop and carry out an ongoing study of
8 the operation of the risk assessment requirements of
9 subchapter III of chapter 6 of title 5, United States
10 Code (as added by section 4 of this Act); and

11 (2) submit an annual report to the Congress on
12 the findings of the study.

13 (b) ADMINISTRATIVE PROCEDURE ACT.—Not later
14 than December 31, 1996, the Administrative Conference
15 of the United States shall—

16 (1) carry out a study of the operation of the
17 Administrative Procedure Act (as amended by sec-
18 tion 3 of this Act); and

19 (2) submit a report to the Congress on the find-
20 ings of the study, including proposals for revision, if
21 any.