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 is 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 tat 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 o 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:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Comprehensive Regulatory Reform Act of 1995".

SEC. 2. DEFINITIONS.

Section 551 of title 5, United States Code, is amended—

(1) in the matter preceding paragraph (1), by striking "this subchapter" and inserting "chapters 5, 6, 7, and 8 of this title"; and

(2) in paragraph (13), by striking "; and" and inserting a semicolon;

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

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

"(15) 'Director' means the Director of the Office of Management and Budget.".

SEC. 3. RULEMAKING.

Section 553 of title 5, United States Code, is amended to read as follows:

"§ 553. Rulemaking

"(a) This section applies to every rulemaking, according to the provisions thereof, except to the extent that there is involved—

"(1) a matter pertaining to a military or foreign affairs function of the United States;

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

"(3) an interpretive rule, general statement of policy or guidance, or rule of agency organization, procedure, or practice that is not generally applicable or does not alter or create rights or obligations of persons outside the agency; or

"(4) a rule relating to the acquisition, management, or disposal by an agency of real or personal property, or of services, that is promulgated in compliance with criteria and procedures established by the Administrator of General Services.

"(b)(1) General notice of proposed rulemaking shall be published in the Federal Register, unless all persons subject thereto are named and either personally served or otherwise have actual notice of the proposed rulemaking in accordance with law. Each notice of proposed rulemaking shall include—

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

"(B) a succinct explanation of the need for and specific objectives of the proposed rule, including an explanation of the agency's determination of whether or not the rule is a major rule within the meaning of section 621(2);

"(C) an explanation of the specific statutory interpretation under which a rule is proposed, including an explanation of—

"(i) whether the interpretation is expressly required by the text of the statute; or

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

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

"(D) the proposed provisions of the rule;

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

"(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 less burdensome than the approach used in the proposed rule;

"(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 source of such information and the purposes for which the agency plans to rely on such information; and

"(H) a statement specifying where the file of the rulemaking proceeding maintained pursuant to

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

"(2) Except when notice or hearing is required by statute, a final rule may be adopted and may become effective without prior compliance with this subsection and subsections (c) and (f) if—

"(A) the agency for good cause finds that providing notice and public procedure thereon before the rule becomes effective is contrary to an important public interest or unnecessary due to the insignificant impact of the rule;

"(B) the agency publishes the rule in the Federal Register with such finding and a succinct explanation of the reasons therefor; and

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

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

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

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

"(2)(A) To collect relevant information, and to identify and elicit full and representative public comment on the significant issues of a particular rulemaking, the agency may use such other procedures as the agency determines are appropriate, including—

"(i) the publication of an advance notice of proposed rulemaking;

"(ii) the provision of notice, in forms which are more direct than notice published in the Federal Register, to persons who would be substantially affected by the proposed rule, but who are unlikely to receive notice of the proposed rulemaking through the Federal Register;

"(iii) the provision of opportunities for oral presentation of data, views, information, or rebuttal arguments at informal public hearings, which may be held in the District of Columbia and other locations;

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

"(v) the adoption or modification of agency procedural rules to reduce the cost or complexity of participation in a rulemaking.

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

"(3) To ensure an orderly and expeditious proceeding, an agency may establish reasonable procedures to regulate the course of informal public hearings under paragraphs (2) and (3), including the designation of representatives to make oral presentations or engage in direct or cross-examination on behalf of several parties with a common interest in a rulemaking. Transcripts shall be made of all such public hearings.

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

supported in the rulemaking file maintained pursuant to subsection (f); and

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

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

"(d) An agency shall publish the final rule in the Federal Register not less than 60 days before the effective date of such rule. An agency may make a rule effective in less than 60 days after publication in the Federal Register if the rule grants or recognizes an exemption, relieves a restriction, or if the agency for good cause finds that such a delay in the effective date would be contrary to an important public interest and publishes such finding and an explanation of the reasons therefor, with the final rule.

"(e)(1) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

"(2) Each person subject to a major rule may petition—

"(A) for the issuance, amendment, or repeal of such rule;

"(B) for the amendment or repeal of an interpretive rule or general statement of policy or guidance;

"(C) for an interpretation regarding the meaning of the rule; and

"(D) for a variance or exemption from the terms of the rule.

"(2) Any person subject to a rule may petition an agency for the performance of any analysis provided under chapter 6 of this title if such person presents a reasonable likelihood that the rule is a major rule within the meaning of section 621(2). The agency shall grant the petition and promptly conduct the analysis sought if the agency determines that the rule is a rule for which an analysis is required under chapter 6. If the rule does not satisfy the decisional criteria set forth in section 624, then the agency shall take immediate action to either revoke or amend the rule to conform the rule to the requirements of chapter 6 and the decisional criteria under section 624.

"(3) The agency shall grant or deny a petition made pursuant to this subsection, and give written notice of its determination to the petitioner, with reasonable promptness, but in no event later than 180 days after the petition

was received by the agency. The written notice of the agency's determination shall include an explanation of the determination and a response to each factual and legal claim that forms the basis of the petition. A decision to deny a petition shall be subject to judicial review immediately upon denial as final agency action under the statute granting the agency authority to carry out its action.

"(f)(1) The agency shall maintain a file for each rulemaking proceeding conducted pursuant to this section and shall maintain a current index to such file. The file and the material excluded from the file pursuant to paragraph (4) shall constitute the rulemaking record for purposes of judicial review. Except as provided in paragraph (4), the file shall be made available to the public beginning on the date on which the agency makes an initial publication concerning the rule.

"(2) The rulemaking file shall include—

"(A) the notice of proposed rulemaking, any supplement to, or modification or revision of, such notice, and any advance notice of proposed rulemaking;

"(B) copies of all written comments received on the proposed rule;

"(C) a transcript of any public hearing conducted on the rulemaking;

"(D) copies, or an identification of the place at which copies may be obtained, of all material described by the agency pursuant to subsection (b)(1)(G) and of other factual and methodological material not described by the agency pursuant to such subsection that pertains directly to the rulemaking and that was available to the agency in connection with the rulemaking, or that was submitted to or prepared by or for the agency in connection with the rulemaking; and

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

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

"(4) The file required by paragraph (1) need not include any material that need not be made available to the public under section 552(b)(4) if the agency includes in such file a statement that notes the existence of such material and the basis upon which the material is exempt from public disclosure under such section. The agency may not substantially rely on any such material in formulating

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

"(5) No court shall hold unlawful or set aside an agency rule because of a violation of this subsection unless the court finds that such violation has precluded fair public consideration of a material issue of the rulemaking taken as a whole. Judicial review of compliance or noncompliance with this subsection shall be limited to review of action or inaction on the part of an agency.

"(g) Notwithstanding any other provision of law, subsections (b)(1)(C), (c)(4)(D), and (e) shall apply to and supplement the procedures governing rulemaking under statutes that are not generally subject to this section.

"(h) Nothing in this section authorizes the use of appropriated funds available to any agency to pay the attorney's fees or other expenses of persons participating or intervening in agency proceedings.".

SEC. 4. ANALYSIS OF AGENCY RULES.

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

"SUBCHAPTER II—ANALYSIS OF AGENCY RULES

"§ 621. Definitions

"For purposes of this subchapter and subchapter III—

"(1) the term 'rule' has the same meaning as in section 551(4) of this title, and—

"(A) includes any statement of general applicability that alters or creates rights or obligations of persons outside the agency; and

"(B) does not include a rule of particular applicability that approves or prescribes the future rates, wages, prices, services, corporate or financial structures, reorganizations, mergers, acquisitions, accounting practices, or disclosures bearing on any of the foregoing;

"(2)(A) the term 'major rule' means—

"(i) a rule or a group of closely related rules that the agency proposing the rule, the Director, or a designee of the President reasonably determines is likely to have a gross annual effect on the economy of $50,000,000 or more in reasonably quantifiable increased direct and indirect costs, or has a significant impact on a sector of the economy; or

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

"(I) a substantial increase in costs or prices for wage earners, consumers, individual industries, nonprofit organizations, Federal, State, or local government agencies, or geographic regions;

"(II) significant adverse effects on competition, employment, investment, productivity, innovation, the environment, public health or safety, or the ability of enterprises whose principal places of business are in the United States to compete in domestic or export markets;

"(III) a serious inconsistency or interference with an action taken or planned by another agency;

"(IV) the material alteration of the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

"(V) disproportionate costs to a class of persons within the regulated sector, and relatively severe economic consequences for the class;

"(B) the term 'major rule' does not include—

"(i) a rule that involves the internal revenue laws of the United States; or

"(ii) a rule or agency action that authorizes the introduction into, or removal from, commerce, or recognizes the marketable status, of a product pursuant to sections 408, 409(c), and 706 of the Federal Food, Drug, and Cosmetic Act;

"(3) the term 'benefit' means the reasonably identifiable significant benefits, including social and economic benefits, that are expected to result directly or indirectly from implementation of a rule or an alternative to a rule;

"(4) the term 'cost' means the reasonably identifiable significant costs and adverse effects, including social and economic costs, reduced consumer choice, substitution effects, and impeded technological advancement, that are expected to result directly or indirectly from implementation of, or compliance with, a rule or an alternative to a rule;

"(5) the term 'market-based mechanism' means 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; and

"(6) the term 'cost-benefit analysis' means an evaluation of the costs and benefits of a rule, quantified to the extent feasible and appropriate and otherwise qualitatively described, that is prepared in accordance with the requirements of this subchapter at

the level of detail appropriate and practicable for reasoned decisionmaking on the matter involved, taking into consideration the significance and complexity of the decision and any need for expedition.

"§ 622. Rulemaking cost-benefit analysis

"(a) Prior to publishing notice of a proposed rulemaking for any rule (or, in the case of a notice of a proposed rulemaking that has been published on or before the date of enactment of this subchapter, not later than 30 days after such date of enactment), each agency shall determine whether the rule is or is not a major rule within the meaning of section 621(2)(A)(i) and, if it is not, whether it should be designated a major rule under section 621(2)(A)(ii). For the purpose of any such determination or designation, a group of closely related rules shall be considered as one rule.

"(b)(1) If an agency has determined that a rule is not a major rule within the meaning of section 621(2)(A)(i) and has not designated the rule a major rule within the meaning of section 621(2)(A)(ii), the Director or a designee of the President may, as appropriate, determine that the rule is a major rule or designate the rule a major rule not later than 30 days after the publication of the notice of proposed rulemaking for the rule (or, in the case of a notice of proposed rulemaking that has been

published on or before the date of enactment of this subchapter, not later than 60 days after such date of enactment).

"(2) Such determination or designation shall be published in the Federal Register, together with a succinct statement of the basis for the determination or designation.

"(c)(1)(A) When the agency publishes a notice of proposed rulemaking for a major rule, the agency shall issue and place in the rulemaking file an initial cost-benefit analysis, and shall include a summary of such analysis in the notice of proposed rulemaking.

"(B)(i) When the Director or a designee of the President has published a determination or designation that a rule is a major rule after the publication of the notice of proposed rulemaking for the rule, the agency shall promptly issue and place in the rulemaking file an initial cost-benefit analysis for the rule and shall publish in the Federal Register a summary of such analysis.

"(ii) Following the issuance of an initial cost-benefit analysis under clause (i), the agency shall give interested persons an opportunity to comment pursuant to section 553 in the same manner as if the draft cost-benefit analysis had been issued with the notice of proposed rulemaking.

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

"(A) an analysis of the benefits of the proposed rule, and an explanation of how the agency anticipates each benefit will be achieved by the proposed rule, including a description of the persons or classes of persons likely to receive such benefits;

"(B) an analysis of the costs of the proposed rule, and an explanation of how the agency anticipates each such cost will result from the proposed rule, including a description of the persons or groups of persons likely to bear such costs;

"(C) an identification (including an analysis of the costs and benefits) of reasonable alternatives authorized under the statute granting the rulemaking authority for achieving the identified benefits of the proposed rule, including alternatives that—

"(i) require no government action;

"(ii) will accommodate differences among geographic regions and among persons with differing levels of resources with which to comply; and

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

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

"(D) an assessment of the feasibility of establishing a regulatory program that operates through the application of market-based mechanisms;

"(E) in any case in which the proposed rule is based on one or more scientific evaluations or information or is subject to the risk assessment requirements of subchapter III, a description of actions undertaken by the agency to verify the quality, reliability, and relevance of such scientific evaluations or scientific information in accordance with the risk assessment requirements of subchapter III;

"(F) an analysis, to the extent practicable, of the effect of the rule on—

"(i) the cumulative burden of compliance with the rule and other existing regulations on persons complying with it; and

"(ii) the net effect on small businesses with fewer than 100 employees, including employment in such businesses;

"(G) an analysis of whether the identified benefits of the proposed rule justify the identified costs of the proposed rule, and an analysis of whether the proposed rule will achieve greater net benefits to so-

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

"(d)(1) When the agency publishes a final major rule, the agency shall also issue and place in the rulemaking file a final cost-benefit analysis, and shall include a summary of the analysis in the statement of basis and purpose.

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

"(A) a description and comparison of the benefits and costs of the rule and of the reasonable alternatives to the rule described in the rulemaking, including the market-based mechanisms identified pursuant to subsection (c)(2)(D); and

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

"(i) whether the benefits of the rule justify the costs of the rule; and

"(ii) whether the rule will achieve greater net benefits to society than any of the reasonable alternatives described in the rulemaking, including the market-based incentives identified pursuant to subsection (c)(2)(D).

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

shall include, to the extent feasible, a quantification or numerical estimate of the quantifiable benefits and costs. Such quantification or numerical estimate shall be made in the most appropriate unit of measurement, using comparable assumptions, including time periods, shall specify the ranges of predictions, and shall explain the margins of error involved in the quantification methods and in the estimates used. An agency shall describe the nature and extent of the nonquantifiable benefits and costs of a final rule pursuant to this section in as precise and succinct a manner as possible. An agency shall not be required to make such evaluation primarily on a mathematical or numerical basis.

"(B) Where practicable, the description of the benefits and costs of a proposed and final rule required under this section shall describe such benefits and costs on an industry by industry basis.

"(2)(A) In evaluating and comparing costs and benefits and in evaluating the risk assessment information developed pursuant to subchapter III, the agency shall not rely on cost, benefit, or risk assessment information that is not accompanied by data, analysis, or other supporting materials that would enable the agency and other persons interested in the rulemaking to assess the accuracy, reli-

ability, and uncertainty factors applicable to such information.

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

"(f) The preparation of the initial or final cost-benefit analysis required by this section shall only be performed by an officer or employee of the agency. The preceding sentence shall not preclude a person outside the agency from gathering data or information to be used by the agency in preparing any such cost-benefit analysis or from providing an explanation sufficient to permit the agency to analyze such data or information. If any such data or information is gathered or explained by a person outside the agency, the agency shall specifically identify in the initial or final cost-benefit analysis the data or information gathered or explained and the person who gathered or explained it, and shall describe the arrangement by which the information was procured by the agency, including the total amount of funds expended for such procurement.

"§ 623. Petition for cost-benefit analysis

"(a)(1) Any person subject to a major rule may petition the relevant agency, the Director, or a designee of the President to perform a cost-benefit analysis under this subchapter for the major rule, including a major rule in

effect on the date of enactment of this subchapter for which a cost-benefit analysis pursuant to such subchapter has not been performed, regardless of whether a cost-benefit analysis was previously performed to meet requirements imposed before the date of enactment of this subchapter.

"(2) The petition shall identify with reasonable specificity the major rule to be reviewed.

"(3) The agency, the Director, or a designee of the President shall grant the petition if the petition shows that there is a reasonable likelihood that the costs of the major rule outweigh the benefits, or that reasonable questions exist as to whether the rule provides greater net benefits to society than any reasonable alternative to the rule that may be more clearly resolved through examination pursuant to this subchapter and subchapter III.

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

"(b) For each major rule for which a petition has been granted under subsection (a), the agency shall conduct a cost-benefit analysis in accordance with this sub-

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

"(c) For purposes of this section, the term 'major rule' means any major rule or portion thereof.

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

"(2) The petition shall identify with reasonable specificity why the guidance or general statement of policy would be major if adopted as a rule.

"(3) The agency shall grant the petition if the petition shows that there is a reasonable likelihood that the guidance or general statement of policy would be major if adopted as a rule.

"(4) A decision to grant or deny a petition under this subsection shall be made not later than 180 days after the petition is submitted. If the agency fails to act buy such date, the petition shall be deemed to have been granted. A decision to deny a petition shall be subject to judicial

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

"(c) For purposes of this section, the term 'major rule' means any major rule or portion thereof.

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

"(2) The petition shall identify with reasonable specificity why the guidance or general statement of policy would be major if adopted as a rule.

"(3) The agency shall grant the petition if the petition shows that there is a reasonable likelihood that the guidance or general statement of policy would be major if adopted as a rule.

"(4) A decision to grant or deny a petition under this subsection shall be made not later than 180 days after the petition is submitted. If the agency fails to act buy such date, the petition shall be deemed to have been granted. A decision to deny a petition shall be subject to judicial

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

"§ 624. Decisional criteria

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

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

"(2) the rule will achieve greater net benefits to society than any of the reasonable alternatives identified pursuant to section 622(d)(2)(B).

Subject to the provisions of subsection (b), the requirements of this section shall supplement any other decisional criteria otherwise provided by law.

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

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

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

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

"(1) include a written explanation of such determination in the initial and final cost-benefit analysis required by section 622; and

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

"§ 625. Judicial review

"(a) Each court with jurisdiction to review final agency action under the statute granting the agency authority to conduct the rulemaking shall have jurisdiction to review final action under this subchapter.

"(b) Any cost-benefit analysis of, or risk assessment concerning, a rule shall constitute part of the whole rulemaking record of agency action for the purpose of judicial review of the rule, and shall be considered by a court in determining the legality of the rule. The court shall apply the same standards of judicial review that govern the review of agency findings under the statute granting the agency authority to conduct the rulemaking. The court

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

"§ 626. Deadlines for rulemaking

"(a) Beginning on the date of enactment of this section, all deadlines in statutes that require agencies to propose or promulgate any rule subject to this subchapter shall be suspended until such time as the requirements of this subchapter are satisfied.

"(b) Beginning on the date of enactment of this section, the jurisdiction of any court of the United States to enforce any deadline that would require an agency to propose or promulgate a rule subject to this chapter shall be suspended until such time as the requirements of this subchapter are satisfied.

"(c) In any case in which the failure to promulgate a rule by a deadline would create an obligation to regulate through individual adjudications, the deadline shall be suspended to allow the requirements of this subchapter to be satisfied.

"§ 627. Agency review of rules

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

"(i) each rule of the agency that is in effect on such effective date and which, if adopted on such effective date, would be a major rule under section 621(2)(A);

"(ii) each rule of the agency that is inconsistent or in conflict with any other obligation or requirement established by any Federal statute, rule, or other agency statement, interpretation, or action that has the force of law; and

"(iii) each rule of the agency in effect on the date of enactment of this section (in addition to the rules described in clauses (i) and (ii)) that the agency has selected for review.

"(B) Each proposed schedule required by subparagraph (A) shall include—

"(i) a brief explanation of the reasons the agency considers each rule on the schedule to be a major rule under section 621(2)(A), or the reasons why the agency selected the rule for review;

"(ii) a date set by the agency, in accordance with subsection (b)(1), for the completion of the review of each such rule; and

"(iii) a statement that the agency requests comments from the public on the proposed schedule.

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

"(2) Not later than 90 days before publishing in the Federal Register the proposed schedule required under paragraph (1), each agency shall make the proposed schedule available to the Director or a designee of the President, or to the Vice President or other officer to whom oversight authority has been delegated under section 643. The President or that officer may select for review in accordance with this section any additional rule.

"(3) Not later than 1 year after the date of enactment of this section, each agency shall publish in the Federal Register a final schedule for the review of the rules referred to in paragraphs (1) and (2). Each agency shall publish with the final schedule the response of the agency to comments received concerning the proposed schedule.

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

"(A) each rule on the schedule promulgated pursuant to subsection (a);

"(B) each major rule under section 621(2) promulgated, amended, or otherwise renewed by an agency after the date of the enactment of this section; and

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

"(2) Except as provided pursuant to subsection (f), the review of a rule required by this section shall be completed not later than 10 years after the date of enactment of this section or 10 years after the date on which the rule is promulgated, amended, or renewed, whichever is earlier.

"(c) An agency shall publish in the Federal Register a notice of its proposed action under this section with respect to a rule being reviewed. The notice shall include—

"(1) an identification of the specific statutory authority under which the rule was promulgated and an explanation of whether the agency's interpretation of the statute is expressly required by the current text of that statute or, if not, whether it is within the range of permissible interpretations of the statute;

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

"(3) an explanation of the proposed agency action with respect to the rule, including action to repeal or amend the rule to resolve inconsistencies or conflicts with any other obligation or requirement established by any Federal statute, rule, or other agency statement, interpretation, or action that has the force of law; and

"(4) a statement that the agency seeks proposals from the public for modifications or alternatives to the rule which may accomplish the objectives of the rule in a more effective or less burdensome manner.

"(d) If an agency proposes to repeal or amend a rule under review pursuant to this section, the agency shall, after issuing the notice required by subsection (c), comply with the provisions of this chapter, chapter 5, and any other applicable law. The requirements of such provisions and related requirements shall apply to the same extent and in the same manner as in the case of a proposed agency action to repeal or amend a rule that is not taken pursuant to the review required by this section.

"(e) If an agency proposes to renew without amendment a rule under review pursuant to this section, the agency shall—

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

"(2) publish in the Federal Register notice of the renewal of such rule, an explanation of the continued need for the rule, and, if the renewed rule is a major rule under section 621(2), an explanation of the reasonable determination of the agency that the rule complies with section 624.

"(f) Any agency, which for good cause finds that compliance with this section with respect to a particular rule during the period provided in subsection (b) of this section is contrary to an important public interest may request the President, or the officer designated by the President pursuant to subsection (a)(2), to establish a period longer than 10 years for the completion of the review of such rule. The President or that officer may extend the period for review of a rule to a total period of not more than 15 years. Such extension shall be published in the Federal Register with an explanation of the reasons therefor.

"(g) In any case in which an agency has not completed the review of a rule within the period prescribed by subsection (b) or (f) of this section, the agency shall immediately publish in the Federal Register a notice proposing to amend, repeal, or renew the rule under subsection (c), and shall complete proceedings pursuant to subsection (d) or (e) not later than 180 days after the date on which the review was required to be completed under subsection (b) or (f).

"(h) Nothing in this section shall relieve any agency from its obligation to respond to a petition to issue, amend, or repeal a rule, for an interpretation regarding the meaning of a rule, or for a variance or exemption from the terms of a rule, submitted pursuant to any other provision of law.

"SUBCHAPTER III—RISK ASSESSMENTS

"§ 631. Definitions

"For purposes of this subchapter—

"(1) the term 'best estimate' means an estimate that, to the extent feasible and scientifically appropriate, is based on—

"(A) central estimates of risk using the most plausible assumptions;

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

"(C) any other methodology designed to provide the most unbiased representation of the most plausible level of risk, given the current scientific information available to the agency concerned;

"(2) the term 'emergency' means an imminent and substantial endangerment to public health or the environment;

"(3) the term 'hazard identification' means identification of a substance, activity, or condition as potentially posing a risk to human health or safety or the environment based on empirical data, measurements, or testing showing that it has caused significant adverse effects at some levels of dose or exposure not necessarily relevant to level of dose or exposure that are normally expected to occur;

"(4) the term 'negative data' means data indicating that under certain conditions a given substance or activity did not induce an adverse effect;

"(5) the term 'risk assessment' means—

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

tent practicable) or describing the degree of toxicity, exposure, or other risk the hazards pose for exposed individuals, populations, or resources; and

"(B) the document containing the explanation of how the assessment process has been applied to an individual substance, activity, or condition;

"(6) the term 'risk characterization'—

"(A) means the element of a risk assessment that involves presentation of the degree of risk to individuals and populations expected to be protected, as presented in any regulatory proposal or decision, report to Congress, or other document that is made available to the public; and

"(B) includes discussions of uncertainties, conflicting data, estimates, extrapolations, inferences, and opinions; and

"(7) the term 'substitution risk' means a potential increased risk to human health, safety, or the environment resulting from market substitutions, a reduced standard of living, or a regulatory alternative designed to decrease other risks.

"§ 632. Applicability

"(a) Except as provided in subsection (b), this subchapter shall apply to all risk assessments and risk characterizations prepared by, or on behalf of, or prepared by others and adopted by, any Federal agency in connection with health, safety, and environmental risks.

"(b)(1) This subchapter shall not apply to risk assessments or risk characterizations performed with respect to—

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

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

"(C) a health, safety, or environmental inspection or individual facility permitting action; or

"(F) a screening analysis clearly identified as such.

"(2)(A) An analysis shall not be treated as a screening analysis for the purposes of paragraph (1)(D) if the result of the analysis is used—

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

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

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

"(B) Among the analyses that may be treated as a screening analyses for the purposes of paragraph (1)(D) are product registrations, reregistrations, tolerance settings, and reviews of premanufacture notices and existing chemicals under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. 2601 et seq.).

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

"§ 633. Rule of construction

"Nothing in this subchapter shall be construed to—

"(1) 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

"(2) require the disclosure of any trade secret or other confidential information.

"§ 634. Requirement to prepare risk assessments

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

chapter, is pending on the date of enactment of this subchapter, or is subject to a granted petition for review pursuant to section 553(e) or 622(g)—

"(1) a risk assessment in accordance with this subchapter;

"(2) for each such proposed or final rule, an assessment, quantified to the extent feasible, of incremental risk reduction or other benefits associated with each significant regulatory alternative to the rule or proposed rule; and

"(3) for each such proposed or final rule, quantified to the extent feasible, a comparison of any human health, safety, or environmental risks addressed by the regulatory alternatives to other relevant risks chosen by the head of the agency, including at least 3 other risks regulated by the agency and to at least 3 other risks with which the public is familiar.

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

"§ 635. Principles for risk assessment

"(a)(1) The head of each agency shall apply the principles set forth in subsection (b) when preparing any risk assessment, whether or not required by section 634, to ensure that the risk assessment and all of its components—

"(A) distinguish scientific findings and best estimates of risk from other considerations;

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

"(C) rely, to the extent available and practicable, on scientific findings.

"(2) An agency shall not be required to repeat discussions or explanations required under this section in each risk assessment document if there is a reference to the relevant discussion or explanation in another agency document.

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

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

"(B) When conflicts among such data appear to exist, or when animal data are used as a basis to assess human health, the assessment shall include a discussion of possible reconciliation of conflicting information, and, as appropriate, differences in study designs, mechanisms of action, comparative physiology, routes of exposure, bioavailability, pharmacokinetics, and any other relevant factor, including the availability of raw data for review. Greatest emphasis shall be placed on data that indicates the biological basis of the resulting harm in humans. Animal data shall be reviewed with regard to relevancy to humans.

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

"(A) present a representative description and explicit explanation of plausible and alternative similar assumptions, inferences, or models (including the assumptions incorporated into the model) and the sensitivity of the conclusions to them;

"(B) explain the basis for any choices;

"(C) identify any science policy or value judgments;

"(D) describe any model used in the risk-assessment and make explicit the assumptions incorporated into the model; and

"(E) indicate the extent to which any significant model has been validated by, or conflicts with, empirical data.

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

"(4) A risk assessment shall be prepared at the level of detail appropriate and practicable for reasoned decisionmaking on the matter involved, taking into consideration the significance and complexity of the decision and any need for expedition.

"§ 636. Principles for risk characterization and communication

"In characterizing risk in any risk assessment document, regulatory proposal or decision, report to Congress, or other document that is made available to the public, each agency characterizing the risk shall comply with each of the following:

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

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

"(i) shall provide—

"(I) the best estimate or estimates for the specific populations or natural resources that are the subject of the characterization (based on the information available to the department, agency, or instrumentality) or, in lieu of a single best estimate, an array of multiple estimates (showing the distribution of estimates and the best estimate) based on assumptions, inferences, or models which are equally reasonably plausible, given current scientific understanding;

"(II) a statement of the reasonable range of scientific uncertainties; and

"(III) descriptions of the distribution and probability of risk estimates to reflect differences in exposure variability in populations and uncertainties;

"(ii) in addition to a best estimate or estimates, may present plausible upper-bound or conservative estimates, but only in conjunction with equally plausible lower-bound estimates; and

"(iii) shall ensure that, where a safety factor, as distinguished from an inherent quantitative uncertainty factor, is used, such factor shall reflect safety factors commonly used to ensure human safety in other human activities.

"(2) The head of the agency shall explain the exposure scenarios used in any risk assessment, and, to the extent feasible, provide a statement of the size of the corresponding population at risk and the likelihood of such exposure scenarios.

"(3) To the extent feasible, the head of the agency shall provide a statement that places the nature and magnitude of individual and population risks to human health in context.

"(4) When a Federal agency provides a risk assessment or risk characterization for a proposed or final regulatory action, such assessment or characterization shall include a statement of any significant substitution risks to human health identified by

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

"(5) An agency shall present a summary in connection with the presentation of the agency's risk assessment or the regulation if—

"(A) the agency provides a public comment period with respect to a risk assessment or regulation;

"(B) a commentator provides a risk assessment, and a summary of results of such risk assessment; and

"(C) such risk assessment is reasonably consistent with the principles and the guidance provided under this subtitle.

"§ 637. Regulations; plan for assessing new information

"(a)(1) Not later than 1 year after the date of enactment of this subchapter, the Director or a designee of the President shall—

"(A) issue a final regulation that has been subject to notice and comment under section 553 that directs agencies to implement the risk assessment and characterization principles set forth in sections 635 and 636; and

"(B) provide a format for summarizing risk assessment results.

"(2) The regulation under paragraph (1) shall be sufficiently specific to ensure that risk assessments are conducted consistently by the various agencies.

"(b)(1) Review of the risk assessment for any major rule shall be conducted by the head of the agency on the written petition of a person showing a reasonable likelihood that—

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

"(B) the risk assessment produces substantially different results;

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

"(D) the risk assessment does not take into account material significant new scientific data or scientific understanding.

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

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

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

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

"(5) A risk assessment completed pursuant to a petition may be the basis for initiating a regulatory review pursuant to section 622(g).

"(c) The regulations under this section shall be developed after notice and opportunity for public comment, and after consultation with representatives of appropriate State agencies and local governments, and such other departments, agencies, offices, organizations, or persons as may be advisable.

"(d) At least every 4 years, the Director or a designee of the President shall review, and when appropriate, revise, the regulations published under this section.

"§ 638. Decisional criteria

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

"(1) the risk assessment under section 634 is based on a scientific and unbiased evaluation, reflecting reasonable exposure scenarios, of the risk addressed by the major rule and are supported by the best available scientific data, as determined by a peer review panel in accordance with section 639; and

"(2) 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 achieve an equivalent reduction in risk in a more cost-effective and flexible manner.

"(b) Notwithstanding any other provision of law, no covered agency shall prohibit or refuse to approve a substance or product on the basis of safety where the substance or product presents an insignificant human risk under the intended conditions of use.

"§ 639. Establishment of program

"(a) The Director of the Office of Science and Technology shall develop a systematic program for the peer review of work products covered by subsection (c), which program shall be used uniformly across the agencies.

"(b) The program under subsection (a)—

"(1) shall provide for the creation of peer review panels consisting of independent and external

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

"(2) shall not exclude peer reviewers merely because they represent entities that may have a potential interest in the outcome, if that interest is fully disclosed;

"(3) shall exclude, to the maximum extent practicable, any peer reviewer who has been involved in any previous analysis of the tests and evidence presented for certification by the peer review panel; and

"(4) shall provide for a timely completed peer review, meeting agency deadlines, which contains a balanced presentation of all considerations, including minority reports and an agency response to all significant peer review comments.

"(c) The draft peer review and the agency's responses shall be made available to the public for comment and shall be made part of the administrative record of the final peer review for purposes of judicial review of any final agency action.

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

"SUBCHAPTER IV—EXECUTIVE OVERSIGHT

"§ 641. Procedures

"The Director or a designee of the President shall—

"(1) establish procedures for agency compliance with this chapter; and

"(2) monitor, review, and ensure agency implementation of such procedures.

"§ 642. Promulgation and adoption

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

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

"(2) The time for review of any final analysis required under chapter 6 shall not exceed 30 days following the receipt of the analysis by the Director, a designee of the President, or such officer.

"(3)(A) The times for each such review may be extended for good cause by the President or such officer for an additional 30 days.

"(B) Notice of any such extension, together with a succinct statement of the reasons therefor, shall be inserted in the rulemaking file.

"§ 643. Delegation of authority

"(a) The President may delegate the authority granted by this subchapter to the Vice President or to an officer within the Executive Office of the President whose appointment has been subject to the advice and consent of the Senate.

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

"(2) Any notice with respect to a delegation to the Vice President shall contain a statement by the Vice President that the Vice President will make every reasonable effort to respond to congressional inquiries concerning the exercise of the authority delegated under this section.

"§ 644. Judicial review

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

643 shall not be subject to judicial review in any manner under this chapter.".

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

"§ 611. Judicial review

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

"(A) certified, pursuant to section 605(b), that such rule would not have a significant economic impact on a substantial number of small entities;

"(B) prepared a final regulatory flexibility analysis pursuant to section 604; or

"(C) did not prepare an initial regulatory flexibility analysis pursuant to section 603 or a final regulatory flexibility analysis pursuant to section 604 except as permitted by sections 605 and 608,

an affected small entity may petition for the judicial review of such certification, analysis, or lack of analysis, in accordance with this subsection. A court having jurisdiction to review such rule for compliance with section 553 or under any other provision of law shall have jurisdiction to review such certification or analysis.

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

"(B) If an agency delays the issuance of a final regulatory flexibility analysis pursuant to section 608(b), a petition for judicial review under this subsection shall be filed not later than 2 years after the date the analysis is made available to the public.

"(3) For purposes of this subsection, the term 'affected small entity' means a small entity that is or will be adversely affected by the final rule.

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

"(5)(A) Notwithstanding section 605, if the court determines, on the basis of the rulemaking record, that there is substantial evidence to conclude that the rule would have a significant economic impact on a substantial number of small entities, the court shall order the agency to prepare a final regulatory flexibility analysis pursuant to section 604.

"(B) If the agency prepared a final regulatory flexibility analysis, the court may order the agency to take corrective action consistent with section 604 if the court de-

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

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

"(A) to prepare the analysis required by section 604; or

"(B) to take corrective action consistent with section 604.

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

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

"(c) Nothing in this section bars judicial review of any other impact statement or similar analysis required by any other law if judicial review of such statement or analysis is otherwise provided by law.".

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

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

(d) TECHNICAL AND CONFORMING AMENDMENTS.—

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

"CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS

"SUBCHAPTER I—REGULATORY ANALYSIS

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

"SUBCHAPTER I—REGULATORY ANALYSIS".

SEC. 5. JUDICIAL REVIEW.

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

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

(b) RIGHT OF REVIEW.—Section 702 of title 5, United States Code, is amended—

(1) in the second sentence by striking "seeking relief other than money damages and"; and

(2) in the last sentence by striking "or impliedly".

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

(d) SCOPE OF REVIEW.—Section 706 of title 5, United States Code, is amended to read as follows:

"§ 706. Scope of Review

"(a) To the extent necessary to reach a decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

"(1) compel agency action unlawfully withheld or unreasonably delayed; and

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

"(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

"(B) contrary to constitutional right, power, privilege, or immunity;

"(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

"(D) without observance of procedure required by law;

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

"(F) without substantial support in the rulemaking file, viewed as a whole, for the asserted or necessary factual basis, as distinguished from the policy or legal basis, of a rule adopted in a proceeding subject to section 553; and

"(G) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court; and

"(3) award monetary relief, including money damages, where appropriate.

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

"(c) In reviewing an agency interpretation of a statute governing the authority for an agency action, including agency action taken pursuant to a statute that provides for review of final agency action, the reviewing court shall—

"(1) hold erroneous and unlawful—

"(A) an agency interpretation that is other than the interpretation of the statute clearly intended by Congress; or

"(B) an agency interpretation that is outside the range of permissible interpretations of the statute; and

"(2) hold arbitrary, capricious, or an abuse of discretion—

"(A) an agency action as to which the agency—

"(i) has improperly classified an interpretation as being within or outside the range of permissible interpretations; or

"(ii) has not explained in a reasoned analysis why it selected the interpretation

and why it rejected other permissible interpretations of the statute; or

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

"(d) Notwithstanding any other provision of law, the provisions of this subsection shall apply to, and supplement, the requirements contained in any statute for the review of final agency action which is not otherwise subject to this subsection.".

(e) COURT OF FEDERAL CLAIMS.—

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

(A) in paragraph (1), by amending the first sentence to read as follows: "The United States Court of Federal Claims shall have jurisdiction to render judgment upon any claim against the United States for monetary relief founded either upon the Constitution or any Act of Congress or any regulation of an executive department, or upon any expressed or implied contract with the United States, in cases not sounding in tort, or for invalidation of any

Act of Congress or any regulation of an executive department that adversely affects private property rights in violation of the fifth amendment of the United States Constitution.";

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

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

"(4) In cases otherwise within its jurisdiction, the Court of Federal Claims shall also have ancillary jurisdiction, concurrent with the courts designated in section 1346(b), to render judgment upon any related tort claim authorized under section 2674.

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

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

(f) CONSENT DECREES.—

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

"§ 707. Consent Decrees

"In interpreting any consent decree in effect on or after the date of enactment of this section that imposes on an agency an obligation to initiate, continue, or complete rulemaking proceedings, the court shall not enforce the decree in a way that divests the agency of discretion granted to it by the Congress or the Constitution to respond to changing circumstances, make policy or managerial choices, or protect the rights of third parties.".

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

"707. Consent decrees.".

SEC. 6. CONGRESSIONAL REVIEW.

(a) IN GENERAL.—Title 5, United States Code, is amended by inserting immediately after chapter 7 the following new chapter:

"CHAPTER 8—CONGRESSIONAL REVIEW OF AGENCY RULEMAKING

"§ 801. Congressional review of agency rulemaking

"(a)(1) Before a rule takes effect as a final rule, the agency promulgating such rule shall submit to the Congress a report containing a copy of the rule, the notice

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

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

"(A) The later of the date occurring 45 days after the date on which—

"(i) the Congress receives the report submitted under paragraph (1); or

"(ii) the rule is published in the Federal Register.

"(B) If the Congress passes a joint resolution of disapproval described under subsection (g) relating to the rule, and the President signs a veto of such resolution, the earlier date—

"(i) on which either House of Congress votes and fails to override the veto of the President; or

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

"(C) The date the rule would have otherwise taken effect, if not for this section (unless a joint resolution of disapproval under subsection (g) is approved).

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

"(c)(1) Notwithstanding any other provision of this section (except subject to paragraph (3)), a rule that would not take effect by reason of this section may take effect if the President makes a determination under paragraph (2) and submits written notice of such determination to the Congress.

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

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

"(B) necessary for the enforcement of criminal laws; or

"(C) necessary for national security.

"(3) An exercise by the President of the authority under this subsection shall have no effect on the procedures under subsection (g) or the effect of a joint resolution of disapproval under this section.

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

"(d)(1) Subsection (g) shall apply to any rule that is published in the Federal Register (as a rule that shall take effect as a final rule) during the period beginning on the date occurring 60 days before the date the Congress adjourns sine die through the date on which the succeeding Congress first convenes.

"(2) For purposes of subsection (g), a rule described under paragraph (1) shall be treated as though such rule were published in the Federal Register (as a rule that shall take effect as a final rule) on the date the succeeding Congress first convenes.

"(3) During the period between the date the Congress adjourns sine die through the date on which the succeeding Congress first convenes, a rule described under paragraph (1) shall take effect as a final rule as otherwise provided by law.

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

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

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

"(g)(1) For purposes of this subsection, the term 'joint resolution' means only a joint resolution introduced after the date on which the report referred to in subsection (a) is received by Congress the matter after the resolving clause of which is as follows: 'That Congress disapproves the rule submitted by the _____ relating to _____, and such rule shall have no force or effect.' (The blank spaces being appropriately filled in.)

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

"(B) For purposes of this subsection the term 'submission or publication date' means the later of the date on which—

"(i) the Congress receives the report submitted under subsection (a)(1); or

"(ii) the rule is published in the Federal Register.

"(3) If the committee to which a resolution described in paragraph (1) is referred has not reported such resolution (or an identical resolution) at the end of 20 calendar days after its submission or publication date, such committee may be discharged by the Majority Leader of the Senate or the Majority Leader of the House of Representatives, as the case may be, from further consideration of such resolution and such resolution shall be placed on the appropriate calendar of the House involved.

"(4)(A) When the committee to which a resolution is referred has reported, or when a committee is discharged (under paragraph (3)) from further consideration of, a resolution described in paragraph (1), it shall at any time thereafter be in order (even though a previous motion to the same effect has been disagreed to) for any Member of the respective House to move to proceed to the consideration of the resolution, and all points of order against the resolution (and against consideration of the resolution) shall be waived. The motion shall be highly privileged in the House of Representatives and shall be privileged in the Senate and shall not be debatable. The motion shall not be subject to amendment, or to a motion to postpone, or to a motion to proceed to the consideration of other

business. A motion to reconsider the vote by which the motion is agreed to or disagreed to shall not be in order. If a motion to proceed to the consideration of the resolution is agreed to, the resolution shall remain the unfinished business of the respective House until disposed of.

"(B) Debate on the resolution, and on all debatable motions and appeals in connection therewith, shall be limited to not more than 10 hours, which shall be divided equally between those favoring and those opposing the resolution. A motion further to limit debate shall be in order and shall not be debatable. An amendment to, or a motion to postpone, or a motion to proceed to the consideration of other business, or a motion to recommit the resolution shall not be in order. A motion to reconsider the vote by which the resolution is agreed to or disagreed to shall not be in order.

"(C) Immediately following the conclusion of the debate on a resolution described in paragraph (1), and a single quorum call at the conclusion of the debate if requested in accordance with the rules of the appropriate House, the vote on final passage of the resolution shall occur.

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

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

"(5) If, before the passage by one House of a resolution of that House described in paragraph (1), that House receives from the other House a resolution described in paragraph (1), then the following procedures shall apply:

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

"(B) With respect to a resolution described in paragraph (1) of the House receiving the resolution—

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

"(ii) the vote on final passage shall be on the resolution of the other House.

"(6) This subsection is enacted by Congress—

"(A) as an exercise of the rulemaking power of the Senate and House of Representatives, respectively, and as such it is deemed to be a part of the rules of each House, respectively, but applicable only with respect to the procedure to be followed in that House in the case of a resolution described in paragraph (1), and it supersedes other rules only to the extent that it is inconsistent with such rules; and

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

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

"8. Congressional Review of Agency Rulemaking ..... 801".

SEC. 7. STUDIES AND REPORTS.

(a) RISK ASSESSMENTS.—The Administrative Conference of the United States shall—

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

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

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

(1) carry out a study of the operation of the Administrative Procedure Act (as amended by section 3 of this Act); and

(2) submit a report to the Congress on the findings of the study, including proposals for revision, if 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:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Comprehensive Regulatory Reform Act of 1995".

SEC. 2. DEFINITIONS.

Section 551 of title 5, United States Code, is amended—

(1) in the matter preceding paragraph (1), by striking "this subchapter" and inserting "chapters 5, 6, 7, and 8 of this title"; and

(2) in paragraph (13), by striking "; and" and inserting a semicolon;

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

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

"(15) 'Director' means the Director of the Office of Management and Budget.".

SEC. 3. RULEMAKING.

Section 553 of title 5, United States Code, is amended to read as follows:

"§ 553. Rulemaking

"(a) This section applies to every rulemaking, according to the provisions thereof, except to the extent that there is involved—

"(1) a matter pertaining to a military or foreign affairs function of the United States;

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

"(3) an interpretive rule, general statement of policy, or rule of agency organization, procedure, or practice that is not generally applicable or does not alter or create rights or obligations of persons outside the agency; or

"(4) a rule relating to the acquisition, management, or disposal by an agency of real or personal property, or of services, that is promulgated in compliance with criteria and procedures established by the Administrator of General Services.

"(b)(1) General notice of proposed rulemaking shall be published in the Federal Register, unless all persons subject thereto are named and either personally served or otherwise have actual notice of the proposed rulemaking in accordance with law. Each notice of proposed rulemaking shall include—

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

"(B) a succinct explanation of the need for and specific objectives of the proposed rule, including an explanation of the agency's determination of whether or not the rule is a major rule within the meaning of section 621(2);

"(C) an explanation of the specific statutory interpretation under which the rule is proposed, including an explanation of—

"(i) whether the interpretation is expressly required by the text of the statute; or

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

such interpretation is within the range of permissible interpretations of the statute, and why the agency selected that interpretation;

"(D) the proposed provisions of the rule;

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

"(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 less burdensome than the approach used in the proposed rule;

"(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 source of such information and the purposes for which the agency plans to rely on such information; and

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

"(2) Except when notice or hearing is required by statute, a final rule may be adopted and may become effective without prior compliance with this subsection and subsections (c) and (f) if—

"(A) the agency for good cause finds that providing notice and public procedure thereon before the rule becomes effective is contrary to an important public interest or unnecessary due to the insignificant impact of the rule;

"(B) the agency publishes the rule in the Federal Register with such finding and a succinct explanation of the reasons therefor; and

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

"(3) Whenever the provisions of a final rule that an agency plans to adopt are so different from the provisions of the proposed rule that the original notice of proposed rulemaking did not fairly apprise the public of the issues ultimately to be resolved in the rulemaking or of the substance of the rule, the agency shall publish in the Federal Register a notice of the final rule the agency plans to

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

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

"(2)(A) To collect relevant information, and to identify and elicit full and representative public comment on the significant issues of a particular rulemaking, the agency may use such other procedures as the agency determines are appropriate, including—

"(i) the publication of an advance notice of proposed rulemaking;

"(ii) the provision of notice, in forms which are more direct than notice published in the Federal Register, to persons who would be substantially affected by the proposed rule, but who are unlikely to receive notice of the proposed rulemaking through the Federal Register;

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

be held in the District of Columbia and other locations;

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

"(v) the adoption or modification of agency procedural rules to reduce the cost or complexity of participation in a rulemaking.

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

"(3) To ensure an orderly and expeditious proceeding, an agency may establish reasonable procedures to regulate the course of informal public hearings under paragraphs (2) and (3), including the designation of representatives to make oral presentations or engage in direct or cross-examination on behalf of several parties with a common interest in a rulemaking. Transcripts shall be made of all such public hearings.

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

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

"(B) a discussion of, and response to, any significant factual or legal issues raised by the comments on the proposed rule prior to its promulgation, including a description of the reasonable alternatives to the rule proposed by the agency and by interested persons, and the reasons why each such alternative was rejected;

"(C) an explanation of how the factual conclusions upon which the rule is based are substantially supported in the rulemaking file maintained pursuant to subsection (f); and

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

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

"(d)(1) An agency shall publish the final rule in the Federal Register not less than 60 days before the effective date of such rule. An agency may make a rule effective in less than 60 days after publication in the Federal Register if the rule grants or recognizes an exemption, relieves

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

"(2) In promulgating a final rule, an agency may not substantially rely on any material that was not identified in the notice of proposed rulemaking. Notwithstanding the preceding sentence, an agency may rely on such material—

"(A) if such material was placed in the rulemaking file promptly upon its receipt by the agency and, if such material is of central relevance to the rulemaking, the agency provided a reasonable opportunity for interested persons to comment thereon;

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

"(C) if, in the case of material developed by or for the agency, such material was placed in the rulemaking file promptly upon its completion and, if such material is of central relevance to the rulemaking, was made available in time for interested

persons to have an adequate opportunity to comment thereon.

"(e)(1) Each person subject to a major rule may petition—

"(A) for the issuance, amendment, or repeal of such rule;

"(B) for the amendment or repeal of an interpretive rule or general statement of policy;

"(C) for an interpretation regarding the meaning of the rule; and

"(D) for a variance or exemption from the terms of the rule.

"(2) Each person subject to a rule may petition an agency for the performance of any analysis provided under chapter 6 of this title if such person presents a substantial question that the rule is a major rule within the meaning of section 621(2). The agency shall grant the petition and promptly conduct the analysis sought if the agency determines that the rule is a rule for which an analysis is required under chapter 6. If the rule does not satisfy the decisional criteria set forth in section 623, then the agency shall take immediate action to either revoke or amend the rule to conform the rule to the requirements of chapter 6 and the decisional criteria under section 623.

"(3) The agency shall grant or deny a petition made pursuant to this subsection, and give written notice of its determination to the petitioner, with reasonable promptness, but in no event later than 180 days after the petition was received by the agency. The written notice of the agency's determination shall include an explanation of the determination and a response to each factual and legal claim that forms the basis of the petition. Such notice shall constitute final agency action for purposes of appeal.

"(f)(1) The agency shall maintain a file for each rulemaking proceeding conducted pursuant to this section and shall maintain a current index to such file. The file and the material excluded from the file pursuant to paragraph (3) shall constitute the rulemaking record for purposes of judicial review. Except as provided in paragraph (3), the file shall be made available to the public beginning on the date on which the agency makes an initial publication concerning the rule.

"(2) The rulemaking file shall include—

"(A) the notice of proposed rulemaking, any supplement to, or modification or revision of, such notice, and any advance notice of proposed rulemaking;

"(B) copies of all written comments received on the proposed rule;

"(C) a transcript of any public hearing conducted on the rulemaking;

"(D) copies, or an identification of the place at which copies may be obtained, of all material described by the agency pursuant to subsection (b)(1)(G) and of other factual and methodological material not described by the agency pursuant to such subsection that pertains directly to the rulemaking and that was available to the agency in connection with the rulemaking, or that was submitted to or prepared by or for the agency in connection with the rulemaking; and

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

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

"(4) The file required by paragraph (1) need not include any material that need not be made available to the public under section 552(b)(4) if the agency includes in such file a statement that notes the existence of such material and the basis upon which the material is exempt

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

"(5) No court shall hold unlawful or set aside an agency rule because of a violation of this subsection unless the court finds that such violation has precluded fair public consideration of a material issue of the rulemaking taken as a whole. Judicial review of compliance or noncompliance with this subsection shall be limited to review of action or inaction on the part of an agency.

"(g) Notwithstanding any other provision of law, except as otherwise provided in this section, subsections (b)(1)(C), (c)(4)(D), and (e) shall supplement, and not supplant, any other law or regulation governing rulemaking procedures.

"(h) Nothing in this section authorizes the use of appropriated funds available to any agency to pay the attorney's fees or other expenses of persons participating or intervening in agency proceedings.".

SEC. 4. ANALYSIS OF AGENCY RULES.

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

"SUBCHAPTER II—ANALYSIS OF AGENCY RULES

"§ 621. Definitions

"For purposes of this subchapter and subchapter III—

"(1) the term 'rule' has the same meaning as in section 551(4) of this title, and—

"(A) includes any statement of general applicability that alters or creates rights or obligations of persons outside the agency; and

"(B) does not include a rule of particular applicability that approves or prescribes the future rates, wages, prices, services, corporate or financial structures, reorganizations, mergers, acquisitions, accounting practices, or disclosures bearing on any of the foregoing;

"(2)(A) the term 'major rule' means—

"(i) a rule or a group of closely related rules that the agency proposing the rule, the Director, or a designee of the President reasonably determines is likely to have a gross annual effect on the economy of $50,000,000 or more

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

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

"(I) a substantial increase in costs or prices for wage earners, consumers, individual industries, nonprofit organizations, Federal, State, or local government agencies, or geographic regions; or

"(II) significant adverse effects on competition, employment, investment, productivity, innovation, the environment, public health or safety, or the ability of enterprises whose principal places of business are in the United States to compete in domestic or export markets;

"(B) the term 'major rule' does not include—

"(i) a rule that involves the internal revenue laws of the United States; or

"(ii) a rule or agency action that authorizes the introduction into, or removal from,

commerce, or recognizes the marketable status, of a product pursuant to sections 408, 409(c), and 706 of the Federal Food, Drug, and Cosmetic Act;

"(3) the term 'benefit' means the reasonably identifiable significant benefits, including social and economic benefits, that are expected to result directly or indirectly from implementation of a rule or an alternative to a rule;

"(4) the term 'cost' means the reasonably identifiable significant costs and adverse effects, including social and economic costs, reduced consumer choice, substitution effects, and impeded technological advancement, that are expected to result directly or indirectly from implementation of, or compliance with, a rule or an alternative to a rule;

"(5) the term 'market-based mechanism' means 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; and

"(6) the term 'cost-benefit analysis' means an evaluation of the costs and benefits of a rule, quantified to the extent feasible and appropriate and otherwise qualitatively described, that is prepared in accordance with the requirements of this subchapter at the level of detail appropriate and practicable for reasoned decisionmaking on the matter involved, taking into consideration the significance and complexity of the decision and any need for expedition.

"§ 622. Rulemaking cost-benefit analysis

"(a) Prior to publishing notice of a proposed rulemaking for any rule (or, in the case of a notice of a proposed rulemaking that has been published on or before the date of enactment of this subchapter, not later than 30

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

"(b)(1) If an agency has determined that a rule is not a major rule within the meaning of section 621(2)(A)(i) and has not designated the rule a major rule within the meaning of section 621(2)(A)(ii), the Director or a designee of the President may, as appropriate, determine that the rule is a major rule or designate the rule a major rule not later than 30 days after the publication of the notice of proposed rulemaking for the rule (or, in the case of a notice of proposed rulemaking that has been published on or before the date of enactment of this subchapter, not later than 60 days after such date of enactment).

"(2) Such determination or designation shall be published in the Federal Register, together with a succinct statement of the basis for the determination or designation.

"(c)(1)(A) When the agency publishes a notice of proposed rulemaking for a major rule, the agency shall issue

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

"(B)(i) When the Director or a designee of the President has published a determination or designation that a rule is a major rule after the publication of the notice of proposed rulemaking for the rule, the agency shall promptly issue and place in the rulemaking file an initial cost-benefit analysis for the rule and shall publish in the Federal Register a summary of such analysis.

"(ii) Following the issuance of an initial cost-benefit analysis under clause (i), the agency shall give interested persons an opportunity to comment pursuant to section 553 in the same manner as if the draft cost-benefit analysis had been issued with the notice of proposed rulemaking.

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

"(A) an analysis of the benefits of the proposed rule, and an explanation of how the agency anticipates each benefit will be achieved by the proposed rule, including a description of the persons or classes of persons likely to receive such benefits;

"(B) an analysis of the costs of the proposed rule, and an explanation of how the agency anticipates each such cost will result from the proposed

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

"(C) an identification (including an analysis of the costs and benefits) of reasonable alternatives authorized under the statute granting the rulemaking authority for achieving the identified benefits of the proposed rule, including alternatives that—

"(i) require no government action;

"(ii) will accommodate differences among geographic regions and among persons with differing levels of resources with which to comply; and

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

"(D) an assessment of the feasibility of establishing a regulatory program that operates through the application of market-based mechanisms;

"(E) in any case in which the proposed rule is based on one or more scientific evaluations or information or is subject to the risk assessment requirements of subchapter III, a description of actions undertaken by the agency to verify the quality, reliabil-

ity, and relevance of such scientific evaluations or scientific information in accordance with the risk assessment requirements of subchapter III;

"(F) an analysis, to the extent practicable, of the effect of the rule on—

"(i) the cumulative burden of compliance with the rule and other existing regulations on persons complying with it; and

"(ii) the net effect on small businesses with fewer than 100 employees, including employment in such businesses;

"(G) an analysis of whether the identified benefits of the proposed rule justify the identified costs of the proposed rule, and an analysis of whether the proposed rule will provide greater net benefits to society than any of the alternatives to the proposed rule, including alternatives identified in accordance with subparagraph (C).

"(d)(1) When the agency publishes a final major rule, the agency shall also issue and place in the rulemaking file a final cost-benefit analysis, and shall include a summary of the analysis in the statement of basis and purpose.

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

"(A) a description and comparison of the benefits and costs of the rule and of the reasonable alternatives to the rule described in the rulemaking, including the market-based mechanisms identified pursuant to subsection (c)(2)(D); and

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

"(i) whether the benefits of the rule justify the costs of the rule; and

"(ii) whether the rule will provide greater net benefits to society than any of the reasonable alternatives described in the rulemaking, including the market-based incentives identified pursuant to subsection (c)(2)(D).

"(e)(1)(A) The analysis of the benefits and costs of a proposed and a final rule required under this section shall include, to the extent feasible, a quantification or numerical estimate of the quantifiable benefits and costs. Such quantification or numerical estimate shall be made in the most appropriate unit of measurement, using comparable assumptions, including time periods, shall specify the ranges of predictions, and shall explain the margins of error involved in the quantification methods and in the estimates used. An agency shall describe the nature and extent of the nonquantifiable benefits and costs of a final

rule pursuant to this section in as precise and succinct a manner as possible. An agency shall not be required to make such evaluation primarily on a mathematical or numerical basis.

"(B) Where practicable, the description of the benefits and costs of a proposed and final rule required under this section shall describe such benefits and costs on an industry by industry basis.

"(2)(A) In evaluating and comparing costs and benefits and in evaluating the risk assessment information developed pursuant to subchapter III, the agency shall not rely on cost, benefit, or risk assessment information that is not accompanied by data, analysis, or other supporting materials that would enable the agency and other persons interested in the rulemaking to assess the accuracy, reliability, and uncertainty factors applicable to such information.

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

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

agency in preparing any such cost-benefit analysis or from providing an explanation sufficient to permit the agency to analyze such data or information. If any such data or information is gathered or explained by a person outside the agency, the agency shall specifically identify in the initial or final cost-benefit analysis the data or information gathered or explained and the person who gathered or explained it, and shall describe the arrangement by which the information was procured by the agency, including the total amount of funds expended for such procurement.

"(g)(1) Each person subject to a major rule may petition for the issuance of a cost-benefit analysis for the rule, including a major rule in effect on the date of enactment of this subchapter for which a cost-benefit analysis meeting the requirements of this subchapter has not been performed.

"(2) The agency shall grant the petition and promptly conduct the analysis sought if the agency determines that the rule is a rule for which a cost-benefit analysis is required under this subchapter. If the rule does not satisfy the decisional criteria set forth in section 623, then the agency shall take immediate action to either revoke or amend the rule to conform the rule to the requirements of this subchapter and the decisional criteria under section 623.

"(3) The agency shall grant or deny a petition made pursuant to this subsection, and give written notice of its determination to the petitioner, with reasonable promptness, but in no event later than 180 days after the petition was received by the agency. The written notice of the agency's determination shall include an explanation of the determination and a response to each factual and legal claim that forms the basis of the petition.

"§ 623. Decisional criteria

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

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

"(2) the rule will substantially achieve greater net benefits to society than any of the reasonable alternatives identified pursuant to section 622(d)(2)(B).

Subject to the provisions of subsection (b), the requirements of this section shall supplement any other decisional criteria otherwise provided by law.

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

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

"(2) If the text of a statute expressly requires that a rule shall be promulgated even if the rule does not satisfy both criteria provided in subsection (a), the rule must impose lower net costs to society than any of the reasonable alternatives identified pursuant to section 622(d)(2)(B).

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

"(1) include a written explanation of such determination in the initial and final cost-benefit analysis required by section 622; and

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

"§ 624. Judicial review

"Any cost-benefit analysis of, or risk assessment concerning, a rule shall constitute part of the whole rulemaking record of agency action for the purpose of judicial review of the rule, and shall be considered by a court in determining the legality of the rule. The court shall apply

the same standards of judicial review that govern the review of agency findings under the statute granting the agency authority to conduct the rulemaking. The court shall set aside agency action that fails to satisfy the decisional criteria of section 623.

"§ 625. Deadlines for rulemaking

"(a) Beginning on the date of enactment of this section, all deadlines in statutes that require agencies to propose or promulgate any rule subject to this subchapter shall be suspended until such time as the requirements of this subchapter are satisfied.

"(b) Beginning on the date of enactment of this section, the jurisdiction of any court of the United States to enforce any deadline that would require an agency to propose or promulgate a rule subject to this chapter shall be suspended until such time as the requirements of this subchapter are satisfied.

"(c) In any case in which the failure to promulgate a rule by a deadline would create an obligation to regulate through individual adjudications, the deadline shall be suspended to allow the requirements of this subchapter to be satisfied.

"§ 626. Agency review of rules

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

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

"(i) each rule of the agency that is in effect on such effective date and which, if adopted on such effective date, would be a major rule under section 621(2)(A);

"(ii) each rule of the agency that is inconsistent or in conflict with any other obligation or requirement established by any Federal statute, rule, or other agency statement, interpretation, or action that has the force of law; and

"(iii) each rule of the agency in effect on the date of enactment of this section (in addition to the rules described in clauses (i) and (ii)) that the agency has selected for review.

"(B) Each proposed schedule required by subparagraph (A) shall include—

"(i) a brief explanation of the reasons the agency considers each rule on the schedule to be a major rule under section 621(2)(A), or the reasons why the agency selected the rule for review;

"(ii) a date set by the agency, in accordance with subsection (b)(1), for the completion of the review of each such rule; and

"(iii) a statement that the agency requests comments from the public on the proposed schedule.

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

"(2) Not later than 90 days before publishing in the Federal Register the proposed schedule required under paragraph (1), each agency shall make the proposed schedule available to the Director or a designee of the President, or to the Vice President or other officer to whom oversight authority has been delegated under section 643. The President or that officer may select for review in accordance with this section any additional rule.

"(3) Not later than 1 year after the date of enactment of this section, each agency shall publish in the Federal Register a final schedule for the review of the rules referred to in paragraphs (1) and (2). Each agency shall publish with the final schedule the response of the agency to comments received concerning the proposed schedule.

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

"(A) each rule on the schedule promulgated pursuant to subsection (a);

"(B) each major rule under section 621(2) promulgated, amended, or otherwise renewed by an agency after the date of the enactment of this section; and

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

"(2) Except as provided pursuant to subsection (f), the review of a rule required by this section shall be completed not later than 10 years after the date of enactment of this section or 10 years after the date on which the rule is promulgated, amended, or renewed, whichever is earlier.

"(c) An agency shall publish in the Federal Register a notice of its proposed action under this section with respect to a rule being reviewed. The notice shall include—

"(1) an identification of the specific statutory authority under which the rule was promulgated and an explanation of whether the agency's interpretation of the statute is expressly required by the current text of that statute or, if not, whether it is

within the range of permissible interpretations of the statute;

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

"(3) an explanation of the proposed agency action with respect to the rule, including action to repeal or amend the rule to resolve inconsistencies or conflicts with any other obligation or requirement established by any Federal statute, rule, or other agency statement, interpretation, or action that has the force of law; and

"(4) a statement that the agency seeks proposals from the public for modifications or alternatives to the rule which may accomplish the objectives of the rule in a more effective or less burdensome manner.

"(d) If an agency proposes to repeal or amend a rule under review pursuant to this section, the agency shall, after issuing the notice required by subsection (c), comply with the provisions of this chapter, chapter 5, and any other applicable law. The requirements of such provisions and related requirements shall apply to the same extent and in the same manner as in the case of a proposed agency action to repeal or amend a rule that is not taken pursuant to the review required by this section.

"(e) If an agency proposes to renew without amendment a rule under review pursuant to this section, the agency shall—

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

"(2) publish in the Federal Register notice of the renewal of such rule, an explanation of the continued need for the rule, and, if the renewed rule is a major rule under section 621(2), an explanation of the reasonable determination of the agency that the rule complies with section 623.

"(f) Any agency, which for good cause finds that compliance with this section with respect to a particular rule during the period provided in subsection (b) of this section is contrary to an important public interest may request the President, or the officer designated by the President pursuant to subsection (a)(2), to establish a period longer than 10 years for the completion of the review of such rule. The President or that officer may extend the period for review of a rule to a total period of not more than 15 years. Such extension shall be published in the Federal Register with an explanation of the reasons therefor.

"(g) In any case in which an agency has not completed the review of a rule within the period prescribed by subsection (b) or (f) of this section, the agency shall immediately publish in the Federal Register a notice proposing to amend, repeal, or renew the rule under subsection (c), and shall complete proceedings pursuant to subsection (d) or (e) not later than 180 days after the date on which the review was required to be completed under subsection (b) or (f).

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

"SUBCHAPTER III—RISK ASSESSMENTS

"§ 631. Definitions

"For purposes of this subchapter—

"(1) the term 'best estimate' means an estimate that, to the extent feasible and scientifically appropriate, is based on—

"(A) central estimates of risk using the most plausible assumptions;

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

"(C) any other methodology designed to provide the most unbiased representation of the most plausible level of risk, given the current scientific information available to the agency concerned;

"(2) the term 'emergency' means a clearly imminent and substantial endangerment to public health or the environment;

"(3) the term 'hazard identification' means identification of a substance, activity, or condition as potentially posing a risk to human health or safety or the environment based on empirical data, measurements, or testing showing that it has caused significant adverse effects at some levels of dose or exposure not necessarily relevant to level of dose or exposure that are normally expected to occur;

"(4) the term 'negative data' means data indicating that under certain conditions a given substance or activity did not induce an adverse effect;

"(5) the term 'risk assessment' means—

"(A) the iterative process of identifying hazards, and quantifying (to the maximum extent practicable) or describing the degree of toxicity, exposure, or other risk the hazards

pose for exposed individuals, populations, or resources; and

"(B) the document containing the explanation of how the assessment process has been applied to an individual substance, activity, or condition;

"(6) the term 'risk characterization'—

"(A) means the element of a risk assessment that involves presentation of the degree of risk to individuals and populations expected to be protected, as presented in any regulatory proposal or decision, report to Congress, or other document that is made available to the public; and

"(B) includes discussions of uncertainties, conflicting data, estimates, extrapolations, inferences, and opinions; and

"(7) the term 'substitution risk' means a potential increased risk to human health, safety, or the environment resulting from market substitutions, a reduced standard of living, or a regulatory alternative designed to decrease other risks.

"§ 632. Applicability

"(a) Except as provided in subsection (b), this subchapter shall apply to all risk assessments and risk charac-

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

"(b)(1) This subchapter shall not apply to risk assessments or risk characterizations performed with respect to—

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

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

"(C) a health, safety, or environmental inspection or individual facility permitting action; or

"(D) a screening analysis clearly identified as such.

"(2)(A) An analysis shall not be treated as a screening analysis for the purposes of paragraph (1)(D) if the result of the analysis is used—

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

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

"(B) Among the analyses that may be treated as a screening analyses for the purposes of paragraph (1)(D) are product registrations, reregistrations, tolerance settings, and reviews of premanufacture notices and existing chemicals under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. 2601 et seq.).

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

"§ 633. Rule of construction

"Nothing in this subchapter shall be construed to—

"(1) 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

"(2) require the disclosure of any trade secret or other confidential information.

"§ 634. Requirement to prepare risk assessments

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

chapter, or is subject to a granted petition for review pursuant to section 553(e) or 622(g)—

"(1) a risk assessment in accordance with this subchapter;

"(2) for each such proposed or final rule, an assessment, quantified to the extent feasible, of incremental risk reduction or other benefits associated with each significant regulatory alternative to the rule or proposed rule; and

"(3) for each such proposed or final rule, quantified to the extent feasible, a comparison of any human health, safety, or environmental risks addressed by the regulatory alternatives to other relevant risks chosen by the head of the agency, including at least 3 other risks regulated by the agency and to at least 3 other risks with which the public is familiar.

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

"§ 635. Principles for risk assessment

"(a)(1) The head of each agency shall apply the principles set forth in subsection (b) when preparing any risk

assessment, whether or not required by section 634, to ensure that the risk assessment and all of its components—

"(A) distinguish scientific findings and best estimates of risk from other considerations;

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

"(C) rely, to the extent available and practicable, on scientific findings.

"(2) An agency shall not be required to repeat discussions or explanations required under this section in each risk assessment document if there is a reference to the relevant discussion or explanation in another agency document.

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

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

"(B) When conflicts among such data appear to exist, or when animal data are used as a basis to assess human health, the assessment shall include a

discussion of possible reconciliation of conflicting information, and, as appropriate, differences in study designs, mechanisms of action, comparative physiology, routes of exposure, bioavailability, pharmacokinetics, and any other relevant factor, including the availability of raw data for review. Greatest emphasis shall be placed on data that indicates the biological basis of the resulting harm in humans. Animal data shall be reviewed with regard to relevancy to humans.

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

"(A) present a representative description and explicit explanation of plausible and alternative similar assumptions, inferences, or models (including the assumptions incorporated into the model) and the sensitivity of the conclusions to them;

"(B) explain the basis for any choices;

"(C) identify any science policy or value judgments;

"(D) describe any model used in the risk-assessment and make explicit the assumptions incorporated into the model; and

"(E) indicate the extent to which any significant model has been validated by, or conflicts with, empirical data.

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

"(4) A risk assessment shall be prepared at the level of detail appropriate and practicable for reasoned decisionmaking on the matter involved, taking into consideration the significance and complexity of the decision and any need for expedition.

"§ 636. Principles for risk characterization and communication

"In characterizing risk in any risk assessment document, regulatory proposal or decision, report to Congress, or other document that is made available to the public, each agency characterizing the risk shall comply with each of the following:

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

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

"(i) shall provide—

"(I) the best estimate or estimates for the specific populations or natural resources that are the subject of the characterization (based on the information available to the department, agency, or instrumentality) or, in lieu of a single best estimate, an array of multiple estimates (showing the distribution of estimates and the best estimate) based on assumptions, inferences, or models which are equally reasonably plausible, given current scientific understanding;

"(II) a statement of the reasonable range of scientific uncertainties; and

"(III) descriptions of the distribution and probability of risk estimates to reflect differences in exposure variability in populations and uncertainties;

"(ii) in addition to a best estimate or estimates, may present plausible upper-bound or conservative estimates, but only in conjunction

with equally plausible lower-bound estimates; and

"(iii) shall ensure that, where a safety factor, as distinguished from an inherent quantitative uncertainty factor, is used, such factor shall reflect safety factors commonly used to ensure human safety in other human activities.

"(2) The head of the agency shall explain the exposure scenarios used in any risk assessment, and, to the extent feasible, provide a statement of the size of the corresponding population at risk and the likelihood of such exposure scenarios.

"(3) To the extent feasible, the head of the agency shall provide a statement that places the nature and magnitude of individual and population risks to human health in context.

"(4) When a Federal agency provides a risk assessment or risk characterization for a proposed or final regulatory action, such assessment or characterization shall include a statement of any significant substitution risks to human health identified by the agency or contained in information provided to the agency by a commentator.

"(5) An agency shall present a summary in connection with the presentation of the agency's risk assessment or the regulation if—

"(A) the agency provides a public comment period with respect to a risk assessment or regulation;

"(B) a commentator provides a risk assessment, and a summary of results of such risk assessment; and

"(C) such risk assessment is reasonably consistent with the principles and the guidance provided under this subtitle,

"§ 637. Regulations; plan for assessing new information

"(a)(1) Not later than 1 year after the date of enactment of this subchapter, the Director or a designee of the President shall—

"(A) issue a final regulation that has been subject to notice and comment under section 553 that directs agencies to implement the risk assessment and characterization principles set forth in sections 635 and 636; and

"(B) provide a format for summarizing risk assessment results.

"(2) The regulation under paragraph (1) shall be sufficiently specific to ensure that risk assessments are conducted consistently by the various agencies.

"(b)(1) Review of the risk assessment for any major rule shall be conducted by the head of the agency on the written petition of a person showing a reasonable likelihood that—

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

"(B) the risk assessment produces substantially different results;

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

"(D) the risk assessment does not take into account material significant new scientific data or scientific understanding.

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

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

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

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

"(5) A risk assessment completed pursuant to a petition may be the basis for initiating a regulatory review pursuant to section 622(g).

"(c) The regulations under this section shall be developed after notice and opportunity for public comment, and after consultation with representatives of appropriate State agencies and local governments, and such other departments, agencies, offices, organizations, or persons as may be advisable.

"(d) At least every 4 years, the Director or a designee of the President shall review, and when appropriate, revise, the regulations published under this section.

"§ 638. Decisional criteria

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

"(1) the risk assessment under section 634 is based on a scientific and unbiased evaluation, reflecting realistic exposure scenarios, of the risk ad-

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

"(2) 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 achieve an equivalent reduction in risk in a more cost-effective and flexible manner.

"§ 639. Establishment of program

"(a) The Director of the Office of Science and Technology shall develop a systematic program for the peer review of work products covered by subsection (c), which program shall be used uniformly across the agencies.

"(b) The program under subsection (a)—

"(1) shall provide for the creation of peer review panels consisting of independent and external experts who are broadly representative and balanced to the extent feasible;

"(2) shall not exclude peer reviewers merely because they represent entities that may have a potential interest in the outcome, if that interest is fully disclosed;

"(3) shall exclude, to the maximum extent practicable, any peer reviewer who has been involved in

any previous analysis of the tests and evidence presented for certification by the peer review panel; and

"(4) shall provide for a timely completed peer review, meeting agency deadlines, which contains a balanced presentation of all considerations, including minority reports and an agency response to all significant peer review comments.

"(c) The draft peer review and the agency's responses shall be made available to the public for comment and shall be made part of the administrative record of the final peer review for purposes of judicial review of any final agency action.

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

"SUBCHAPTER IV—EXECUTIVE OVERSIGHT

"§ 641. Procedures

"The Director or a designee of the President shall—

"(1) establish procedures for agency compliance with this chapter; and

"(2) monitor, review, and ensure agency implementation of such procedures.

"§ 642. Promulgation and adoption

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

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

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

"(2) The time for review of any final analysis required under chapter 6 shall not exceed 30 days following the receipt of the analysis by the Director, a designee of the President, or such officer.

"(3)(A) The times for each such review may be extended for good cause by the President or such officer for an additional 30 days.

"(B) Notice of any such extension, together with a succinct statement of the reasons therefor, shall be inserted in the rulemaking file.

"§ 643. Delegation of authority

"(a) The President may delegate the authority granted by this subchapter to the Vice President or to an officer within the Executive Office of the President whose ap-

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

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

"(2) Any notice with respect to a delegation to the Vice President shall contain a statement by the Vice President that the Vice President will make every reasonable effort to respond to congressional inquiries concerning the exercise of the authority delegated under this section.

"§ 644. Judicial review

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

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

"§ 611. Judicial review

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

"(A) certified, pursuant to section 605(b), that such rule would not have a significant economic impact on a substantial number of small entities;

"(B) prepared a final regulatory flexibility analysis pursuant to section 604; or

"(C) did not prepare an initial regulatory flexibility analysis pursuant to section 603 or a final regulatory flexibility analysis pursuant to section 604 except as permitted by sections 605 and 608,

an affected small entity may petition for the judicial review of such certification, analysis, or lack of analysis, in accordance with this subsection. A court having jurisdiction to review such rule for compliance with section 553 or under any other provision of law shall have jurisdiction to review such certification or analysis.

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

"(B) If an agency delays the issuance of a final regulatory flexibility analysis pursuant to section 608(b), a petition for judicial review under this subsection shall be filed not later than 2 years after the date the analysis is made available to the public.

"(3) For purposes of this subsection, the term 'affected small entity' means a small entity that is or will be adversely affected by the final rule.

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

"(5)(A) Notwithstanding section 605, if the court determines, on the basis of the rulemaking record, that there is substantial evidence to conclude that the rule would have a significant economic impact on a substantial number of small entities, the court shall order the agency to prepare a final regulatory flexibility analysis pursuant to section 604.

"(B) If the agency prepared a final regulatory flexibility analysis, the court may order the agency to take corrective action consistent with section 604 if the court determines, on the basis of the rulemaking record, that the final regulatory flexibility analysis was prepared by the agency without complying with section 604.

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

"(A) to prepare the analysis required by section 604; or

"(B) to take corrective action consistent with section 604.

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

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

"(c) Nothing in this section bars judicial review of any other impact statement or similar analysis required by any other law if judicial review of such statement or analysis is otherwise provided by law.".

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

(c) PRESIDENTIAL AUTHORITY.—Nothing in this Act shall limit the exercise by the President of the authority and responsibility that the President otherwise possesses

under the Constitution and other laws of the United States with respect to regulatory policies, procedures, and programs of departments, agencies, and offices.

(d) TECHNICAL AND CONFORMING AMENDMENTS.—

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

"CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS

"SUBCHAPTER I—REGULATORY ANALYSIS

"SUBCHAPTER II—ANALYSIS OF AGENCY RULES

"SUBCHAPTER III—RISK ASSESSMENTS

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

"SUBCHAPTER I—REGULATORY ANALYSIS".

SEC. 5. JUDICIAL REVIEW.

(a) DEFINITIONS.—Section 701(b)(2) of title 5, United States Code, is amended by inserting before the period at the end the following: ", except that 'agency action' does not include action or inaction alleged to constitute a breach of contract or to cause an inability to perform, or to frustrate the purpose of a contract, where jurisdiction over a claim raising such an allegation would be proper under section 1346(a)(2) or 1491(a)(1) of title 28, United States Code".

(b) RIGHT OF REVIEW.—Section 702 of title 5, United States Code, is amended—

(1) in the second sentence by striking "seeking relief other than money damages and"; and

(2) in the last sentence by striking "or impliedly".

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

(d) SCOPE OF REVIEW.—Section 706 of title 5, United States Code, is amended to read as follows:

"§ 706. Scope of Review

"(a) To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

"(1) compel agency action unlawfully withheld or unreasonably delayed; and

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

"(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

"(B) contrary to constitutional right, power, privilege, or immunity;

"(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

"(D) without observance of procedure required by law;

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

"(F) without substantial support in the rulemaking file, viewed as a whole, for the asserted or necessary factual basis, as distinguished from the policy or legal basis, of a rule adopted in a proceeding subject to section 553; and

"(G) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court; and

"(3) award monetary relief, including money damages, where appropriate.

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

"(c) In reviewing an agency interpretation of a statute governing the authority for an agency action, including agency action taken pursuant to a statute that provides for review of final agency action, the reviewing court shall—

"(1) hold erroneous and unlawful—

"(A) an agency interpretation that is other than the interpretation of the statute clearly intended by Congress; or

"(B) an agency interpretation that is outside the range of permissible interpretations of the statute; and

"(2) hold arbitrary, capricious, or an abuse of discretion—

"(A) an agency action as to which the agency has not explained in a reasoned analysis why it selected the interpretation, rather than other permissible interpretations of the statute; or

"(B) in the case of agency action subject to chapter 6 of this title, an interpretation that does not give the agency the broadest discretion to develop rules that will satisfy the decisional criteria of section 623.

"(d) Notwithstanding any other provision of law, the provisions of this subsection shall apply to, and supplement, the requirements contained in any statute for the review of final agency action which is not otherwise subject to this subsection.".

(e) COURT OF FEDERAL CLAIMS.—

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

(A) in paragraph (1), by amending the first sentence to read as follows: "The United States Court of Federal Claims shall have jurisdiction to render judgment upon any claim against the United States for monetary relief founded either upon the Constitution or any Act of Congress or any regulation of an executive department, or upon any expressed or implied contract with the United States, in cases not sounding in tort, or for invalidation of any Act of Congress or any regulation of an executive department that adversely affects private property rights in violation of the fifth amendment of the United States Constitution.";

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

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

"(4) In cases otherwise within its jurisdiction, the Court of Federal Claims shall also have ancillary jurisdic-

tion, concurrent with the courts designated in section 1346(b), to render judgment upon any related tort claim authorized under section 2674.

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

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

SEC. 6. CONGRESSIONAL REVIEW.

(a) IN GENERAL.—Title 5, United States Code, is amended by inserting immediately after chapter 7 the following new chapter:

"CHAPTER 8—CONGRESSIONAL REVIEW OF AGENCY RULEMAKING

"§ 801. Congressional review of agency rulemaking

"(a)(1) Before a rule takes effect as a final rule, the agency promulgating such rule shall submit to the Congress a report containing a copy of the rule, the notice of proposed rulemaking, and the statement of basis and purpose for the rule, including a complete copy of any analysis required under chapter 6 of this title, and the proposed effective date of the rule. In the case of a rule that is not a major rule within the meaning of section

621(2), summary of the rulemaking proceedings shall be submitted.

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

"(A) The later of the date occurring 45 days after the date on which—

"(i) the Congress receives the report submitted under paragraph (1); or

"(ii) the rule is published in the Federal Register.

"(B) If the Congress passes a joint resolution of disapproval described under subsection (g) relating to the rule, and the President signs a veto of such resolution, the earlier date—

"(i) on which either House of Congress votes and fails to override the veto of the President; or

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

"(C) The date the rule would have otherwise taken effect, if not for this section (unless a joint resolution of disapproval under subsection (g) is approved).

"(b) A rule shall not take effect as a final rule if the Congress passes a joint resolution of disapproval described under subsection (g).

"(c)(1) Notwithstanding any other provision of this section (except subject to paragraph (3)), a rule that would not take effect by reason of this section may take effect if the President makes a determination under paragraph (2) and submits written notice of such determination to the Congress.

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

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

"(B) necessary for the enforcement of criminal laws; or

"(C) necessary for national security.

"(3) An exercise by the President of the authority under this subsection shall have no effect on the procedures under subsection (g) or the effect of a joint resolution of disapproval under this section.

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

"(d)(1) Subsection (g) shall apply to any rule that is published in the Federal Register (as a rule that shall take effect as a final rule) during the period beginning on the date occurring 60 days before the date the Congress adjourns sine die through the date on which the succeeding Congress first convenes.

"(2) For purposes of subsection (g), a rule described under paragraph (1) shall be treated as though such rule were published in the Federal Register (as a rule that shall take effect as a final rule) on the date the succeeding Congress first convenes.

"(3) During the period between the date the Congress adjourns sine die through the date on which the succeeding Congress first convenes, a rule described under paragraph (1) shall take effect as a final rule as otherwise provided by law.

"(e) Any rule that takes effect and later is made of no force or effect by the enactment of a joint resolution under subsection (g) shall be treated as though such rule had never taken effect.

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

"(g)(1) For purposes of this subsection, the term 'joint resolution' means only a joint resolution introduced after the date on which the report referred to in subsection (a) is received by Congress the matter after the resolving clause of which is as follows: 'That Congress disapproves the rule submitted by the _____ relating to _____, and such rule shall have no force or effect.' (The blank spaces being appropriately filled in.)

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

"(B) For purposes of this subsection the term 'submission or publication date' means the later of the date on which—

"(i) the Congress receives the report submitted under subsection (a)(1); or

"(ii) the rule is published in the Federal Register.

"(3) If the committee to which a resolution described in paragraph (1) is referred has not reported such resolution (or an identical resolution) at the end of 20 calendar days after its submission or publication date, such committee may be discharged by the Majority Leader of the

Senate or the Majority Leader of the House of Representatives, as the case may be, from further consideration of such resolution and such resolution shall be placed on the appropriate calendar of the House involved.

"(4)(A) When the committee to which a resolution is referred has reported, or when a committee is discharged (under paragraph (3)) from further consideration of, a resolution described in paragraph (1), it shall at any time thereafter be in order (even though a previous motion to the same effect has been disagreed to) for any Member of the respective House to move to proceed to the consideration of the resolution, and all points of order against the resolution (and against consideration of the resolution) shall be waived. The motion shall be highly privileged in the House of Representatives and shall be privileged in the Senate and shall not be debatable. The motion shall not be subject to amendment, or to a motion to postpone, or to a motion to proceed to the consideration of other business. A motion to reconsider the vote by which the motion is agreed to or disagreed to shall not be in order. If a motion to proceed to the consideration of the resolution is agreed to, the resolution shall remain the unfinished business of the respective House until disposed of.

"(B) Debate on the resolution, and on all debatable motions and appeals in connection therewith, shall be lim-

ited to not more than 10 hours, which shall be divided equally between those favoring and those opposing the resolution. A motion further to limit debate shall be in order and shall not be debatable. An amendment to, or a motion to postpone, or a motion to proceed to the consideration of other business, or a motion to recommit the resolution shall not be in order. A motion to reconsider the vote by which the resolution is agreed to or disagreed to shall not be in order.

"(C) Immediately following the conclusion of the debate on a resolution described in paragraph (1), and a single quorum call at the conclusion of the debate if requested in accordance with the rules of the appropriate House, the vote on final passage of the resolution shall occur.

"(D) Appeals from the decisions of the Chair relating to the application of the rules of the Senate or the House of Representatives, as the case may be, to the procedure relating to a resolution described in paragraph (1) shall be decided without debate.

"(5) If, before the passage by one House of a resolution of that House described in paragraph (1), that House receives from the other House a resolution described in paragraph (1), then the following procedures shall apply:

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

"(B) With respect to a resolution described in paragraph (1) of the House receiving the resolution—

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

"(ii) the vote on final passage shall be on the resolution of the other House.

"(6) This subsection is enacted by Congress—

"(A) as an exercise of the rulemaking power of the Senate and House of Representatives, respectively, and as such it is deemed to be a part of the rules of each House, respectively, but applicable only with respect to the procedure to be followed in that House in the case of a resolution described in paragraph (1), and it supersedes other rules only to the extent that it is inconsistent with such rules; and

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

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

"8. Congressional Review of Agency Rulemaking ..... 801".

SEC. 7. STUDIES AND REPORTS.

(a) RISK ASSESSMENTS.—The Administrative Conference of the United States shall—

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

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

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

(1) carry out a study of the operation of the Administrative Procedure Act (as amended by section 3 of this Act); and

(2) submit a report to the Congress on the findings of the study, including proposals for revision, if any.