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THE COMPREHENSIVE REGULATORY REFORM ACT OF 1995—S. 343

MAY 26 (legislative day, MAY 15), 1995.—Ordered to be printed

Mr. ROTH (for Mr. HATCH), from the Committee on the Judiciary, submitted the following

REPORT

together with

ADDITIONAL AND SUPPLEMENTAL VIEWS

[To accompany S. 343]

The Committee on the Judiciary, to which was referred the bill (S. 343) to require Federal agencies to analyze rules to improve their effectiveness and to decrease their compliance costs, to provide for periodic review of regulations, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill, as amended, do pass.

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The amendment is as follows:

99–010

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 "this chapter and chapters 6, 7, and 8";

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

(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, guidance, or rule of agency organization, procedure, or practice that is not generally applicable and 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(4);

"(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 explanation 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;

"(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 is 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 (1) and (2), 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)(i) an explanation of whether the specific statutory interpretation upon which the rule is based is expressly required by the text of the statute; or

"(ii) if the specific statutory interpretation upon which the rule is based is not expressly required by the text of the statute, an explanation that the interpretation is within the range of permissible interpretations of the statute as identified by the agency, and why the agency has rejected other interpretations proposed in comments to the agency;

"(D) 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

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

"(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, interpretive rule, general statement of policy, or guidance; and

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

"(3)(A) Any person subject to a rule, interpretive rule, general statement of policy, or guidance may petition an agency for the amendment or repeal of any rule, interpretive rule, general statement of policy, or guidance.

"(B) If such petition presents a reasonable likelihood that, considering its future impact, the rule, interpretive rule, general statement of policy, or guidance is, or has the effect of, a major rule within the meaning of section 621(4), and its amendment or repeal is required to satisfy the decisional criteria of section 624, the agency shall grant the petition and shall, within one year, conduct a cost-benefit analysis under chapter 6.

"(C) If, considering its future impact, the rule, interpretive rule, general statement of policy, or guidance does not satisfy the requirements of chapter 6, including the decisional criteria set forth in section 624, the agency shall take immediate action either to revoke or to amend the rule, interpretive rule, general statement of policy, or guidance to conform it to the requirements of chapter 6, including the decisional criteria in section 624.

"(4) 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.

"(5) Following a decision to grant or deny a petition to conduct a cost-benefit analysis for a rule, interpretive rule, general statement of policy, or guidance under this subsection, no further petition for such rule, interpretive rule, general statement of policy, or guidance, submitted by the same person, shall be considered by any agency unless such petition is based on a change in a fact, circumstance, or provision of law underlying or otherwise related to the rule, interpretive rule, general statement of policy, or guidance occurring since the initial petition was granted or denied, that warrants the amendment or repeal of the rule, interpretive rule, general statement of policy, or guidance.

"(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.

"(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, this section 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—

"(1) the term 'benefit' means the reasonably identifiable significant incremental 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;

"(2) the term 'cost' means the reasonably identifiable significant incremental 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;

"(3) 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;

"(4)(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, health, safety, or the environment, 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;

"(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 freely 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;

"(6) the term 'performance-based standards' means requirements, expressed in terms of outcomes or goals rather than mandatory means of achieving outcomes or goals, that permit the regulated entity discretion to determine how best to meet specific requirements in particular circumstances;

"(7) the term 'reasonable alternatives' means the range of regulatory options that the agency has discretion to consider under the text of the statute granting rulemaking authority, interpreted, to the maximum extent possible, to embrace the broadest range of options that satisfy the decisional criteria of section 624(b); and

"(8) the term 'rule' has the same meaning as in section 551(4), 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—

"(i) 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;

"(ii) a rule relating to monetary policy or to the safety or soundness of Federally insured depository institutions or any affiliate of such an institution (as defined in section 2(k) of the Bank Holding Company Act of 1956), credit unions, Federal Home Loan Banks, government sponsored housing enterprises, farm credit institutions, foreign banks that operate in the United States and their affiliates, branches, agencies, commercial lending companies, or representative offices, (as those terms are defined in section 1 of the International Banking Act of 1978); or

"(iii) a rule relating to the payment system or the protection of deposit insurance funds or the farm credit insurance fund.

"§ 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(4)(A)(i) and, if it is not, whether it should be designated a major rule under section 621(4)(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(4)(A)(i) and has not designated the rule a major rule within the meaning of section 621(4)(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 in the same manner as if the initial 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 that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority, as supplemented by the decisional criteria in section 624, for achieving identified benefits, including, where appropriate, 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 or performance-based standards, market-based mechanisms, or other flexible regulatory alternatives that permit the greatest flexibility in achieving the identified benefits of the proposed rule;

"(D) an assessment of the feasibility of establishing a regulatory program that operates through the application of voluntary programs, voluntary consensus standards, performance-based standards, market-based mechanisms, or other flexible regulatory alternatives;

"(E) in any case in which the proposed rule is based on one or more scientific evaluations, scientific information, or a risk assessment, or is subject to the risk assessment requirements of subchapter III, a description of the actions undertaken by the agency to verify the quality, reliability, and relevance of such scientific evaluations or scientific information in accordance with the 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 or, where applicable, lower net costs, than any of the alternatives to the proposed rule, including alternatives identified in accordance with subparagraphs (C) and (D).

"(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 flexible regulatory alternatives identified pursuant to subsection (c)(2) (C) and (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 or, where section 624(c) applies, lower net costs, than any of the reasonable alternatives that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority, as supplemented by the decisional criteria in section 624, for achieving identified benefits, including, where appropriate, alternatives referred to in subsection (c)(2) (C) and (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 and appropriate, 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 relevant information 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.

"§ 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 and the amendment or repeal requested.

"(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, considering the future impact of the rule—

"(A) the rule is a major rule; and

"(B) the proposed amendment or repeal of the rule is required to satisfy the decisional criteria of section 624.

"(4) A decision to grant, or final agency action to deny, a petition under this subsection shall be made not later than 180 days after submittal.

"(5) Following a decision to grant or deny a petition to conduct a cost-benefit analysis for a rule under this subsection, no further petition for such rule, submitted by the same person, shall be considered by any agency, the Director, or a designee of the President, unless such petition is based on a change in a fact, circumstance, or provision of law underlying or otherwise related to the rule occurring since the initial petition was granted or denied, that warrants the amendment or repeal of the rule.

"(b) Not later than 1 year after the date on which a petition has been granted for a major rule under subsection (a), the agency shall conduct a cost-benefit analysis in accordance with this subchapter, and shall propose amendments to, or repeal of, the rule if required by the decisional criteria set forth in 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 interpretive rule, guidance, or general statement of policy that would have the effect of a major rule if the interpretive rule, guidance, or general statement of policy had been adopted as a rule.

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

"(4) A decision to grant, or final agency action to deny, a petition under this subsection shall be made not later than 180 days after the petition is submitted.

"(e) For each interpretative rule, guidance, or general statement of policy for which a petition has been granted under subsection (d), the agency shall—

"(1) immediately withdraw the interpretive rule, guidance, or general statement of policy; or

"(2) within one year, propose a rule in compliance with this subchapter incorporating, with such modifications as the agency considers appropriate, the regulatory standards or criteria contained in such interpretive rule, general statement of policy, or guidance.

"(f) Upon withdrawing an interpretive rule, guidance, or general statement of policy, or where such interpretive rule, guidance, or general statement of policy is not withdrawn and a final rule is not promulgated within 2 years of granting a petition under subsection (d), the agency shall be prohibited from enforcing against any person the regulatory standards or criteria contained in such interpretive rule, guidance, or general statement of policy, unless and until they are included in a rule promulgated in accordance with this subchapter.

"(g)(1) Any person subject to a major rule may petition the relevant agency to modify or waive the specific requirements of the major rule and to authorize such person to demonstrate compliance through alternative means not otherwise permitted by the major rule. The petition shall identify with reasonable specificity the requirements for which the waiver is sought and the alternative means of compliance being proposed.

"(2) The agency shall grant the petition if the petition shows that there is a reasonable likelihood that the proposed alternative means of compliance would achieve the specific benefits of the major rule with an equivalent or greater level of protection of health, safety, and the environment than would be provided by the major rule, and would not impose an undue burden on the agency that would be responsible for enforcing such alternative means of compliance.

"(3) Following a decision to grant or deny a petition under this subsection, no further petition for such rule, submitted by the same person, shall be considered by any agency unless such petition is based on a change in a fact, circumstance, or provision of law underlying or otherwise related to the rule occurring since the initial petition was granted or denied, that warrants the granting of such further petition.

"§ 624. Decisional criteria

"(a) The requirements of this section shall supplement any other decisional criteria otherwise provided by law.

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

"(1) the potential benefits from the rule justify the potential costs of the rule; and

"(2) the rule will produce the most cost-effective result of any of the reasonable alternatives that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority.

"(c) If a statute requires or permits that a rule be promulgated and that rule cannot, applying the express decisional criteria in the statute, satisfy the criteria provided in subsection (b), the agency shall not promulgate the rule unless the rule imposes—

"(1) lower costs than any of the reasonable alternatives; or

"(2) the least costs taking into account benefits that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority.

"(d) If an agency promulgates a rule that is subject to subsection (c), the agency shall prepare a written explanation of why the agency was required to promulgate a rule with potential costs that were not justified by the potential benefits and shall

transmit that explanation along with 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 agency action under this subchapter.

"(b)(1) 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 and shall be considered by a court in determining the legality of the agency action, but only to the extent that it relates to the agency's decisional responsibilities under section 624 or the statute granting the agency authority to take the agency action.

"(2) No analysis required by this subchapter shall be subject to judicial review separate or apart from judicial review of the agency action to which it relates.

"(3) 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 take the action.

"(4) The court shall set aside agency action that fails to satisfy the decisional criteria of section 624, applying the applicable judicial review standards.

"§ 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 by another deadline, the deadline for such regulation 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, considering its future impact, would be a major rule under this subchapter;

"(ii) each rule of the agency that is inconsistent or incompatible with, or duplicative of, 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(4)(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 sched-

ule 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(4) 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 in subsection (f)—

"(A) in the case of a regulation that takes effect after the date of enactment of this section, the regulation shall terminate on the date that is 5 years after the date on which the regulation takes effect, unless the review required by this section has been completed by the date that is 5 years after the date on which the regulation takes effect; and

"(B) in the case of a regulation in effect on the date of enactment of this section, the regulation shall terminate on the date that is 7 years after the date of enactment of the Regulatory Reform Act of 1995, unless the review required by this section has been completed by the date that is 7 years after the date of enactment of the Regulatory Reform Act of 1995.

"(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, an explanation 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;

"(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(4), an explanation of how 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) is contrary to an important public interest, may request the President, or an officer designated by the President, to establish a period longer than 5 years, in the case of a regulation that takes effect after the date of enactment of this section, or 7 years, in the case of a regulation in effect on the date of enactment of this section, 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 10 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 issue 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.

"§ 628. Special rule

"Notwithstanding any other provision of the Comprehensive Regulatory Reform Act of 1995, or the amendments made by such Act, for purposes of this subchapter and subchapter IV, the head of each appropriate Federal banking agency (as defined in section 3(q) of the Federal Deposit Insurance Act), the National Credit Union Administration, the Federal Housing Finance Board, the Office of Federal Housing Enterprise Oversight, and the Farm Credit Administration, shall have authority with respect to such agency that otherwise would be provided under such subchapters to the Director, a designee of the President, Vice President, or any officer designated or delegated with authority under such subchapters.

"SUBCHAPTER III—RISK ASSESSMENTS

"§ 631. Definitions

"For purposes of this subchapter—

"(1) the term 'benefit' has the meaning given such term in section 621(1);

"(2) 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 and realistic 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 plausible and realistic level of risk, given the current scientific information available to the agency concerned;

"(3) the term 'cost' has the meaning given such term in section 621(2);

"(4) the term 'cost-benefit analysis' has the meaning given such term in section 621(3);

"(5) the term 'emergency' means an actual, immediate, and substantial endangerment to health, safety, or the human environment;

"(6) the term 'hazard identification' means identification of a substance, activity, or condition that may cause to health, 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 combined degree of toxicity and actual exposure, or other risk the hazards pose for individuals, populations, or natural resources; and

"(7) the term 'major cleanup plan' means any proposed or final environmental cleanup plan for a facility, or Federal guidelines for the issuance of any such plan, the expected costs, expenses, and damages of which are likely to exceed, in the aggregate, $10,000,000, including a corrective action requirement under the Solid Waste Disposal Act (notwithstanding section 4(b)(1)(C) of such Act, but only to the extent of such requirement), a removal or remedial action under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, and any other environmental restoration or damage assessment carried out by, on behalf of, or as required or ordered by, an agency or Federal court, or pursuant to the authority of a Federal statute with respect to any substance;

"(8) the term 'major rule' has the meaning given such term in section 621(4);

"(9) the term 'negative data' means data that fail to show that a given substance or activity induces an adverse effect under certain conditions;

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

"(A) the process of identifying hazards, and of quantifying (to the maximum extent practicable) or describing the combined degree of toxicity and actual exposure, or other risk the hazards pose for individuals, populations, or natural resources; and

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

"(11) 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) may include discussions of uncertainties, conflicting data, estimates, extrapolations, inferences, and opinions, as appropriate;

"(12) the term 'rule' has the meaning given such term in section 621(7); and

"(13) the term 'substitution risk' means a potential increased risk to 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 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 initiation of manufacture, of a substance, mixture, or product, or recognizes the marketable status of a product;

"(C) a health, safety, or environmental inspection, compliance or enforcement action, 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 previously authorized substance, product, or activity after its initial introduction into manufacture or commerce; or

"(ii) to characterize a finding of risk 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 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. 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 for a major rule 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, plausible, and realistic, and inclusive of all relevant data;

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

"(D) use situation- or decision-specific information to the maximum extent practicable.

"(2) An agency shall not be required to repeat discussions or explanations required under this section in each risk assessment document if there is an unambiguous reference to the relevant discussion or explanation in another reasonably available agency document that was prepared in accordance with this subchapter.

"(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, including negative data, and summarize the remaining data that finds, or fails to find, a correlation between a health risk and a substance 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. 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) give preference to the model, assumption, input parameter that represents the most plausible or realistic inference from supporting scientific information;

"(C) identify any science policy or value judgments and employ those judgments only where the policy determination has been approved by the head of the agency, after notice and opportunity for public involvement, as appropriate for the circumstance under consideration;

"(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) Risk assessments that provide a quantification or numerical output shall be calculated using the best estimate for each input parameter and shall use, as available, probabilistic descriptions of the uncertainty and variability associated with each input parameter.

"(4) 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.

"(5) 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.

"(6) Where relevant, practicable, and appropriate, data shall be developed consistent with standards for the development of test data promulgated pursuant to section 4 of the Toxic Substances Control Act, and standards for data requirements promulgated pursuant to section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act.

"(c)(1) The head of each agency shall promote early involvement by all stakeholders in the development of risk assessments that may support or affect agency rules, guidance, and other significant actions, by publishing as part of its semiannual regulatory agenda, required under section 602—

"(A) a list of risk assessments and supporting assessments, including hazard, dose or exposure assessments, under preparation or planned by the agency;

"(B) a brief summary of relevant issues addressed or to be addressed by each listed risk assessment or supporting assessment;

"(C) an approximate schedule for completing each listed risk assessment and supporting assessment;

"(D) an identification of potential rules, guidance, or other agency actions supported or affected by each listed risk assessment and supporting assessment; and

"(E) the name, address, and telephone number of an agency official knowledgeable about each listed risk assessment and supporting assessment.

"(2)(A) The head of each agency shall provide an opportunity for meaningful public participation and comment on any risk assessment throughout the regulatory process commensurate with the consequences of the decision to be made.

"(B) In cases where the risk assessment will support a major rule, the agency shall publish, at the earliest opportunity in the process, an advanced notice of relevant risk assessment related information that includes, at a minimum, an identification of—

"(i) all relevant hazard, dose, exposure, and other risk related documents that the agency plans to consider;

"(ii) all risk related guidance that the agency considers relevant;

"(iii) all hazard, dose, exposure, and other risk assumptions on which the agency plans to relay and the bases therefor; and

"(iv) all data and information deficiencies that could affect agency decisionmaking.

"(d)(1) No agency shall automatically incorporate or adopt any recommendation or classification made by an entity described in paragraph (2) concerning the health effects or value of a substance without an opportunity for notice and comment. Any risk assessment or risk characterization document adopted by an agency on the basis of such a recommendation or classification shall comply with this title.

"(2) An entity referred to in paragraph (1) includes—

"(A) any foreign government and its agencies;

"(B) the United Nations or any of its subsidiary organizations;

"(C) any international governmental body or standards-making organization; and

"(D) any other organization or private entity without that does not have a place of business located in the United States or its territories.

"§ 634. Principles for risk characterization and communication

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

"(1) The head of the agency shall describe the exposure scenarios used in any risk assessment, and, to the extent feasible, provide an estimate of the size of the corresponding population or natural resource at risk and the likelihood of such exposure scenarios.

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

"(A) the range and distribution of exposures derived from exposure scenarios used in a risk assessment, including, where appropriate, central and high-end estimates, but always including a best estimate of the risk to the general population;

"(B) the range and distribution of risk estimates, including best estimates and, where quantitative estimates of the range of distribution of risk estimates are not possible, a list of qualitative factors influencing the range of possible risks; and

"(C) a statement of the major sources of uncertainties in the hazard identification, dose-response, and exposure assessment phases of risk assessment and their influence on the results of the assessment.

"(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.

"§ 635. Requirement to prepare assessment

"(a) Except as provided in section 632 and in addition to any requirements applicable under subchapter II, the head of each agency shall prepare—

"(1) for each major rule relating to health, safety, or the environment, and for each major cleanup plan, that is proposed by the agency after the date of enactment of this subchapter, 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 623, a risk assessment in accordance with this subchapter;

"(2) for each such proposed or final plan, and each reasonable alternative within the statutory authority of the agency taking action, a cost-benefit analysis equivalent to that which would be required under subchapter II if subchapter II were applicable; and

"(3) for each such proposed or final plan, quantified to the extent feasible, a comparison of any 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 major cleanup plan is subject to this subchapter if—

"(1) construction has not commenced on a significant portion of the work required by the plan; or

"(2) if construction has commenced on a significant portion of the work required by the plan, unless—

"(A) it is more cost-effective to complete construction of the work than to apply the provisions of this subchapter; or

"(B) the application of the provisions of this subchapter, including any delays caused thereby, will result in an actual and immediate risk to human health or welfare.

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

"§ 636. Requirements for assessments

"(a) The head of the agency, subject to review by the Director or a designee of the President, shall make a determination that, notwithstanding any other provision of law—

"(1) for each major rule and major cleanup plan subject to this subchapter, the risk assessment required under section 635 is based on a scientific, plausible, and realistic evaluation, reflecting reasonable exposure scenarios, of the risk addressed by the major rule and is supported by the best available scientific data, as determined by a peer review panel in accordance with section 640; and

"(2) for each major cleanup plan subject to this subchapter, the plan has benefits that justify its costs and that there is no alternative that is allowed by the statute under which the plan 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 agency shall prohibit or refuse to approve a substance or product on the basis of safety where the substance or product presents a negligible or insignificant human risk under the intended conditions of use.

"(c) Notwithstanding any other provision of law, issuance of a record of decision or a final permit condition or administrative order containing a major cleanup plan, or denial of, or completion of agency review pursuant to, a petition for review of a major cleanup plan under section 637(c), shall constitute final agency action subject to judicial review at the time this action is taken.

"§ 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 risk characterization principles set forth in sections 633 and 634; 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) Review of a risk assessment or any entry (or the evaluation underlying the entry) on an agency-developed database (including, but not limited to, the Integrated Risk Information System), shall be conducted by the head of the agency on the written petition of a person showing a reasonable likelihood that—

"(1) the risk assessment or entry is inconsistent with the principles set forth in sections 633 and 634;

"(2) the risk assessment or entry contains different results than if it had been properly conducted under sections 633 and 634;

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

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

"(c) Review of a risk assessment, a cost-benefit analysis, or both, for a major cleanup plan shall be conducted by the head of the agency on the written petition of a person showing a reasonable likelihood that—

"(1) the risk assessment warrants revision under any of the criteria set forth in subsection (b); or

"(2) the cost-benefit analysis warrants revision under any of the criteria set forth in section 624.

"(d)(1) Not later than 90 days after receiving a petition under subsection (b), the head of the agency shall respond to the petition by agreeing or declining to review the risk entry, the cost-benefit analysis, or both, referred to in the petition, and shall state the basis for the decision.

"(2) 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

(1), unless the Director agrees in writing with an agency determination that an extension is necessary in view of limitations on agency resources. Prior to completion of the agency review, the agency's written conclusions concerning the review shall be subjected to peer review pursuant to section 640.

"(3) A risk assessment review completed pursuant to a petition may be the basis for initiating a petition pursuant to any other provision of law.

"(4) Following a decision to grant or deny a petition under subsection (b) or (c), no further petition for such risk assessment, entry, or cost-benefit analysis, submitted by the same person, shall be considered by any agency unless such petition is based on a change in a fact, circumstance, or provision of law underlying or otherwise related to the matters covered by the initial petition, occurring since the initial petition was granted or denied, that warrants the granting of such further petition.

"(e) 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.

"(f) 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. 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.

"§ 639. Regulatory priorities

"(a)(1) Not later than 180 days after the date of enactment of this section, the Director of the Office of Management and Budget, in consultation with the Office of Science and Technology Policy, shall enter into appropriate arrangements with an accredited scientific body to—

"(A) conduct a study of the methodologies for using comparative risk to rank dissimilar health, safety, and environmental risks; and

"(B) to conduct a comparative risk analysis in accordance with paragraph (2).

"(2) The study of the methodologies under paragraph (1)(A) shall be conducted as part of the first comparative risk analysis under paragraph (1)(B). The study shall—

"(A) seek to develop and rigorously test methods of comparative risk analysis;

"(B) have sufficient scope and breadth to test approaches for improving comparative risk analysis and its use in setting priorities for health, safety, and environmental risk prevention and reduction; and

"(C) review and evaluate the experience of States that have conducted comparative risk analyses.

"(3)(A) The comparative risk analysis under paragraph (1)(B) shall compare and rank, to the extent feasible, health, safety, and environmental risks potentially regulated across the spectrum of programs relating to health, safety, and the environment administered by the departments, agencies, and instrumentalities of the Federal Government.

"(B) In carrying out the comparative risk analysis under this paragraph, the Director shall ensure that—

"(i) the scope and specificity of the analysis are sufficient to provide the President and the heads of agencies guidance in allocating resources across agencies and among programs in agencies to achieve the greatest degree of risk prevention and reduction for the public and private resources expended;

"(ii) the analysis is conducted through an open process, by individuals with relevant expertise, including, as appropriate—

"(I) toxicologists;

"(II) biologists;

"(III) engineers; and

"(IV) experts in the fields of medicine, industrial hygiene, and environmental effects;

"(iii) the analysis is conducted, to the extent feasible, consistent with the risk assessment and risk characterization principles described in sections 633 and 634;

"(iv) the methodologies and principal scientific determinations made in the analysis are subjected to peer review under section 640 and the conclusions of the peer review are made publicly available as part of the final report;

"(v) there is an opportunity for public comments on the results of the analysis prior to making them final; and

"(vi) the results of the analysis are presented in a manner that distinguishes between the scientific conclusions and any policy or value judgments embodied in the comparisons.

"(4) The comparative risk analysis shall be completed, and a report submitted to Congress not later than 3 years after the date of enactment of this section. The analysis shall be reviewed and revised not less often than every 5 years thereafter for a minimum of 15 years following the release of the initial analysis.

"(b) Not later than 180 days after the date of enactment of this section, the Director of the Office of Management and Budget, in collaboration with the head of each Federal agency, shall enter into a contract with the National Research Council to provide technical guidance to the agencies on approaches to using comparative risk analysis in setting health, safety, and environmental priorities to assist the agencies in complying with subsection (c).

"(c)(1) In exercising authority under any laws protecting health, safety, or the environment, the head of an agency shall prioritize the use of the resources available under such laws to address the risks to health, safety, and the environment that—

"(A) the agency determines are the most serious; and

"(B) can be addressed in a cost-effective manner, with the goal of achieving the greatest overall net reduction in risks with the public and private sector resources to be expended.

"(2) In identifying the sources of the most serious risks under paragraph (1), the head of the agency shall consider, at a minimum—

"(A) the plausible likelihood and severity of the effect; and

"(B) the plausible number and groups of individuals potentially affected.

"(3) The head of the agency shall incorporate the priorities identified in paragraph (1) into the budget, strategic planning, and research activities of the agency by, in the agency's annual budget request to Congress—

"(A) identifying which risks the agency has determined are the most serious and can be addressed in a cost-effective manner under paragraph (1), and the basis for that determination;

"(B) explicitly identifying how the agency's requested funds will be used to address those risks;

"(C) identifying any statutory, regulatory, or administrative obstacles to allocating agency resources in accordance with the priorities established under paragraph (1); and

"(D) explicitly considering the requirements of paragraph (1) when preparing the agency's regulatory agenda or other strategic plan, and providing an explanation of how the agenda or plan reflects those requirements and the comparative risk analysis when publishing any such agenda or strategic plan.

"(4) In March of each year, the head of each agency shall submit to Congress specific recommendations for repealing or modifying laws that would better enable the agency to prioritize its activities to address the risks to health, safety, and the environment that are the most serious and can be addressed in a cost-effective manner consistent with the requirements of paragraph (1).

"§ 640. Establishment of program

"(a) The Director of the Office of Science and Technology or the Director, as appropriate, shall develop a systematic program for the peer review of work products covered by subsection (c), which program shall be used, in as uniform a manner as is practicable, 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 experts who were associated with the generation of the specific work product either directly by substantial contribution to its development, or indirectly by consultation and development of the specific product;

"(4) shall provide for differing levels of peer review depending on the significance or complexity of the issue or the need for expedition;

"(5) shall contain balanced presentations of all considerations, including minority reports and an agency response to all significant peer review comments; and

"(6) shall provide an opportunity for interested parties to submit issues for consideration by peer review panels.

"(c) Matters requiring peer review shall include—

"(1) risk assessments and cost-benefit analyses for major rules;

"(2) quantitative estimates of risk or hazard that are used in making regulatory determinations, including all entries into the Integrated Risk Information System;

"(3) risk assessment and risk characterization regulations and cost-benefit guidelines; and

"(4) any other significant or technical work product, as designated by the head of each agency, the Director of the Office of Science and Technology, or the Director.

"(d) All underlying data shall be submitted to peer reviewers, except to the extent necessary to protect confidential business information and trade secrets. To ensure such protections, the head of the agency may require that peer reviewers enter into confidentiality agreements.

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

"(f) The proceedings of peer review panels under this section shall be subject to the applicable provisions of the Federal Advisory Committee Act.

"SUBCHAPTER IV—EXECUTIVE OVERSIGHT

"§ 641. Procedures

"(a) 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.

"(b) Not later than 12 months after the date of enactment of this subchapter the Office of Management and Budget shall issue regulations to assist agencies in preparing the cost-benefit analyses required by this subchapter. The regulations shall—

"(1) ensure that cost and benefit evaluations are consistent with this subchapter and, to the extent feasible, represent realistic and plausible estimates;

"(2) be adopted following public notice and adequate opportunity for comment; and

"(3) be used consistently by all agencies covered by this subchapter.

"§ 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) JUDICIAL REVIEW.—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) CHAPTER ANALYSIS.—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

"Sec.
"601. Definitions.
"602. Regulatory agenda.
"603. Initial regulatory flexibility analysis.
"604. Final regulatory flexibility analysis.
"605. Avoidance of duplicative or unnecessary analyses.
"606. Effect on other law.
"607. Preparation of analysis.
"608. Procedure for waiver or delay of completion.
"609. Procedures for gathering comments.
"610. Periodic review of rules.
"611. Judicial review.
"612. Reports and intervention rights.

"SUBCHAPTER II—ANALYSIS OF AGENCY RULES

"621. Definitions.
"622. Rulemaking cost-benefit analysis.
"623. Petition for cost-benefit analysis.
"624. Decisional criteria.
"625. Judicial review.
"626. Deadlines for rulemaking.
"627. Agency review of rules.
"628. Special rule.

"SUBCHAPTER III—RISK ASSESSMENTS

"631. Definitions.
"632. Applicability.
"633. Principles for risk assessment.
"634. Principles for risk characterization and communication.
"635. Requirement to prepare risk assessment.
"636. Requirements for assessments.
"637. Regulations; plan for assessing new information.
"638. Rule of construction.
"639. Regulatory priorities.
"640. Establishment of program.

"SUBCHAPTER IV—EXECUTIVE OVERSIGHT

"641. Procedures.
"642. Promulgation and adoption.
"643. Delegation of authority.
"644. Judicial review.".

(2) SUBCHAPTER HEADING.—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) 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 of an agency hearing provided by statute;

"(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; or

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

"(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, 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.".

(b) 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 or action of an agency, 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.

(c) JUDICIAL PROCEEDINGS.—

(1) CONSENT DECREES.—Chapter 7 of title 5, United States 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) AFFIRMATIVE DEFENSE.—Chapter 7 of title 5, United States Code, is further amended by adding at the end the following new section:

"§ 708. Affirmative defense

"Notwithstanding any other provision of law, it shall be an affirmative defense in any enforcement action brought by an agency that the regulated person or entity is complying with a rule, regulation, adjudication, directive, or order of such agency or any other agency that is inconsistent, incompatible, contradictory, or otherwise

cannot be reconciled with the agency rule, regulation, adjudication, directive, or order being enforced.".

(3) AGENCY INTERPRETATIONS IN CIVIL AND CRIMINAL ACTIONS.—

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

"§ 709. Agency interpretations in civil and criminal actions

"(a)(1) No civil or criminal penalty shall be imposed in any action brought in a Federal court, including an action pending on the date of enactment of this section, for the alleged violation of a rule, if the defendant, prior to the alleged violation—

"(A) reasonably determined, based upon a description, explanation, or interpretation of the rule contained in the rule's statement of basis and purpose, that the defendant was in compliance with, exempt from, or otherwise not subject to, the requirements of the rule; or

"(B) was informed by the agency that promulgated the rule, or by a State authority to which had been delegated the responsibility for ensuring compliance with the rule, that the defendant was in compliance with, exempt from, or otherwise not subject to, the requirements of the rule.

"(2) In determining, for purposes of paragraph (1)(A), whether a defendant reasonably relied upon a description, explanation, or interpretation of the rule contained in the rule's statement of basis and purpose, the court shall not give deference to any subsequent agency description, explanation, or interpretation of the rule relied on by the agency in the action that had not been published in the Federal Register or otherwise directly and specifically communicated to the defendant by the agency, or by a State authority to which had been delegated the responsibility for ensuring compliance with the rule, prior to the alleged violation.

"(b)(1) In a civil or criminal action in Federal court to redress an alleged violation of a rule, including an action pending on the date of enactment of this section, if the court determines that the rule in question is ambiguous, the court shall not give deference to an agency interpretation of the rule if the defendant relied upon an interpretation of the rule to the effect that the defendant was in compliance with or was exempt or otherwise not subject to the requirement of the rule, and the court determines that such determination is reasonable.

"(2) Without regard to whether the defendant relied upon an interpretation that the court determines is reasonable under paragraph (1), if the court determines that the rule failed to give the defendant fair warning of the conduct that the rule prohibits or requires, no civil or criminal penalty shall be imposed.

"(c)(1) No agency action shall be taken, or any action or other proceeding maintained, seeking the retroactive application of a requirement against any person that is based upon—

"(A) an interpretation of a statute, rule, guidance, agency statement of policy, or license requirement or condition; or

"(B) a determination of fact,

if such interpretation or determination is different from a prior interpretation or determination by the agency or by a State or local government exercising authority delegated or approved by the agency, and if such person relied upon the prior interpretation or determination.

"(2) This subsection shall take effect on the date of enactment of the Comprehensive Regulatory Reform Act of 1995 and shall apply to any matter for which a final unappealable judicial order has not been issued.

"(d) This section shall apply to the review by a Federal court of any order of an agency assessing civil administrative penalties.".

(B) UNPUBLISHED AGENCY GUIDANCE.—Section 552(a)(1) of title 5, United States Code, is amended by inserting at the end the following new sentence: "In an action brought in a Federal court seeking a civil or criminal penalty for the alleged violation of a rule, including actions pending on the date of enactment of this sentence, no consideration shall be given to any interpretive rule, general statement of policy, or other agency guidance of general or specific applicability, relied upon by the agency in the action, that had not been published in the Federal Register or otherwise directly and specifically communicated to the defendant by the agency, or by a State authority to which had been delegated the responsibility for ensuring compliance with the rule, prior to the alleged violation.".

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

"707. Consent decrees.
"708. Affirmative defense.
"709. Agency interpretations in civil and criminal actions.".

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, 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(4), 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.

"(h) This section shall not apply to rules that concern monetary policy proposed or implemented by the Board of Governors of the Federal Reserve System or the Federal Open Market Committee.".

(b) TECHNICAL AMENDMENT.—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. ACCOUNTING.

(a) DEFINITIONS.—For purposes of this section, the following definitions apply:

(1) REGULATION.—The term "regulation" means an agency statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the procedures or practice requirements of an agency. The term shall not include—

(A) administrative actions governed by sections 556 and 557 of title 5, United States Code;

(B) regulations issued with respect to a military or foreign affairs function of the United States; or

(C) regulations related to agency organization, management, or personnel.

(2) AGENCY.—The term "agency" means any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency, but shall not include—

(A) the General Accounting Office;

(B) the Federal Election Commission;

(C) the governments of the District of Columbia and of the territories and possessions of the United States, and their various subdivisions; or

(D) Government-owned contractor-operated facilities, including laboratories engaged in national defense research and production activities.

(b) ACCOUNTING STATEMENT.—

(1) IN GENERAL.—(A) The President shall be responsible for implementing and administering the requirements of this section.

(B) Every 2 years, not later than June of the second year, the President shall prepare and submit to Congress an accounting statement that estimates the costs of Federal regulatory programs and corresponding benefits in accordance with this subsection.

(2) YEARS COVERED BY ACCOUNTING STATEMENT.—Each accounting statement shall cover, at a minimum, the 5 fiscal years beginning on October 1 of the year in which the report is submitted and may cover any fiscal year preceding such fiscal years for purpose of revising previous estimates.

(3) TIMING AND PROCEDURES.—(A) The President shall provide notice and opportunity for comment for each accounting statement. The President may delegate to an agency the requirement to provide notice and opportunity to comment for the portion of the accounting statement relating to that agency.

(B) The President shall propose the first accounting statement under this subsection not later than 2 years after the date of the enactment of this Act and shall issue the first accounting statement in final form not later than 3 years after the date of the enactment of this Act. Such statement shall cover, at a minimum, each of the 8 fiscal years beginning after the date of the enactment of this Act.

(4) CONTENT OF ACCOUNTING STATEMENT.—(A) Each accounting statement shall contain estimates of costs and benefits with respect to each fiscal year covered by the statement in accordance with this paragraph. For each such fiscal year for which estimates were made in a previous accounting statement, the statement shall revise those estimates and state the reasons for the revisions.

(B)(i) An accounting statement shall estimate the costs of Federal regulatory programs by setting forth, for each year covered by the statement—

(I) the annual expenditure of national economic resources for the regulatory program; and

(II) such other quantitative and qualitative measures of costs as the President considers appropriate.

(ii) For purposes of the estimate of costs in the accounting statement, national economic resources shall include, and shall be listed under, at least the following categories:

(I) Private sector costs.

(II) Federal sector administrative costs.

(III) Federal sector compliance costs.

(IV) State and local government administrative costs.

(V) State and local government compliance costs.

(VI) Indirect costs, including opportunity costs.

(C) An accounting statement shall estimate the benefits of Federal regulatory programs by setting forth, for each year covered by the statement, such quantitative and qualitative measures of benefits as the President considers appropriate. Any estimates of benefits concerning reduction in health, safety, or environmental risks shall present the most plausible level of risk practical, along with a statement of the reasonable degree of scientific certainty.

(c) ASSOCIATED REPORT TO CONGRESS.—

(1) IN GENERAL.—At the same time as the President submits an accounting statement under subsection (b), the President, acting through the Director of the Office of Management and Budget, shall submit to Congress a report associated with the accounting statement (hereinafter referred to as an "associated report"). The associated report shall contain, in accordance with this subsection—

(A) analyses of impacts; and

(B) recommendations for reform.

(2) ANALYSES OF IMPACTS.—The President shall include in the associated report the following:

(A) Analyses prepared by the President of the cumulative impact of Federal regulatory programs covered in the accounting statement on the following:

(i) The ability of State and local governments to provide essential services, including police, fire protection, and education.

(ii) Small business.

(iii) Productivity.

(iv) Wages.

(v) Economic growth.

(vi) Technological innovation.

(vii) Consumer prices for goods and services.

(viii) Such other factors considered appropriate by the President.

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

(3) RECOMMENDATIONS FOR REFORM.—The President shall include in the associated report the following:

(A) A summary of recommendations of the President for reform or elimination of any Federal regulatory program or program element that does not represent sound use of national economic resources or otherwise is inefficient.

(B) A summary of any recommendations for such reform or elimination of Federal regulatory programs or program elements prepared by persons commenting during the comment period on the accounting statement.

(d) GUIDANCE FROM OFFICE OF MANAGEMENT AND BUDGET.—The Director of the Office of Management and Budget shall, in consultation with the Council of Economic Advisers, provide guidance to agencies—

(1) to standardize measures of costs and benefits in accounting statements prepared pursuant to sections 3 and 7 of this Act, including—

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

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

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

(e) RECOMMENDATIONS FROM CONGRESSIONAL BUDGET OFFICE.—After each accounting statement and associated report submitted to Congress, the Director of the Congressional Budget Office shall make recommendations to the President—

(1) for improving accounting statements prepared pursuant to this section, including recommendations on level of detail and accuracy; and

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

SEC. 8. 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.

I. THE DEVELOPMENT OF S. 343

A. BACKGROUND

The public has become increasingly concerned about the growth of the Federal Government and the number and scope of its regulatory programs. In the recent congressional elections, the public sent a clear message to Washington that they want a smaller, more efficient, and more effective government. This message reflects a deep and growing concern about the rising costs of federal regulations and their intrusiveness into the lives of most Americans.

Although regulatory programs are intended to provide important protections and benefits to the public, it is clear that the regulatory process is failing to meet these goals in a cost-effective manner. Many regulations impose undue costs, and the regulatory process itself is too unresponsive and inefficient. The cumulative cost of regulation is enormous and is rising at an alarming rate.

Over the past 25 years, and particularly during the Reagan Administration, both regulations and the regulatory process itself have received increasing scrutiny. That scrutiny, coupled with the recognition of the limited resources available for regulatory efforts, has revealed that regulation imposes enormous costs and is too inefficient and ineffective. The public outcry for a less burdensome, more efficient regulatory process has increased interest in the tools to achieve reform, including cost-benefit analysis, risk assessment, comparative risk analysis, market mechanisms, review of existing regulations, regulatory accounting, and congressional review of agency rules. All of these tools are required in the subject legislation. We have entered an era in government regulation where, now more than ever, efficiency must be a paramount concern. While many regulations provide important benefits and protections to the public, too often, regulations have been unduly costly or ineffective. The dual impact of rising regulatory costs and limited resources necessitates a smarter, more cost-effective approach to regulation. The goal is to increase the benefits and decrease the costs of regulation. The evolution to this efficiency paradigm is best understood in its historical context.[1]

Since the 1880's, regulation in the United States has evolved through several stages. Near the turn of the century, a market regime emerged in response to the rise of a new corporate economy. Corporations had expanded to internalize many functions previously accomplished through market transactions. Some large corporations adopted joint strategies to manage competition and expansion, although with mixed success. The growth of a large-scale corporate economy forced the integration of formerly local economies and threatened the economic independence that many businesses and consumers held earlier. Popular demands led government officials to try to force a return to the market (as in the case

[1] *See generally,* Marc Allen Eisner, *Regulatory Politics in Transition,* The Johns Hopkins Univ. Press (1993).

of antitrust) or to create administrative agencies to set rates approximating those that would have existed under market conditions. The market was the regulatory benchmark.

A second wave of regulation followed the economic collapse of the Great Depression. Alarmed by the widespread economic and social dislocations of the depression, President Roosevelt focused on economic recovery and actively encouraged the organization of economic interests. Regulators allowed economic associations to play a central role in defining and implementing regulatory policy. They created a wide-ranging system of government-sponsored self-regulation. (*See, e.g.,* The National Industrial Recovery Act.) By integrating interest groups into the regulatory process through quasi-corporate arrangements, they aimed to promote economic stability, allow regulators to draw on the expertise and resources of the regulated, and minimize confrontations. This associational regime, while rooted in the 1920's, emerged during the New Deal.

The regulatory efforts in the 1960's and 1970's contrasted with the New Deal and the Progressive Eras. Many proponents of social regulation rejected earlier regulatory goals and were deeply suspicious of the distribution of economic power and excesses of capitalist production. Many major regulatory initiatives, instead of promoting economic stability or revitalizing markets, were intended to protect the public from health and environmental risks. Some social regulations even extended into the production process itself.

The 1970's heralded a wave of new environmental, health and safety regulations. Congress created a series of new agencies with broad powers, including the Occupational Safety and Health Administration, the Environmental Protection Agency, the National Highway Traffic Safety Administration, the Consumer Product Safety Commission, and the Nuclear Regulatory Commission. Sweeping legislative mandates directed the agencies to regulate the environment, health, and safety, with little compromise.[2]

It soon became apparent that the costs of the new regulation were enormous and had to be monitored and controlled. The Nation's poor economic performance in the 1970's and 1980's reshaped the political agenda. High interest rates, sluggish growth, and mounting foreign competition forced policymakers to reconsider whether many policies were justified. Public officials and policy analysts identified regulation as a cause of stagflation. Beginning with President Nixon, each President has implemented executive review processes to force agencies to consider the costs and benefits of their regulations. Increasingly, the economic analysis of regulation was conducted by economic staffs or policy offices within the agencies themselves. At the same time, a number of deregulatory initiatives were implemented. Increasingly, efficiency became the standard for regulatory actions.

Deregulation of economic regulation and reform of social regulation began in earnest in the mid-1970's and carried over into the 1980's. In the context of economic regulation, there was a broad commitment to reevaluate well-established regulatory policies and to eliminate unnecessary or irrational regulations. While economic

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[2] *See* W. Kip Viscusi, *Fatal Tradeoffs: Public and Private Responsibilities for Risk* 248, Oxford Univ. Press, New York (1992).

regulations guaranteed a degree of industrial stability, these gains were realized at undue costs from stunted competition and innovation. Most observers agreed that economic deregulation could benefit consumers by reducing prices, revitalizing economic growth, stimulating new competition and reducing production costs. Consumers benefited from the deregulation of many industries, including air transportation, surface transportation, energy, telecommunications and commercial banking.

At the same time, the rising cost of new social regulations stimulated efforts to inject economic criteria into the regulatory decision-making process and to reconsider policies deemed too costly or intrusive. Regulatory reform focused on improving the internal management of the agencies by promoting the consideration of economic costs and benefits of alternatives.

The central regulatory reform efforts involved Executive review of agency initiatives. Many of these efforts, however, failed to substantially improve the regulatory process because they were not sufficiently enforceable. Moreover, agency compliance was far from uniform, and the review process of each administration has been subject to shifting political winds.

President Richard Nixon established the first modern regulatory review program. To address concerns over inflation, the Nixon administration made initial efforts to impose Executive review processes and provided a foundation on which later administrations would build. Concerns over the economic impact of environmental policy led the White House to establish an interagency "quality of life" committee to study the need for regulatory review in June 1971. In October 1971, President Nixon established the Quality of Life review process ("QOL"), supervised by OMB. Under QOL, agencies were required to consider various regulatory alternatives and their costs when developing "significant" regulations. The proposed and final regulations were submitted to OMB, which circulated them to other agencies for comment.

The Nixon review process gave OMB a critical role in the review of regulations. However, it relied on the agencies to determine whether their regulations were "significant" and thus subject to OMB review. Therefore, many agencies ignored the process. OMB's authority was limited; the agencies retained final authority over the issuance of rules. Finally, the review process focused almost exclusively on EPA.

President Gerald Ford expanded upon the initiatives of President Nixon. In an attempt to promote price stability, Congress authorized the creation of the Council on Wage and Price Stability in the Office of the President. The dual mission of the Council was to monitor private-sector events affecting price stability, and to review government programs and determine their inflationary impact. President Ford's Executive Order 11821 standardized this review by requiring inflationary impact statements for all major legislative proposals and regulations. Executive Order 11821 directed OMB to develop criteria for identifying major regulations and to prescribe procedures for their evaluation.

Although President Ford's Executive review process made regulators more sensitive to the costs of regulations and eliminated some irrational regulatory proposals, the program was plagued by

several problems. First, agency compliance was voluntary. The Council had to rely on the agencies to determine whether their activities were subject to review. Second, the quality of analyses was limited. Third, the impact statements were not integrated into the decisionmaking process, but were prepared after a proposal had been developed. Fourth, the Council lacked the power to reject regulations that failed the cost-benefit test. President Jimmy Carter continued President Ford's efforts to reduce the costs of regulations. The Council on Wage and Price Stability and the inflationary impact statement remained in place. In addition, President Carter established the Regulatory Analysis and Review Group ("RARG"), consisting of representatives of many Executive agencies, in January 1978. RARG reviewed a limited number of select regulations deemed to have a potentially significant impact on inflation—costing industry at least $100 million annually.

During its last 2 years, the Carter administration made a systematic, but short-lived, attempt to comprehensively coordinate regulatory policy. In October 1978, President Carter created the United States Regulatory Council to coordinate and improve regulations. The Regulatory Council, which was composed of 20 Executive departments and 18 independent regulatory agencies, initiated a variety of projects to promote innovative regulatory approaches and to coordinate regulatory efforts. It also started a calendar of Federal regulations and issued a set of pamphlets on innovative approaches to regulation.[3]

More importantly, President Carter issued Executive Order 12044 in March 1978. Executive Order 12044 directed agencies to identify "significant" regulations imposing costs on the economy of $100 million or more per year or causing a major increase in costs or prices to various groups or regions, and to prepare an economic analysis for such regulations. The Carter Executive order extended earlier efforts by establishing guidelines for the development of regulations. The Carter review process explicitly applied economic analysis to determine whether new rules were justified and provided the foundation for the growing role of Executive review in the post comment period and in the review of existing rules.

Despite these advances, the Carter regulatory review process was inadequate. As before, agencies were free to determine which of their proposed rules had a significant impact on the economy. RARG was limited by its narrow mandate and lack of enforcement powers. And the number of regulators and new Federal regulations spiralled higher than ever.

The Reagan Presidency wrought important changes in the regulatory landscape that were to have a lasting impact. To stem the rising tide of regulations, President Reagan issued Executive Order 12291 shortly after taking office. This order incorporated and expanded upon the key provisions of Executive Order 12044, including a review of existing regulations, selecting the least costly regulatory alternative when developing new regulations, and requiring agencies to prepare regulatory cost-benefit analyses for major regulations. President Reagan directed agencies to develop regulations

[3] *See* Project on Alternative Regulatory Approaches, Guidebook Series on Alternative Regulatory Approaches, Books 1–6 (Washington, DC, September 1981).

only if there was a clear need, the benefits outweighed the costs, and the least costly alternative was chosen. Most important, Executive Order 12291 centralized review and clearance of regulatory actions in OMB's Office of Information and Regulatory Affairs. Agencies had to respond to OMB comments and incorporate those comments and the agencies' responses in the rulemaking file before issuing a final regulation. President Reagan also issued Executive Order 12498 in March 1985, directing agencies to prepare a yearly agenda containing all significant regulatory actions for the coming year. Except for emergency situations, agencies were prohibited from taking any significant regulatory actions that had not been included in the agenda, unless those actions were cleared by OMB.

The Reagan approach to regulation was unprecedented in several respects. First, regulatory review was strengthened and centralized in OMB and the White House more than ever. For the first time, no regulations could be promulgated unless they were first reviewed by a central clearinghouse. Centralizing regulatory review also helped to coordinate agency actions and minimize the economic impact of these actions. Executive review also compelled agencies to enhance their policy-planning and policy-evaluation staffs and to internalize the review process. Second, regulations had to be justified under cost-benefit analysis. Third, the market became the benchmark to assess the need for policies and to design them. Fourth, White House officials and regulators were sensitive to the cumulative costs of regulation, and this sparked regulatory reform and deregulation. During the 1970's, Murray Weidenbaum pioneered attempts to estimate the costs of regulation, including budgetary outlays and compliance costs. He noted that the administrative costs had increased dramatically during the 1970's, driven in part by the creation of new regulatory agencies. However, he found that the increases in the regulatory budget were insignificant compared with the compliance costs and the total costs to the economy. The high cost of regulation, particularly social regulation, led Weidenbaum to urge policymakers and analysts to assess the economic impact of regulations to justify public policies.[4]

President George Bush continued President Reagan's Executive orders when he took office in 1989. Concerned about the continuing increase in the cost of regulations, he also established the President's Council on Competitiveness in March 1989 to oversee regulatory issues. The Council focused on reducing the cost of new and existing regulations. During a time of increasing social legislation, these efforts met with limited success.

On October 4, 1993, President Bill Clinton issued Executive Order 12866, revoking prior Executive orders, but incorporating or restating some of the key provisions from those prior orders. One and one-half years after the implementation of Executive Order 12866, there is little evidence that the order has had a significant impact. In a time of increasingly limited government resources and reduced legislative initiatives, there is concern that the agencies have done too little to curb the rising costs and inefficiencies of reg-

[4] *See* Murray L. Weidenbaum, "On Estimating Regulatory Costs," *Regulation* 2, No. 3 (1978), at 14–17.

ulation. Indeed, the administration's First Year Report on Executive Order 12866 noted:

> Agencies today face unusual pressure to regulate. With budgetary constraints so tight, and with the difficulty of enacting new legislation in the highly partisan atmosphere that has characterized the last Congress, the only means left for the agencies to implement their initiatives is through regulation. This puts inordinate pressure on any attempt to hold steady or reduce the amount of regulation in which they are engaged.[5]

Recently, the Clinton administration listed 4,300 additional rulemakings scheduled for fiscal year 1995 and beyond, with 872 final rules set to be released in the 6 months between October 1994 and April 1995.[6] Without significant new controls, the volume of regulations will only grow larger. This cannot continue.

B. THE COMPREHENSIVE REGULATORY REFORM ACT OF 1995, S. 343

S. 343, the Comprehensive Regulatory Reform Act of 1995, is the most recent attempt by the committee to deal with the costly, burdensome and abusive regulatory process. It is the product of at least 30 years of work in the Senate on improving the process by which Federal regulations are promulgated and enforced. In the 88th Congress, in 1964, the Subcommittee on the Administrative Practice and Procedure held 3 days of hearings and heard from 36 witnesses on a bill intended to "update and improve the procedural rules that govern proceedings before the departments and agencies."[7] Hearings on this subject continued in the 89th,[8] the 94th,[9] and the 95th Congresses.[10] During the 96th Congress, the Subcommittee on Administrative Practice and Procedure embarked on an ambitious schedule of 10 days of hearings, receiving testimony from over 100 witnesses on all manner of regulatory reform.[11]

In addition, the Committee on Governmental Affairs has devoted 6 years to an extensive study of the Federal regulatory process. In July 1975, that committee, then known as the Committee on Government Operations, was directed by S. Res. 71 to conduct a comprehensive study of Federal regulation. The study was issued in six

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[5] "The First Year of Executive Order No. 12866," a report prepared by Sally Katzen, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (Dec. 20, 1994).

[6] *See* Regulatory Plan and Unified Agenda of Federal Regulations (Nov. 14, 1994).

[7] Hearings on S. 1663 to amend the Administrative Procedure Act before the Subcommittee on Administrative Practice and Procedure of the Senate Committee on the Judiciary, 88th Cong., 2d sess. (1964).

[8] Hearings on Bills to Amend the Administrative Procedure Act before the Subcommittee on Administrative Practice and Procedure of the Senate Committee on the Judiciary, 89th Cong., 1st sess. (1965).

[9] Hearings on the Administrative Procedure Act Amendments of 1976 before the Subcommittee on Administrative Practice and Procedure of the Senate Committee on the Judiciary, 94th Cong., 2d sess. (1976).

[10] Hearings on the Administrative Procedure Act Amendments of 1978 before the Subcommittee of Administrative Practice and Procedure of the Senate Committee on the Judiciary, 95th Cong., 2d sess. (1978).

[11] Hearings on Regulatory Reform before the Subcommittee on Administrative Practice and Procedure of the Senate Committee on the Judiciary, 96th Cong., 1st sess. (1979) (in four parts). These hearings are summarized in S. Rept. 96–1018, 96th Cong., 2d sess., pt. 2 at 14–16 (1980).

volumes over a 2-year period.[12] During the last Congress, the Committee on Governmental Affairs also held 11 days of hearings on regulatory reform legislation and heard testimony from 80 witnesses.[13]

The Committee on the Judiciary and the Committee on Governmental Affairs each reported regulatory reform legislation in the 96th Congress. Though these bills had many similar provisions, their differences required that efforts be made to reconcile them before the floor consideration.[14] The Congress adjourned before this work had been completed. However, part of the Judiciary Committee legislation, dealing with the impact of Federal regulation on small businesses, was separately enacted as the Regulatory Flexibility Act.[15]

The continuing problem of overregulation and regulatory abuse was a major issue during the 1994 congressional election cycle. The new Republican majorities in both the Senate and the House made regulatory reform a high priority for the 104th Congress.

Majority Leader Robert Dole introduced The Comprehensive Regulatory Reform Act, S. 343, on February 2, 1995. The bill was then jointly referred to both the Committee on Judiciary and the Committee on Governmental Affairs. The Judiciary Committee subsequently referred the bill to the Subcommittee on Administrative Oversight and the Courts.

Along with Majority Leader Dole, Judiciary Committee Chairman Orrin Hatch and Subcommittee Chairman Charles Grassley took the lead in developing a comprehensive approach to regulatory reform.

As chairman of the Administrative Oversight and the Courts Subcommittee, Senator Grassley began the extensive process by holding a hearing over a 2-day period and then offering a substitute amendment at a subsequent markup on S. 343, where the substitute was adopted and reported to the full Judiciary Committee. Chairman Hatch held a full committee hearing and then held markup sessions on 3 separate days, where Chairman Hatch and Senator Grassley offered a modified substitute to S. 343.

Throughout the process, the drafters built upon extensive work that had taken place in the 97th Congress in the form of S. 1080. Although not as comprehensive as S. 343, S. 1080 addressed cer-

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[12] The volumes of the Study on Federal Regulation by the Committee on Governmental Affairs were published over a period from January 1977 to December 1978. They are:

1. Senate Committee on Government Operation, 95th Cong., 1st sess., 1 Study on Federal Regulation, "The Regulatory Appointments Process" (Committee print 1977).
2. Senate Committee on Government Operations, 95th Cong., 1st sess., 2 Study on Federal Regulation, "Congressional Oversight of Regulatory Agencies" (Committee print 1977).
3. Senate Committee on Governmental Affairs, 95th Cong., 1st sess., 3 Study on Federal Regulation, "Public Participation in Regulatory Agency Proceedings" (Committee print 1977).
4. Senate Committee on Governmental Affairs, S. Doc. 95–72, 95th Cong., 1st sess., 4 Study on Federal Regulation, "Delay in Regulatory Process" (Committee print 1977).
5. Senate Committee on Governmental Affairs, S. Doc. No. 95–91, 95th Cong., 2nd sess., 5 Study on Federal Regulation, "Regulatory Organization" (Committee print 1977).
6. Senate Committee on Governmental Affairs, S. Doc. No. 96–13, 96th Cong., 1st sess., 6 Study on Federal Regulation, "Framework for Regulation" (Committee print 1978)

[Hereinafter cited by volume of the Study on Federal Regulation.]

[13] Hearings on Regulatory Reform Legislation before the Senate Committee on Governmental Affairs, 96th Cong., 1st sess., (1979) (in two parts). These hearings are summarized in S. Rept. No 96–1018, pt. 1 at 52–55 (1980).

[14] The parliamentary route followed by each of these bills was relatively complicated and shall not be recounted here. For a short summary, see S. Rept. 96–1018, pt. 2 at 12–14, 17.

[15] Public Law 96–354, 94 Stat. 1165 (codified at 5 U.S.C. 601 et seq.).

tain fundamental problems of rulemaking and the oversight of that process. This bill had strong bipartisan support and eventually passed the Senate 94–0. However, the leadership of the House of Representatives refused to take action on S. 1080, and the bill failed to proceed.

S. 343 is founded upon the structure of S. 1080, but has been expanded based upon the further development of administrative law and policy over the last 14 years.

Like S. 1080, S. 343 modifies the rulemaking provisions of section 553 of the APA to expand effective public participation in agency rulemaking. The bill's amendments to the modest notice and comment provisions of section 553 require an agency to set out more thoroughly what it is trying to achieve with a new regulation, the legal basis for it, and a more thorough and substantive response to the issues raised and alternatives proposed by public comment on the proposed rule. These modifications are intended to improve agency decisionmaking by exposing the process to better public scrutiny and creating a more complete and useful record for more meaningful review by the President, the Congress and the courts.

To accomplish the major goals of reducing costs and improving the effectiveness of regulations, S. 343 codifies the analytical techniques of cost-benefit analysis and risk assessment for "major" rules. These analytical tools have been used for some time. As the Administrative Conference of the United States has observed,

> Since 1974 executive branch agencies have been subject to a series of Presidential executive orders that required agencies to prepare comprehensive impact analyses for major rulemaking proposals.

(ACUS, Recommendation 85–2: *Agency Procedures for Performing Regulatory Analysis of Rules*, reprinted in Subcommittee Hearing on S. 343, statement of Thomasina V. Rogers, Chair, Administrative Conference of the United States.)

The wide use of these analytical techniques was reported to the committee as far back as 1981, when we were considering S. 1080. The Congressional Research Service identified over 200 examples of Congress's incorporating these techniques into various statutes. (Congressional Research Service, *Survey of United States Code Provisions Containing Requirements for Cost-Benefit, Economic Impact, or Cost-Effectiveness Analysis* 1 (1981), reprinted in Hearing on S. 1080 Before the Subcommittee on Regulatory Reform, 97th Cong., 1st sess. 1141 (1981).)

C. LEGISLATIVE HISTORY

S. 343 was introduced into the 104th Congress by Senate Republican Leader Robert Dole on February 2, 1995. Seventeen Senators joined Senator Dole as original cosponsors: Senators Nickles, Bond, Hutchison, Murkowski, Lott, Cochran, Hatch, Domenici, Kassebaum, Coats, Abraham, Inhofe, Smith, Santorum, Thompson, Warner, and Kyl. The bill was jointly referred to the Judiciary Committee and the Governmental Affairs Committee on February 3, 1995.

The Subcommittee on Administrative Oversight and the Courts held a 2-day hearing primarily intended to highlight regulatory is-

sues, including current problems and possible solutions. A variety of panels ranging from the Administration, independent business owners and regulatory specialists testified before the Subcommittee.

The first day of the hearing was February 22, 1995. The subcommittee heard testimony from Thomasina Rogers, Chair of the Administrative Conference of the United States. She was accompanied by Ernest Gellhorn, Chairman of the Committee on Rulemaking with the Administrative Conference of the United States. Mr. Gellhorn did not offer testimony, but was present only to assist in answering questions. Rick Keith, assistant general manager of the Westbend Elevator Company in Mallard, IA, and Sal Risalvato, on behalf of the National Federation of Independent Businesses, testified as well. Marshall Breger of the Heritage Foundation and Peter Ferrara of the National Center for Policy Analysis concluded the hearing on February 22.

The subcommittee hearing on S. 343 was completed on February 24, 1995. Testimony was given by Sally Katzen, Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget; C. Boyden Gray, with Wilmer, Cutler and Pickering law firm; Turner T. Smith, Jr., with Hunton and Williams; David Vladeck of Public Citizen; Peter Strauss, professor of administrative law, Columbia University Law School; Robert Cynkar of Shaw, Pittman, Potts and Trowbridge; and George Clemons Freeman, on behalf of the American Bar Association.

On March 15, 1995, the Subcommittee on Administrative Oversight and the Courts reported S. 343 to the full committee in the form of a substitute without recommendation.

On March 17, 1995, Chairman Orrin G. Hatch convened a Judiciary Committee hearing to consider S. 343. Those testifying included Congressman David McIntosh, R–IN; Sally Katzen, Administrator of the Office of Information and Regulatory Affairs; Philip K. Howard, author of The Death of Common Sense (1994); Kelvin Herstad, a small business owner from Deluth, MN; Robert Morris, a doctor from Milwaukee, WI; George Clemons Freeman, Jr., the co-chairman of the A.B.A. Group on Regulatory Reform; Christopher DeMuth, president of the American Enterprise Institute, and Cass Sunstein, a law professor at the University of Chicago.

The first executive session of the Judiciary Committee was scheduled for the week of March 27, 1995. At the request of Senator Biden, Chairman Hatch delayed that meeting until April 4. On April 3, Senator Biden again asked for a delay and the chairman rescheduled the meeting to April 5.

On April 5 the Judiciary Committee met in executive session to consider S. 343. Chairman Hatch offered the Hatch-Grassley substitute as an amendment in the form of a substitute, which was accepted by unanimous consent.

On April 6, 1995, the Judiciary Committee met to continue its consideration of S. 343. As a result of negotiations between the majority staff, the minority staff, and representatives of the administration, five pages of amendments were proposed. Additionally, there were a total of 21 amendments proposed by the minority. A total of four amendments were offered. One of the five pages from the negotiations was accepted. An amendment by Senator Biden

and one by Senator Kennedy were tabled. An amendment by Senator Feingold was discussed by not voted upon. At the conclusion of the day's session, the committee agreed to a unanimous-consent agreement whereby S. 343 would be favorably reported out of committee by 6 p.m. on April 26. During the interim period the majority staff, minority staff, and representatives of the administration would negotiate on the bill.

Between April 6 and April 26, the task force met on four separate days for over 22 hours. On April 25, Senator Biden asked Chairman Hatch to postpone the executive session until April 27 and proposed meeting from 10 a.m. until 1 p.m. The chairman agreed. Later, Senators Kennedy and Simon asked that the session begin at 8 a.m. instead of 10 a.m. and the meeting was so rescheduled. On April 27, 1995, Chairman Hatch convened an executive session of the Judiciary Committee to consider S. 343. When he sought unanimous-consent for a revised agreement in order to vitiate the prior unanimous-consent agreement, Senator Kennedy objected. Thus, the original agreement to favorably report out S. 343 at 6 p.m. on April 26, 1995, remained in place.

On April 26, 1995, the Senate Committee on the Judiciary approved S. 343 pursuant to the prior unanimous-consent agreement.

II. The Need for Reform

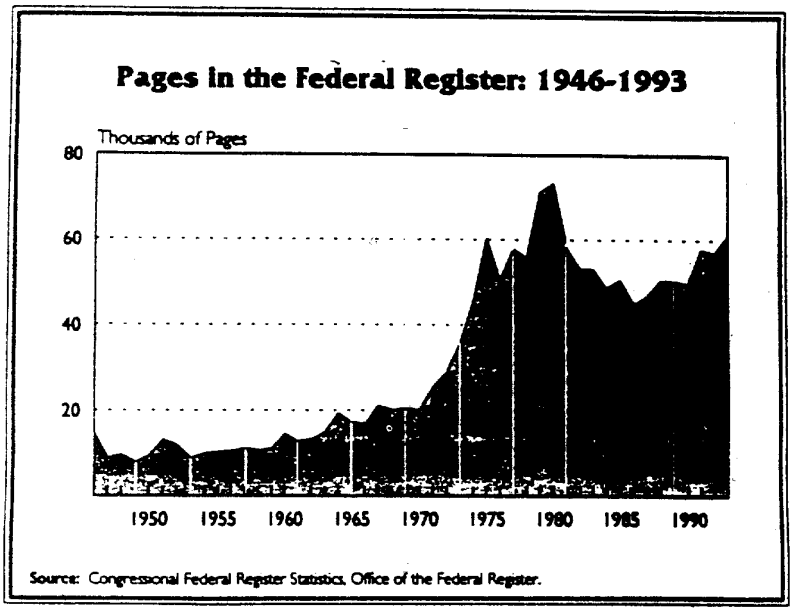
Prior to the reporting of S. 343, the last major action on regulatory reform by the committee took place in the 97th Congress, when the committee reported S. 1080 unanimously to the Senate. At that time, we detailed the state of the regulatory system that underscored the need for reforming the regulatory procedures by which agency decisions are made and reviewed. We noted the explosive growth of federal regulations, S. Rept. 284, 97th Cong., 1st Sess. 9–13 (1981), reviewed analyses questioning the effectiveness of much of the regulation, *id.* at 17–20, and described the extraordinary costs imposed by regulation. Id. at 29–50.

Despite the House of Representatives's failure to act on S. 1080, President Reagan did initiate some reforms that helped centralize and strengthen White House review of Federal agency rulemaking. In his order on "Federal Regulations," President Reagan required a regulatory impact analysis to be completed on all regulations before they could be issued. (Executive Order No. 12291, 3 C.F.R. 127 (1982).) President Bush continued to enforce President Reagan's Executive Order during his administration. In addition President Bush set up the President's Council on Competitiveness in March 1989. The Council focused on reducing the cost of new and existing regulations and was chaired by Vice-President Quayle.

By any measure, the rapid growth of federal regulation is now continuing unabated. In 1993, President Clinton issued his Executive Order imposing a "Regulatory Planning Review" on the regulatory process. (Executive Order No. 12866, 58 Fed. Reg. 51735.) But the problem of the growth of Federal regulations remains. For example, in 1993, the number of pages in the Federal Register reached 60,950 pages, which is their highest since 1980. In addition, by 1994 the Federal regulatory establishment reached its largest size ever at 132,690 individuals. (M. Warren, "Reforming the Federal Regulatory Process: Rhetoric or Reality?" Occasional Paper

138, Center for the Study of American Business (June 1994)). The size and growth of the Federal Register is graphically reflected in table 1.

TABLE 1


Pages in the Federal Register: 1946-1993
Thousands of Pages
80
60
40
20
1950
1955
1960
1965
1970
1975
1980
1985
1990
Source: Congressional Federal Register Statistics, Office of the Federal Register.

Despite the laudable goals of many programs, experience has taught us that, too often, regulations have been more costly and less effective than they could have been. There is a wide consensus on the need for regulatory reform and on how to achieve it. This consensus includes such diverse sources as the Clinton Administration,[16] Justice Stephen Breyer,[17] The Business Roundtable,[18] the Administrative Conference of the United States,[19] the Carnegie Commission,[20] Resources for the Future,[21] the National Research Council,[22] The Brookings Institution,[23] the American Enterprise Institute,[24] and other think tanks, commissions, [25] and independent scholars at universities throughout the country.[26]

In addition, the direct costs of complying with government regulation are large and ever increasing. A study done in 1992 estimated that the cost of complying with Federal regulations in 1991 was approximately $542 billion (Thomas D. Hopkins, *Costs of Regulation: Filling the Gaps* 2 (1992) (report prepared for the Regulatory Information Service Center, Washington, DC)). In recent testimony by Thomas D. Hopkins before the Committee on Governmental Affairs, he estimated that some $600 billion annually is spent by those regulated to comply with all Federal regulations.

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[16] National Performance Review, *Creating a Government that Works Better and Costs Less*, Washington, DC (1993); address by President Bill Clinton, Washington, DC (Feb. 21, 1995); National Performance Review, *Improving Regulatory Systems*, Washington, DC (Sept. 1993).

[17] Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation*, Harv. Univ. Press, Cambridge, MA (1993); Stephen Breyer, *Regulation and Its Reform* (1982).

[18] The Business Roundtable, *Toward Smarter Regulation* (1994); The Business Roundtable, *Cost of Government Regulation Study* (March 1979).

[19] *See, e.g.*, ACUS Recommendation 85-2, "Agency Procedures for Performing Regulatory Analysis of Rules" (1985); ACUS Recommendation 88-9, "Presidential Review of Agency Rulemaking" (1988); ACUS recommendation 93-4, "Improving the Environment for Agency Rulemaking" (1993).

[20] Carnegie Commission on Science, Technology, and Government, *Risk and the Environment: Improving Regulatory Decisionmaking*, Washington, DC (June 1993).

[21] Paul Portney, *Public Policies for Environmental Protection*, Resources for the Future, Washington, DC (1990); Paul Portney, "Economics and the Clean Air Act," 4 J. Econ. Perspectives 173 (Fall 1990); *Worst Things First?: The Debate Over Risk-Based National Environmental Priorities*, Resources for the Future, Washington, DC (Adam N. Finkel and Dominic Golding, eds. 1994); *Public Policies for Environmental Protection*, Resources for the Future, Washington, D.C. (Paul Portney, Ed., 4th ed. 1993).

[22] National Research Council, *Science and Judgment in Risk Assessment*, National Academy Press, Washington, DC (1994); National Research Council, *Issues in Risk Assessment*, National Academy Press, Washington, DC (1993); National Research Council, *Valuing Health Risks, Costs, and Benefits for Environmental Decision Making*, National Academy Press, Washington, DC (1990); National Research Council, *Improving Risk Communication*, National Academy Press, Washington, DC (1989); National Research Council, *Risk Assessment in the Federal Government: Managing the Process*, National Academy Press, Washington, D.C. (1983).

[23] *See, e.g*, Lester Lave, *The Strategy of Social Regulation*, Brookings Institution, Washington, DC (1981); Lester Lave, *Quantitative Risk Assessment in Regulation*, Brookings Institution, Washington, D.C. (1982); Robert W. Crandall, *Controlling Industrial Pollution: The Economics and Politics of the Clean Air Act*, Brookings Institution, Washington, DC (1983).

[24] *See, e.g.*, American Enterprise Institute, *Benefit-Cost Analysis of Social Regulation: Case Studies from the Council on Wage and Price Stability*, Washington, DC (James C. Miller and Bruce Yandle, eds. 1979); M. J. Bailey, *Reducing Risks to Life: Measurement of Benefits*, American Enterprise Institute, Washington, DC (1980); Robert W. Hahn and J. A. Hird, "The Costs and Benefits of Regulation," 8 Yale J. on Reg. 233 (Winter 1991); W. Kip Viscusi, *Product-Risk Labelling: A Federal Responsibility*, American Enterprise Institute, Washington, DC (1993).

[25] *Worst Things First?: The Debate Over Risk-Based National Environmental Priorities*, Resources for the Future, Washington, D.C. (Adam M. Finkel and Dominic Golding, eds. 1994); *Public Policies for Environmental Protection*, Resources for the Future, Washington, D.C. (Paul Portney, ed., 4th ed. 1993).

[26] Murray L. Weidenbaum, *Business and Government in the Global Marketplace*, Prentice Hall, Englewood Cliffs, NJ (5th ed. 1995); W. Kip Viscusi et al., *Economics of Regulation and Antitrust*, D.C. Heath & Co., Lexington, MA (1992); W. Kip Viscusi, "Pricing Environmental Risks," Policy Study No. 112 (Center for the Study of Am. Bus. June 1992); W. Kip Viscusi, *Fatal Tradeoffs: Public and Private Responsibilities for Risk*, Oxford Univ. Press, NY (1992); M.K. Landy et al., *EPA: Asking the Wrong Questions*, Oxford Univ. Press, NY (1990); Cass R. Sunstein, *After the Rights Revolution*, Harv. Univ. Press, Cambridge, MA (1990).

(Thomas D. Hopkins, Hearing Before the Committee on Government Affairs on Regulatory Reform, at 1, Feb. 8, 1995.)

Adding the indirect cost of Federal regulation, which include higher consumer prices, less productive investment and lower GDP, increases the total economic costs to a range of $881 billion to over $1.6 trillion per year. (William G. Laffer, "Realistic Options for Reducing the Burden of Excessive Regulation," Heritage Foundation Memo to President-Elect Clinton, 1/19/93, pp. 5–6.)

The Environmental Protection Agency's most recent estimate of direct compliance costs of Federal environmental regulations was in 1990, when it estimated the annual cost at $115 billion. This was the same as Hopkins' estimate. In 1992, Hopkins estimated environmental compliance to be $122 billion (1991 dollars), which was 2 percent of the GDP. More than half the total environmental regulation costs are associated with water pollution control. Air pollution control is the second largest spending area, accounting for just over one-third of all federally mandated pollution costs. Land pollution control accounts for the rest of the environmental costs. Land pollution costs include solid waste; hazardous waste; RCRA and Superfund regulations. These cost estimates do not reflect implementation of the 1990 Clean Air Act Amendments. In 1992, Hopkins predicted the direct costs of environmental regulation will reach $178 billion by the year 2000.

Regulations have high out-of-pocket expenses, that both directly and indirectly affect consumers. Studies on GNP losses from environmental regulations in 1989 and 1990 estimate that GNP is from 2.6 percent to 5.8 percent lower than it would have been without environmental regulations. In addition, without "destructive regulation" the economy would have grown faster over the past 20 or 30 years, and each family would have a total income on the order of $8,000 to $17,000 higher per year, not counting regulations that produced more benefit than cost. (William G. Laffer, III, "The Re-Regulation Explosion: Costs and Consequences," The Heritage Lectures, #422, 8/26/92, p.7.)

It has also been estimated that 30 percent of the decline in U.S. manufacturing and productivity that began in the 1970's was due to EPA and OSHA regulation. (W. Gray, *The Cost of Regulation: OSHA, EPA and the Productivity Slowdown,* 77 American Economic Rev. 998 (1987).)

A sizable portion of these overburdensome costs are due to the misallocation of resources. For example, Justice Breyer has ably pointed out that spending around $4 billion per life on hazardous waste land-disposal bans, while failing to implement vaccination and mammography programs that could save lives at well under $100,000 per life, means something is wrong and lives are being wasted. (Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* at 17–19, (1993).) Similarly, the requirement set for pulp mills that imposes over $99 billion for each life-year saved. (Subcommittee Hearing on S. 343, statement of Peter J. Ferrara at 3.) Justice Stephen Breyer documented regulatory extremes by noting, "Experts calculate that the EPA rules, regulating sources such as benzene storage vessels and coke-product recovery plants, save a total of three to four lives per year, at a cost of well over $200 million; one regulation costs approximately $180 million

to save a single statistical life." (S. Breyer, *supra,* at 15). Justice Breyer also points out another recent case involving an EPA ban on asbestos pipe, shingles, and paper that cost from $200 million to $300 million to save a total of seven to eight lives over 13 years. (*Id.* at 14.) In striking down the regulation, a Federal court concluded, "[O]ver the next 13 years, we can expect more than a dozen deaths from ingested *toothpicks*—a death toll more than twice what the EPA predicts will flow from the quarter-billion dollar bans of asbestos pipe, shingles and roof coatings." (*Corrosion Proof Fittings* v. *E.P.A.,* 947 F.2d 1201, 1223 n. 23 (5th Cir. 1991), quoted in *Breaking the Vicious Circle, id.* at 14.)

Moreover, it is estimated that a reallocation of resources to more cost-effective programs could save an additional 60,000 lives per year at no additional cost, and that the same number of lives we are currently saving could be saved for $31 billion less. (Tammy O. Tengs, "Optimizing Societal Investments in Preventing Premature Death," Doctoral Dissertation, Harvard School of Public Health, June 1994; Tammy O. Tengs et al, "Five Hundred Life-Saving Interventions and their Cost-Effectiveness," *Risk Analysis,* in press, as quoted in "Reform of Risk Regulation: Achieving More Protection at Less Cost, Center for Risk Analysis, Harvard School of Public Health, at 16 (March 1995).)

These points confirm the conclusion of the representative of the National Federation of Independent Business ("NFIB") who testified before the committee: "Today, it doesn't matter whether one is a white male, a woman, or a minority, if you're in business, your common concern is TOO MUCH GOVERNMENT!" (Hearing on S. 343 before the Senate Committee on the Judiciary, 104th Cong., 1st sess. (1995) (statement of Kelvin R. Herstad at 8) (emphasis in original) [hereinafter Hearing on S. 343].

Indeed, the burdens of overregulation are dramatically exemplified in the small business community. Government paperwork alone has been estimated to consume 1 billion hours of small business owner's time, at an annual cost of $100 billion. (Susan Eckerly, *supra,* at 1.) The difficulties in dealing with these burdens were expressed by small business operators in detail for the committee. (*See* both Committee Hearing and Subcommittee Hearing on S. 343, statements by Kelvin R. Herstad and Sal Risalvato.)

This was recognized by the Clinton administration which acknowledged that "We have spent too much money for programs that don't work."[27] Indeed, "The average American believes that we waste 48 cents of every tax dollar."[28] The growing number and cost of regulation is undermining the faith of the public in government. With regulations, as with any other government programs, the American public has a right to ask whether it is getting its money's worth.

Without a doubt, we have become hostage to the unregulated regulatory process. As American Enterprise Institute President Christopher DeMuth stated in his testimony before the committee:

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[27] National Performance Review, *Creating a Government that Works Better and Costs Less* 2 (Sept. 7, 1993).

[28] *Id.* at 1.

> Federal regulation has grown enormously in recent decades and is today much more costly than all of the domestic (nondefense) discretionary spending programs of the federal government combined. Yet regulation is subject to none of the public finance constraints that govern and moderate direct federal spending: spending authorizations, limits on available tax revenues, regular annual review and appropriations by the Congress, and so forth. Regulation is instead a form of delegated lawmaking, in which Congress authorizes administrative agencies to issue rules with the force of law, most of whose effects—direct expenditures and other costs, as well as benefits—are realized entirely within the private sector, with no interposition of the public fisc. (Hearing on S. 343, statement of Christopher DeMuth at 2.)

Professor Cass Sunstein, who testified before the committee against this bill made the point by underscoring the fact that "No one can dispute the claim that Federal regulation is too expensive. We could accomplish the same amount at much lower expense. Nor should anyone dispute the claim that government ought to engage in better risk assessment and priority setting. Too often large amounts are devoted to small problems, and small amounts are devoted to large problems." (Hearing on S. 343, statement by Prof. Cass R. Sunstein at 3). Table 2, which Professor Sunstein provided to the committee, supports this statement.

TABLE 2

[Millions of 1992 dollars]

Budgeted regulations	Year	Agency	Status	Cost-per-life-saved
1. Steering column protection	1967	NHTSA	F	0.1
2. Unvented space heaters	1980	CPSC	F	0.1
3. Cabin fire protection	1985	FAA	F	0.3
4. Passive restraints/belts	1984	NHTSA	F	0.4
5. Fuel system integrity	1975	NHTSA	F	0.4
6. Trihalomethanes	1979	EPA	F	0.4
7. Underground constr.	1989	OSHA–S	F	0.4
8. Alcohol & drug control	1985	FRA	F	0.7
9. Servicing wheel rims	1984	OSHA–S	F	0.7
10. Seat cushion flammability	1984	FAA	F	0.8
11. Floor emergency lighting	1984	FAA	F	0.9
12. Crane susp. pers. platf	1988	OSHA–S	F	1.2
13. Children's sleepware flammability	1973	CPSC	F	1.8
14. Side doors	1979	NHTSA	F	1.8
15. Concr. & masonry constr.	1988	OSHA–S	F	1.9
16. Hazard communication	1983	OSHA–S	F	2.4
17. Asbestos	1986	OSHA–H	F	2.8
18. Benzene/fugitive emiss.	1984	EPA	F	3.8
Regulations failing BCA test				
19. Grain dust	1987	OSHA–S	F	8.8
20. Radionuclides/uran.mines	1984	EPA	F	9.3
Regulations failing HHA (and BCA) test				
21. Benzene	1987	OSHA–H	F	23.1
22. Ethylene oxide	1984	OSHA–H	F	34.6
23. Uran. mill tail./inact.	1983	EPA	F	37.3
24. Acrylonitrile	1978	OSHA–H	F	50.8
25. Uran. mill tail./active	1983	EPA	F	71.6
26. Asbestos	1989	EPA	F	72.9

TABLE 2—Continued

[Millions of 1992 dollars]

Budgeted regulations	Year	Agency	Status	Cost-per-life-saved
27. Coke ovens	1976	OSHA–H	F	83.4
28. Arsenic	1978	OSHA–H	F	125.0
29. DES (cattlefeed)	1979	FDA	F	178.0
30. Arsenic/glass manufact.	1986	EPA	F	192.0
31. Benzene/storage	1984	EPA	R	273.0
32. Radionuclides/DOE facil.	1984	EPA	R	284.0
33. Radionuclides/elim. phos.	1984	EPA	R	365.0
34. Acrylonitrile	1978	OSHA–H	R	416.0
35. Benzene/ethylbenz./styr.	1984	EPA	R	652.0
36. Benzene/maleic anhydride	1984	EPA	R	1,107.0
37. Formaldehyde	1987	OSHA–H	F	119,000.00

Source—Lutter & Morrall, Health-Health Analysis, 8 Journal of Risk and Uncertainty 43, 59 (1994).

The Committee is deeply concerned about the adverse impact of the growing regulatory burden on the American public. Perhaps because regulatory costs generally directly impact businesses and governments and are off-budget expenditures, they have not been adequately scrutinized. Yet, these regulatory costs are like hidden taxes. While American workers see their tax burden on their Form 1040, they are told virtually nothing about their regulatory burden. Ultimately, however, these hidden taxes are passed on to the American consumer and taxpayer through higher prices, diminished wages, increased taxes, or reduced government services. These hidden taxes amount to about $6,000 per year for the average American household.[29] And the decisions to create and impose regulations, especially at the agency level, are remote from public view, where there is greater potential for waste. Regulations are created as their need is perceived, without the constraints of a budget or forced tradeoffs with other important priorities. Because regulatory costs do not appear directly in the government budget, it comes as no surprise that governments are tempted to implement programs by way of regulations instead of expenditures at a time of soaring deficits.

The committee believes S. 343 will remedy this unjustifiable status quo by putting in place an improved administrative process that will require regulators to use reasoned decision-making and force the agencies to be more responsive and accountable to the American people, as well as to the Congress. After all, it is the American people, through their Congress, who have delegated their authority to the agencies.

III. Votes of the Committee

Pursuant to paragraph 7 of rule XXVI of the Standing Rules of the Senate, each committee is to announce the results of rollcall votes taken in any meeting of the committee on any measure or amendment. The Senate Judiciary Committee, with a quorum present, met on Thursday, April 6, 1995, at 8:20 a.m. to mark up S. 343. The following rollcall votes occurred on amendments proposed thereto:

[29] *See* Thomas D. Hopkins, "Costs of Regulation: Filling the Gaps" (Rep. Prepared for Reg. Info. Service Center) (August 1992).

(1) The Biden amendment to alter the petition process. The amendment was tabled: 9 yeas to 7 nays with 1 present.

YEAS	NAYS
Thurmond	Biden
Simpson (Proxy)	Kennedy
Grassley	Leahy (Proxy)
Brown (Proxy)	Simon (Proxy)
Thompson	Kohl (Proxy)
Kyl	Feinstein
DeWine	Feingold (Proxy)
Abraham	
Hatch	

Present—Heflin

(2) The Kennedy amendment to exempt OSHA. The amendment was tabled 10 yeas to 7 nays.

YEAS	NAYS
Thurmond	Biden (Proxy)
Simpson	Kennedy (Proxy)
Grassley	Leahy
Brown	Simon (Proxy)
Thompson	Kohl (Proxy)
Kyl	Feinstein (Proxy)
DeWine	Feingold (Proxy)
Abraham	
Heflin (Proxy)	
Hatch	

IV. Section-by-Section Analysis

SECTION 1

Section 1 sets out the short title of this bill, the "Comprehensive Regulatory Reform Act of 1995."

SECTION 2

Section 2 makes technical amendments to section 551 of title 5, United States Code, and adds a definition that "Director" means the Director of the Office of Management and Budget.

SECTION 3

Section 3 substantially rewrites section 553 of title 5, United States Code, which is the Administrative Procedure Act (hereinafter ("A.P.A.") section governing informal (notice and comment) rulemaking. New section 553 would have the following provisions:

New Subsection 553(a)

This subsection sets out the basic requirement that the procedures of section 553 apply to all rulemakings except those specifically exempted. Current section 553 does not clearly state its applicability, due in large part to the exemptions which are located in different parts of the section. The committee concluded that the ap-

plicability and requirements of section 553 should be reorganized in this way so as to more clearly express the provisions of this statute.

New Paragraph 553(a)(1)

Paragraph (a)(1) maintains the current exemption for a rule to the extent it involves a matter pertaining to a military or foreign affairs function of the United States.

New Paragraph 553(a)(2)

This paragraph tightens the existing rulemaking exemption for "a matter relating to agency management or personnel." 5 U.S.C. 553(a)(2). Under this provision only a rule relating exclusively to internal personnel rules and personnel practices of an agency is exempted from normal section 553 rulemaking procedures. The Committee adopts the discussion of this provision as it appears on pages 109–110 of its report on S. 1080 (Senate Report 97–284 (1981)(hereinafter "Report on S. 1080")).

New Paragraph 553(a)(3)

Currently the A.P.A. contains an exception for "interpretative rules and general statements of policy," allowing an agency to bypass the public notice and comment requirements otherwise applicable to agency regulations. 5 U.S.C. 553(b)(A). Since the A.P.A. was first enacted in 1946, there has been continuous confusion and ambiguity concerning whether or not a regulation is merely clarifying or interpreting an already existing right or obligation or is a statement of new requirements. We intend, under this exemption, to allow an agency to make generally applicable statements that are genuinely interpretive and to make interpretations or policy statements applicable to a particular person for a particular regulated situation without following section 553 rulemaking procedures. The Committee adopts the discussion of this provision as it appears on pages 110-114 of its report on S. 1080 (Senate Report 97–284 (1981)).

New Paragraph 553(a)(4)

This paragraph exempts rules relating to the acquisition, management, or disposal of real or personal property or services by an agency from the notice and comment procedures. Such rules do not restrict the public at large, but rather are internal rules of operation for the executive agencies themselves. As such, they do not add to the cumulative burden which regulation places on society. Therefore, the committee sees no reason to group them with burdensome regulations in requiring notice and comment.

New Subsection 553(b)

This subsection considerably expands the amount of information which must be included in a notice of proposed rulemaking. In general, these expanded notice provisions will require an agency to give the public a clearer idea of the problem an agency believes a proposed rule addresses, of the contemplated provisions of the proposed rule, of how the rule will remedy the identified problem, and of the agency thinking behind the rule. These provisions will "re-

quire more careful and thoughtful internal planning, evaluation and management of agency action and provide more informed public participation in the rulemaking process." (Hearing on S. 1080, statement of Nicholas Calio, Report on S. 1080).

The fact that these provisions will require an agency to begin the public rulemaking process with a much clearer sense of what a particular rule is designed to achieve obviously means that the notice of proposed rulemaking will be a less tentative document than at present. A related purpose of these notice-and-comment procedures is for the agency to learn from the public more about the potential effect of a particular proposal. Accordingly, though the committee has expanded the notice requirements of the A.P.A. so that the public will be fully apprised of an agency proposal, the committee does not expect that these modifications will preclude an agency from changing its thinking with respect to a particular rulemaking after receiving public comment. The expanded notice provisions are intended to give the public a clear idea of agency thinking, so that if such thinking should be changed, helpful comments to that effect will be forthcoming. Indeed, these provisions do not preclude an agency from using various informal and flexible techniques, such as the so-called advance notice of proposed rulemaking, to solicit information from the public or to otherwise test ideas before issuing a notice of proposed rulemaking. In some instances, these expanded notice requirements may be a practical incentive for an agency to employ such informal techniques to more satisfactorily prepare the notice of proposed rulemaking. The committee concluded that any attempt to require such informal mechanisms in this legislation might detract from the flexibility and informality which recommends them. However, the committee strongly encourages agencies to use such techniques whenever appropriate.

The committee expects that these expanded notice provisions will improve the rule eventually proposed by an agency; and, by setting out more definitely the rationale for the rule, make public comment more specific and useful:

> The required statements on statutory authority, congressional intent, regulatory objectives, and sources of information will focus the agency's inquiry on the actual need, purpose and likely success of its proposal. Simultaneously, those statements will allow affected parties and the public to grasp the bases and intent of the agency's action and better formulate their support or challenge to it. Id.

New Paragraph 553(b)(1)

The beginning of new paragraph (b)(1) essentially maintains the present requirement governing how notice of a proposed rulemaking shall be given; that is, it shall be published in the Federal Register unless each person subject to the proposed rule is personally served with the notice or had actual notice of the proposed rulemaking. This provision does not preclude an agency from taking additional steps to ensure that those affected by a proposed rule are aware of the rulemaking, and the Committee encourages agencies to take such steps, The individual subparagraphs of subsection (b)(1) specify what information must be included in the notice.

New Subparagraph 553(b)(1)(A)

This subparagraph requires an agency to state in the notice when comments from the public will be received and the "time, place, and nature" of any hearings which the agency is planning to hold. Under this provision, an agency must give the public all the basic information of a more mechanical nature that they need to know to adequately participate in the rulemaking.

New Subparagraph 553(b)(1)(B)

Subparagraph (B) provides that the explanation of the agency of whether the proposed rule is a "major rule" within the meaning of that term as defined in new section 621 of title 5, United States Code, must be published in the notice of proposed rulemaking. The requirement of "a succinct explanation of the need for, and the specific objectives of the rule" is intended to give the public a clear understanding of the perceived problem addressed by a proposed rule and how the agency expects the rule will resolve it. Obviously included in this basic rationale for the rule will be some explanation of the deficiencies in the existing regulatory scheme which necessitate the promulgation of the rule. In addition, this requirement will focus the attention of the agency on assessing whether a proposed rule reasonably can be expected to provide an improvement in the status quo. Thus, the agency should be able to identify such a reasonable improvement in the notice. The notice of proposed rulemaking should identify and discuss the factual information and policy determinations, including the justifications for any assumptions that underlie the agency's determination of need.

New Subparagraph 553(b)(1)(C)

Under subparagraph (C), an agency must explain its statutory authority to propose the rule which is the subject of the rulemaking. The committee expects that this explanation will be specific, setting out the explicit congressional delegation of rulemaking authority involved. As statutory language may be quite general or ambiguous, this subparagraph also requires an agency to succinctly explain how the rulemaking is consistent with the intent of Congress in delegating this authority to the agency. This provision forces the agency to comply with the standards set forth by the Supreme Court in *Chevron* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984. For a further discussion of these standards, see new section 706.)

New Subparagraph 553(b)(1)(D)

Under current law, the notice of proposed rulemaking must contain "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. 553(b)(3). The committee concluded that this formulation allowed an agency to make too generalized a statement of a proposed rule, limiting the ability of interested persons to effectively comment on a rule an agency was likely to implement. Consequently, this subparagraph tightens this language, requiring that the notice include the "proposed provisions of the rule."

New Subparagraph 553(b)(1)(E)

This subparagraph requires that a summary of any preliminary regulatory analysis, required to be issued for a proposed "major rule" under new chapter 6 of title 5, United States Code, be published in the notice of proposed rulemaking. The committee did not require the whole preliminary regulatory analysis to be published in the notice because of the expense involved in printing a lengthy analysis and because the whole analysis will be in the rulemaking file, available for public inspection and copying. The complete preliminary regulatory analysis must be placed in the rulemaking file pursuant to subparagraphs 553(f) (1) and (2). The committee intends that the summary published in the notice will be a concise presentation of the substance of the preliminary regulatory analysis, yet comprehensive enough to basically advise the public of its contents.

New Subparagraph 553(b)(1)(F)

This subparagraph requires the agency in the notice to solicit suggestions from the public for more effective or less burdensome ways to achieve the objective of the rulemaking. The committee does not expect an agency unfailingly to generate by itself the "right" approach to a particular problem. The agency should learn, and the rulemaking benefit, from the ideas, expertise, and information contributed by interested members of the public. Consequently, the committee does not intend this requirement to degenerate into a mere recitation that the "agency seeks proposals." Rather, an agency complying with this provision in good faith should tailor its invitation for alternatives to the particular rulemaking so as to stimulate helpful public comment.

New Subparagraph 553(b)(1)(G)

In adopting subparagraph (G), the committee is requiring agencies to provide a comprehensive description of the underlying data and scientific and other information which supports the proposal of the agency as well as other relevant information considered, including data which does not support the agency proposal. This description should indicate both the source of the supporting information and, where appropriate, the purposes for which the agency plans to rely on such information. Material that pertains directly to the rulemaking and that the agency has considered in connection with the rulemaking must be, described so as to disclose any information which may contradict the assumptions or conclusions of the agency which underlie the proposed rule. Subparagraph 553(c)(1)(G) would require an agency to identify the data upon which it relied or planned to rely in proposing a rule concerning the health effects of a particular substance, and to indicate the purpose or purposes for which the agency would rely upon the data. The agency would also describe other information that pertained directly to the rulemaking, such as what steps the agency had undertaken to verify the quality and reliability of the information and evaluations upon which the agency plans to rely.

The intent of this provision is to make all relevant scientific evaluations, data, and other information considered by or submitted to an agency in connection with a rulemaking available to the public

in a manner which will aid public understanding both of the basis for the regulation and of the evidence challenging that basis; and which will ensure that the opportunity for public participation in the rulemaking will allow the public to present informed and meaningful comments.

New Subparagraph 553(b)(1)(H)

This provision requires an agency to identify where the rulemaking file may be inspected or where copies of the file may be obtained.

New Paragraph 553(b)(2)

Paragraph 553(b)(2) continues in limited form the current A.P.A. exemption for those rules for which the agency has found, for good cause, that notice-and-comment rulemaking is unnecessary. It allows an agency to delay compliance with section 553 rulemaking procedures, to comply only partially, or to not comply at all for a rule which will have only an "insignificant impact."

For example, a rule has insignificant impact when it details the performance of ministerial functions within the agency which have slight external effects, such as the appropriate processing of filings and forms within the agency's offices, *United States* v. *Hayes,* 325 F.2d 307 (4th Cir. 1963), or when it is merely a published notice of changes of address within the agency structure in accordance with section 552(a)(1)(A) of title 5. An agency which consolidates two offices within its headquarters may rearrange its structure and may be required to publish such changes for the guidance of the public. But notice and comment are not necessary for the implementation of such actions. Also, events of an ephemeral nature which pass quickly but which are required to be done by rule, such as a temporary air space limitation for commercial aircraft over a missile range, are the kinds of events of insignificant public impact for which delay or exemption is appropriate. The person asserting that there is a need for prompt notice and an opportunity for comment is able to ask for such action by petition or by seeking injunctive relief.

New Subparagraph 553(b)(2)(A)

This subparagraph establishes an exemption from section 553 rulemaking procedures for an emergency rule or a rule with an insignificant impact.

New Subparagraph 553(b)(2)(B)

This paragraph qualifies the exemption from notice-and-comment rulemaking set out in new subparagraph 553(b)(2)(A). Under this provision, the exemption for rules with an insignificant impact is applicable only if the agency publishes the rule in the Federal Register with a statement explaining the finding of the agency that the rule will have an insignificant impact.

This provision codifies the notion that a mere agency recital that a rule will have insignificant impact does not mean that the rule will in fact have only an insignificant impact. This is an approach adopted by the courts in applying the existing exemptions. *E.g., Mobil Oil Corp.* v. *Dept. of Energy,* 610 F.2d 796 (T.E.C.A. 1979).

("It is axiomatic that a mere recital of good cause does not create good cause." Id. at 803.) Under this new paragraph, an agency must publicly justify its use of the rulemaking exemption for rules with an insignificant impact.

New Subparagraph 553(b)(2)(C)

This paragraph requires the agency to comply with notice and comment procedures "to the maximum extent feasible" before it promulgates a rule and must fully comply as soon as practicable thereafter.

The committee intends that an agency shall follow the rulemaking procedures normally required before a rule is made effective even in the context of emergencies, "to the maximum extent feasible." "Feasible" here means "possible." Compliance with those procedures "as soon as practicable thereafter" has a similar meaning: as soon as the agency can fully comply, it must.

New Subsection 553(b)(3)

The committee has determined that a successful public comment process requires fair and complete notice to the public of the subject of the rulemaking and of the agency's approach to that subject. When the agency's approach changes greatly in the course of the rulemaking, the public may no longer be in a position to offer valuable comment. Accordingly, paragraph (b)(3) is intended to require agencies to keep interested members of the public fairly and contemporaneously apprised of the material issues being considered by the agency and of the potential substance of rules under consideration. The committee adopts the discussion of this section in the Report on S. 1080 at pages 120–122.

New Paragraph 553(c)(1)

Paragraph (1) of subsection (c) restates and elaborates on the current section 553(c). The significant new requirement is that agencies provide interested persons a period of not less than 60 days for the submission of written data, views, arguments and statements. Existing law provides no minimum comment period. The new 60-day requirement is in accord, however, with the practice of many agencies. It was also the minimum comment period specified for significant rules in Executive Order 12044, issued by President Carter. Executive Order 12044, 43 Fed. Bed. 12,661 (1978). Given the complexity of many of the issues involved in agency rulemaking, the committee believes that the 60-day period is necessary and will not result in delays in agency rulemaking. It should be emphasized, however, that the provisions of the bill regarding emergency rules will give agencies the necessary flexibility to place a rule into effect before allowing a normal comment period where a delay would seriously injure the public interest.

New Subparagraph 553(c)(2)(A)

The committee believes that increased public comment will serve to greatly enhance the effectiveness and efficiency of agency rulemaking. This subparagraph facilitates such increased comment by authorizing the agency to notice proposed rulemakings in advance, give special notice to those likely to be subject to a rule but un-

likely to receive actual notice from the Federal Register, and opportunities for public hearings among other options. This procedure is entirely optional but the committee strongly encourages agencies to participate in the activities authorized by this subparagraph.

New Subparagraph 553(c)(2)(B)

As the decision to use or not to use the procedures in the above subparagraph are entirely discretionary, such decision is not subject to judicial review.

New Paragraph 553(c)(3)

Although the committee is strongly in favor of expanded public comment, it also recognizes the countervailing interests in having the rulemaking proceed at a reasonable pace. Therefore, this subsection authorizes agencies to establish "reasonable procedures to regulate the course of informal public hearings". This subsection is in no way meant to provide the opportunity for an agency to exclude from the hearing a person, group of people, or organization which would otherwise be permitted to appear. Rather, it is meant to provide the agency with the ability to facilitate hearings by designating representatives for several parties with a common interest in the rulemaking.

New Paragraph 553(c)(4)

This subsection requires the agency to publish a statement of a rule's basis and purpose upon final publication of the rule. The committee intends that the agency statement, of basis and purpose be more complete and significantly more informative than the minimal statement provided for in current law. In contrast to present law, such statements no longer should be "general." Instead, agencies should articulate carefully and fully the basis and purpose of a rule grounded upon the rulemaking file as constituted on the date of the final rulemaking. This statement must accompany final publication of the rule, which must occur not less than 30 days before the effective date of the rule.

The agency will be required to articulate the reasons behind the rulemaking as well as the factual and policy determinations that support it. This will afford a reviewing court the opportunity to "consider whether [the agency's decision] embodies an abuse of discretion or error of law." *Kennecott Copper Corp.* v. *EPA,* 462 F.2d 846, 849 (D.C. Cir. 1972). Only if the agency is required to "articulate the standards and principles that govern [its] discretionary decisions in as much detail as possible," *Environmental Defense Fund, Inc.,* v. *Ruckelshaus,* 439 F.2d 584, 598 (D.C. Cir. 1971), will a reviewing court be able to determine whether the agency "[took] a 'hard look' at the salient problems and [had] not genuinely engaged in reasoned decision-making." *Greater Boston Television Corp.* v. *FCC,* 444 F.2d 841, 851 (D.C. Cir. 1970). As a general matter, this will require the agency to cite the credible and reliable evidence in the rulemaking record and the policy bases which support its determinations, identify the factors considered in promulgating the rule, and explain how information received by the agency was developed and evaluated.

It is important that the basis and purpose of the rule be delineated fully at the time of promulgation to avoid "post hoc rationalizations" by the agency or the courts. The requirement that the statement accompany the rule is also intended to further this goal. As the Supreme Court stated in *FPC* v. *Texaco Inc.*, 417 U.S. 380, 397 (1974) (citing *Burlington Truck Lines* v. *U.S.*, 371 U.S. 156, 168-69 (1962), "we can not 'accept * * * post hoc rationalizations for agency action'; for an agency's order must be upheld, if at all, 'on the same basis articulated in the order by the agency itself.'" Post hoc rationalizations serve to defeat the purpose of notice and comment rulemakings by permitting the one-sided articulation or creation of a "rationale" without the opportunity for public examination or commentary.

New Subparagraph 553(c)(4)(A)

The subparagraph (A) provision for "a statement of the need for, and the objectives of, the rule" is intended to require an agency to demonstrate adequate support for its determination that the final rule reasonably can be expected to improve significantly the status quo. Thus, the agency should make a threshold determination that there is a need for such a rule and that there is a reasonable likelihood of significant improvement as a result of the rule. This provision is intended to avoid regulation where significant improvement can not reasonably be predicted based on the information available to the agency. The agency's determination of need should be based on adequate information which, if questioned, has been validated and confirmed on the basis of generally accepted standards in relevant fields of expertise.

New Subparagraph 553(c)(4)(B)

This subparagraph is intended to ensure that an agency will genuinely consider and respond to reasonable alternatives to a rule proposed by persons outside the agency. The agency need not consider approaches which are not lawful under the applicable statutes. Indeed, since an agency may not promulgate a rule for which it lacks statutory authority, it is only common sense that it need not consider such a rule. In such a case, the agency should explain its conclusion that a particular alternative is not lawful. An agency is not precluded, however, from describing alternatives which are not lawful under applicable statutes where otherwise required by law to do so or where it believes a public airing of the issues will be in the public interest. This subparagraph also is intended to put on the record alternatives considered by the agency on its own and the reasons why the agency rejected these alternatives. As a result, the committee accepts that this provision will create an incentive for an agency to approach the resolution of a particular problem from the broadest possible perspective, always searching for more effective or less burdensome ways to fulfill its basic statutory mandate. In addition, by requiring an agency to address and respond to the reasonable alternatives proposed by the public, this subparagraph creates an incentive for interested members of the public to devote their time and energy to develop such alternatives. Both of these incentives only serve to improve the quality of rulemaking.

New Subparagraph 553(c)(4)(C)

This subparagraph requires essentially the same information to be published in the statement of basis and purpose as must be published in the notice of proposed rulemaking. This requirement is reiterated here to ensure that the agency addresses any comments from the public challenging the agency's assertion in the proposed rule. The committee felt that this legal issue should be segregated from other issues raised by public comments and subjected to particular scrutiny because of the serious consequences of expansive agency interpretations of enabling statutes. This reinforces the holding in *Chevron* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984). (For a further discussion of these standards, see new section 706.) In addition, insofar as Congress has inadvertently created ambiguous delegations of authority to agencies, highlighting of statutory ambiguities in this way assists Congress in fulfilling its oversight responsibilities and provides an incentive for the Congress to avoid such ambiguities in the future. Finally, this process will assist the Congress in avoiding the constitutional problems of standardless delegations of lawmaking authority.

New Subparagraph 553(c)(4)(D)

Subparagraph (D) requires an agency to publish in the statement of basis and purpose "a succinct explanation of how the factual conclusions upon which the rule is based are substantially supported in the rulemaking file." Under this provision, the agency must explain how the factual conclusions on which the rule is based are supported by reliable and credible evidence in the rulemaking file. This explanation does not need to be made for every factual conclusion. Rather, this requirement involves only factual conclusions of enough significance that they can be characterized as conclusions "upon which the rule is based."

For those factual conclusions "upon which the rule is based," however, the committee expects the "succinct explanation" will be more than a mere recitation of the agency's factual conclusions. In its "succinct explanation," the agency should meaningfully relate how its finding that a certain fact exists flows from the evidence before the agency, justifying its rejection of any contrary evidence.

This subparagraph further requires the agency to publish a summary of its assessment of the comments presented by the public. This assessment should contain the agency's response to those comments. The agency is not required to respond to each commenter, but should respond to significant issues raised in the comments to the proposed rule. Of course, the committee does not intend that the significance of an issue be determined by the number of commenters who raise it. In some cases, a significant issue may be raised by only one commenter. The committee expects that the agency response will be commensurate with the comment. If comments are cursory or are concerned with trivial issues, they warrant little agency response. As the court noted in *Portland Cement Ass'n.* v. *Ruckelshaus,* 486 F.2d 375, 394 (D.C. Cir. 1973), *cert. denied* 417 U.S. 921(1974), an agency's obligation to respond arises when public comments are "significant enough to step over a threshold requirement of materiality. * * *" What will be required from the agency by way of response will depend on what is pre-

sented. *Oljato Chapter of the Navajo Tribe* v. *Train,* 515 F.2d 654, 666 n. 19 (D.C. Cir. 1975). In each instance, the agency's response should be sufficient to demonstrate that the agency has given due consideration to the comments in arriving at a final rulemaking decision.

Thus, this provision essentially codifies the better case law under the A.P.A., requiring courts to look for an agency's "conscientious attention to the objections raised to the proposed rule, and their reasoned disposition on the basis of technical information and other relevant considerations." *Automotive Parts & Accessories Ass'n* v. *Boyd,* 407 F.2d 330, 341 (D.C. Cir. 1968). *Accord, Natural Resources Defense Council* v. *Nuclear Regulatory Comm'n,* 547 F.2d 633, 646 (D.C. Cir. 1976), cert. denied, 429 U.S. 1090 (1977).

New Subparagraph 553(c)(4)(E)

This subparagraph requires that a summary of any final regulatory analysis, required to be issued for a proposed "major rule" under new subchapter II of chapter 6 of title 5, United States Code, be published in the statement of basis and purpose. The committee did not require the whole final regulatory analysis to be published in the statement of basis and purpose because of the expense involved in printing a lengthy analysis and because the whole analysis will be in the rulemaking file, available for public inspection and copying. The complete final regulatory analysis is a part of the file of the rulemaking. The committee intends that the summary published in the statement of basis and purpose will be a concise presentation of the substance of the final regulatory analysis, yet comprehensive enough to inform the public of its contents.

New Paragraph 553(c)(5)

This paragraph excepts from the requirements of new subsection 553(c) all rules which are promulgated pursuant to a statute which requires an opportunity for an agency hearing before rules are made on the record. It is the goal of the committee to assure the opportunity for public comment. Clearly, where the statute which is the basis for a proposed rule already provides for such opportunity, it would be unnecessary and repetitive to apply further, similar requirements. Thus, the committee is satisfied to defer to the requirements laid out in the existing statute, if such requirements exist.

New Subsection 553(d)

This subsection requires the agency to publish a final rule in the Federal Register at least 60 days in advance of the effective date of said rule. While the committee is cognizant of the desire to promulgate rules expeditiously, it also recognizes the importance of giving the regulated community a fair and reasonable opportunity to comply with a new rule. The committee believes that this provision is crucial to provide the public enough time to prepare for the promulgation of a new rule.

When a rule grants or recognizes an exemption or relieves a restriction, this provision is clearly unnecessary. It is only when new restrictions are created which the regulated community must comply with that the policy of early notification is applicable. Thus, the

committee excepts from the 60 day requirement rules which lift restrictions.

The committee also recognizes that in emergency situations it may be important for a rule to be promulgated without waiting for the 60-day advance notice. Thus, the subsection provides for a waiver of the requirement where the agency for good cause finds that the delay would be contrary to important public policy. The committee views this provision as applicable to emergencies, where delay in the promulgation of the rule would result in unusually serious harm to a public interest. In any case, in order for the agency to invoke this exception, it must publish a finding and explanation of the reasons for such invocation with the final rule.

New Subsection 553(e)

This subsection expands the rights of petition under the A.P.A. by providing that an interested person may petition for advice or interpretation regarding the application of a rule, or, where permitted by law, for a variance or exemption. It also requires the agency to respond in writing and with reasonable promptness to such a petition and to state the reasons which support the agency's conclusions.

The provision for advice or interpretation is not novel; it codifies the better practices of some agencies to respond to inquiries, sometimes only informally and sometimes formally, such as the Internal Revenue Service's private rulings. In the view of the committee, a person faced with conflicting rules and apparent inconsistencies in agency decisions, for example, should be able to obtain advice promptly from agencies to eliminate the potential for duplicative liability. This provision is intended to require agencies to reasonably respond to petitions for such interpretations. The provision for variances or exemptions is also not out of the ordinary; some agencies already are required to consider and act upon such requests, as the Supreme Court recognized in *U.S.* v. *Storer Broadcasting,* 351 U.S. 192, 201, 205 (1955).

This subsection also requires a written response with a statement of reasons to be issued with reasonable promptness. In *Oljato Chapter of the Navajo Tribe* v. *Train,* 515 F.2d 654, 667 (D.C. Cir. 1975), Judge Leventhal noted that "the substantiality of the [agency's] response [to a petition] must necessarily be related to the substantiality of the issues raised." The Committee endorses this reasoning as spelled out in the *Oljato* case:

> Naturally the expansiveness of the Administrator's articulation of reasons depends on the complexity and substantiality of the issues raised. We are by no means demanding comprehensive responses to frivolous petitions, but nor are we sanctioning summary dismissals of meritorious claims * * *. In large part what we will demand by way of response from the Administrator will depend on what is presented by petitioners in support of this claim. *Id.* at 666–667 n. 19.

The nature and substantiality of the agency's response will depend in each case on the relevance and importance of the issues raised in a petition, on the detail with which the petitioner's claims

are presented, and on the quality and substantiality of the data, evidence and other material submitted in support of those claims.

This subsection requires further that an agency respond to any petition "no later than 180 days after the petition was received by the agency". This is to ensure that petitions are dealt with in a reasonable period of time. Previously, agency reaction to similar petition processes was inordinately slow. Thus, the committee believes it necessary to place this reasonable time limit on the agency.

It must be emphasized that the committee does not intend that this subsection create rights to a particular interpretation, or to a variance or exemption. If an agency is precluded by law from granting a variance or exemption from a rule, for example, this subsection does not give it the authority to do so. Similarly, this subsection does not contemplate a particular procedure by which an agency must respond to these petitions. An agency may employ, or even already have in place, any procedure for responding to such petitions which is consistent with and which achieves the goals of this subsection.

New Subsection 553(f)

Subsection (f) specifies the categories of documents that comprise the rulemaking file. This file, plus the material excluded from the file pursuant to new paragraph 553(f)(2), constitutes the record of the rulemaking for purposes of judicial review. Thus, for example, the complete preliminary and final regulatory analysis and transcripts of any hearings, are part of the whole rulemaking record.

The current A.P.A. contains no provision setting out what is to be the record of informal rulemaking, or indeed requiring that there is to be such a record. In order to make the judicial review provisions of the A.P.A. viable, however, the courts have found it necessary to imply a requirement that administrative decisions be based on some kind of a record. *E.g., Citizens to Preserve Overton Park, Inc.* v. *Volpe,* 401 U.S. 402, 420 (1971); *Camp.* v. *Pitts,* 411 U.S. 138, 142 (1973). See generally 1 K. Davis supra at section 6:5. Obviously, requiring a record for rulemaking in such a backhanded manner injects considerable, and unnecessary, uncertainty into judicial review of rulemaking:

> The problem with the "records" currently certified to the courts is that their content is unknown until judicial review is well under way. This may lead either to inclusion of far more documents than are needed to understand the rule or to exclusion of documents that have a legitimate bearing on it. As a result the courts are confronted with huge, unwieldy records, and are forced to spend undue effort in weighing the parts of each record and extracting underlying reasons from the documents, jobs which the agencies should have done themselves. (Report on S. 1080, statement of Raymond Momboisse, at 11.)

Furthermore, a requirement for a rulemaking record articulated essentially in judicial precedents is by nature indefinite in its application to specific rulemakings and leaves an agency with enormous discretion to determine the contents of the record:

> Agency practice has often varied widely from court requirements. A chief reason for this is the current absence of any general statutory requirement that a record, available to the public, be established at some point before a final decision is made. Unless some special statutory provision requires otherwise, no discrete record is currently necessary in informal rule making until a court challenge is begun * * * [T]he agency's instinct is to find everything that conceivably supports its decision and claim that these materials, together with publicly filed comments, constitute the record. Unfavorable material, on the other hand, especially if its existence is known only to the agency, will not be handled so carefully. In fact, such material may even be concealed. *Id.* (Statement of Raymond Momboisse, at 11–12.)

Accordingly, the Committee intends that paragraph (f) be a clear statutory articulation both of a requirement that informal rulemaking be based on material in a public file compiled contemporaneously with the progress of the rulemaking and of the categories of material that must be included in the file. By specifying these categories, the committee intends for the file to include those materials that might reasonably be expected to play an important role during a rulemaking or on judicial review of a rule. The record for judicial review includes not only the rulemaking file, but also confidential material excluded from the file pursuant to paragraph (4). If courts are to scrutinize rulemakings carefully on judicial review, they should have access to the complete text of significant confidential material, which the agency will place in the public file only in summary or aggregate form. It may be necessary for reviewing courts to exercise their inherent authority to preserve the confidentiality of such material during judicial review through appropriate in camera inspections, protective orders or similar devices.

SECTION 4

New Section 621

Section 621 sets out the definitions of important terms used in subchapter II.

Subsection 621(1)

This paragraph defines the term "benefit" as meaning the reasonably identifiable significant incremental 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. The Committee intends that this term be defined broadly, so as not to exclude from consideration any significant beneficial effects that might derive from a rule or an alternative to a rule. Further, the benefits resulting directly or indirectly from a rule are not limited to effects which can be quantified. For example, they may include, where identifiable and significant, benefits of a less tangible nature, such as increased freedom of choice for consumers or other groups, or a positive impact on human enjoyment of the environment. In other words, qualitative and noneconomic as well as quantitative and economic benefits must be evaluated.

At the same time, the definition specifies that the benefits to be considered are only those that are "reasonably identifiable." The committee intends this qualification to exclude speculative benefits and to clarify that the identification of benefits to a rule or an alternative to a rule should be supported by adequate information and not by mere assumptions or guesses.

In this regard, the committee intends to preclude the use, in determining or calculating benefits under this legislation, of speculative or theoretical benefits derived from the prevention of loss of so-called "non-use" values. For example, the U.S. Department of Interior has proposed calculating non-use values by assigning to a resource a dollar value based upon what people might be willing to pay (hypothetically) to preserve or restore the resource even if the resource is not directly used by the person or has no commercial economic value, i.e., the so-called "contingent valuation method." *See e.g.,* 59 Fed. Reg. 23,097 (May 4, 1994). Thus, the committee intends that agencies not rely on speculative and unreliable methods, such as contingent valuation or other survey methods, to calculate "use values" for a resource.

The use of the term "incremental" in the definition of benefits is meant to ensure that agencies recognize the role of diminishing returns in taking action toward any regulatory objective. In many cases, great benefits may be obtained by relatively inexpensive and simple steps. It is the intent of the word "incremental" that the agencies must apply cost-benefit analysis so as to assess the utility of each further increment of control or action, as well as ensuring that the action level finally chosen has benefits that outweigh its costs.

Finally, the definition of benefits is limited to those that are "significant." This language specifies that agencies should not devote society's finite resources to achieving benefits whose significance is *de minimis*. In other words, an agency is not required to expend resources to quantify alleged benefits that existing science views as either speculative or *de minimis*.

Subsection 621(2)

This paragraph defines the term "cost" in a manner essentially identical to that of the term "benefit," while further specifying that "costs" includes 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. Costs, therefore, are defined broadly to ensure agency consideration of any significant, identifiable adverse effects (including all identifiable adverse health, safety, or environmental effects) associated with a rule or an alternative. Indirect or secondary adverse effects should be considered, even though the agency may not always be able to measure such adverse effects precisely. Like benefits, the adverse effects that must be considered are those that are "significant" and "identifiable," and agencies should also consider intangible costs, although agencies should take care to base their cost estimates on information of reliable quality.

In particular, the committee expects agencies, in meeting the requirements of this legislation, to be mindful of the fact that, in

some cases, a rule that establishes some otherwise acceptable regulatory level or value can nonetheless impose a huge impact outside the scope of the statute under which the rule is adopted. Examples of this include the use of Safe Drinking Water Act maximum containment levels in establishing the remedy required by the Superfund program, as well as the use of CERCLA's reportable quantities in the U.S. Department of Transportation's (DOT's) hazardous materials regulations. At present, the "secondary" impacts of the levels or limits in these regulations are neither calculated nor considered when they are initially adopted.

Thus, for instance, the costs and benefits of Superfund remedies that must incorporate the drinking water standard are not considered in setting that standard. However, neither are these costs really considered at the time the Superfund remedy is chosen because, by that time, the drinking water standard is seen as a mandatory item that must be met no matter what the cost. Similarly, the reportable quantities established by EPA under CERCLA are set without regard to the fact that they are incorporated into DOT's hazardous materials transportation rules. The committee views such lack of consideration of the "secondary" impact of regulations to be inconsistent with the thrust and the purpose of this legislation and intends that agencies view the "costs" of their rules in a broad manner that encompasses secondary impacts.

Subsection 621(3)

Under this paragraph, the term "cost-benefit" analysis is defined to mean 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 subchapter II of the legislation 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. By this definition, which calls on agencies to perform an "evaluation" of costs and benefits, the committee intends to make it clear that a traditional, formal "cost-benefit analysis" designed to reduce everything to a monetary value is not required.

Subsection 621(4)

This paragraph defines the term "major rule" as used in the legislation. This definition establishes the criteria for determining or designating the rules for which cost-benefit analyses shall be performed under section 622 and which shall be treated as major rules for other purposes under this legislation.

This paragraph provides two basic definitions for a "major rule." These definitions are disjunctive and not conjunctive or cumulative. Thus, the test set out in clause (A)(i) is distinct from, and does not apply to, that in clause (A)(ii). It is possible, of course, that a rule might meet the criteria for being "major" under both tests, but that outcome is not required. A rule need meet the standard of only one of these clauses to be major.

In evaluating whether a rule is major, both definitions apply to a "rule or a group of closely related rules." In this manner, the definition of "major rule" recognizes that a number of different rules

which, though not strictly "major" independently of each other, may be so related in either design or ultimate effect that together they have an impact of sufficient significance that they should be considered "major" and subject to cost-benefit analysis.

Clause (A)(i) sets out the basic elements of the first definition of "major rule." It provides that a rule is a major rule if it has a gross annual effect on the economy of $50 million or more in reasonably quantifiable increased direct and indirect costs, or has a significant impact on a sector of the economy. The committee intends that the phrase "direct and indirect costs" should be read broadly to include the secondary costs that can be said to result from the rule and that can reasonably be measured in monetary terms. Thus, costs are not limited to those expenses for equipment and labor necessary to meet the terms of the rule, but also include indirect costs, such as adverse effects on health, employment, wages, consumer prices, the costs due to use of the rule's provisions in other regulatory contexts (as noted above), and the like. Remote or highly speculative costs, however, should not be included. As society's ability to make such quantified estimates expands, the class of costs encompassed by this definition will also expand. "Gross annual effect," meanwhile, should also include that portion of the amortized capital costs of compliance that may reasonably be attributed in a given year.

Clause (A)(ii) sets out the second definition for a "major rule." It provides that an agency, or the Director of OMB or the President's designee, may designate a rule as major due to certain specific significant effects of the rule, irrespective of whether the rule will have an annual effect on the economy of $50 million or will have a significant impact on a sector of the economy. This definition may be characterized as being relatively more subjective than that in clause (A)(ii) because, not setting out a clear standard like an impact of $50 million, it relies heavily on the judgment of the agency, and of the Director or the President's designee, regarding the ultimate impact of the rule. In spite of this subjective element, the committee concluded that this alternate definition for major rules was necessary due to the inadequacy of the simple "$50,000,000 test" in capturing rules whose disruptive impact was significant enough to warrant cost-benefit analysis, but whose impact did not rise to that level or was not reducible to a monetary measure. In addition, the "$50,000,000 test" tends to focus heavily on economic matters, or at least on quantifiable effects, thereby not completely reflecting the committee's view that cost-benefit analysis is not merely an economic impact analysis, but encompasses all effects of a rule. If a rule "is likely" to produce any of the effects set out in subclauses (I) through (V)—that is, if there is a substantial probability that any of those effects will result as a consequence of the rule—the rule should be designated as "major" and subjected to cost-benefit analysis.

The committee cautions agencies, in applying either of these statutory definitions, not to seek to avoid the requirements of the legislation by artful characterization, by claiming that a rule is procedural only, or by splitting a rule into numerous pieces. Rules which impose paperwork or procedural requirements on individuals or businesses or which specify a procedure that may increase the costs

to an individual or business can have the same adverse effect on the economy and the Nation's competitiveness as a rule imposing substantive requirements, and all such rules should be subject to the requirements of this legislation. Where, for example, a rule establishes or effectuates a presumption and the presumption, if sustained, may lead to the imposition of costs, expenses, or damages exceeding the statutory threshold in a given year, the rule should be subject to the requirements of this legislation. Similarly, agencies are not permitted to divide a rule into segments or pieces and then claim that the segment or piece does not exceed the monetary threshold of this bill. Such piecemealing is completely contrary to the intent of this legislation. For the purpose of determining the application of the threshold, an agency must consider the effect of the entire subject matter of the rule at issue, including any item which is logically related or practically integral thereto.

Finally, the language in (B) provides that the term "major rule" does not include a rule that involves the internal revenue law of the United States nor a rule or agency action that authorizes the introduction into, or removal from, commerce, or recognizes the marketable status of a product.

Subsection 621(5)

This paragraph defines "market-based mechanism" in broad, straightforward and practical terms, to include any regulatory program that imposes legal accountability for achieving the regulatory objective on each regulated entity, affords maximum flexibility to each regulated entity in so meeting the regulatory objectives, and permits regulated entities to respond freely to changes in pertinent economic conditions and circumstances.

Subsection 621(6)

Under this paragraph, "performance-based standards" include requirements, expressed in terms of outcomes or goals instead of mandatory measures, that permit discretion and the use of market-based mechanisms in determining how best to meet specific requirements in particular circumstances.

Subsection 621(7)

The term "reasonable alternative" under this section is defined as meaning the range of regulatory options, including taking no regulatory action, that the agency has discretion to consider under the statute pursuant to which the rulemaking is authorized, as interpreted, to the maximum extent possible, to embrace the broadest range of options that satisfy the decisional criteria of section 624(b). In other words, an agency must consider the broadest range of alternatives that the text of such statute grants it discretion to consider, and must interpret that grant of discretion, to the maximum extent possible, so as to allow the agency to consider the broadest range of options that satisfy the cost-benefit decisional criteria of section 624(b).

Subsection 621(8)

This paragraph provides that "rule" has the same meaning as already provided under section 551(4), while further specifying that,

for purposes of subchapter II, it includes any statement of general applicability that alters or creates rights or obligations of persons outside the agency. The committee intends by this provision to subject to the requirements of this legislation agency interpretive rules, guidance documents, and statements of policy which, while not fitting within the classic definition of "rule," have the practical effect of imposing binding obligations on regulated entities. In this regard, the committee is concerned by the practice of some agencies to evade the requirements of notice- and-comment rulemaking by styling seemingly prescriptive regulatory standards or criteria as "guidance" materials (or by strongly encouraging States with delegated programs to adopt such standards or criteria as a matter of State law), while at the same time claiming that those materials do not have the force of law or have binding effect. By defining "rule" in this way for purposes of subchapter II, the committee intends that the practical scope and effect of agency pronouncements and issuances, rather than the agency's own characterization of them, control for the purposes of ascertaining whether or not such materials are properly considered as being "rules" subject to the requirements of this legislation if they are determined to be, or designated as, "major." The committee does not intend to discourage agencies from utilizing truly nonbinding guidance materials in carrying out their regulatory responsibilities; in fact, informal guidance on complying with existing regulations is to be encouraged, not discouraged. However, agencies should not attempt to evade the requirements of this legislation, or of the APA in general, through self-serving mischaracterizations of such materials.

New Section 622

Section 622 sets forth the basic requirements for the cost-benefit analysis that must be developed by the agency in conjunction with its proposal and promulgation of a major rule. Under subsection (a), an agency must determine whether or not a rule is "major" within the meaning of section 621(4)(A)(i) before publishing the notice of proposed rulemaking. If an agency determines that the rule is not major under that definition, it may also decide, again before publishing the notice, whether it will designate the rule as major on the grounds set out in 621(4)(A)(ii). In those circumstances where a notice of proposed rulemaking had already been published prior to the date of enactment of this legislation, this determination or designation must be made not later than 30 days after enactment.

Where the agency determines that the rule is not "major," under section 622(b), the Director or the President's designee may, as appropriate, make a determination or designation of the rule as "major" not later than 30 days after publication of the notice of proposed rulemaking (or, in the case of a notice proposed rulemaking that has been published after the date of enactment, not later than 60 days after enactment). Such determination or designation by the Director or by the President's designee shall be published in the Federal Register, along with a succinct statement of the basis for the determination or designation. This provision is not intended to displace the agency as the entity with primary responsibility for deciding whether a rule is major. Rather, it is intended as an over-

sight device to ensure that agencies evaluate the potential impact of a rule thoroughly and fairly. The committee considers such oversight to be critical to the effective application of cost-benefit analysis.

Section 622(c) prescribes the requirements for an initial cost-benefit analysis to be included in the notice of proposed rulemaking for each major rule. Under section 622(c)(1)(A), the agency must place its initial cost-benefit analysis in the formal rulemaking file so that it is available, along with the rest of the agency's supporting documentation, for public notice and comment. In those circumstances where the Director or the President's designee has made the determination or designation of a rule as "major," section 622(c)(1)(B) specifies that the agency must "promptly" issue and place the initial analysis in the rulemaking file, publish notice of such analysis in the Federal Register, and afford interested persons the same opportunity for comment as if the agency had initially made such determination or designation.

In general, the initial cost-benefit analysis must set out the benefits and costs, and identify the "reasonable alternatives" that the agency has discretion to adopt under the statute granting the rulemaking authority as supplemented by the decisional criteria in section 624 to ensure consideration of the broadest range of options that could meet section 624. Paragraph (A) of section 622(c)(2) requires that the initial cost-benefit analysis contain an analysis of the anticipated benefits of the proposed rule, including benefits that cannot be quantified. When a benefit involves public health, for example, the agency should evaluate the underlying data and information to ensure that it is reliable and accurate and that the rule addresses the true cause of the particular public health problems. It can be expected that the group of benefits that are quantifiable will expand as measurement techniques improve, in some degree due to the impetus of this legislation. For intangible benefits that cannot be quantified, agencies should discuss the nature of the benefits and should explain the factual information and judgments that support the significance ascribed to such benefits by the agency.

It must be remembered, in any event, that at this point the analysis is "initial." This does not mean that the agency is free to make only minimal efforts to evaluate the potential effects of a proposed major rule. Rather, it serves to underscore the fact that this analysis is made at the beginning of the rulemaking process, before the agency has had the benefit of public comment. Accordingly, although the committee expects an agency to make its best efforts to analyze the ramifications of a proposed rule at this stage, we recognize that these efforts are, by definition, preliminary and, practically speaking, cannot be the kind of thorough and probing evaluation that the legislation demands of the final analysis.

The agency must also explain how it expects the rule will produce each benefit. This explanation is central to the goals of this legislation because this explanation gives the public added insight into what the agency hopes to achieve with a particular rulemaking and how it expects to do so. With this information, interested persons outside the agency are in a better position to make useful comments on the rule, to either improve its effectiveness or reduce

its burdens. This explanation must also describe the persons or classes of persons who will benefit from a proposed rule, the so-called "distributive effects" of a rule. The agency should include in this explanation an identification of any special persons or classes of persons which might be intended by the enabling statute to benefit from the rule being promulgated.

Paragraph (B) of section 622(c)(2) sets out the requirements for the description of the costs of a rule in a manner paralleling paragraph (A), governing the description of benefits. Both provisions are shaped by the same concern that the broadest range of reasonably identifiable effects—effects on individuals, on industries, on different levels of government—be taken into account in rulemaking. Consequently, paragraph (B) requires agencies to succinctly describe all the anticipated costs of a proposed rule, including costs which cannot be quantified, or which are indirect results of the rule, such as the loss of the use of a product or service. As explained above in the discussion of section 621(2), "costs" is not limited to economic impacts, but includes social effects as well. A deleterious impact on the environment, a restriction of consumer choice, or a constraint on the movement of populations could all be considered social costs of a rule.

Paragraph (C) of section 622(c)(2) requires that an agency identify and thoroughly evaluate all of the reasonable alternatives to the proposed rule that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority. The agency should list those alternatives, along with an analysis of the costs and the benefits of each of these alternatives. This paragraph specifically provides that an agency should consider permissible alternatives that require no government action (including voluntary or consensus standard-setting and taking no regulatory action at all), alternatives that account for differences among geographic regions (including the use of State or local level implementation and enforcement), and alternatives that employ voluntary or performance-based standards. The agency's analysis of the costs and benefits of alternatives under this provision should be similar to the corresponding analysis for the proposed rule.

Paragraph (D) of section 622(c)(2) further specifies that the initial cost-benefit analysis must include an assessment of the feasibility of establishing a regulatory program that operates through the application of voluntary programs, voluntary consensus standards, market-based mechanisms, or other flexible regulatory alternatives.

Paragraph (E) of section 622(c)(2) provides that, in any case in which the proposed rule is based on one or more scientific evaluations, scientific information, or a risk assessment, or is subject to the risk assessment requirements of subchapter III, the initial cost-benefit analysis must include a description of the actions undertaken by the agency to verify the quality, reliability, and relevance of such scientific evaluations or scientific information in accordance with the requirements of subchapter III.

Paragraph (F) of section 622(c)(2) requires that the initial cost-benefit analysis contain an analysis, to the extent practicable, of the effect of the proposed rule on the cumulative burden of compliance with the rule and other existing regulations on persons com-

plying with it, as well as an analysis of the net effect of the rule on small businesses with fewer than 100 employees, including employment in such businesses. The committee believes that it is important for each agency that engages in rulemaking to measure and account for the cumulative regulatory burden it is imposing on a particular industry as it issues each new major rule. In this regard, the committee would welcome the development—by OMB or some other suitable governmental entity—of a common, government-wide methodology for quantifying the cumulative regulatory burden on each sector of industry and for reporting it to Congress, the President, and the public. As the committee understands it, there exists feasible methods for doing this that employ a net present value cash flow analysis, utilize well-understood and commonly-used business financial data, and yield comparable results when applied across agencies. The committee strongly encourages the use of such a method in meeting the requirements of this provision.

Paragraph (G) of section 622(c)(2) requires that the agency analyze (1) for proposals meeting the criteria of section 624(b), whether the benefits of the proposed alternative justify its costs and that the alternative proposed will achieve greater net benefits than any of the other "reasonable alternatives," or (2) for proposals to which section 624(c) applies (i.e., because none of the reasonable alternatives have benefits that justify their costs), how the proposal will result in lower net costs than any of the other reasonable alternatives. In general, what this provision is intended to do is to force agencies, at the very beginning of the rulemaking process, to seriously and comprehensively assess all the effects of regulations. All too often, in the committee's estimation, agencies have failed to undertake such an assessment, and this legislation is designed to remedy this serious deficiency in the agencies' rulemaking process.

Under paragraph (G), the agency must explain whether the benefits of the proposed rule will "justify" its costs. The choice of the word "justify" is an important one. It signifies two things: first, that precise numerical quantification of costs and benefits is neither required nor anticipated in all cases; second, that agencies are free to bring to bear judgmental factors, to supplement their numerical analysis, in making the required determination. In other words, an agency must be able to conclude that, considering all of the relevant quantified and nonquantified and economic and noneconomic benefits and costs, and the persons or groups to whom those benefits and costs pertain, on balance the proposed action is worthwhile to society.

When an agency publishes a final major rule, section 622(d)(1) requires the agency to include a final cost-benefit analysis in the rulemaking file. As provided in section 622(d)(2), this final cost-benefit analysis must contain a description and comparison of the reasonable alternatives the agency considered in promulgating the final rule. The final cost-benefit analysis must also explain how the agency applied the section 624 decisional criteria to select the final rule from among the reasonable alternatives considered. Pursuant to section 622(d)(2)(B), the final cost-benefit analysis must discuss, for final rules selected under section 624(b), how the benefits of the final rule justify its costs and how the final regulatory option se-

lected will achieve greater net benefits than any of the other regulatory alternatives, including reasonable alternatives brought to the agency's attention in comments submitted during the rulemaking process, even if those alternatives were not among those listed by the agency in its initial cost-benefit analysis. For final rules to which the fall-back decisional criteria of section 624(c) apply, because none of the reasonable alternatives have benefits which justify its costs, the agency must discuss how the selected final regulatory alternative will result in lower net costs than any of these other reasonable alternatives.

As the initial and final cost-benefit analyses are part of the formal rulemaking record, the agency's application of the decisional criteria in selecting among the reasonable alternatives is an issue that may be considered by a reviewing court under the APA in its review based on the rulemaking record as a whole. Judicial review of agency action under this legislation is discussed in further detail elsewhere in this report.

Subsection (e) of section 622 requires agencies to quantify or to estimate numerically the costs and benefits of a rule whenever it is reasonably possible to do so. The Committee intends that agencies should perform this quantification even if uncertainties in the data preclude a precisely accurate numerical estimate. By requiring that benefits and costs be quantified "in the most appropriate unit of measurement," the Committee intends to emphasize that benefits and costs need not be expressed in monetary terms except where appropriate to best describe the particular type of cost or benefit.

Finally, subsection (f) provides that the agency decisionmaker is the person who must perform the initial and final cost-benefit analyses and make the various determinations required under this legislation. This requirement is important, for it preserves the role of regulatory analysis as a process which shapes regulatory decisionmaking. At the same time, the complexities of a particular rule might compel an agency to hire consultants to gather data, and perform some analysis of that data, for use in the cost-benefit analysis. This subsection specifically allows for such use of consultants as long as this practice does not usurp the position of the agency as the primary entity evaluating the effects of a rule. When a consultant is employed according to the provisions of this subsection, that fact must be disclosed in the initial and final cost-benefit analyses, including a description of the arrangement with the consultant.

New Section 623

To maximize the effectiveness and reach of regulatory reform, the committee recognizes that the legislation should extend the benefits of its cost-benefit and other reasoned decisionmaking principles to existing major rules. It is the existing federal rules that the public is complaining about, and rightly so, in many instances. It is thus extremely important that the reasoned decisionmaking requirements of the legislation be used to correct past errors. In short, where an update of the science or of the decision in question is warranted under the new cost-benefit principles, the committee believes it should be undertaken.

Section 623 seeks to achieve the goal of extending the benefits of cost-benefit principles to existing rules through a "reopener" petition process that empowers ordinary Americans to help find and correct past regulatory mistakes. The Committee believes that the people on the receiving end of regulation, not just those issuing the regulations, should have a say on prioritization here. In effect, the petition process is intended as means of adopting an efficient "management by exception" approach that will create a level playing field by letting any interested member of the public petition. Section 623 does this by providing that any person subject to an existing major rule, including a rule that was in effect on the date of enactment of this legislation, may petition the relevant agency to perform a cost-benefit analysis for such major rule.

Under section 623(a)(2), the petitioner is required to identify with reasonable specificity the major rule to be reviewed and the amendment or repeal that is requested. Under section 623(a)(3), a petition shall be granted if it demonstrates that there is a reasonable likelihood that the future impact of the rule (measured as of the time at which the petition is filed) is such that the rule would meet the definition of a "major rule" under the legislation, and that the proposed amendment or repeal of the rule is required in order to satisfy the decisional criteria of section 624. For example, if the petition demonstrates that there is a reasonable likelihood that the potential future benefits of the rule do not justify its potential future costs, or that there are reasonable alternatives to the rule that provide greater future net benefits than the rule itself does, the agency shall grant the petition.

An agency must grant or deny a petition within 180 days of submittal and shall consider any comments its receives in granting or denying a petition. A denial is subject to judicial review as final agency action. If the petition is granted, the agency must, within a year, undertake a cost-benefit analysis of the rule in accordance with the requirements of section 622 and propose either to revise the rule to bring it into conformity with section 624 or to repeal the rule in its entirety. Following a decision to grant or deny a petition, no further petition that raises identical concerns regarding the same rule, submitted by the same person, shall be considered, unless such further petition is based on a change in a relevant fact, circumstance, or provision of law underlying or otherwise related to the rule and such change has occurred since the initial petition was granted or denied.

Section 623 also contains a provision, embodied in subsections (d) through (f), which is intended to prevent agencies from evading the requirements of this legislation through the use of interpretive rules, guidance documents or policy statements. The Committee considers this provision extremely important, as it is already the case that agencies often seek to avoid notice-and-comment rulemaking requirements by styling seemingly prescriptive regulatory standards or criteria as "guidance" or "policy" documents, while claiming that those documents do not have the force of law or otherwise have the binding effect. If anything, without such a provision, this legislation could provide an incentive for agencies to resort to such practice to an even greater extent, as a way of evading

the new requirements that the legislation would impose on the notice-and-comment process.

Agencies are certainly encouraged to provide explanatory materials to regulated entities where appropriate. However the Committee considers the practice of issuing guidance documents that purport to be nonbinding (and, as such, not subject to judicial review) but which, in reality, impose requirements that the regulated community disregards at its peril, to be inherently unfair. Indeed, the committee considers this practice to violate, at a minimum, the spirit of the notice-and-comment provisions of the APA and further expects that the definition of the term "rule" in section 621(8)—which clarifies that the term includes "any statement of general applicability that alters or creates rights or obligations of persons outside the agency"—will help put a stop to this practice.

To further ensure that agencies do not seek to evade the requirements of this legislation through the use of putatively "non-binding" guidance or other materials, section 623(d) provides that any person subject to an interpretive rule, guidance, or general statement of policy may petition an agency to withdraw, as contrary to the provisions of subchapter II, any such interpretive rule, guidance document, or policy statement, including such materials in effect at the time of enactment of this legislation, that would have the effect of a "major" rule. The petition must explain with reasonable specificity why the interpretive rule, guidance document, or policy statement has the effect of a "major" rule, and the petition shall be granted if it shows that there is a reasonable likelihood that such is the case. An interpretive rule, guidance document, or policy statement has the effect of a "major" rule if, as applied or as likely to be applied, it causes the equivalent economic impact of a "major" rule.

The agency must either grant or deny a petition within 180 days of its being submitted. A denial is subject to judicial review as final agency action under section 625. If the petition is granted, the agency has two options. It may either withdraw the interpretive rule, guidance document, or policy statement, or it can choose to propose a rule meeting the requirements of subchapter II that incorporates the regulatory standards or criteria that are contained in the interpretive rule, guidance, or policy statement. If it chooses the latter course of action, the agency must propose the rule within one year and must promulgate it within two years. Where the interpretive rule, guidance, or policy statement is withdrawn, or where an agency chooses to pursue the rulemaking option and a final rule has not been promulgated within the required two years, until such time as a final rule is promulgated pursuant to the requirements of this legislation, the agency is prohibited under section 623(f) from taking any enforcement action against any person based on the regulatory standards or criteria contained in the interpretive rule, guidance, or policy statement.

Finally, section 623(g) establishes a process by which a person subject to a major rule can petition the relevant agency to modify or waive specific requirements of the rule and authorize that person to demonstrate compliance through an alternative means that would not otherwise be allowed under the rule. Its purpose is to authorize alternative approaches to regulatory compliance that

would be more sensible, innovative, flexible, and more effective and efficient, while at the same time providing at least an equivalent level of protection of health, safety, and the environment. This provision is needed, as affected facilities, municipalities, and States currently have no process by which they may propose and utilize more effective regulatory approaches. The Committee intends section 623(g) to provide a framework that favors new approaches and which rewards good performance.

Under subsection (g)(1), a petition under this section must identify with reasonable specificity the requirements for which a modification is sought, along with an identification of the alternative means of compliance that the petitioner is proposing. Under subsection (g)(2), the agency must grant the petition if it shows that there is a reasonable likelihood that the proposed alternative compliance method would (1) achieve the specific benefits of the major rule with at least an equivalent level of protection of health, safety, and the environment, and (2) not impose an undue burden on the agency that would be responsible for enforcing the alternative compliance method.

Determining whether or not a proposed alternative method of compliance would provide an "equivalent" level of protection will, of course, inherently involve a case-by-case evaluation of the facts and circumstances surrounding each particular situation, and the burden of establishing that the alternative compliance method provides such "equivalent" protection would rest, in the first instance, with the petitioner. Agencies are expected, however, to undertake a careful and searching evaluation of each petition, in order to give full expression to the committee's intent that alternative compliance techniques and strategies be employed wherever desired by the regulated community and warranted under the standards set forth in this section. In this regard, the committee notes that "equivalent" protection does not mean "identical" protection, and agencies can and should, in the exercise of their sound discretion, evaluate and balance the full range of consequences of a proposed alternative compliance method in determining whether health, safety, and the environment would be protected. At the same time, in undertaking this evaluation, agencies should not attempt to "second guess" the rationale or the business judgment of the person seeking the alternative compliance method. That is, in ruling on a petition, an agency shall not take into consideration its own assessment of whether the proposed alternative compliance method makes sense, economically or otherwise, for the petitioner, but should evaluate the petitioner solely in light of the standards set forth in subsection (g)(2).

Further, agencies are cautioned, in applying the "undue burden" prong of the standard in subsection (g)(2), not to reject petitions solely on the grounds that the proposed alternative method of compliance would impose an administrative inconvenience on the agency that would be responsible for enforcing the alternative method. By "undue" burden, the committee intends agencies to focus on truly significant matters, involving such questions as whether compliance with the proposed alternative method could be effectively monitored and enforced at all, not merely whether that alternative might impose new, or even novel, obligations on an agency. In this

regard, the committee expects that before rejecting petitions on the ground that the proposed alternative would impose an undue burden on the agency, the agency will work cooperatively with the petitioner in an attempt to work out a plan or method for ensuring compliance that is acceptable to all concerned.

Consistent with the other provisions of section 623, a decision to grant or deny a petition under subsection (g) must be made within a reasonable time (e.g., 180 days of the petition's being filed). Denial of a petition is subject to judicial review as final agency action under section 625 of this legislation. Subsection (g)(3) provides that, following a decision to grant or deny a petition, no further petition for such rule, submitted by the same person, shall be considered by the agency unless such petition is based on a change in a relevant fact, circumstance, or provision of law underlying or otherwise related to the rule that has occurred since the initial petition was granted or denied. By this, the committee intends to avoid having agencies burdened by a series of meritless petitions being filed by persons disappointed in having had earlier petitions denied. Nothing in subsection (g), however, should be construed to prevent a person who has filed a petition under that subsection from also challenging a rule, or the application of a rule, on any other legally cognizable grounds, or from petitioning the relevant agency, under section 553 of the APA or under the other provisions of section 623, to revise or repeal such rule.

New Section 624

Section 624 establishes decisional criteria for Federal agencies that reflect the straightforward, common-sense way in which real people make real decisions. It requires that every Federal agency, while respecting the existing instructions Congress has given it in other statutes, answer two simple questions before a major rule ($50 million impact or more on the economy) is promulgated—is this action "worth it," and does this way of doing it produce, in light of the existing statutory instructions, the greatest overall benefits to society (in comparison to the reasonable alternatives considered by or proposed to it).

Section 624(a) provides that the section 624 decisional criteria supplement the decisional criteria for rulemaking otherwise applicable under the statute pursuant to which a rule is promulgated. In effect, agencies will continue to follow the instructions provided by Congress in other Federal legislation, as supplemented by the additional decisional criteria of section 624.

The decisional criteria in section 624 do *not* override congressional directives where the proposed rule cannot satisfy the decisional criteria in section 624(b) as a result of the express decisional criteria in the statute granting the rulemaking authority. In other words, section 624 addresses the exercise of agency discretion.

Section 624(b)(1) requires that every "major rule" have potential benefits that "justify" its potential costs. Benefits are defined broadly by section 621(1) to mean the "reasonably identifiable significant incremental benefits, including social and economic benefits, that are expected to result directly or indirectly from implementation" of the rule. Costs are similarly defined in section 621(2)

to mean the "reasonably identifiable significant incremental 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." While cost and benefit estimates should be quantified to the extent possible, *qualitative* and *noneconomic* as well as quantitative and economic benefits and costs must be evaluated. Specifically, section 622(e)(1)(A) requires only that "a proposed and final rule required under this section shall include, *to the extent feasible*, a quantification or numerical estimate of the quantifiable benefits and costs." (Emphasis added.) Any quantification or numerical estimate must be made "in the most appropriate unit of measurement," must use "comparable assumptions, including time periods," and must "explain the margins of error involved in the quantification methods and in the estimates used." An agency must also "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," and "shall not be required to make such evaluation primarily on a mathematical or numerical basis."

Sections 622(c) and (d) call for an assessment of "incremental" costs and "incremental" risk reduction or other benefits associated with the proposed action and with each significant regulatory alternative. It is essential, and this language considering "incremental" costs and benefits is intended to ensure, that the agencies recognize the role of diminishing returns in taking action toward any regulatory objective. In many cases, high levels of benefit may be obtained by relatively cheap and simple steps; it is the intent of the word "incremental" that the agencies must apply cost-benefit analysis so as to assess the utility of each further increment of control or action, as well as ensuring that the action level finally chosen has benefits that outweigh its costs.

The decisional framework established by section 622 and the decision criteria established by section 624 combine to create a strong, flexible set of legal parameters applicable across-the-board to the exercise of agency discretion in major rulemakings. As indicated by the definition of "cost-benefit analysis" in section 621(3), the methodology and level of detail for cost-benefit analyses shall be "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."

It is for this reason that section 621(3)'s definition of "cost-benefit analysis" calls for "an evaluation" (emphasis added) of costs and benefits—not a formal "cost-benefit analysis" that attempts to reduce every cost and every benefit to monetary values. Further, the benefits need only "justify" the costs. By this, the Committee means that the agency must be able to conclude that, considering all of the relevant quantified and nonquantified and economic and noneconomic benefits and costs and the persons or groups to whom those benefits and costs pertain, on balance the proposed action is "worth it" to society.

The determination required of the agencies is a highly judgmental one, requiring the good-faith exercise of an agency's

best professional judgment in light of its underlying legislative directions from Congress. The determination will not be driven solely by numerical or economic analysis, except in the unlikely event that all significant, relevant benefits and costs can be and have been quantified. In short, this legislation structures the exercise of agency discretion by requiring the reasoned exercise of rational decisionmaking, in light of other express congressional instructions.

It is important to emphasize that both risk assessments and cost-benefit analyses can be "tiered"—that is, they can be tailor-made to fit the nature of the decisionmaking process and the decision confronting a particular agency, as long as the basic elements of reasoned decisionmaking and the logic of the cost-benefit and risk assessment methodology are respected. This legislation aims at ensuring the essential rationality of both the decisionmaking process and the ultimate decisions by Federal agencies, recognizing the wide variance in the types of decisions and types of situations faced by agency officials. We anticipate that the cost-benefit analysis procedures and regulations to be developed by the Office of Management and Budget under sections 641(a) and (b) will provide agencies with sufficient flexibility so that the basic principles of cost-benefit analysis can be made workable in the individual circumstances faced by each.

In short, sections 622 and 624 focus on decisionmaking, not on simply multiplying procedural burdens. Their mandates are flexible and goal-oriented. The cost-benefit requirements should be molded to the nature of the decisionmaking faced by the agency in question.

Section 624(b) contains the heart of the new decisional criteria in this legislation. It has a number of steps. First, as noted above, it requires that any major rule have potential benefits that justify its potential costs. When an agency is considering rulemaking, however, there may be a number of regulatory options available to it that have such benefits justifying costs. Those options constitute, in the first instance, the "reasonable alternatives" that the agency must consider.

Because the new section 624 decisional criteria *supplement* the existing decisional criteria applicable to an agency's action, the term "reasonable alternatives" is defined in section 621(7) to mean "the range of regulatory options that the agency has discretion to consider under the text of the statute granting rulemaking authority, interpreted, to the maximum extent possible, to embrace the broadest range of options that satisfy the decisional criteria of section 624(b)." This means that the agency must consider the broadest range of alternatives that the text of that statute grants it discretion to consider, and must interpret that grant of discretion, to the maximum extent possible, so as to allow it to consider the broadest range of options that satisfy the new cost-benefit decisional criteria of section 624(b) (*i.e.*, whose benefits justify their costs). This agency interpretation of the statute, as supplemented by the provisions of the bill, is reviewable under 5 U.S.C. 706(c)(2)(B). An agency interpretation that does not give the agency the broadest discretion to develop rules that satisfy the section 624 decisional criteria may be set aside as arbitrary and capricious.

Section 624(b)(2) goes on to require that among the regulatory alternatives defined, the agency must choose the alternative that has the greatest net benefits (*i.e.*, "most cost-effective result"). The language "of any of the reasonable alternatives that the agency has discretion to adopt under the decisional criteria of the statute granted in the rulemaking authority" in section 624(b)(2) is intended to be read in light of the definition of "reasonable alternatives" in section 621(7), since that definition instructs the agency as to the exercise of the scope of the discretion it has "under the decisional criteria of the statute granting the agency the rulemaking authority."

If, having gone through the analysis just noted, an agency finds that, applying the express decisional criteria in the text of the statute granting the rulemaking authority, none of the reasonable alternatives, as defined, can satisfy both sections 624(b)(1) and (2), it shall reconsider the reasonable alternatives and apply section 624(c). If the criteria in section 624(b)(1) cannot be satisfied, it will be because there are no alternatives satisfying the express decisional criteria in the text of the statute granting the rulemaking authority that have benefits that justify their costs. In such a case, the agency must look at the full range of alternatives that satisfy those express decisional criteria, which by definition (at that stage in the analysis) will only include those with costs not justified by benefits. From those, it shall select, from among such alternatives that have costs that do not justify their benefits, the alternative that either imposes the lowest cost or the lowest net social costs (the "least costs taking into account benefits") from among those available alternatives.

In determining whether the "express" decisional criteria of a statute authorize promulgation of rules regardless of whether benefits justify costs, it is the committee's belief that the "plain meaning" rule will be used in construing the statute. Thus, if the textual language contains a standard requiring a particular regulatory outcome, regardless of the costs and benefits (or either), those "decisional criteria" must be met and the supplemental decisional criteria of this statute apply only in the selection among alternatives that meet the statutory decisional criteria. The alternative selected in that case will either be the one (meeting the statutory decisional criteria) that has the greatest net benefits under subsection (b)(2) or (where no such alternative has net benefits) the one that imposes the lowest net costs under subsection (c)(2), depending on the facts in the particular rulemaking.

How a command to "supplement" an agency's decisional responsibilities can affect the discretion granted an agency under its enabling statute is demonstrated by the experience with the National Environmental Policy Act, 42 U.S.C. 4331, *et seq.* (NEPA). That statute requires Federal agencies "to the fullest extent possible" to implement their enabling legislation in accordance with the goals and policies of NEPA. 42 U.S.C. 4332. NEPA also provides that its requirements are "supplementary to" the decisional criteria of existing legislation. *Id.* at 4335.

Prior to 1970, the regulatory authority of the Atomic Energy Commission ("AEC") (now the Nuclear Regulatory Commission ("NRC")) was interpreted as focusing exclusively on radiological

health and safety concerns. *New Hampshire* v. *AEC*, 406 F.2d 170 (1st Cir. 1969). Following passage of NEPA and the decision of the U.S. Court of Appeals in *Calvert Cliffs' Coordinating Committee* v. *AEC*, 449 F.2d 1109 (D.C. Cir. 1971), the NRC has routinely included nonradiological environmentally based conditions in its licenses. At the same time, courts have held that NEPA does not expand or override the jurisdictional bounds established by Congress. *See, e.g., Natural Resources Defense Council* v. *EPA*, 859 F.2d 156 (D.C. Cir. 1988); *NRDC* v. *EPA*, 822 F.2d 104 (D.C. Cir. 1987). In short, NEPA supplements agency decisionmaking authority on a generic basis by expanding the range of factors to be considered to include an important and frequently neglected factor—impact on the environment.[30] Here, we also supplement agency decisionmaking authority on a generic basis by adding new decisional criteria so that agency decisionmaking is guided, within the framework of existing, program-specific decisional criteria, by the decisionmaking principles involved in section 624's flexible evaluation of costs and benefits.

In certain instances the express decisional criteria of the statute may dramatically limit the agency's discretion to identify alternatives that satisfy those criteria. An example of this category is *American Textile Manufacturers Institute* v. *Donovan*, 452 U.S. 490 (1981), where the Supreme Court interpreted the phrase "to the extent feasible" as not requiring the Department of Labor to ensure that cotton dust health standards issued under OSHA meet a rigorous cost-benefit analysis test before their issuance. Senate bill 343 does not overturn *Donovan's* construction of OSHA. However, whether or not OSHA precludes the Department from evaluating costs and benefits in developing reasonable alternatives that satisfy the OSHA decisional criteria,[31] section 624 supplements the Department's decisional responsibilities by requiring it to consider cost-benefit principles in choosing among regulatory options that fully satisfy the OSHA decisional criteria. Accordingly, if under OSHA there are only, for example, two regulatory options that meet the "to the extent feasible" decisional criteria and at least one of them has benefits that justify its costs, the supplementary decisional criteria in section 624(b) will apply. If neither has benefits that justify its costs, then the supplementary decisional criteria in 624(c) would govern the choice between those two options based on a cost-benefit evaluation of each of them. Under the *Donovan* holding, any other statute that uses the express term "feasible" as

[30] NEPA also demonstrates that Congress recognized as early as 1969 that protecting human health and the environment through Federal legislation required a careful balance between environmental and economic factors. See 42 U.S.C. 4332(B) (must consider economic factors). Since the enactment of NEPA, however, the agencies—and occasionally Congress—have attempted to achieve greater environmental benefits without considering the economic costs of regulatory activities. Senate bill 343 therefore seeks to return the scales to a balance point, where agencies must improve human health and the environment while at the same time weighing the costs and benefits of their actions.

[31] In this regard, while the Court in *Donovan* held that section 6(b)(5) of OSHA did not *require* the Department of Labor to engage in cost-benefit analysis, it did not appear expressly to preclude the Department from engaging in such an analysis if it so chose. Cf. Donovan, 452 U.S. at 512 ("We therefore reject the argument that Congress required cost-benefit analysis in [section] 6(b)(5).") (emphasis added) *with Donovan*, 452 U.S. at 544 (J. Rehnquist, dissenting) ("As I read the Court's opinion * * * [i]t concludes that * * * the Act does not require the Secretary [of Labor] to engage in a cost-benefit analysis, which suggests of course that the Act *permits* the Secretary to undertake such an analysis if he so chooses.") (emphasis in original).

a decisional criteria may likewise fall into this category, depending on the full statutory analysis made by a court.

In the case of other statutes, such as the Clean Air Act and the Clean Water Act, the decisional criteria may constrain the reasonable alternatives to, for example, "demonstrated" or "available" technologies, although this range will likely be much broader than under the OSHA decisional criteria. In the case of such provisions in the Clean Air Act and Clean Water Act, the supplemental criteria of section 624 (b) or (c) of this legislation will govern the selection of a particular "demonstrated" or "available" technology from the range of such technologies in the same fashion as noted above.[32]

Finally, at least in situations where consideration of costs and benefits (or either) is not precluded in the express decisional criteria of the underlying legislation, section 624 will supplement an agency's authority under its express decisional criteria itself and thus govern the range of alternatives that will satisfy those decisional criteria (as opposed, as noted above, to only the choice among alternatives satisfying those criteria). By way of illustration, the section 624 supplementary criteria can, again by analogy to NEPA, supplement a general statutory criteria like "public interest" or "feasible" where, under the statute in question, the agency has discretion to consider costs or cost-benefit principles but has not, in the past, exercised that discretion. If the Agency were to exercise that discretion (e.g., in response to the supplementary commands of this legislation), the range of permissible alternatives might be increased. Accordingly, this legislation defines the "reasonable alternatives" which an agency must take into account under section 624 as including the "range of regulatory options that the agency has discretion to consider under the text of the statute granting the rulemaking authority, interpreted, *to the maximum extent possible,* to embrace the *broadest range of options* that satisfy the decisional criteria of section 624(b)." Section 621(7) (emphasis added). Likewise, in order to be upheld on review under section 706(c)(2)(B), as revised by this legislation, a phrase such as "to the extent feasible" would have to be interpreted, consistent with the statute in question, by the agency in a manner that gives the agency the "broadest discretion" to adopt a rule that satisfies the decisional criteria of section 624.

In sum, all this legislation does is supplement, in a manner that produces the most good or least harm (depending on the facts of a particular rulemaking), the discretion given the agency to identify and select from reasonable alternatives that satisfy the decisional criteria in the regulatory statute (supplemented, where

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[32] Most statutes already require or allow agencies to consider the costs (or costs and benefits) of their regulatory actions, so the "supplemental" decisional criteria of section 624 can require clearer focus on justifying and reducing regulatory costs without changing existing law. *See e.g.,* 7 U.S.C. 136(bb)(Federal Insecticide, Fungicide, and Rodenticide Act); 15 U.S.C. 2601(c) (Toxic Substances Control Act); 33 U.S.C. 1314(b)(1)(B) (Clean Water Act); 43 U.S.C. 300g-1(b)(5) (Safe Drinking Water Act); 15 U.S.C. 1262 (Federal Hazardous Substances Act); 15 U.S.C. 2058(c)(1) (Consumer Product Safety Act); 42 U.S.C. 9621(a) (Comprehensive Environmental Response, Compensation and Liability Act). Even the Clean Air Act—with its emphasis on technology-based standards—accommodates a cost-benefit approach. See e.g., 42 U.S.C. 7408(b)(1) (air quality standards); *id.* section 7478(3) (best available control technology); *id.*section 7412(d)(2) (maximum achievable control technology); *id.* section 7521(a)(3)(A)(mobile source emission standards).

permissible, as noted above). It does not override, in any case, the decisional criteria that Congress has directed the agency to apply.

The reports to Congress required by section 624(d) should delineate any difficulties created by the operation of sections 624 (b) and (c), and allow this committee and other committees of competent jurisdiction to focus on any legislative changes necessary in existing statutes in order to allow reasoned decisionmaking to prevail more simply and easily in all of the Federal regulatory programs covered by this legislation.

New Section 625

The committee had three choices as to how it could approach the issue of judicial review of agency actions under this legislation. First, the legislation could have remained silent on the question. The consequence of such silence would have been that final actions under this legislation would have been subject to judicial review under 28 U.S.C. 1331 (the Federal question statute) in a federal district court, under section 702 of the APA, or, possibly, where judicial review was provided in a Federal court of appeals, in the court of appeals under a theory of "pendent jurisdiction." Needless procedural litigation in the court of appeals and the district courts over the details of the location, time, and standards for judicial review would undoubtedly result from this choice. *See, e.g., E.I. Du Pont de Nemours & Co.* v. *Train,* 430 U.S. 112 (1977).

Second, the committee could have refused to provide any judicial review by expressly precluding judicial review. The Committee believes that this option would have relieved an agency from any accountability under this legislation.

Third, the committee could expressly provide for judicial review in the same court, at the same time, and under the same standards for judicial review that would govern judicial review under the regulatory statute in question. This would assure that judicial review would not be bifurcated in two different courts and would eliminate confusion as to governing judicial review standards. For the reasons discussed below, the committee has chosen this third option.

In the committee's view, the availability of effective judicial review of an agency's compliance with the decisional criteria of subchapter II is critically important to ensuring that agencies make such requirements a genuine element of their decisionmaking. To this end, section 625 expressly establishes that such agency compliance shall be judicially reviewable, in the same court that reviews agency findings under the statute granting the agency authority to take the action in question, at the same time as that review takes place, and applying the same standards of judicial review. In short, just as the new procedures and decisional criteria in subchapters II and III are supplemental to the procedures and decision criteria otherwise applicable to any agency action, they are equally subject to the same judicial review, as are those procedures and criteria.

The promulgation of rules by agencies, whether "major" rules or not, are, of course, already subject to judicial review under the particular statute granting the agency authority to conduct the rulemaking. In this regard, section 625 serves to clarify that an agency's cost-benefit analysis for a rule under section 622, and any risk assessment the agency performs in connection with a rule under

subchapter III, shall constitute part of the whole record of the rulemaking and shall be considered by the court in determining the legality of the agency action, but only to the extent such cost-benefit analysis or risk assessment relates to the agency's decisional responsibilities under section 624 or the statute granting the agency authority to take the agency action. Of course, where procedural irregularities under this legislation rise to the level of prejudicial error under the normal doctrine of prejudicial error in the APA, as recodified by the legislation (and as further discussed elsewhere in this report), such procedural errors would constitute errors in the agency's decisional responsibilities.

The importance of the decisional criteria of section 624 is such that section 625 expressly recognizes that a reviewing court must set aside agency action that fails to satisfy those decisional criteria under the normal standards of court review, as noted below. Technical, scientific or factual determinations by agencies under the provisions of subchapters II and III would not, however, be reviewed de novo. Rather, unless integral to the resolution of a question of statutory interpretation under new section 706(c)(1) of the Administrative Procedure Act, they would be reviewed under the arbitrary and capricious standard. Under revised section 706(c)(2) of the Administrative Procedure Act, as well as under existing case law discussed in the section-by-section analysis of section 706(c)(2), the arbitrary and capricious standard of review requires only reasoned decisionmaking and does not allow a court to substitute its judgment for that of an agency.

This legislation does not involve courts in unprecedented new review of scientific judgments. Courts routinely review complex scientific records and require reasoned decisionmaking by agencies under the arbitrary and capricious standard of review. They have been doing so for years in cases arising under the health, safety and environmental statutes that have been on the books since the early 1970s, and *must* do so if agency decisions are to be held accountable to law.

Section 625 also makes it clear that the judicial review provided for shall not be separate or apart from judicial review of the agency action to which it relates. Section 625 grants no new rights to interlocutory review; parties would have available only such rights in that regard as may already exist. In other words, section 625 takes account of the fact that it is essential that judicial review be "channeled" so that the entire decision related to a rule, including the determination as to whether a rule is a "major" rule, and the application of the decisional criteria under this legislation and under the statute granting the agency authority to conduct the rulemaking, is coordinated. Inefficient bifurcated review must be avoided. For example, a "major" rule promulgated by EPA under the Clean Air Act would be subject to judicial review under section 625 (to determine whether the rule satisfied the decisional criteria of section 624) at the same time and in the same court as when it was also subject to judicial review under section 307(b)(1) of the Clean Air Act (to determine compliance with the applicable provisions of the Clean Air Act). As a second example, petitions under section 623 shall be judicially reviewable in the same court that would review denial of any petitions under section 553(e) of the Administrative

Procedure Act that relate to the underlying organic legislation at issue. In short, the language of section 625 is intended to ensure that time and effort are not wasted during judicial review because the proper coordination of that review was not established during passage of this legislation.

The conduct of judicial review should, of course, proceed under the traditional standards of review established by Congress in the Administrative Procedure Act, as interpreted by the courts. It is essential, however, that the courts apply those standards without undue deference to agency determinations. When conducting judicial review, the reviewing court should use the normal standards of review, but apply them carefully, as we note elsewhere in this report, to assure that the proper measure of deference is given to agency decisions, as explained in such decisions as *Chevron U.S.A.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984), as codified by the changes made to section 706 of title 5 by this legislation.

Finally, the effectiveness of a rule or other action would not be delayed automatically by a petition for judicial review. The high standards for obtaining a stay under existing law would continue to apply.

New Section 626

While the Committee does not consider an across-the-board regulatory moratorium to be necessary or desirable in order for the beneficial consequences of this legislation to be realized, at the same time, the committee wishes to ensure that full and complete compliance by agencies with the requirements of this legislation should not be arbitrarily frustrated by rulemaking deadlines imposed by other statutes or by courts. As a result, this legislation does not prohibit an agency from adopting a rule after the date of enactment. It only prohibits an agency from relying on deadlines as a justification for not complying with this legislation.

Accordingly, section 626(a) provides that, beginning on the date of enactment of this legislation, all statutory deadlines that would otherwise require agencies either to propose or to promulgate any rule subject to the requirements of subchapter II are suspended until those requirements are satisfied. Recognizing the practical reality that agencies often fail to meet such deadlines and that, as a consequence, rulemaking schedules are established through court-approved settlement agreements and consent decrees, section 626(b) further provides that, beginning on the date of enactment, the jurisdiction of any court of the United States to enforce a deadline pertaining to a rulemaking subject to this legislation is also suspended until such time as the requirements of subchapter II are met. It should be noted, however, that while section 626 authorizes the suspension of such deadlines, the committee does not anticipate that full and complete compliance by agencies with this legislation, which is designed to be inherently flexible in nature and applicability, will typically lead to many rulemaking deadlines being missed, nor should this section be construed as permitting any agency to delay the promulgation any rule, except as necessary to meet the requirements of the legislation.

Further, in providing for the suspension of deadlines under this section, the committee is mindful of the need for agencies to preserve any lead times for compliance explicitly contained in, or implicitly created by, the underlying statute. For example, where a statute requires that an agency promulgate a rule by a specific date and also mandates that regulated entities come into compliance with the requirement of that rule within a certain time following promulgation, Congress has clearly intended to provide to such entities a period of lead time for achieving compliance. Where the initial rulemaking is delayed beyond the statutory deadline due to the agency's needing additional time to meet the requirements of this legislation, this lead time will be cut short unless the agency provides for an extension of the compliance deadline as well. With this consideration in mind, the committee intends that, where an agency promulgates a rule after a statutory deadline under section 626, the agency will exercise its discretion to provide sufficient time for those entities subject to the rule to come into compliance, consistent with congressional intent regarding the need to allow for such period of lead time. This reflects current law. *See, e.g., Natural Resources Defense Council* v. *EPA,* 22 F.3d 1125, 1135 (D.C. Cir. 1994); *Natural Resources Defense Council* v. *Thomas,* 805 F.2d 410, 435 (D.C. Cir. 1986); *Citizens to Save Spencer County* v. *EPA,* 600 F.2d 844, 871 (D.C. Cir. 1979).

Finally, subsection (c) provides that in those situations where an agency's failure to promulgate a rule by a given deadline creates an obligation to regulate through individual adjudications by another deadline, this second deadline is suspended until such time as the agency adopts a rule that meets the requirements of this legislation. Without this provision, agencies would have an incentive in such situations to delay the promulgation of rules that were subject to the requirements of this legislation, since the case-by-case regulatory standards would not have to satisfy those requirements. The committee notes that in using the term ''adjudications'' in section 626(c), it does not intend to restrict the reach and effect of the subsection solely to ''adjudications'' as the term is defined in section 551 of the APA. Rather, as used in section 626(c), the committee intends the term to mean any case-by-case, permitting, or other regulatory process that leads to the establishment of an individualized regulatory requirement or standard, such as under section 112(j) of the Clean Air Act.

New Section 627

Section 627 ensures that rules will be terminated or revised as they become obsolete. It is only common sense that the utility of a rule may change as circumstances change. Thus, that a rule withstood cost-benefit analysis at the time of its promulgation provides no assurance that it remains cost-effective 5 years later.

Section 627 therefore requires agencies formally to review their major rules and certain other rules within a prescribed period of time (5 or 7 years in most cases), measuring the utility of the rules against the decisional criteria of section 624. To ensure that this review is in fact conducted, subsection (b)(2) provides that a regulation shall terminate if the review is not conducted within the prescribed period of time. The effect of section 627, then, should be to

make certain that rules remain in force only so long as they remain cost-effective.

New Subchapter III

This subchapter on risk assessment is intended, the committee believes, to bring about several important reforms to the way the government currently assesses risks to human health and the environment, the most important of which are: (1) bringing greater consistency to the risk assessment process across Federal agencies; (2) encouraging the use of site specific data whenever possible; (3) identifying the value/policy judgments which are made in developing risk estimates when site specific data cannot be used; (4) assuring that the risk assessor uses the most plausible and realistic assumptions and scenarios in lieu of site specific data; and (5) allowing a greater role for the public to comment on specific risk assessments and the assumptions/policies on which they are based.

Up until recently, policymakers paid little attention to the significant policy decisions made by scientists in conducting risk assessments despite the fact that these policy decisions or value judgements could have a significant impact on the resulting estimate. The committee intends through these reforms first to make the process more transparent to the public and decisionmakers and second, to allow the public an opportunity to participate in and comment on the key judgements and assumptions being used.

The committee also intends to stop the longstanding practice of presenting conservative (inflated) risk estimates as the primary way of dealing with uncertainty. Instead the legislation directs risk assessors to use the most plausible, realistic assumptions at each stage of the risk assessment process to ensure that the final estimate comes as close as possible to reflecting the public's true risk from a given activity or substance. This applies to the selection of exposure scenarios as well as to the specific steps used in calculating a substance's potency, such as the selection of models to extrapolate risks from high doses to low doses or the conversion factor used to translate animal data to potential human risk levels.

Because of this focus on presenting the most plausible or likely estimate of risk, the bill includes a clear preference for point estimates of risk. Where point estimates cannot be made, risk ranges are also acceptable if they are based on probability distributions weighted according to their likelihood of occurrence. In other words, risk estimates which are provided to the public and decisionmakers should, to the maximum extent possible, inform them of the risk levels which are most likely to occur or be most representative of actual conditions.

New Subsection 631(1)

The term benefit has the meaning given in 621(1).

New Subsection 631(2)

The definition of the term "best estimate" is crucial to the reforms of the risk assessment process sought by this Committee. First and foremost, the "best estimate" of risk means a point estimate of individual and population risk that is based on the most plausible and likely scenarios and assumptions. It is the risk esti-

mate which the risk assessor believes is the most likely to occur. Single point estimates, such as plausible upper bounds or worst-case scenarios, must be accompanied by lower bounds or optimistic scenarios and realistic (or likely) estimates of risk.

If point estimates of risk are not technically feasible, "best estimate" also means multiple estimates of risk based on different scenarios that are weighted according to the probability of each scenario's occurrence. Such weighted probability distributions can be provided along with point estimates that represent the best estimate, but should not be substituted for these point estimates unless the point estimates are technically infeasible.

Agency assumptions and value judgments about proper margins of safety must be acknowledged explicitly, described in detail and supported with data that measure the number of citizens exposed to various levels of risk.

New Subsection 631(3)

The term "cost" has the same meaning as the term in section 621(3).

New Subsection 631(4)

The term "cost-benefit analysis" has the same meaning as the term in section 621(3).

New Subsection 631(5)

The term "emergency" means an actual, imminent, and substantial endangerment to public health, safety, or the environment. Imminent means about to occur, impending and in the context of a potentially acute impact on public health or the environment. Emergency is specifically not intended to address impending public or environmental exposure to low levels of contaminants that have the potential for long-term, chronic impacts on public health or the environment. The emphasis here is on conditions that will cause immediate and substantial harm to human health.

New Subsection 631(6)

The term "hazard identification" means identification of a substance, activity, or condition that may cause adverse effects to public health, 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 combined degree of toxicity and actual exposure*, or other risk the hazards pose for individuals, populations, or natural resources. Hazard identification is generally the first step in the risk assessment process and may be driven to some extent by an agency's statutory mandate. Addressing potential or actual adverse effects and hazard identification includes determining whether such effects are potentially acute or chronic, carcinogenic or noncarcinogenic, persistent or ephemeral or, indeed, plausible versus merely possible, all are important subcomponents of the concept of hazard identification. It is also worth noting that the term adverse effects is utilized in this definition, although it is not utilized in the definition of the term benefit as noted above.

New Subsection 631(7)

The term "major cleanup plan" includes both any proposed or final environmental cleanup plan for a Federal facility or Federal guidelines for the issuance of such plans, whereby the expected costs, expenses and damages are expected to exceed (in the aggregate) $10 million. This section makes clear that its application is broad-based and includes such plans as the corrective action requirement under the Solid Waste Disposal Act, a removal or remedial action under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as well as any other environmental or damage assessment performed by a federal agency pursuant to Federal statute, court order or decree, or under agency authority.

New Subsection 631(8)

The term "major rule" is the same as used in section 621(4).

New Subsection 631(9)

The term "negative data" means data that fail to show that a given substance or activity induces an adverse effect under certain conditions. All assumptions (*e.g.*, model fitting assumptions science policy judgments, data set comparison or statistical thresholds) that may impact the interpretation of whether data is "negative data" must be clearly revealed to assure that negative data are properly factored into risk assessments.

New Subsection 631(10)

The term "risk assessment" means—

"(A) the process of identifying hazards, and of quantifying (to the maximum extent practicable) or describing the combined degree of toxicity and actual exposure, or other risk the hazards pose for individuals, populations, or natural resources; and

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

A risk assessment traditionally includes the components of *hazard identification*, dose response assessment, exposure assessment and risk characterization. Risk assessments are not designed for making judgments, but rather to inform them. In order to properly inform judgments, risk assessments must disclose the bases for decisions made and the quality and quantity of the information available at various stages and in the various components of the risk assessment. Risk assessments are intended to be iterative activities that can be modified, upgraded and improved with additional information, techniques or technologies.

New Subsection 631(11)

The term "risk characterization" means—

"(A) 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) may include discussions of uncertainties, conflicting data, estimates, extrapolations, inferences, and opinions, as appropriate."

Risk characterization is traditionally the final component of a risk assessment and can be the major component with respect to explaining risk. The risk management decision is that part of the regulatory process wherein the decision is made as to what to do where some risk has been determined to exist. Risk characterization may be the most critical component of a risk assessment in terms of developing public understanding of the nature of a risk and the bases for justifying the costs and benefits of addressing a risk through some sort of regulatory or other control program.

New Subsection 631(12)

The term "rule" has the same meaning as the term in section 621(7).

New Subsection 631(13)

The term "substitution risk" means a potential increased risk to health, safety, or the environment resulting from a regulatory alternative designed to decrease other risks. Substitution risk can also refer to risks to health, safety, or the environment resulting from a reduced standard of living, or market substitutions caused by a regulatory alternative. In sum, substitution risks are the direct and indirect risks to human health and the environment that result from a regulatory option designed to reduce other risks. The term "central estimate of risk" means the overall risk estimate and is expressed as a probability distribution reflecting variabilities and uncertainties in the analysis. This will often be referred to by risk assessors in the scientific community as the "best" estimate of risk with quantified upper and lower bounds of uncertainty. Quantification of uncertainty should be provided to the maximum extent practicable and qualitative expressions of uncertainty to the extent necessary should be thoroughly explained; in particular, including the reasons why quantitative certainty is not possible or practicable.

New section 632

This section clarifies that the requirements for risk assessments and risk characterizations apply to any agency which evaluates health, safety and environmental risks, whether the risk assessment or characterization is prepared by the agency, on behalf of the agency, or is prepared by others and adopted by the agency. In addition, this section creates certain exceptions under which risk assessments and characterizations will not be required. Those situations are: agency-designated emergencies; actions to authorize marketing or manufacturing a substance, mixture or product; certain inspection, compliance and enforcement actions; or certain clearly-identified screening analyses.

New Subsection 632(a)

The language here indicates that this subchapter will apply to all risk assessments and risk characterizations prepared for, by or on

behalf of, any agency in connection with health, safety, and environmental risks.

New Paragraph 632(b)(1)

The committee does not intend that the risk assessment requirements of this legislation apply to certain cases in which regulatory agencies need the flexibility to react quickly to emerging health and safety problems. As approved by the Committee, S. 343 exempts from the risk assessment provisions of the legislation the following: situations designated by the head of an agency as emergency; actions to authorize marketing or manufacturing a substance, mixture or product; certain inspection, compliance or enforcement actions; or clearly identified screening analyses.

These provisions were added by the Committee to address the specific concerns expressed by the regulatory agencies, such as the Food and Drug Administration. The committee was mindful of the comments expressed by several agencies, including the Environmental Protection Agency, the Food and Drug Administration, and the Agriculture Department, that officials must have the ability to respond to public health and safety problems, whether it be an outbreak of listeria in ice cream or e coli bacteria in raw meat. The Committee believes that the provisions of Section 632, especially the exception for emergency designation, will address these concerns.

In addition, the committee found very compelling the argument that the risk assessment provisions of this bill should not apply to individual product approvals, such as those for pharmaceutical or medical devices, or for individual product disapprovals or removals from the marketplace. Accordingly, section 632 exempts from the risk assessment provisions rules or agency actions that authorize the introduction into commerce, or initiation of manufacture, of a substance, mixture or product, or recognizes the marketable status of a product. In adopting such language, the Committee intends that actions to remove from the market specific products, or to disapprove specific products, also be included within the ambit of section 632.

The Committee wishes to clarify, however, that the provisions of S. 343 with respect to risk assessment shall apply to agency actions governing product approvals or disapprovals in general, or to agency actions governing inspection, compliance or enforcement actions in general, that is, actions not with respect to individual products or enforcements. In other words, agency policy relating to risk assessment and risk management which is established, not just in formal regulations, but also in final guidances and protocols, would be subject to the requirements of S. 343.

Under the committee bill, risk assessments and risk characterizations contained in any informal guidance must comply with the requirements of the bill, if they have general application and are not limited to an individual substance, product, or temporary emergency situation. This subchapter shall not apply to risk assessments or its characterizations performed with respect to:

(A) A situation the head of any agency finds to be an emergency which by definition (631(5)) requires action to

protect public health of the environment from significant impending threat.

(B) A rule or agency action that authorizes the introduction into or removal from commerce a product or substance. Thus, section 632(b) excludes from the formal requirements for risk assessment and risk characterization any rule or agency action that authorizes the introduction into commerce, or other recognizes the marketable status of, a product. This provision is intended to give agencies charged with protecting health or safety the ability to deal with and prevent health exigencies.

Many products are subject to premarket approval and notification under existing regulatory statutes, including chemicals, pesticides, new drugs, medical devices, and food additives. As the substantive and procedural requirements for obtaining approval of these products are very burdensome, complex, lengthy and costly, and in any event include evaluations of safety that reflect the objectives of this legislation, it is unwise and unnecessary to impose the formal requirements for risk assessment and characterization that are included in S. 343.

(C) A health, safety or environmental inspection, compliance or enforcement action or individual facility permitting action, including both construction and operating permits. We recognize that most permits apply generic requirements already established by rules to which this legislation may have applied, and while risk assessments and risk characterization may be relevant and appropriate to some such agency actions (e.g., some permitting actions), such instances would be highly dependent on site specific or individualized circumstances and, therefore, not appropriately subject to the requirements of this subchapter.

(D) A screening analysis clearly identified as such because such analyses are generally preliminary in nature and not appropriate to provide the bases for major *affirmative* regulatory action.

New Subparagraph 632(b)(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 previously authorized substance, product, or activity after its initial introduction into manufacture or commerce; or

(ii) to characterize a finding of risk from a substance or activity in any agency document or other communication made available to the public, the media, or Congress—we do not intend that a screening analysis is to be used for the purpose of imposing restrictions on previously authorized substances or to characterize a finding of risk as the basis for any affirmative major regulatory agency action or in any agency document or other communication made available to the public, media or Congress. Screening analyses can and should be used to determine that certain kinds of processes, facilities or contaminants are not worth

further regulatory oversight or control. Screening analyses can be very useful in the initial stages of prioritization of agency activities on the basis of risk assessments by weeding out de minimis or insignificant potential sources of risk.

New Subparagraph 632(b)(2)(B)

This provision enhances the quality of data used by agencies in risk assessments. Each federal agency must abide by the same standards and guidelines for toxicological data development that are imposed on outside parties who submit data to agencies.

New Paragraph 632(b)(3)

This paragraph makes clear that the risk assessment mandates of this subchapter do not apply to any requirement that mandates product informational labels, such as the Surgeon General's cigarette warning labels.

New Section 633

New Paragraph 633(a)(1)

The head of each agency shall apply the principles in subsection (b) when preparing a risk assessment for a major rule to insure (A)–(D). The committee believes that for the general public and the regulated public to understand the bases for agency actions relying to some significant degree on risk assessment, full disclosure is necessary. The head of an agency must take the steps necessary to explain the scientific and technical, legal and policy bases for agency action to assure that the true character of the final choices are revealed and to the maximum extent practicable reflect the best available scientific information addressing "real world" probabilities that significant adverse impacts will be avoided.

New Paragraph 633(a)(2)

This provision makes clear that subsection (a) allows incorporation by reference as long as references are adequately explained, adequately available, and prepared in accordance with this subchapter.

New Subsection 633(b)

This subsection details the principles to be applied in preparing a risk assessment. They are as follows:

New Subparagraph 633(b)(1)(A)

The risk assessment shall consider both laboratory and "epidemiological" data including negative data and summarize the remaining data that finds or fails to find a correlation between a health risk and a substance or activity. In a risk assessment, all relevant data that exists should be discussed as part of a complete risk assessment. Risk assessments that provide a quantification or numerical output shall use a central estimate risk which, as noted previously is preferably a "best" estimate with quantified upper and lower bounds of uncertainty.

New Subparagraph 633(b)(1)(B)

Reconciliation of, or at a minimum, thorough discussion of conflicting data (whether between epidemiological data or animal and epidemiological data) is extremely important. The committee stresses in this provision the importance of evaluating data for its relevance to human health risk. There can be a variety of scenarios in which data may have little or no relevance to biological reality (*e.g.*, such as where anatomical differences make animal data irrelevant) and regulatory decisions based on such scenarios may not be based on reasoned decisionmaking.

New Paragraph 633(b)(2)

This provision requires that when a risk assessment is based on a significant assumption, preference or model, the agency preparing the assessment must—

(A) elaborate and make clear the basis of such assumptions, preferences, or models by presenting explicit representative explanations and alternatives

(B) This provision gives preference to the model assumption that represents the most plausible or realistic inference—this is the real world approach that has been endorsed in several court decisions, including *Vinyl Chloride* (*NRDC* v. *EPA*, 824 F.2d 1146 (D.C. Cir., 1987), *Gulf South* (*Gulf South Insulation* v. *CPSC*, 701 F.2d 1137 (5th Cir., 1983), and *Benzene* (*Industrial Union Dept., AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607 (1980).

(C) This subsection allows use of science policy and value judgments only where they have been approved by the agency head after notice and comment.

(D)(E) These provisions address models. Any model that is utilized in a risk assessment should be identified and if it has not been validated, should either be validated or there should be thorough going explanation as to why it cannot be validated.

New Paragraph 633(b)(3)

Risk assessments that provide a quantification or numerical output shall use a central estimate of risk which preferably will be expressed as a "best" estimate with quantified upper *and* lower bounds of uncertainty. In any event, to the extent that a range of numerical or quantified risks is identified, the uncertainty in such range must be explained qualitatively if quantification is not practicable.

New Paragraph 633(b)(4)

A risk assessment should clearly separate hazard identification from risk characterization and make clear the relationship between the level of risk and the level of exposure. For example, a potential for significant adverse impacts may be identified for certain exposure scenarios, but if the exposure scenario is highly implausible then the potential for significant adverse impacts is likely to be minimal.

New Paragraph 633(b)(5)

This paragraph makes clear that a risk assessment should be prepared at the level of detail appropriate and practicable for reasoned decisionmaking. Thus, an agency is given the needed leeway for practical risk assessments.

New Paragraph 633(b)(6)

The purpose of this paragraph is to enhance the quality of data used by agencies in risk assessments: each Federal agency shall abide by the same standards and guidelines for toxicological data development that are imposed on outside parties who submit data to agencies. This is achieved by requiring, to the extent relevant, practicable, and appropriate, that data utilized by the agency for a risk assessment be developed consistent with guidelines for the development of data under two sets of guidelines. The first is promulgated pursuant to section 4 of the Toxic Substances Control Act (15 U.S.C. 2604) ("TSCA"). This set of standards, which appears at 40 C.F.R. Parts 796–799, address such issues as chemical fate testing guidelines, environmental effects testing guidelines, and health effects testing guidelines. The second is promulgated pursuant to section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a) ("FIFRA"). This set of standards, found at 40 C.F.R. Part 158, address such issues as environmental fate and toxicology data requirements.

The referenced guidelines have been established by the Environmental Protection Agency and are generally accepted to be appropriate guidelines to be followed in developing toxicological data for use in risk assessments. The committee believes that this provision is necessary because in the past agencies have relied on suspect data, which would not have been acceptable if submitted by an outside party. Thus, this provision simply requires agencies to abide by the guidelines imposed on outside parties and ensures that the data relied on by the agency as the basis for risk assessments supporting regulatory determinations is of comparable quality.

New Subparagraph 633(c)(1)(A–E)

This section makes clear and effectuates an important element in regulatory reform: involvement by the regulated community ("stakeholders") in the development of risk assessment guidelines.

New Subparagraph 633(c)(2)(A)

This provision provides an opportunity for meaningful public participation and comment on risk assessment throughout the regulatory process "commensurate with the consequences of the decision to be made."

New Subparagraph 633(c)(2)(B)

This subsection requires advanced publication and, therefore, identification by an agency of the relevant factors and criteria concerning risk assessment information that will become a basis for the promulgation of a major rule.

New Paragraph 633(d)(1–2)

This provision commands that no agency shall automatically incorporate or adopt any recommendations or classification made by an entity described in paragraph (2), which includes Foreign-governments or agencies, the United Nations or its subsidiaries, or any international body or organization. This provision is intended to prevent the automatic adoption of foreign generated data or standards as the basis of federal regulation, subjecting such data or standards to the same procedural requirements and validation protections as domestic data or standards. Thus, whether standard setting or expert organizations are national or international, any proposed standards or requirements should be evaluated in light of the statutory program that may ultimately form the basis for regulatory decisions. No data or standards should be automatically adopted or incorporated by reference.

New Section 634

New Subsection 634(1)

The committee believes communication by federal agencies to Congress and the public of risk assessment determinations and characterizations to be meaningful ought to contain certain key components. These include descriptions of exposure scenarios and, where feasible, an estimation of the corresponding population or natural resource at risk and the likelihood of such exposure scenarios.

New Paragraph 634(2)(A)

If a numerical estimate of risk is provided, the head of an agency shall provide range and distribution of exposures scenarios including, where appropriate, central and high-end estimates, but always including a central estimate of risk to the general population.

New Paragraph 634(2)(B)

A list of qualitative factors influencing the range of possible risk must also be included. Where quantitative risk estimates of the range of distribution of risks are not possible there should be a thorough discussion as to why they are not possible or not practicable.

New Subsection 634(3)

The head of an agency also shall provide the nature and magnitude of individual and population risks to human health in context.

New Subsection 634(4)

This subsection addresses the communication of substitution risks, either identified by the agency or provided by a commentator. Where substitution risks are not appropriate, the agency may discuss why it does not believe the substitution of risk information is worthy of consideration or that indeed it is or to solicit additional information with respect to the potential substitution risks.

New Subsection 634(5)

This provision essentially requires the agency to address risk assessments provided by those commenting on potential agency risk assessments that underlie regulatory control decisions. The committee intends to reach the situation in which the agency picks and chooses what it will address in its response to comments and often ignores risk assessments presented by commenters. This will encourage the private sector to engage in significant risk assessment efforts rather than discouraging them. Private entities often create high quality risk assessment information that has often been summarily dismissed as biased because it comes from industry. Any bias can be evaluated objectively.

New Section 635

Section 635 provides transition rules to determine when the reforms of this subchapter will be applied to major cleanup plans which are already under development as of the date of enactment. To assure that these transition rules guarantee protection of human health, this section explicitly states that it does not apply to emergencies, which will include any actual, immediate, and substantial endangerment to health, safety, or the human environment. For circumstances where no emergency exists, this section is carefully tailored to balance two important objectives: extension of the benefits of these reforms to cleanup and restoration projects where it is feasible to do so and avoidance of dangerous or costly disruptions to ongoing cleanup and restoration projects. As a general rule, application of the risk assessment and cost-benefit requirements does not entail serious disruption where construction has not yet commenced because, in such instances, the agency has only performed studies and analyses and normally need only provide a supplement which applies appropriate risk assessment and cost-benefit principles to existing data or which analyzes a new factor or issue that is relevant under the principles established in this bill. In effect, the analysis required for projects prior to construction is similar to a supplementary EIS which is required to comply with the NEPA law but which can usually be performed expeditiously and without significant delay to the construction project. In the current context, the supplementary analysis will simply be addressing risk assessment and cost-benefit requirements, rather than NEPA requirements. For instance, in a completed record of decision for a remedial action, the lead agency will already have performed a risk assessment and set forth and analyzed remedial alternatives; in the supplementary analysis performed by this section, the lead agency need only assure that the existing data developed in the risk assessment are analyzed according to the principles of this bill, that the list of remedial alternatives is complete, and that the alternative chosen has the greatest net benefits and is the most cost effective and flexible.

This section recognizes that the prospect of disruption increases once construction has commenced as a part of a removal, remedial, corrective or restoration action. Under these circumstances, a risk assessment and cost-benefit analysis need not be performed where the delays incident to performance of such analyses will result in an actual and immediate risk to human health or where the dis-

ruption of the construction work will not lead to a cost effective result. The committee expects, however, that where none of these circumstances exist, substantial benefits will accrue from the application of these reforms to construction activity without significant offsetting disadvantages, such as risks to public health or the waste of public or private resources.

New Paragraph 635(a)(1–2)

The head of an agency must prepare for each major rule relating to health, safety, or the environment, and for each major cleanup plan, a risk assessment according to the terms of this subchapter. This command is applicable to appropriate agency actions proposed after the date of enactment of this subchapter, pending on the date of enactment, or which is subject to a granted petition pursuant to the act. A risk assessment must also be done if a cost-benefit analysis would have to be completed under the Act.

New Paragraph 635(a)(3)

The requirements for comparative risk analysis in this subsection are based on including at least three other risks regulated by the agency and at least three other risks with which the public is familiar. The key here is that the risks are in some fashion relevant to the risks being evaluated even though not necessarily exactly the same kind of risk. Risks can be relevant in a number of different contexts even if they are not exactly the same kind of risk (i.e., risk of getting cancer, risk of getting struck by lightning) if they are of a similar order of magnitude—for example, very small. The comparison can be based on similar types of risks such as the risk from naturally occurring background radiation and the risk from some human enhanced source of radiation. They can be similar in terms of projected impact (i.e., the number of people potentially impacted) however, quite different with respect to the likely impact (i.e., the difference between hypothetical extrapolated health risk and "actuarial" risks that are in some sense more "real" as based on statistical evidence of actual adverse effects).

New Subsection 635(b)

This subsection details when major cleanup plans are subject to this subchapter.

New Subsection 635(c)

This subsection requires that a risk assessment prepared pursuant to this subchapter shall be a component of and used to develop any cost-benefit analysis required by this subchapter and be included in the same administrative record.

New Section 636

Section 636 provides that major cleanup plans must be based on scientific, plausible, and realistic risk assessments utilizing reasonable exposure scenarios and must select the alternative which has the greatest net benefits and which is the most cost effective and flexible. A major cleanup plan encompasses all of the activities envisioned for the entire facility or site, including any removal action, any remedial or corrective action, any environmental restoration,

and any natural resource damage assessment. For the purpose of determining whether the monetary threshold may be exceeded, the lead agency must evaluate the potential cost of all such activities, in the aggregate, for the entire facility or site; the requirements of this section, however, will be applied to each individual removal action, remedial action, corrective action, restoration action, or damage assessment as it is determined for the facility or the site. Where a federal agency is proceeding at a site under the National Contingency Plan, for instance, the applicability of this section will be determined based on the potential costs of all removal and remedial actions and natural resource damages expected for the entire facility or site. Once the Federal agency has made this threshold determination, the risk assessment, cost/benefit, cost effectiveness, and flexibility requirements of this section must be satisfied for each removal or remedial action and for each natural resource damage assessment, unless the circumstances surrounding the specific action or assessment constitute an emergency.

New Subsection 636(a)–(c)

This provision is a direction by Congress that agency heads, subject to the review by the Director of OMB or a designee of the President, will assure that risk assessments prepared for major rules or major cleanup plans shall be based on "good science," supported by the best available scientific data as determined by a peer review panel pursuant to section 640. This provision also contains a requirement that agency heads assure that a cost-benefit analysis must be done for any major cleanup plan subject to this act and that the plan will be implemented in a cost effective manner or will provide greater net benefits. Issuance of a record of decision, a final permit condition, or an administrative order for a cleanup plan, shall constitute final agency action under section 636(c), subjecting the agency action to judicial review at the time the action is taken.

New Subsection 636(b)

This section precludes agencies from denying approval of a substance or product on the basis of safety, if that substance or product poses a negligible or insignificant human risk under the intended conditions of use. This language would strike a provision in food and drug law commonly referred to as the "Delaney Clause."

The so-called "Delaney Clause" sets a "zero risk" standard in the food and drug law for substances which are potentially carcinogenic.

When the Delaney Clause was first enacted in 1958, it was a policy that was appropriate at that time. Today, though, the provisions are outdated and work against the best interests of the American people by stifling research on new technologies or ingredients which could improve the public health. Advances in science now make it possible to detect minute quantities of substances which potentially cause cancer.

The initial Delaney provision, added to the Federal Food, Drug and Cosmetic Act almost 40 years ago, provided that:

> No [food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the

> evaluation of the safety of food additives, to induce cancer in man or animal. [Section 409(c)(3), Federal Food, Drug and Cosmetic Act.]

The Delaney prohibitions of the Federal Food, Drug and Cosmetic Act were expanded in 1960 to cover color additives [Section 512(d)(1)] and in 1968 to cover animal drugs [section 721(b)(5)(B)]. Thus, the Delaney language requires that any potentially carcinogenic substance, in no matter how minute a quantity, be banned, even if it poses a negligible or insignificant risk to human health.

The Delaney clause is interpreted and applied by two agencies: the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). EPA applies it to all pesticide residues in processed food that are defined as "food additives." FDA applies it to all food substances that are defined as food additives, as well as to animal drugs and color additives.

Specifically, the Delaney language covers food additives, pesticide residues that concentrate in processed foods, color additives, animal feed additives and animal drugs. Ironically, a broader group of substances used for virtually identical purposes are not covered by the Delaney language. These are: pesticide residues that do not concentrate on processed foods; constituents of food additives; food substances which are not considered "additives," either because they are generally recognized as safe or were approved by the FDA or the U.S. Department of Agriculture during 1938–1958; dietary supplement ingredients; environmental contaminants in the food supply; cosmetic ingredients; undetected animal drug residues; and ingredients in nonprescription and prescription drugs.

It is important to have a single safety standard for all food substances, including constituents of these substances. The benefits to American consumers are obvious: they will be assured of a uniform, rational protection of the public health.

The purpose of S. 343, the Comprehensive Regulatory Reform Act, is to make our country's regulatory process function better and be more responsive to the public interest. One of the principal tools for achieving that purpose contained in S. 343 is the provision which will set forth reasonable guidelines for risk assessment. As Chairman Grassley said during subcommittee consideration of S. 343, "Better rules, broadly speaking, are the rules that do more social and economic good than harm."

Unfortunately, the Delaney Clause does not allow that flexibility. In fact, the Delaney Clause may be one of the few laws on the books which actually precludes the application of modern science and risk assessment.

A good example of this is the January 1990 decision by the Food and Drug Administration to terminate the provisionally listed uses of FD&C Red No. 3, a color additive. The agency action was based on life-time studies in rats, in which only the highest doses of the additive caused benign tumors in male animals. Not only were the levels causing the benign tumors literally thousands of times greater than any possible exposure to humans, scientists noted that the mechanism which caused the rat tumors did not even exist in humans. At the time of the FDA action, Secretary of Health and Human Services Louis B. Sullivan said that the color was not a

health hazard, but that he had no choice but to act given the unyielding provisions of Delaney.

The experience with the artificial sweetener saccharin is also illustrative of the problems posed by the Delaney language; moreover, it shows the widespread public and congressional recognition of the problems that Delaney poses, and the public's acceptance for a reasonable government solution to the problem.

In 1977, the Food and Drug Administration announced it was going to take steps to remove from the market saccharin, the only artificial sweetener approved for use at that time. FDA's action was based on a Canadian Government study showing that the sweetener caused tumors in laboratory animals when fed in high doses. Although FDA noted in a March 9, 1977, release that saccharin had been in use for more than eight decades, that it had never been known to harm people, and that Canadian data did not indicate an immediate hazard to public health, the agency concluded, "The law is clear. It says that no ingredient that causes cancer in man or animals may be added to our food supply."

Public and congressional reaction was swift. By November of that year, President Carter had signed into law the Saccharin Study and Labeling Act (Public Law 95–203), which held off the proposed ban for 18 months pending a new scientific review. The moratorium was then again extended by the Congress in 1980 (Public Law 96–273), in 1981 (Public Law 97–42), in 1983 (Public Law 98–22), and in 1985 (Public Law 99–46). Thus, on four occasions, the Congress passed, and the President signed into law, exceptions to Delaney for saccharin.

Beyond the two above-cited examples, it is clear that the Delaney Clause gives rise to a host of problems:

First, as noted, it sets a zero risk standard, which has proven too inflexible.

Second, the Delaney Clause is scientifically outdated. Due to the advances in modern technology, we now have the ability to detect minute quantities of potential carcinogens, abilities which were neither possible nor foreseeable almost 40 years ago. Scientific advancements since 1958 allow us to identify threshold levels and application of a de minimis concept, that is, a concept allowing negligible risk, with reasonable certainty of safety.

Third, a zero-risk standard for food and drug approvals stifles research and development of new technologies which can improve production and better meet consumer needs.

The fourth problem has been referred to as the "Delaney paradox." Pesticide residues on raw commodities such as fruit are not considered food additives and thus not subject to Delaney. On foods processed from those same commodities, the same residue could become illegal. In other words, a pesticide on an apricot is not considered a food additive and thus is not subject to the absolute prohibition contained in Delaney. If that same apricot were made into jam, Delaney could kick in.

In addition, it is important to note that the Delaney restrictions have had a very serious, negative effect on America's farmers, an effect felt in virtually every State. Under the strict interpretation of the Delaney language, even though detectable levels of pesticides may represent a negligible health risk, many essential crop protec-

tion products will be banned, only because they are detectable. In many cases, this means that farmers will lose the benefits of the few remaining crop protection products available to them.

Recognizing this fact, in 1988, the Environmental Protection Agency announced it would establish a de minimis exception from Delaney if the dietary risk to humans from pesticide residues were negligible. Although the EPA statement followed from a recommendation made by the National Academy of Sciences in its 1987 report, "Regulating Pesticides in Food: The Delaney Paradox," it was challenged in Federal Court and subsequently overturned by the U.S. Court of Appeals Ninth Circuit in *Les* v. *Reilly*.

The effect of the Court of Appeals ruling is that approval to use up to 80 pesticides, some of the most effective on the market, is scheduled to be removed. These are products used on virtually every crop in the United States, including corn, tomatoes, wheat, citrus, sugarcane, potatoes, apples, and cotton.

While critics of a Delaney modification have argued that changing the law will lead to unsafe products being marketed, or the public health being injured, that is not the case. Although the language approved by the committee does repeal the zero-risk standard of Delaney, it preserves the requirement that products be adjudged safe under intended conditions of use.

Further, the bill approved by the committee leaves intact two existing safety standards contained within food and drug law. Section 402(a)(1) of the Federal Food, Drug and Cosmetic Act bans any added food substance that may render the substance injurious to health. This has been definitively interpreted by the Supreme Court and applied by the FDA since first enacted in 1906 as banning any food substance if there is a "reasonable possibility of no harm to humans under the conditions of use." This standard is equivalent to negligible risk.

The second section is 409(a) of the Food, Drug and Cosmetic Act (left intact by S. 343), which bans any food additive that is not the subject of a regulation promulgated by FDA setting forth its safe conditions of use. Legislative history on Delaney established a clear standard for this provision:

> Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance. [S. Rpt. 2422 (1958).]

Both FDA and EPA have adhered to this standard since 1958 and the committee sees no reason why the agencies should, or would, change this interpretation.

Since the early 1970's, FDA has on several occasions applied these two safety standards to animal carcinogens that are not subject to the three Delaney Clause provisions. In case, FDA has applied the principles of risk assessment and risk characterization, including information about the mechanism of action. In the future, these principles will continue to be applied, subject to the requirements of S. 343, to all food substances.

In general, FDA has applied a standard of permitting the use of a substance that represents less than a one-in-a-million individual

lifetime cancer risk. FDA has determined that this level of risk "imposes no additional risk of cancer to the public," [44 Fed. Reg. 17070, 17093 (Mar. 20, 1979)] and "is consistent with the likelihood that no cancers will result." [46 Fed. Reg. 15500, 15501 (Mar. 6, 1981), 47 Fed. Reg. 49628, 49631 (Nov. 2, 1982)].

FDA has also characterized the one-in-a-million lifetime risk as representing "no significant carcinogenic burden in the total diet of man," [42 Fed. Reg. 10412, 10422 (Feb. 22, 1977)], and "for all practical purposes, zero," [50 Fed. Reg. 51551, 51557 (Dec. 18, 1985)], or "the functional equivalent of no risk at all," [51 Fed. Reg. 28331, 28344 (Aug. 7, 1986)] and "so low that there is a reasonable certainty of no harm," [51 Fed. Reg. 4173, 4174 (Feb. 3, 1986)].

EPA has also applied similar risk assessment principles in regulating chemicals, including pesticide residues, that concentrate in processed foods. EPA has most often referred to the level of risk as "acceptable." In the early 1980's, EPA approved a number of pesticides that were deemed to present only an "insignificant" level of cancer risk. Since the late 1980's, EPA has referred to these risks as "negligible."

It is apparent that a wide variety of words could be used to signify a level of risk so low as to be meaningless to human health. Both agencies, working together to establish consistent risk assessment principles, have concluded that insignificant or negligible risks present no real threat to health and therefore should not be banned. The terms "negligible" and "insignificant" are unquestionably synonyms.

Accordingly, while some may assert that the Delaney Clause is needed to protect the public from dangerous substances in the food supply, that is wrong. Under the committee bill, substances would be permitted only if the regulatory process concluded that the risks were insignificant. It is important to underscore that the FDA and the EPA would have to define what substances pose no harm. Developing the thresholds is entirely within the agencies' discretion.

Further, both Food and Drug Commissioner Kessler and EPA Administrator Browner have testified before Congress in favor of modification of Delaney. In fact, as recently as March 28, 1995, at a House Appropriations Agriculture Subcommittee hearing, Commissioner Kessler told the committee: "There is room for appropriate modification of Delaney." He also confirmed for the House panel that "zero risk is impossible to achieve."

As noted previously, the committee is concerned about the inflexibility of the Delaney Clause, which we believe is the only provision in Federal regulatory law calling for an absolute or "zero-risk" standard for product approvals.

It is the intent of the committee that the language contained in section 636(b) apply only to the three provisions in the Federal Food, Drug and Cosmetic Act that preclude any risk analysis at all in the approval or disapproval of food additives, color additives or animal drugs.

Indeed, it is the belief of the committee that the language embodied in S. 343 will allow the Food and Drug Administration and the Environmental Protection Agency the latitude to determine the thresholds for marketing of animal drugs, or food/color additives, as appropriate, under a standard of "negligible or insignificant risk."

In other words, the agencies have the latitude under the committee bill to interpret by regulation how the terms "negligible" and "insignificant" are to be applied.

In allowing the agencies this discretion, the committee notes that imposition by regulation of a zero-risk standard would be precluded under the requirement that the measure of risk be "negligible" or "insignificant."

The committee is aware of the opposition expressed by the Administration to the way this provision is drafted. Administration officials have told the committee that they believe the language is overly broad and may address situations beyond Delaney.

For example, the FDA told the committee that it believed the language would limit its ability to remove from the market defective products such as certain sleep apnea monitors, which are used to guard against Sudden Infant Death Syndrome in infants. It is the committee's understanding that a situation had arisen in which the defective design of certain monitors led to the electrocution of infants.

According to the FDA's interpretation of the committee bill, this language could have precluded the agency from removing such defective products from the market.

The committee is puzzled by this interpretation, since under the provisions of S. 343 as reported, the FDA would have to find the possibility of electrocution "insignificant" or "negligible." The committee is hard-pressed to conclude that FDA would have rendered such a judgment.

Likewise, an official from the Consumer Product Safety Commission told the Committee that he believed the language would preclude the Commission from acting to remove products from the market based on a "reasonably foreseeable misuse" standard.

Again, the committee is perplexed by this interpretation of the law and notes that the language clearly does not apply to removals of products from the market. It is not the intent of the committee that the language contained in Section 636(b) apply to the enforcement actions of the Consumer Product Safety Commission.

During consideration of S. 343, some raised the concern that the language included on negligible or insignificant risk may not adequately protect the health of women and children. The committee is very sensitive to this concern and notes its expectation that the administering agencies shall likewise give consideration to the health effects of products on women, children and other sensitive populations. While the agencies already have broad authority to make scientific determinations, they should be allowed to tailor their regulations to meet specific circumstances. This bill would not preclude that.

The committee was reluctant to codify a requirement that the agencies comply with a 1993 National Academy of Sciences report on pesticides, as such a requirement could well become outdated in the future. The committee recognizes that the NAS study contained a number of beneficial recommendations to improve data on consumption, exposure and percent of crop treated in order to improve risk assessments with regard to infants and children.

In fact, the committee is pleased that the EPA has begun to implement many of the NAS recommendations. EPA, for example,

currently takes children's risk into consideration when setting tolerances for pesticides and routinely builds in a safety factor of at least a hundredfold.

To allow the agencies the flexibility to make these judgments on their own seems sensible, given the general intent of the bill to allow the agencies flexibility to respond appropriately to public health needs. In addition, States and the Federal Government are already aware of the need to protect children and other vulnerable populations and are working to make these protections a reality.

And, a May 1994 California Department of Pesticide Regulation review of the NAS report concluded: "The current California and federal pesticide regulatory systems adequately protect infants and children from risks posed by pesticide residues in the diet." While several potential areas for improvement were identified, the current safety of fruits and vegetables for children was emphasized.

Because of the importance of the health of women, infants and children, the committee intends to monitor closely implementation of the changes embodied in S. 343.

Additionally, the committee wishes to respond to the suggestion that only the Delaney Clause provision relating to pesticides should be amended. The committee notes that this limited approach would be irrational public policy at best, and would be in complete conflict with current scientific knowledge and FDA regulatory policy.

It is not wise public policy to set up two different standards for food additives: one for food additives generally; and one for concentrated pesticide residues that are regulated as food additives. It is equally unwise to set up differing standards for food substances that are technically classified as "food additives" and for food substances that escape the technicality because they are generally recognized as safe or prior-sanctioned. Accordingly, the committee believes the most sound approach, and the one that was adopted by the committee, is to modify all sections of the law which impose the Delaney standard.

New Section 640

This provision requires that the Director of the Office of Science and Technology or the Director of the Office of Management and Budget establish a program of peer review to review the risk assessments and cost-benefit analyses for major rules, as well as certain other quantitative estimates. This section also establishes criteria to assure the impartiality of peer review panels and that the findings of the panels, as well as the agencies' responses, be made public for comment and final peer review. These findings and responses are to be made part of the administrative record for purposes of judicial review. The committee believes that peer review of risk assessment operates most effectively when it is open to public input on relevant issues. This section recognizes that interested parties often have valid issues that are outside the scope of inquiry by the review panel. Such relevant issues should be considered by peer review panels even though they are not among issues prescribed by the agency for review.

New Subsection 644(b)

The committee has included a section in this bill to amend the Regulatory Flexibility Act to repeal its prohibition against judicial review.

The Regulatory Flexibility Act is based on two premises. First, Federal departments and agencies often do not recognize the impact of their rules on small businesses. Second, small businesses are affected disproportionately by Federal regulations compared to their larger counterparts.

In 1980, The Regulatory Flexibility Act was enacted to reduce, where appropriate, the impact of Federal regulations on small businesses and certain other small entities. The Act requires Federal agencies to assess the impact of their proposals on these small entities before issuing the rule. Agencies have two options under the statute—performing a regulatory flexibility analysis or issuing a certification that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Unfortunately, too many Federal regulators fail to carry out their responsibilities under the Regulatory Flexibility Act. When Federal agencies fail to comply with these requirements, they impose significant and burdensome requirements that can threaten the viability of small businesses. All too often, these agencies view the act as nothing more than another procedural impediment to the adoption of a particular rule. As a result, some agencies have issued boilerplate "no impact" certifications without faithfully performing the underlying assessment of impacts on small businesses required by the act. As long as Federal departments and agencies continue to act in this manner, small businesses will be the losers. The committee believes Federal agencies have a significant responsibility under the Regulatory Flexibility Act that should not be ignored or overlooked.

The authors of the original act apparently were concerned that a litigation explosion might result under this law if businesses attempted to delay the implementation of regulations through court review of regulatory flexibility analyses. To prevent this, the sponsors included a provision prohibiting judicial review of agency compliance with the Regulatory Flexibility Act.

Today, we realize it is highly unlikely there would be a flood of litigation of judicial review as permitted under the Regulatory Flexibility Act. The fact is most small businesses do not have the desire or the financial resources to bring frivolous, unfounded lawsuits.

Therefore, the committee has included a section in this bill that amends the Regulatory Flexibility Act that removes the prohibition against judicial review and establishes procedures for permitting certain court challenges. This section will insure that small businesses have the opportunity to force federal regulators to comply with the purposes and requirements of the Regulatory Flexibility Act.

It is the committee's belief that this amendment will add teeth to the act and give small businesses a legal means for countering continued violations of the act. The Regulatory Flexibility Act, properly implemented and appropriately strengthened, is an integral element of our efforts to ease the regulatory burdens on small

businesses. The beneficial impact on small business from honest and complete agency compliance with the Regulatory Flexibility Act will be as great as any other effort under regulatory reform.

The committee intends for the judicial review of agency actions under the act to extend the consideration of the accuracy and completeness of any regulatory flexibility analysis prepared by a Federal agency, based on the court's review of the rulemaking record. Otherwise limiting the scope of the court's inquiry (for example, to merely reviewing whether an agency followed procedural steps outlined in the Act by issuing documents purporting to be responsive to the Act's requirements) would offer no meaningful assurance that the original purposes of the act are being met. This amendment should help achieve the act's goal of minimizing the economic impact of Federal rules on small entities.

New Section 706

S. 343 incorporates certain substantial reforms made to the Administrative Procedure Act by S. 1080 in 1982, particularly changes made to APA sections 553 and 706(a). The committee hereby incorporates modified language taken from the committee on the Judiciary's Report on S. 1080 concerning those sections as follows:

SECTION 5

New Section 706

Section 706 makes important changes in the provisions of the A.P.A. dealing with judicial review of agency actions.

New Subsection 706(a)

This subsection makes several changes to the provisions of the APA governing the scope of judicial review of agency actions. The addition of a new clause (F) to section 706(a)(2) provides a separate, clearer standard for review of certain factual determinations in informal rulemakings. Relying on the analysis in Recommendation 74–4 of the Administrative Conference, 1 C.F.R. section 305.74–4 (1980), clause (2)(F) requires substantial support for factual determinations in informal rulemaking when (1) the determination of fact is necessary to the rule (that is, where the rule would fail to satisfy the "arbitrary, capricious, [or] an abuse of discretion" criterion, or where the rule would be in excess of the agency's authority, absent such a finding of fact), or (2) the finding of fact is an asserted basis for the rule (that is, where the agency relies on the finding as part of its rationale for the policy choice reflected in the rule).

Under clause 2(F) the "substantial support" must be found in "the rule making file, viewed as a whole". This provision meshes with other provisions of S. 343 amending section 553, discussed earlier, which require the organized and systematic development of a file on which the rulemaking action is to be based and judicially reviewed.

Section 706 in its present form does not specifically prescribe the standard of review for factual issues raised in review of rules promulgated under section 553 procedures. Courts have thus had to apply the "arbitrary, capricious, [or] an abuse of discretion" test to

these factual issues. Many have looked for analogy to the "substantial evidence" standard now applicable to review of rule makings "on the record" and have formulated an equivalent standard requiring a court to take a "hard look" at agency factual determinations. Other courts have reviewed factual issues in a variety of ways, none easily defined.

Finally, the "substantial support" standard in new clause (2)(F) recognizes that there is a distinction between an exercise of discretion (policy choice) by the agency, which remains subject to the "arbitrary, capricious, [or] an abuse of discretion" standard of clause 2(A), and the factual foundation for such a choice.

The committee believes that these changes to section 706 will not cause any dramatic upheaval in the process of judicial review of agency actions. These amendments to section 706 are not intended to affect any applicable rule of law which provides that in a civil or criminal action reliance on an agency rule or order is a defense. Thus, a defendant who has acted in compliance with an agency rule or order would continue to have any protection the law now provides even if the rule or order is subsequently found to be invalid.

The committee expects that whenever an agency rule or order is challenged in a civil action where a private party is suing under an express or implied right of action for violation of an agency rule (arguably not a "proceeding for judicial enforcement" within the meaning of section 706) the court will apply the same standards of review as those set forth in section 706. In stating this expectation, we do not intend to imply any new standing or right of a defendant to challenge the validity of an agency rule or order. Thus, only if and to the extent that a rule can be reviewed by the court in the action would the reviewing court be expected to apply the same seciton 706 tests of lawfulness of agency action.

New Subsection 706(b)

The Administrative Procedure Act has long provided the "rule of prejudicial error," as stated in the last sentence of existing 5 U.S.C. section 706: "In making the foregoing determinations [regarding judicial review of agency actions], 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." This provision is recodified in this legislation as subsection (b) in 5 U.S.C. section 706. Section 706(b) must be read in conjunction with APA section 706(2)(D), which would require reviewing courts to set aside agency actions whereby procedures required by law were not observed. The committee believes, as more fully discussed below, that only where nonobservance of procedures materially altered the rights of affected parties should a court set aside the rule.

This language prescribes a general test that courts must use in determining whether any error by the agency in promulgating a rule or taking other agency action is either "prejudicial" or, conversely, "harmless"—to a party seeking judicial review of the rule or other agency action. The circumstances that are likely to arise in actual cases, however, and the substantive statutory provisions under whose authority the agencies act, are highly varied. Notwithstanding this, the committee wishes to make clear its intentions

with respect to certain situations. Where an agency has failed to give adequate notice to the public at the proposal stage (or at some other time that is early enough to afford a meaningful opportunity to comment) of the subjects ultimately addressed in the final rulemaking, or has failed to make an initial cost-benefit analysis pursuant to chapter 6 or publish with the proposed rule a summary of that analysis pursuant to chapter 6, such failures would cast serious doubt on any claim that the agency has engaged in reasoned decisionmaking under the terms required by the bill. The committee intends that, with respect to any agency failure to comply with these fundamental requirements, the agency—not the petitioner—must bear the burden of showing that the agency's failure did not significantly change the action. For example, the committee endorses the view expressed by the U.S. Court of Appeals for the District of Columbia Circuit in *McLouth Steel Products Corp.* v. *Thomas,* 838 F.2d 1317, 1324 (D. C. Cir. 1988), and reaffirmed by that court in Shell Oil Co. v. EPA, 950 F.2d 741, 752 (D.C. Cir. 1991), that petitioners do not bear the burden of showing that they would have submitted new arguments if the agency had satisfied the procedures of section 553 "where the agency has entirely failed to comply with notice-and-comment requirements." Shell Oil, 950 F.2d at 752.

On the other hand, some agency failures, while error, may not be *prejudicial* error. When, for example, the agency failed to fully describe an "available alternative" in an analysis subject to section 622 or failed to satisfy a requirement in subchapter III of this bill, it would be incumbent upon the petitioner to show how such a failure was of sufficient importance to the outcome of the rule through comments identifying the deficiency and explaining how correcting the deficiency would require a significant change in the rule. Only if the petitioner demonstrates that the agency's failure to correct the deficiency was arbitrary and capricious because the objection could have resulted in significant change if adequately considered could a court find that the agency had made a "prejudicial error."

It would reflect a basic and clear misreading of the existing act and this bill to suggest that any deviation in a given proceeding from the bill's procedural requirements constitutes prejudicial error that calls for judicial remand or reversal of the agency action. That is not the law now and will not be the law under this bill. Very simply, some—not all—errors are prejudicial. Some are harmless. There is no merit to the notion that any agency error, no matter how inconsequential in practical terms, is "prejudicial." See, e.g., *Small Refiner Lead Phase-Down Task Force* v. *EPA,* 705 F.2d 506, 540–41 (D.C. Cir. 1983) (concluding that EPA "committed error, but not reversible error" when it added certain studies to the rulemaking docket "too late for effective rebuttal" but where the petitioner, notwithstanding the agency's error, had had "ample opportunity" to comment on the matter). The relevant test under existing case law has been whether there is an absence of notice or whether there is a substantial likelihood that the final agency action would have been significantly different had the agency responded to comments demonstrating a failure to meet a procedural obligation.

Accordingly, the committee recognizes that, in a particular case, some kinds of deviations from the bill's required administrative procedures may not affect the fundamental fairness of the agency proceeding and may not undermine the basic requirement of reasoned decisionmaking. These deviations should not, therefore, be considered to be prejudicial error and should not require reversal or remand of agency action.

New Subsection 706(c)

Section 706(c) is one of several provisions of the bill which reflect the basic principle of administrative law that agencies must provide an explanation of the reasons for their proposed and final legislative rules, including the statutory authority for those rules. Under sections 553 and 622, the agency's explanation must establish a clear basis for informed and meaningful public comment and judicial review concerning the agency's interpretation of the statute under which the agency exercises the power delegated to it by Congress. Under section 706(c), the courts review the agency's decision in light of these principles that, at their core, require the courts to insist that agencies explain what they are proposing and, at the end, what they have done.

The bill provides in amended 5 U.S.C. 553(b)(1)(C) and (c)(4) that a notice of proposed rulemaking and a statement of basis and purpose of a final rule must include an explanation of the specific statutory interpretation under which a rule is proposed or promulgated. In addition, for both a proposed and a final rule, the agency must state whether the specific statutory interpretation on which the rule is based is expressly required by the text of the statute and, if the interpretation is *not* expressly required by the text of the statute, the agency must state that the interpretation is within the range of permissible interpretations of the statute that have been identified by the agency in proposing the rule (or by commenters in commenting on the proposed rule). If the agency's interpretation is not expressly required by the text of the statute, the agency must state in proposing the rule why the interpretation that it has chosen is the agency's preferred interpretation, and must state in publishing the final rule why the agency has rejected any other interpretations proposed in comments to the agency.

Provisions in 5 U.S.C. 622, to be added by the bill, reflect a parallel approach with respect to analysis of regulatory alternatives for major rules. Section 622(c)(2)(C) requires that an initial cost-benefit analysis must include an identification of reasonable alternatives that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority, as supplemented by the decisional criteria in section 624, for achieving identified benefits. Section 622(d)(2) provides that the final cost-benefit analysis must describe and compare the benefits and costs of the rule and of the reasonable alternatives to the rule and must contain an analysis, based on the rulemaking record, of whether the rule will achieve greater net benefits (or lower net costs, in cases within the scope of section 624(c)), than any of the reasonable alternatives that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority. The bill, in section 621(7), defines "reasonable alternatives" as the

range of regulatory options that the agency has discretion to consider under the text of the statute granting rulemaking authority, interpreted, to the maximum extent possible, to embrace the broadest range of options that satisfy the decisional criteria of section 624(b).

The bill's judicial review provisions—specifically, 5 U.S.C. section 706(c)—embody the basic principle that, to withstand judicial review, an agency's action, including a rule, must conform to the clear meaning of the statute or, if no single meaning is evident from the text of the statute, the action must be based on an interpretation that is within the range of interpretations that are permissible in light of the statute's text and other evidence of the power Congress intended to give the agency.

In addition, if the agency's action is based on its conclusion that the interpretation adopted by the agency is the only permissible interpretation, and if the reviewing court determines that the agency had discretion to consider other interpretations, the court is to set aside that action as arbitrary, capricious, or an abuse of discretion, even if the interpretation adopted by the agency is permissible. The reason for this requirement is that the agency's action under these circumstances rests on a basic misconception of the scope of the discretion that the agency has been delegated by Congress. As a result, it has failed to exercise the discretion granted it by Congress, and, had it done so, might have concluded that some other permissible interpretation was preferable. For the same reason, if the agency, in taking a final action, has erroneously rejected an alternative interpretation (either one described by the agency in proposing the action or one proposed by a commenter) as being outside the range of permissible interpretations—i.e., if the reviewing court determines that a proposed interpretation rejected by the agency as impermissible is in fact permissible—the reviewing court is to set aside the agency's action even if the interpretation selected by the agency is also permissible. In such a case, the action must be set aside because the agency has again failed to exercise the discretion granted it by Congress since it has not considered the full range of options available to the agency. *See Scenic Hudson Presentation Conference* v. *FPC,* 354 F.2d 608 (2d Cir. 1965).

The bill does not contemplate, however, that a court would set aside an action on the grounds that the agency had improperly classified a particular interpretation as being *within* the range of permissible interpretations if (1) the agency did not rely on *that* interpretation as the basis of its action and (2) the agency *did* rely on a permissible interpretation. Because the agency's error in such a case would be harmless, it would be inappropriate for a court to set aside the agency's action; there is no reason to believe that a different agency action would result from a new agency proceeding based on a correct understanding of the scope of the agency's authority. In contrast, if the agency rejects an interpretation on the grounds that it is impermissible when, in fact, that interpretation is, in the court's view, within the range of permissible interpretations, the agency's action should be set aside because the outcome of the agency proceeding might be different if it is based on a correct understanding of the full range of the agency's discretion.

Finally, section 706(c)(2)(B), as added by the bill, provides that, where the agency action is a major rule subject to chapter 6 (including section 622), a reviewing court is to set aside the rule if the agency's interpretation is not that interpretation, within the range of permissible interpretations, that gives the agency the broadest discretion, consistent with the terms of delegation to the agency in the governing statute, to make rules that satisfy the decisional criteria in section 624. This provision confirms that a court must reject an agency's designation of the range of "reasonable alternatives," as defined in section 621(7), that is based on an interpretation that restricts that range so as to exclude otherwise permissible alternatives.

Since the beginning of the Republic, it has been "emphatically the province and duty of the judicial department to say what the law is." *Marbury* v. *Madison,* 5 U.S. (1 Cranch) 137, 177 (1803); *see Montana* v. *Clark,* 749 F.2d 740, 744 (D.C. Cir. 1984) ("the judiciary is uniquely responsible for the final determination of the meaning of statutes") (citing *FTC* v. *Colgate-Palmolive Co.,* 380 U.S. 374, 385 (1965)), *cert. denied,* 474 U.S. 919 (1985). Thus, the principle is well established that "[t]he judiciary is the final authority on issues of statutory construction." *Chevron U.S.A.* v. *Natural Resources Defense Council,* 467 U.S. 837, 843 n. 9 (1984).

The hallmark of the modern administrative state, however, is Congress' delegation by statute to the executive branch of great power to make law in the form of rules and orders and, in doing so, necessarily to interpret the statutes that establish their authority. In recognition of Congress' decision to delegate law-making power to the executive branch agencies, courts generally will defer to agencies' interpretations of statutes if the statute requires the agency to exercise its discretion and the interpretations are accompanied by a reasoned analysis showing that the interpretation is permissible under the delegation from Congress.

The Supreme Court in its landmark *Chevron* decision summarized the law in this area and articulated a two-part test for courts to follow in reviewing administrative actions in which the agency has interpreted a statute:

> When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

Chevron, 467 U.S. at 842–43. Moreover, "[t]he court need not conclude that the agency construction was the only one it permissibly

could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." *Id.* at 843 n. 11 (citations omitted).

Accordingly, in the first step of *Chevron* review, the court must determine whether Congress, in the statute, has resolved the issue. That is, the court must decide whether there is only one permissible interpretation of the statutory provision at issue as it relates it to the matter being decided. If there is, and the agency's interpretation is not that one permissible interpretation, the agency action is necessarily based on an impermissible interpretation—an interpretation that Congress has precluded—and the court must set aside the agency action.

The second step of *Chevron* review occurs if the court determines that Congress, in the statute, has not resolved the issue. If Congress has not done so, the court must determine whether the agency's action is based on a permissible construction of the statute, even if that construction is not the only permissible one. In other words, a range of permissible interpretations—rather than only a single permissible interpretation—may exist with regard to that matter. A reviewing court's function in that circumstance is to determine whether the agency's interpretation is permissible under the terms of the statutory text and other relevant indicia of congressional intent. As long as the court determines that the agency's interpretation is permissible, the court does not determine whether the agency's interpretation is the one that the court would have adopted if the court had authority to review the matter de novo. *See Chevron,* 467 U.S. 843 n. 11.

Misunderstanding has arisen about step two of *Chevron*. In the years since the Supreme Court decided *Chevron,* some have come to invoke the "*Chevron* doctrine" as if it were a blank check for an agency to adopt any interpretation that it sees fit, as long as the court determines that Congress has not spoken directly to the precise issue. That view ignores the principle, laid down in *Marbury* v. *Madison,* and applied in later cases over almost two centuries, that the judiciary has the ultimate authority to interpret whether the actions of the executive branch are in accord with the law. The court must determine in all cases whether the agency's interpretation is permissible within the bounds of the discretion that Congress has delegated to the agency in the statute. Even where Congress has not directly spoken to the issue, certain agency interpretations may not, in the reviewing court's construction of the parameters of the statute, be a "reasonable policy choice for the agency to make." *Chevron,* 467 U.S. at 845. This "reasonableness" test reflects a proper degree of judicial deference to the agency to which Congress has delegated authority, but it is not absolute deference because it is grounded in a statute; it is not an abdication of the judiciary's responsibility under the Constitution to interpret the laws that Congress makes.

In this regard, the *Chevron* decision was no judicial rubber stamp of the agency's interpretation. The *Chevron* Court itself, in the second step, recognized the twin congressional objectives under the Clean Air Act of promoting environmental protection and limiting burdens on the economy. *See Chevron,* 467 U.S. at 863, 865. After determining that Congress had not "directly spoken to the

precise question at issue," *id.* at 842, the Court concluded that "the Administrator's interpretation represents a reasonable accommodation of manifestly competing interests" since "the regulatory scheme is technical and complex, the agency considered the matter *in a detailed and reasoned fashion, and the decision involves reconciling conflicting policies*." *Id.* at 865 (footnotes omitted) (emphasis added). Thus, the agency acted "within the limits of th[e] delegation" of law-making power from Congress, and the agency's interpretation was "a *reasonable* choice within a gap left open by Congress." *Id.* at 865, 866 (emphasis added). The basis of the Court's decision in the second step was its independent "examination of the legislation and its history." *Id.* at 845. Only after conducting that examination, and reviewing the agency's *explanation* for its choice and its rejection of alternative interpretations, did the Court conclude that the Administrator's actions represented "a reasonable policy choice for the agency to make." *Id.*

The approach in the *Chevron* case, and in section 706(c), reflects the mainstream view of courts in requiring "reasoned decisionmaking" measured by the power given by *Congress* to an agency in a specific statute, not measured by some independent judicial standard for agency action. *See, e.g., Rust* v. *Sullivan,* 500 U.S. 173, 187 (1991); *Madison Gas & Electric Co.* v. *EPA,* 25 F.3d 526, 529 (7th Cir. 1994); *Kansas City* v. *HUD,* 923 F.2d 188, 192 (D.C. Cir. 1991); *Prill* v. *National Labor Relations Board,* 755 F.2d 941 (D.C. Cir. 1985). An example of what, in the committee's view, is a misreading of the *Chevron* doctrine is the second sentence in the following passage: "Under *Chevron,* an agency's construction of a statutory provision it is responsible to implement is binding on a court if it is a permissible construction of the statute. It is a permissible construction unless Congress has unambiguously addressed the precise question in a manner inconsistent with the agency's construction." Davis and Pierce, *Administrative Law Treatise* (3d ed. 1994), vol. I, 235. Perhaps inadvertently, that formulation confuses the first step of *Chevron* with its second step and improperly suggests a judicial role in the second step that is more limited than in fact that role is. The mistake that the authors make is in suggesting that *any* agency interpretation is permissible (step two) as long as Congress has not unambiguously addressed the precise question (step one). A statute need not explicitly forbid a particular agency action for a court to conclude that such action is beyond the bounds of the power delegated by that statute.

Under the existing Administrative Procedure Act and under the Act as amended by the bill, an agency rule may be binding only if it is the product of procedures for reasoned, public rulemaking under 5 U.S.C. 553 (or equivalent or more demanding procedures prescribed in substantive statutes). Because the agency's interpretation of the statute under which it receives delegated rulemaking authority is an essential basis for any legislative rule, the notice of proposed rulemaking under section 553(b)(1) must state clearly that interpretation. If the agency were not required to plainly state its interpretation of the relevant statutory provision, the public would be denied any meaningful opportunity to comment on perhaps the most fundamental element of any proposed rule: "the

legal authority under which the rule is proposed." 5 U.S.C. 553(b)(2) (1988).

In proposed section 553(b)(1)(C), the bill makes explicit what is implicit in the APA and in *Chevron*, i.e., that the agency in the rulemaking must: make clear whether the statute compels the agency's interpretation (*Chevron* step one); and, if it does not, explain that the agency's interpretation is within the range of those interpretations that are "based on a *permissible* [though not necessarily mandated] construction of the statute," *Chevron*, 467 U.S. at 843, and why the agency prefers that interpretation (*Chevron* step two). *See Chevron*, 467 U.S. at 863 ("the agency, to engage in informed rulemaking, must consider varying interpretations" of the governing statute).

Inclusion of information on both *Chevron* steps in the notice of proposed rulemaking is necessary to provide the public with a clear basis on which to evaluate and comment on that aspect of the rulemaking that, under *Chevron*, will have to be addressed by any court that is called on to review the final product of the rulemaking. Fair procedure and fair access to the courts dictate that all members of the public have a meaningful opportunity to comment on the matters—including, first and foremost, statutory interpretation and the scope of the agency's discretion to interpret the statute—that a reviewing court would judge if the proposed rule were to be made law. A person must be given a meaningful opportunity to comment on all of those matters if it is to have not only the opportunity to try to persuade the agency but also the opportunity to shape the rulemaking record that the court will use to review those matters if that person appeals to that court for relief after the agency finally acts.

Thus, section 553(b)(1)(C) is designed in part to require the establishment of an adequate written record that will be available for judicial review of the final rule. That record must include both the public's comments on the existence and nature of the statutory basis for the rule that the agency proposes *and* the agency's responses to those comments. Thus, section 553(c)(4)(B), as proposed to be added, makes clear that the statement of basis and purpose of a final rule must include a discussion of and response to any significant comments on legal issues. Unless the agency assembles a rulemaking record that reflects a full, public review of the agency's statutory interpretation, presented in terms of the *Chevron* two-step analysis, a critical objective of the existing act and of this bill—providing the opportunity for *effective* judicial review of final rules—would be frustrated.

These provisions of the bill embody principles reflected in existing case law. For example, in *Prill* v. *National Labor Relations Board*, 755 F.2d 941, 947 (D.C. Cir.), *cert. denied*, 474 U.S. 948, 971 (1985), Judge Edwards, speaking for the U.S. Court of Appeals for the District of Columbia Circuit, set aside an agency decision that was based on the National Labor Relations Board's conclusion that a particular interpretation of the phrase "concerted activities" in section 7 of the National Labor Relations Act was foreclosed by the statutory language. The court found the Board's conclusion to be erroneous. Because of that "faulty legal premise," which the court found was a result of the Board's "misinterpretation of judicial de-

cisions and its own prior cases," the Board "failed to exercise its lawful discretion." *Id.* at 956, 957.

The standard of review as articulated in Judge Edwards' opinion for the Court in *Prill*, and as codified in section 706(c) of the act as proposed to be added by the bill, is the following:

> [A] *reasonable* construction of the [substantive statute] by the [agency] is entitled to considerable deference. *An agency decision cannot be sustained, however, where it is based not on the agency's own judgment but on an erroneous view of the law.* For it is a fundamental principle of law that "an administrative order cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained." *Id.* at 947 (emphasis added) (quoting *SEC* v. *Chenery Corp.*, 318 U.S. 80, 95 (1943)).

The *Prill* standard is applied not only when courts review agencies' orders but also when courts review agencies' rules under *Chevron*. *See, e.g., Phillips Petroleum Co.* v. *FERC*, 792 F.2d 1165, 1169–72 (D.C. Cir. 1986); *Id.* at 1172 ("Under *Chevron*, reviewing courts accord deference to agency constructions of ambiguous statutes. Where, as here, however, an agency construction is not based on the agency's own judgment, but rather on an erroneous view of the law, the construction cannot be sustained.")

Prill and its progeny have solid grounding in precedent: Judge Edwards in *Prill* relied explicitly on the Supreme Court's landmark decision in *SEC* v. *Chenery Corp.*, 318 U.S. 80 (1943). *See Prill*, 755 F.2d at 947–48. In that case, the Securities and Exchange Commission had made an order that, according to the Commission's statement in issuing the order, was based on the Commission's understanding of judge-made rules of equity rather than on an exercise of the discretionary authority that Congress had delegated to it in the substantive statute. The Supreme Court, in an opinion by Justice Frankfurter, refused to consider alternative grounds advanced by the SEC to support its order because the Commission had presented those alternative grounds only upon judicial review of the order, and not in the administrative proceedings that produced the order:

> The Commission's action cannot be upheld merely because findings might have been made and considerations disclosed which would justify its order as an appropriate safeguard for the interests protected by the Act. There must be such a responsible finding. * * *
>
> There is no such finding here. *Id.* at 94.

The Court made clear that effective judicial review is impossible without a clear explanation by the agency *in the administrative proceeding*[33] of the agency's reasons, including the legal basis, for the way in which it exercised its delegated authority:

> That the scope of such [judicial] review is narrowly circumscribed is beside the point. For the courts cannot exercise their duty of review unless they are advised of the

[33] *See Chenery*, 318 U.S. at 92 ("the difficulty remains that the considerations urged here in support of the Commission's order were not those upon which its action was based").

> considerations underlying the action under review. If the action rests upon an administrative determination—an exercise of judgment in an area which Congress has entrusted to the agency—of course it must not be set aside because the reviewing court might have made a different determination were it empowered to do so. But if the action is based upon a determination of law as to which the reviewing authority of the courts does come into play, an order may not stand if the agency has misconceived the law. In either event *the orderly functioning of the process of review requires that the grounds upon which the administrative agency acted be clearly disclosed and adequately sustained. * * * [A]n administrative order cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained. Id.* at 94–95 (emphasis added).

Thus, under *Chenery* as applied in *Prill* and other cases, the agency must clearly state the statutory basis for its action in the rulemaking record itself, and the agency's action cannot be sustained unless the record discloses an accurate understanding by the agency of the statute's meaning. These principles are reflected in the provisions of the committee's bill that amend sections 553 and 706 of the act, as described above.

The committee emphasizes that, under the bill's judicial review provisions, although the courts have the authority and obligation to determine whether a particular interpretation is permissible within the bounds of the statute as evidenced by the enacted text and other evidence of congressional intent, they are not to impose any view as to the correct policy or the "preferable" interpretation. Nonetheless, in reviewing any major rule that is subject to chapter 6, a court has a special responsibility to ensure that the agency's action fully conforms to the provisions of section 624. Thus, a reviewing court is to set aside an agency action that is based on an interpretation that, even if it is permissible under the substantive statute, is not the interpretation that is, of all the interpretations that are permissible under the substantive statute, the one that gives the agency the broadest possible discretion to make rules that conform to the decisional criteria in section 624.

In many respects, the cost-benefit criteria of section 624(b) are the heart of this bill. The only exception to the decisional criteria in section 624(b) is the very narrowly circumscribed category of rules subject to section 624(c). (Of course, rules within that narrow category must still meet the lowest cost or lowest net cost test established in section 624(c).) In reviewing any agency rule that the agency claims falls within the section 624(c) exception, the court must scrutinize the agency's written explanation in support of its claim to determine whether the claim is valid. Although the court must give due consideration to the agency's explanation, the Committee intends that the court engage in de novo review of the question whether or not it is possible for a rule to satisfy the criteria in section 624(b) without contradicting "the express decisional criteria in the [substantive] statute."

The language in the bill—i.e., "the express decisional criteria in the statute"—prohibits an agency or court[34] from relying on any legislative history or other indicia of congressional intent that are not clearly and unambiguously reflected in the text of the statute as the basis for any conclusion that the rule is exempt from the section 624(b) decisional criteria. Moreover, court decisions, agency decisions, or other statements of the law that were made before enactment of section 624 cannot be relied on as precedent for any holding that the stringent test of section 624(c) has been met in a particular case, since those prior decisions or statements of the law were not made in light of section 624, which establishes decisional criteria that add to, or "supplement", the existing agency decisional criteria.

Finally, subsection (d) of section 706 states that the provisions of subsection (c) "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." By this, the committee intends to ensure that the judicial review of all rulemakings is conducted in accordance with section 706(c), as revised here. Such a provision is necessary because judicial review of certain rulemakings is not typically conducted pursuant to the APA, but according to standards set forth in the statute under which the rulemaking is conducted. For example, section 307(d)(1) of the Clean Air Act provides that the "provisions of . . . section 706 of Title 5 shall not, except as expressly provided in this subsection, apply to actions to which this subsection applies." Instead, judicial review of Clean Air Act rulemakings under section 307 is conducted pursuant to the standards set forth in section 307(d)(9). These standards are essentially identical to those provided for in section 706 of the APA, but do not, of course, reflect the changes now being made to section 706 by this legislation. Section 706(d) makes clear that these provisions supplement and, therefore, govern rulemakings under section 307(d) of the Clean Air Act and any similar statutes that contain language overriding section 706 as it existed prior to enactment of this legislation.

In sum, specifying that the provisions of subsection (c) of section 706 "apply to, and supplement" the requirements for judicial review contained in such statutes as the Clean Air Act, the committee means to extend the reach of the present revisions to 706 to such review provisions in individual enabling statutes. Subsection (d) is intended to do that, without requiring the amendment of each of those individual statutes.

SUBSECTION 5(*b*)

This subsection amends the Tucker Act so as to address the jurisdictional problem colloquially known as the "Tucker Act Shuffle". The committee believes that the Tucker Act, which waives the sovereign immunity of the United States by granting the Court of Federal Claims jurisdiction to entertain monetary claims against the United States, actually complicates the ability of a property owner

[34] A court, in conducting its review, must, of course, ensure that its own construction of the substantive statute gives full effect to the congressional mandate that that statute be interpreted in a way that reconciles it with the decisional criteria in section 624(b) whenever it is possible to do so.

to vindicate the right to just compensation for a government action that has caused a taking. The law currently forces a property owner to elect between equitable relief in the Federal district and monetary relief in the Court of Federal Claims. Further difficulty arises when the law is used by the government to urge dismissal in the district court on the ground that the plaintiff should seek just compensation in the Court of Federal Claims, and is used to urge dismissal in the Court of Federal Claims on the ground that plaintiff should first seek equitable relief in the district court. This "Tucker Act shuffle" is aggravated by section 1500 of the Tucker Act, which denies the Court of Federal Claims jurisdiction to entertain a suit which is pending in another court and brought by the same plaintiff. Section 1500 is so poorly drafted and has brought so many hardships, that Justice Stevens, in *Keene Corporation* v. *United States*, 113 S.Ct. 2035, 2048 (1993), has called for its repeal or amendment.

The committee is confident that section 5(b)(1)(A) of S. 343 solves the problem of the Tucker Act shuffle by extending the jurisdiction of the Court of Federal Claims to include the authority to invalidate Acts of Congress and regulation, when the act or regulation adversely affects property rights in violation of the fifth amendment. Further, section 5(b)(1)(B) explicitly grants the Court of Federal Claims the authority to grant injunctive and declaratory relief where appropriate.

Although concerns regarding the constitutionality of an article I court being given the authority to grant injunctive and/or declaratory relief were raised, the committee is satisfied that the Court of Federal Claims has exercised such powers in the past and that the grant of authority contained in this section is well within congressional authority. Indeed, the Court of Federal Claims currently exercises declaratory authority in contract cases (28 U.S.C. 1491(a)(2) and (3)) and in certain tax cases (28 U.S.C. section 1507). Both Supreme Court and appellate court precedent show that the Congress may vest the Court of Claims with the authority to declare acts of Congress unconstitutional. There are two theories under which this authority may be granted.

First, the public rights doctrine allows Congress greater flexibility to assign jurisdiction to article I courts when the claim is a public claim. Since all claims which may arise under this act will be against the Federal Government, the public rights doctrine clearly applies. In *Northern Pipeline* the Supreme Court affirmatively held that, "[t]here are matters, involving public rights, which may be presented in such form that the judicial power is capable of acting on them, and which are susceptible of judicial determination, but which [C]ongress may or may not bring within the cognizance of the courts of the United States, as it may deem proper." *Northern Pipeline Const.* v. *Marathon Pipe Line Co.*, 458 U.S. 50, 67 (1982) (citing *Murray's Lessee* v. *Hoboken Land & Improvement Co.*, 15 L.Ed. 372 (1856) (emphasis omitted). Although *Marathon* involved two private litigants and thus the Court required the claim be heard by an article III court, cases under S. 343 would always be public since they would always be against the Federal Government. Thus, they would fall within the public rights doctrine described in this case.

Second, it is beyond dispute that the government can only be sued when it permits the suit by waiving its sovereign immunity. The Supreme Court has held that Congress may put conditions on such waiver, one of which may be that the claim be heard in the Court of Federal Claims. In *U.S.* v. *King,* the Supreme Court implicitly stated that the Claims Court may issue declaratory judgements if Congress clearly grants such authority. It held that, "the Court of Claims' jurisdiction to grant [declaratory] relief depends wholly upon the extent to which the United States has waived its sovereign immunity * * * " *United States* v. *King,* 395 U.S. 1 (1969). *See also Overall Roofing & Const., Inc.* v. *United States,* 929 F.2d 687 (Fed. Cir. 1991).

Additional case law supports the committee's view. In *Commodity Futures* v. *Schor,* the Supreme Court recognized that, "[o]ur precedents also demonstrate, however, that Article III does not confer on litigants an absolute right to the plenary consideration of every nature of claim by an Article III court." *Commodity Futures Trading Comm'n* v. *Schor,* 478 U.S. 833, 848 (1986). In *Thomas* v. *Union Carbide,* the Court noted that "[n]either this Court nor Congress has read the Constitution as requiring every federal question arising under federal law * * * to be tried in an Art. III court * * * " *Thomas* v. *Union Carbide Agr. Products Co.,* 473 U.S. 568, 583 (1985)(citing *Palmore* v. *United States,* 411 U.S. 389, 407 (1973).

These cases make it abundantly clear that placing the authority to give declaratory relief, that is, to invalidate Acts of Congress, in the hands of the Court of Federal Claims is not inimical to the Constitution. Since the grant of authority in this section is very narrow in granting the Court of Federal Claims power to issue declaratory judgements in only certain instances, there is every reason to believe that such provision will be entirely effective and constitutional.

The committee believes that the possibility of additional confusion regarding the proper scope of authority of the Court of Federal Claims is minimized by section 5(b)(1)(C). That section explicitly gives the court the authority to render judgment on tort claims which are related to a case properly within the jurisdiction of the court.

Lastly, section 5(b)(2) repeals 28 U.S.C. 1500. As mentioned above, this section is poorly drafted and has been the cause of much confusion for litigants. The committee is positive that by removing this unnecessary provision the jurisdiction of the Court of Federal Claims is made much clearer and easier to understand.

It was brought to the committee's attention that repealing section 1500 will permit the same case to be filed in both a District Court and the Court of Federal Claims. While this is technically correct, the committee is satisfied that is does not create any problems. For nearly the entire history of the Republic it has been technically permissible to file the same case in two District Courts, or a District Court and a State Court. This has not created any problems. The doctrines of res judicata and collateral estoppel guarantee that only one decision may be rendered. That is, while multiple filings of the same case are permitted, once any court has rendered an opinion on the merits, all other courts are required to defer to

the first court's decision. Thus, there is no danger of multiple, conflicting rulings.

The committee is also convinced that since section 1500 presupposes a case within the court's jurisdiction, the repeal of section 1500 will not expand the jurisdiction of the Court of Federal Claims to cover cases not already within its jurisdiction. Thus, the committee is confident that the repeal of section 1500 will be a dramatic improvement in the jurisdictional rules of the Court of Federal Claims with little or no disadvantages.

New Section 707

Section 707 addresses a problem commonly known as "government by consent decree". Plaintiffs frequently sue federal regulatory agencies, claiming the defendant agency has not imposed rules or regulations of sufficient number or severity. To avoid the costly litigation these suits would entail, agencies routinely enter into judicially enforceable consent decrees that abdicate their policymaking discretion to the plaintiff. This practice yields bad policy results and stultifies the democratic process with regard to rulemaking.

As to results, by raising the specter of protracted and expensive litigation, plaintiffs can often dictate the manner in which a regulatory agency will exercise its rulemaking discretion. The consent decrees that embody these commands effectively allow plaintiff to act as if they were the defendant agencies for purposes of administering the rules or regulations at issue in the lawsuits. For example, *Citizens for a Better Environment* v. *Gorsuch*, 718 F.2d 1117 (D.C. Cir. 1982), concerned the EPA's administration of the Clean Water Act. There, as Judge Malcolm Wilkey noted in a scathing dissent, the consent decree agreed to by the EPA "require[d] the agency to apply criteria and standards not found in the Clean Water Act, and require[d] the agency to undertake programs that are not required by the statute." Id. at 1131 (Wilkey, J., dissenting). In short, the special-interest plaintiffs in *Gorsuch* managed to usurp much of the EPA's discretion under the Clean Water Act.

Government by consent decree also thwarts the democratic process in a number of ways. First, consent decrees erode the political accountability of the agencies that agree to them. It is naive to think that plaintiffs and defendant agencies are always at loggerheads. Certainly cases must arise where, absent political obstacles, the defendant agency itself would have taken the action sought by the plaintiff. In cases like these, the prospect of protracted litigation merely provides justification for the agency to do what it could not have done had it been acting solely on its own responsibility.

Second, the damage wrought by consent decrees often cannot be undone by succeeding administrations. Instead, as was the case in *Gorsuch*, a consent decree can bind succeeding administrations to the same extent that it binds the officials who entered into it. Perversely, then, consent decrees often freeze into place the policies of the very officials whose political accountability is eroded by them.

Third, consent decrees are not subject to any democratic safeguards. Unlike the normal rulemaking process, which provides for a public notice and comment period, consent decrees are often entered into behind closed doors and then sprung upon the public as

a fait accompli. Thus, as Judge Wilkey noted, the device [of consent decrees] makes far more difficult the task of those citizens who wish to monitor agency actions and influence their development. *Id.* at 1136. And, as Judge Wilkey further pointed out, the upshot of all this is simple enough: Government by consent decree enshrines at its very center those special interest groups who are party to the decree. *Id.*

Section 707, modeled after U.S. Government-attorney guidelines issued in 1986 by the Department of Justice, bars enforcement of consent decrees to the extent they would divest an 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. By its plain terms, then, the section does not apply to cases where the agency has an express statutory obligation to take the action sought; instead, the section applies only to cases where the agency has discretion as to whether to take that action.

New Section 708

This new Administrative Procedure Act section 708 creates an affirmative defense to an agency enforcement action. Where an enforcement action is taken against an individual, it shall be an affirmative defense that the regulated person is complying with a regulation that is contradictory to the agency regulation being enforced. The scope of the affirmative defense is limited by two qualifications: (1) that the regulations cannot be reconciled by a reasonable person, and (2) that the individual was in fact complying with the contradictory or unreconcilable regulation.

By including the affirmative defense provision in this bill, the committee recognizes that Congress and the administrative agencies have not always written laws and regulations that can be easily reconciled. The inability of Congress and the agencies to reconcile laws and regulations creates onerous burdens on individuals regulated, particularly when enforcement actions are taken. The committee believes that individuals should not be punished for regulators' inconsistencies.

If the executive branch heeds the requirements contained in other sections of this Act to reconcile regulations, the committee believes that the application of this affirmative defense should be limited.

New Section 709

Section 709 is intended to deal with the problem that is appearing with more frequency of agencies' bringing enforcement actions, and seeking civil and criminal penalties, for the alleged violations of rules that are increasingly complex, convoluted, and often unclear. In their zeal to compile enforcement statistics, some government agencies have on occasion initiated cases based upon novel interpretations of their own rules—interpretations that have never been communicated to the regulated community. In some cases, actions have been brought to impose retroactively requirements based on some new agency interpretation of a rule, or new factual determination, even where the person against whom the action is brought has reasonably relied upon a prior agency interpretation or

determination. The committee is concerned, as well, about situations in which agencies develop complicated and ambiguous rules and then seek to punish individuals or companies if they adopt an unintended but erroneous interpretation of what those rules mean. At stake in these cases are penalties worth hundreds of thousands or millions of dollars, and even Federal imprisonment.

Against this backdrop, the committee views new section 709 as an appropriate and necessary restraint on the authority of agencies to pursue civil or criminal penalties for the alleged violation of rules in circumstances where the imposition of such penalties would plainly be unfair. In large measure, section 709 simply makes explicit or clarifies requirements that already exist under the APA. Moreover, nothing in section 709 prevents an agency from changing its interpretation of a rule, consistent with the requirements of sections 552 and 553 of the APA and, subject to the protections provided by this section, enforcing the new interpretation prospectively. Section 709 does, however, prevent the government from extracting civil or criminal penalties, or retroactively imposing regulatory requirements, in cases where the defendant can demonstrate that, prior to the alleged violation, the responsible agency or State authority told the defendant, either directly or through an interpretation duly published in the Federal Register, that the defendant was in compliance with, or was not subject to, the rule at issue. The ultimate result of this legislation will be, in the Committee's view, fairer enforcement leading to better compliance and greater respect by the regulated community for the enforcement practices of the Federal Government.

New Subsection 709(a)

This provision precludes, in two specific situations, the imposition of a civil or criminal penalty for the alleged violation of a rule. First, under subsection (a)(1)(A), no penalty may be imposed where the court finds that, prior to the commencement of the alleged violation, the defendant reasonably determined, based on the agency's own description, explanation, or interpretation of the rule contained in the rule's preamble, that the defendant was in compliance with the requirements of the rule or was otherwise not subject to those requirements. Subsection (a)(2) further provides that, in making its determination whether the defendant's reliance was "reasonable," the court should give no deference to any agency interpretation developed after the preamble interpretation was issued, unless, prior to the alleged violation, this new interpretation was published in the Federal Register or otherwise directly communicated to the defendant.

The committee understands this provision to reflect basic principles of fairness and due process, as expressed in an array of federal cases. For instance, under current law, civil and criminal penalties cannot be imposed for the alleged violation of a rule if the rule did not "adequately express" what an agency intended or otherwise failed to give "fair warning" of the conduct that the rule prohibited or required. *See, e.g., Diamond Roofing* v. *Occupational Safety and Health Review Comm'n,* 528 F.2d 645, 649 (5th Cir. 1976)(A defendant is "entitled to fair notice in dealing with his government," and if a "violation of a regulation subjects private parties

to criminal or civil sanctions, a regulation cannot be construed to mean what an agency intended but did not adequately express."); *accord Gates & Fox Co.* v. *OSHRC*, 790 F.2d 154, 156 (D.C. Cir. 1986) ("Where the imposition of penal sanctions is at issue * * * the due process clause prevents [deference to agency interpretations] from validating the application of a regulation that fails to give fair warning of the conduct it prohibits or requires."); *Lloyd C. Lockrem, Inc.* v. *U.S.*, 609 F.2d 940, 942–44 (9th Cir. 1979); *Director, Office of Worker's Compensation* v. *Mangifest*, 826 F.2d 1318, 1325 (3d Cir. 1987) ("A claimant proceeding in good faith should not be subjected to a trap brought about by an interpretation of a regulation hidden in the bosom of the agency."). Subsection (a)(1)(A) is a logical amplification of this basic principle, as it follows a priori that if, in an enforcement action, an agency seeks to disavow the interpretation of a rule it set forth in the rule's preamble, then the agency did not "adequately express" its understanding of the rule when it first promulgated it.

The committee further notes that, while subsection (a)(2) permits (although it does not require) a court to give deference to a subsequent agency interpretation that was published in the Federal Register or otherwise directly and specifically communicated to the defendant by the responsible agency or appropriate State authority, such publication or communication must also be made in a timely manner. In this regard, section 522 of the APA provides that "[e]xcept to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published." The case law construing the meaning of the phrase "actual and timely notice" establishes that the concept of "timely" notice entails that some reasonable period of time must be afforded an entity responsible for meeting the requirements of an agency pronouncement, such as a changed interpretation, in order that the entity may come into compliance with that pronouncement. *See, e.g., Northern California Power Agency* v. *Morton*, 396 F. Supp. 1187, 1191 (D.C.D.C. 1975), aff'd 539 F.2d 243 (D.C. Cir. 1976) ("What is contemplated [by the phrase "timely notice"] is a reasonably complete code of procedures set out in advance by which actions can be guided and strategies planned."). Accordingly, the committee intends that, in those situations where the agency seeks to rely, in court, on a changed interpretation of a rule, the court shall not give deference to any such interpretation unless the defendant had been made aware of the interpretation (either directly or through publication in the Federal Register) and was given a sufficient period of time to come into compliance with any requirements imposed by the new interpretation.

In addition, the committee wishes to clarify that nothing in this subsection should be read as altering the fundamental principle that the actual language of a regulatory provision, where its meaning is clear, is controlling. That is, where the language of a rule clearly states what the law is, a regulated entity is not compelled by anything in this section to review the rule's preamble in order to ascertain whether there is anything lurking therein that might possibly be construed as casting doubt on, or contradicting, the

plain language of the rule. Subsection (a) merely provides that, where the preamble contains the agency's description or interpretation of the rule, a regulated entity is entitled reasonably to rely on such statements by the agency as to what the rule means.

The second situation where subsection (a) will apply is where, prior to the alleged violation of a rule, the defendant had been informed by the agency that promulgated the rule (or by a State authority to whom had been duly delegated responsibility for enforcing compliance with the rule) that the defendant was in compliance with, or was exempt from, the rule. Under subsection (a)(1)(B), no civil or criminal penalties can be imposed in such circumstances. Again, the committee understands this straightforward provision to codify what should be an axiomatic principle of administrative law and due process. No penalty should be imposed where the court determines that the defendant reasonably relied upon information provided to it by the agency or by the State authority which had been delegated responsibility for implementing or ensuring compliance with the rule.

Of course, the committee does not intend that, in applying this provision, a court should find reasonable reliance where the person that actually provided the information to the defendant had such a low level of responsibility within the agency (or State authority) that the person could not reasonably be said to have spoken "for the agency." At the same time, the committee does not mean to require that any such information must be formally provided by the head of the agency (or the State authority) before a defendant's reliance on it will be considered to have been "reasonable." The committee recognizes that, as a practical matter, officials below the level of "agency head" will typically issue guidance and other materials that speak "for the agency," or otherwise represent the agency's position on a given matter, and information imparted by such lesser officials, made in accordance with standard agency practice, will be sufficient to constitute information provided by "the agency" (or by "the State authority") for purposes of this section. Thus, the committee expects that, in making its determination whether the defendant reasonably relied on information provided by an agency or State authority, the court will take into account such factors as the level of authority of the person within the agency who provided the information, as well the defendant's own reasonable belief as to the nature of the person's authority. What the committee anticipates in this regard is that the court will balance the authority of the person at issue against the defendant's own understanding of that authority in determining whether the defendant's reliance on the information provided by the person was "reasonable." Of course, where the court determines that the defendant did not seek such information in good faith, or otherwise knowingly and willfully misled the person with respect to a material or knowingly and willfully failed to fully and accurately disclose a material fact, the defendant would not be deemed to have reasonably relied on any such information.

New Subsection 709(b)

This subsection clarifies the extent to which, in the enforcement context, a court should give deference to an agency's interpretation

of an ambiguous rule. The courts have not consistently addressed this question. Some decisions have turned on what the court perceived as the desirability of deferring to an agency's interpretation of an unclear rule, while other courts, focusing on whether the defendant had "fair warning" of what was required by an ambiguous rule, have declined to give deference to the agency's construction. Subsection (b) adopts what the committee considers to be the better view of the law by providing that, in the context of an action to impose civil or criminal penalties, an agency's interpretation of an ambiguous rule does not warrant the deference that might otherwise be afforded the interpretation were such penalties not at issue. The approach adopted by the committee has been followed in such cases as *Diamond Roofing Co.* v. *OCSHRC,* 528 F.2d 645 (5th Cir. 1976); *Phelps Dodge Corp.* v. *FMSHRC,* 681 F.2d 1189 (9th Cir. 1982); *Gates & Fox Co.* v. *OSHRC,* 790 F. 2d 154 (D.C. Cir. 1986); *Lloyd C. Lockrem, Inc.* v. *U.S.,* 609 F.2d 940 (9th Cir. 1979); *Kropp Forge Co.* v. *Secretary of Labor,* 657 F.2d 119 (7th Cir. 1981); and *Dravo Corporation* v. *OSAHRC,* 613 F.2d 1227 (3d Cir. 1980). *See also Rollins Environmental Services Inc.* v. *EPA,* 937 F.2d 649, 654-57 (D.C. Cir. 1991)(Edwards, concurring in part and dissenting in part).

Under paragraph (1) of subsection (b), ambiguity in a rule is construed against the agency that promulgated the rule. As the committee views it, this will entail courts' applying what is essentially a two-step process. First, the court, employing conventional principles of regulatory interpretation, will determine whether the rule was, as a matter of law, so unclear or confusing as to be ambiguous. Second, if, and only if, the court makes this threshold determination of ambiguity, then the court will not give any deference to the interpretation of the rule put forth by the agency if, prior to the alleged violation, the defendant interpreted the rule in such a way that it concluded that it was not in violation and the court determines that such interpretation was reasonable. In other words, where the agency is responsible for having promulgated an ambiguous rule, any "reasonable" interpretation of such rule that was embraced by the defendant prior to the alleged violation will be accepted over the interpretation put forward by the agency. In this regard, the committee notes that post hoc interpretations by the defendant's lawyers in court would not warrant such deference. Further, any interpretation relied upon by the defendant would have to be a "reasonable" one, although not the "most reasonable" one or one that is "more reasonable" than that put forth by the agency. Not only would this provision preclude agencies from recovering penalties for a defendant's unwitting violation of an ambiguous rule, the committee expects that it will encourage agencies to write clearer rules to begin with.

Similarly, paragraph (2) of subsection (b) simply codifies well-established principles of due process. Again, it confirms that, notwithstanding whether or not a defendant itself puts forth a "reasonable" interpretation, if the court determines that, as a matter of law, that a rule did not give the defendant "fair warning" of the conduct that the rule prohibits or requires, no civil or criminal penalty may be imposed. *See, e.g., Gates & Fox Co.* v. *OSHA,* 790 F.2d 154, 156 (D.C. Cir. 1986); *Diamond Roofing Co.* v. *OSHRC,* 528

F.2d 645, 649 (5th Cir. 1976); *see also Rollins Environmental Services, Inc.* v. *EPA,* 937 F.2d 649, 654-655 (D.C. Cir. 1991) (J. Edwards, dissenting in part and concurring in part) ("It is true that '[c]ourts must give deference to an agency's interpretation of its own regulations.' * * * 'Where the imposition of penal sanctions is at issue, however, the due process clause prevents that deference from validating the application of a regulation that fails to give fair warning of the conduct it prohibits or requires.'") (citations omitted).

New Subsection 709(c)

Like the rest of section 709, this subsection is intended to ensure that regulatory requirements are enforced fairly, and that persons are not subjected to enforcement actions if they did not have prior notice of the prohibited or required activity at issue. Specifically, section 709(c) bars an agency action, or any other action or proceeding, that would retroactively impose a requirement against a person if (1) the action is based on either (a) an interpretation of a statute, rule, interpretive rule, guidance document, statement of policy, or license requirement or condition, or (b) a determination of fact that is materially different from an interpretation or factual determination previously made by the federal or State agency that is authorized to implement the relevant Federal program, and (2) the person reasonably relied on the previous interpretation or determination.

Like other provisions of section 709, subsection (c) will prevent the imposition of civil and criminal penalties, but it will also prevent the retroactive imposition of regulatory requirements that may be imposed through enforcement actions or other similar proceedings such as licensing or compliance proceedings before an agency or in court. In this regard, the committee recognizes that, in many instances, the retroactive application of a regulatory requirement, such as a permitting or technology requirement is more costly than any monetary fine associated with a new legal interpretation or factual determination. Thus, merely prohibiting the imposition of fines based on a change in agency position will not guarantee fair enforcement of regulatory requirements.

The committee is aware that, in some cases, Federal agencies have tried to regulate retroactively by "reinterpreting" a rule to penalize a responsible person that has relied, in good faith, on a previous interpretation made by the Federal agency or by a State agency authorized to administer the federal program. For example, the Surface Mining Control and Reclamation Act (SMCRA) authorizes State agencies to review and approve reclamation plans for mines within their States. In several cases, mine owners have substantially completed reclamation projects approved or required by the State, only to have a Federal agency come along later and claim that the work needs to be redone based on a different interpretation of regulatory requirements. Subsection (c) prevents such abuses and requires Federal agencies to resolve any difference of interpretation with the relevant State agency, rather than taking action against the private company.

Retroactive application of regulatory requirements may also arise under regulatory programs that involve permits. For example, in

some cases the Clean Air Act requires a facility to obtain a permit before making a physical or operational change that is expected to increase certain emissions above specified "significance" levels. Permit requirements may include, among other things, the installation of control technology. Shortly after this program was enacted, EPA issued guidance stating that, in determining whether an expected emissions increase would exceed a significance level, a facility needed to calculate increased emissions only from the emissions unit being changed. Recently, however, the agency has changed its position and indicated that potential emissions increases from other units at the facility must also be counted. Further, EPA has attempted to use this new interpretation retroactively to impose permit requirements, including the retrofitting of control technology, for actions taken prior to the agency's change in position. Section 709(c) prohibits this sort of retroactive agency action.

An agency's "redetermination" of facts also can lead to unfair retroactive application of a regulatory requirement. For example, based on an EPA-approved approach for calculating emissions, a State agency or a company may determine that emissions from a facility are not high enough to trigger permit requirements. Section 709(c) prohibits EPA from attempting, years later, to use a different or new approach for calculating emissions to impose such requirements retroactively.

At the same time, the committee has been careful to design section 709(c) in a way that ensures that agencies retain their ability to enforce regulatory requirements effectively. The provision protects only those persons and companies that reasonably relied on an interpretation or determination. Thus, under this subsection a person cannot knowingly and willfully mislead an agency into making a particular interpretation or determination. Section 709(c) also requires that the prior interpretation or determination upon which the person relied must have been made by the relevant federal agency or by a State or local agency exercising authority delegated to it under Federal law. This provision is designed to ensure that an informal statement by low-level agency staff does not necessarily bind the agency. However, the requirement that an interpretation or determination be made "by the agency or by a State or local government" is not intended to require that the interpretation or determination be made formally by the agency head. Consistent with the committee's understanding of the analogous provision in subsection (a)(1)(B), an interpretation or determination made in accordance with standard agency practice is intended by the committee to qualify as an interpretation or determination "by the agency."

Finally, the committee stresses that section 709(c) does not prevent an agency from changing an interpretation or factual determination and prospectively applying requirements based on such a change. This provision merely limits application of the reinterpretation or redetermination to the actions taken after the agency's change in position. Nor does it in any way prevent a Federal agency from exercising its oversight responsibility over State agencies as provided by law.

New Subsection 709(d)

This subsection makes it clear that the requirements of section 709 also apply to the review by a Federal court of an agency order imposing administrative penalties, not merely to actions that, in the first instance, arise in Federal court. For example, under section 113(d) of the Clean Air act, EPA is authorized to impose civil penalties of up to $200,000 for violations of the act. Pursuant to this "administrative" authority, EPA can impose such penalties without having to bring an action in federal court. Under section 113, however, defendants can seek review of such penalties in Federal district court, and subsection (d) clarifies that, in such situations, once the case is in Federal court, the requirements of section 709 apply.

SECTION 6

New Section 801

As the number of complexity of Federal statutory programs has increased over the last 50 years, Congress has come to depend more and more upon executive branch agencies to fill out the details of the programs it enacts. As complex as many of the statutory schemes passed by Congress are, the implementing regulations are often more complex by several orders of magnitude. The delegation of legislative rulemaking authority to executive branch agencies has been upheld by the courts, unless Congress has failed to establish sufficient standards to guide agency action. *See, e.g., Panama Refining Co.* v. *Ryan,* 293 U.S. 388 (1935). However, as more and more of Congress' legislative functions have been delegated to Federal regulatory agencies, many have complained that Congress has effectively abdicated its constitutional role as the national legislature in allowing Federal agencies so much latitude in implementing and interpreting congressional enactments.

In many cases this criticism is unjustified. However, there are instances where the criticism is well founded. Our constitutional scheme creates a delicate balance between the appropriate roles of the Congress in enacting laws, and the executive branch in implementing those laws. It must not be forgotten that Federal regulations have the force and effect of law only because Congress has delegated legislative rulemaking authority to executive agencies. Section 6 of S. 343 will help to redress the balance, reclaiming for Congress some of its policymaking authority, without at the same time requiring Congress to become a super regulatory agency.

This section will allow Congress to examine agency rules before they are made effective and to determine whether to take legislative action disapproving rules that do not accurately reflect the intent of Congress in enacting the underlying statutory scheme. It is meant to restore congressional accountability in the legislative arena, and it is expected that these provisions will lead to more disciplined and accountable rulemaking by Federal agencies. The end result will be more efficient, more equitable, and better quality regulation.

To that end, section 6 will add new section 801 to title 5 of the United States Code providing for congressional review of agency rulemaking. Under this new section, before a rule takes effect as

a final rule, the promulgating agency must submit to Congress a report containing a copy of the final rule, a copy of the notice of proposed rulemaking, a statement of basis and purposes for the rule, including a complete copy of any risk analysis performed on the rule, and the proposed effective date of the rule. For non-major rules, only a summary of the rulemaking proceedings must be submitted.

Once the required report to Congress is submitted, the final rule shall take effect 45 days after Congress receives the report, or the rule is published as a final rule in the Federal Register, whichever is later. If Congress passes a joint resolution of disapproval of the rule, and it is signed by the President, or if the President vetoes the resolution but that veto is overridden, the rule shall not become effective as a final rule.

If, however, Congress passes a joint resolution of disapproval of the rule, and the President vetoes the resolution, then the rule shall be effective as a final rule on the date either House of Congress fails to override the President's veto, or the date occurring 30 session days after the date on which Congress received the President's veto and objections, whichever is earlier.

A rule may take effect before the expiration of the 45-day period for congressional action on the rule if the President determines that the rule must be made effective immediately because it is (1) necessary because of an imminent threat to the public health or safety, or other emergency; (2) necessary for the enforcement of the criminal laws; or (3) necessary to the national security. If the President takes such an action, the rule may be made effective immediately, but the procedures for congressional action on the rule shall continue. If Congress passes a joint resolution of disapproval, and if that resolution is signed by the President, or if the President's veto is overridden, the rule shall immediately cease to be effective in accordance with the terms of that resolution. Any such rule shall be treated as though it had never taken effect.

Neither this subsection, nor any action taken pursuant to this subsection, may be reviewed in any court of the United States. The fact that Congress fails to enact a joint resolution of disapproval for any rule shall not be taken to imply any intent on the part of Congress by any agency or court.

The requirement that in order to disapprove a proposed rule Congress must act through a joint resolution alleviates any constitutional concerns that might be raised based upon the Supreme Court's ruling in *INS* v. *Chadha,* 462 U.S. 919 (1983). New section 801 will not create a "legislative veto" over executive branch action, but will merely give Congress the opportunity to take bicameral action, that must be presented to the President for his signature or veto, on a rule before the rule is made effective.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 8, 1995.

Hon. ORRIN G. HATCH,
Chairman, Committee on the Judiciary, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 343, the Comprehensive Regulatory Reform Act of 1995.

Enactment of S. 343 could affect direct spending. Therefore, pay-as-you-go procedures would apply to the bill.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

JUNE E. O'NEILL, *Director.*

CONGRESSIONAL BUDGET OFFICE—COST ESTIMATE

1. Bill number: S. 343.

2. Bill title: Comprehensive Regulatory Reform Act of 1995.

3. Bill status: As ordered reported by the Senate Committee on the Judiciary on April 27, 1995.

4. Bill purpose: S. 343 would impose many additional requirements on federal agencies that issue regulations and would apply such requirements to most agency rules expected to have an effect on the economy of at least $50 million annually. The bill would require all agencies to prepare preliminary cost-benefit analyses, in addition to final cost-benefit analyses.

S. 343 also would require all agencies to review their major rules within five years (for rules adopted after enactment) or ten years (for rules adopted before enactment). This review would include a cost-benefit analysis of the rule over its lifetime and a determination by the agency as to whether the rule is justified. If an agency fails to meet the five- or ten-year deadline for a rule, then that rule becomes void.

The legislation would require each agency to prepare an accounting statement that estimates the annual costs and benefits to the public sector an to the private sector of all the agency's regulatory programs. This statement would be submitted to the Congress every two years and would cover the current year and the four succeeding years.

In addition, S. 343 would allow any person subject to a major rule to petition the agency to amend or repeal the rule or to perform a cost-benefit analysis of the disputed rule.

5. Estimated cost to the Federal Government: We estimate that enactment of S. 343 would increase the total cost of issuing and reviewing regulations by the major federal regulatory agencies by at least $180 million annually. Few of the agencies that would be affected by this bill have had time to study systematically the additional costs that it would impose.

ADDITIONAL COSTS TO ISSUE NEW RULES

The requirements of S. 343 are similar to the work most agencies now conduct for some regulations expected to have an economic impact greater than $100 million annually. This estimate assumes that agencies will try to adhere to their current schedules for implementing new regulations and revising existing rules. CBO has insufficient information at this time to estimate the cost of this bill for all federal agencies; however, we believe the major cost impacts would fall upon the agencies discussed below.

The Environmental Protection Agency currently spends more than $120 million annually on regulatory impact analysis to support rule making efforts for regulations expected to have an economic impact greater than $100 million annually. Based on preliminary information from the agency, we estimate that requiring regulatory analyses and reviews for regulations with annual economic impacts of $50 million or more would increase the agency's costs by $50 million to $100 million annually.

The Department of Agriculture (USDA) currently prepares regulatory impact assessments environmental impact statements, and risk analyses for all regulatory actions affecting human health, safety, or the environment that are expected to result in annual costs to the economy of more than $100 million. Based on information from USDA, we estimate that lowering the threshold for these analyses would increase the number of assessments and cost-benefit studies by 50 to 100 each year. The additional costs associated with such assessments and studies range from less than $100,000 for a relatively routine rule to several million dollars for a major regulatory change. CBO estimates the most of the additional work would cost $150,000 to $250,000 per analysis, or an additional $10 million to $25 million annually for the department.

Based on information from the Food and Drug Administration, CBO estimates that the bill's requirements would add less than $15 million annually to the agency's current spending on pre-market regulatory activities.

The Department of the Interior currently spends about $50 million per year for regulatory analysis. This work is carried out primarily by the Office of Surface Mining, the Minerals Management Service, and the Bureau of Land Management as part of their overall regulatory enforcement activities. Lowering the threshold for regulatory analyses from $100 million to $50 million would increase the number of analyses these agencies would have to prepare, resulting in additional annual costs of less than $20 million.

Requirements in S. 343 also would increase costs for the Occupational Safety and Health Administration, the Mine Safety and Health Administration, and the Consumer Product Safety Commission. Based on information from these agencies, CBO estimates that enactment of the bill would result in total additional costs of less than $15 million per year for these agencies.

The Department of Energy, Department of Transportation, and Department of Defense would incur additional cost to implement the bill. CBO cannot quantify the impact on these agencies at this time, but the additional costs could be significant.

ADDITIONAL COSTS TO REVIEW RULES

The costs to review rules will depend on how the agencies fulfill the bill's requirements. For example, costs will vary as to how quickly agencies act to perform reviews within the five-year or ten-year windows allowed by the bill. Based on limited information from agencies, CBO estimates that the incremental costs resulting from the bill's review requirements would probably range from $20 million to $40 million annually.

6. Comparison with spending under current law: CBO estimates that enactment of this bill would add at least $180 million annually to the cost of issuing regulations.

7. Pay-as-you-go considerations: Section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985 sets up pay-as-you-go procedures for legislation affecting spending or receipts through 1998. Enactment of S. 343 could affect direct spending; therefore, pay-as-you-go procedures would apply to the bill.

The additional regulatory requirements of S. 343 could lead to a delay in the implementation of rules relating to the collection of user fees or other charges. In addition, regulations that authorize the collection of fees could be voided if agencies fail to meet the review deadlines. CBO cannot estimate the potential magnitude of any such effects.

8. Estimated cost to state and local governments: How enactment of S. 343 would affect the budgets of state and local governments is unclear. If regulations that would impose additional requirements on state and local governments are delayed by the enactment of these provisions, then costs to these entities would be less. It is also possible, however, that some regulatory actions that would otherwise provide relief to state and local governments could be delayed, thereby increasing their costs for various activities. CBO has no basis for predicting the direction, magnitude, or timing of such impacts.

9. Estimate comparison: On February 23, 1995, CBO prepared a cost estimate for H.R. 926, as ordered reported by the House Committee on the Judiciary of February 17, 1995. Like S. 343, H.R. 926 would require agencies to perform regulatory impact analyses for rules expected to have an economic impact of at least $50 million annually. However, H.R. 926 would not require a periodic review of rules as would S. 343. Therefore, the estimated cost of H.R. 926 is $20 million to $40 million a year less than that of S. 343.

On May 8, 1995, CBO prepared a cost estimate for S. 291, as ordered reported by the Senate Committee on Governmental Affairs on March 22, 1995. S. 291 would require agencies to review rules and to perform several other additional regulatory analyses, but it would apply to rules with an expected economic effect of at least $100 million annually. Since S. 291 would affect far fewer rules than S. 343, its estimated cost is much less than that of S. 343.

10. Previous CBO estimate: None.

11. Estimate prepared by: Mark Grabowicz.

12. Estimate approved by: Paul N. Van de Water, Assistant Director for Budget Analysis.

VI. Regulatory Impact Statement

Pursuant to paragraph 11(b), rule XXVI of the Standing Rules of the Senate, the committee, after due consideration, concludes that S. 343 will have significant regulatory impact.

VII. ADDITIONAL VIEWS OF SENATORS BIDEN, KENNEDY, LEAHY, SIMON, KOHL AND FEINGOLD

I. THE HEALTH AND SAFETY OF ALL CITIZENS SHOULD BE THE HIGHEST PRIORITY OF THE LAW

Every day, American consumers can choose from among the world's highest quality and safest products—from prescription drugs and medical devices to children's toys. They can confidently buy food in the supermarket knowing its safety has been certified. They can use the most reliable transportation system in the world when they go to work at safe and healthy working places. They enjoy the benefits of cleaner water and air.

In contrast, we look around the world and witness the nuclear melt down at Chernobyl, the release of poisonous gas and resulting death in Bhopal, brutal child labor practices in many Third World countries, the catastrophic death toll due to the E-bola virus in Zaire, and the choking air pollution of Mexico City.

Maintaining the high quality of life in the United States is the purpose of the Federal regulatory process. We recognize that some existing regulations have become obsolete and that agencies might make arbitrary and nonsensical decisions from time-to-time. However, while such anecdotes make good political fodder, they should not become the basis for undermining the ability of government to provide for the health and well-being of all Americans.[1]

We support regulatory reform that:

Resolves identified problems in the regulatory system;

Provides safety and certainty to all citizens;

Acknowledges that each citizen has a responsibility to the community to conduct themselves in a manner that does not threaten the health and safety of others;

Allocates taxpayer resources efficiently and streamlines the regulatory process; and

Preserves Congress' role as the Nation's policymaker.

As a primary function of government is to protect the public's health and safety, we believe that carefully balancing interests and determining the most accurate and best scientific methods and other evidence should be incorporated into the regulatory process but not in a way that allows those principles to impede a primary function of government.

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[1] Indeed, the problem with relying on anecdotes is that many turn out to be false and misleading. Nothing demonstrated this problem more clearly than the testimony given during the full committee hearing on S. 343. The testimony provided anecdotes alleging regulatory improprieties concerning 5-gallon buckets and breast self-examination pads which later turned out to be wrong and misleading. See Judiciary Committee Hearing, Mar. 17, 1995, the testimony of Congressman David McIntosh and his exchange with Senators Leahy and Simon concerning the pad, in addition to the letter of March 1995 from Ann Brown, Chair of the Consumer Product Safety Commission, to Senator Biden concerning 5 gallon buckets ("For the Fourth time Congressman David McIntosh has misinformed Congress and the nation about this matter.").

S. 343 would displace Congress as the arbiter of the ideal that the safety of the people is our highest priority and elevate instead the narrow, self-interested concerns of private parties. We respect and cherish the free enterprise system that has engendered wealth and prosperity for American citizens. We also remain committed to supporting the needs of business and industry but in ways that are consistent with workplace safety, quality of consumer products, clean water and air, and safe and sanitary food.

Fundamentally, S. 343 would abdicate Congress' responsibility to establish policy. This legislation places on agencies a number of procedural requirements that would impede the development of necessary health and safety regulations.

The bill ignores the fact that Congress passed each authorizing statute—the Clean Water Act, the Clean Air Act and the Endangered Species Act for examples—to meet a specific set of circumstances and address a specific set of problems. Senate bill 343 proposes to treat each regulation the same, as if each regulation's purpose and function were interchangeable. We see no reason why public debate should not take place regarding the application of the principles of this bill to each statute.

The majority views fail to acknowledge that today's regulation is an outgrowth of past practices and their resulting unfortunate events. No recognition is given of the shipyard and construction workers killed and disabled by asbestos-related diseases, the fish kills in the Great Lakes or the fact that the Cuyahoga River in Ohio actually caught fire due to the chemicals dumped into it. Reading the majority views, one would never know that people's lives had been destroyed by thalidomide and the deadly waterborne parasite cryptosporidium. They never acknowledge the need for regulation to prevent a repeat of Three Mile Island or Love Canal. There is no mention of the people killed by E. coli bacteria in their hamburgers or the other real threats that our regulatory system is intended to protect us from each day. Indeed, no one would know from the majority's views of the millions of lives made healthier and better because of regulation.

The majority would place an ill-defined notion of "efficiency" ahead of health and safety. The majority poses "economic efficiency" and "health and safety" as opposing concepts when it contends that "[m]any major regulatory initiatives, instead of promoting economic stability or revitalizing markets, were intended to protect the public from health and environmental risks.", p. 2, majority views. The government would have violated a fundamental responsibility to its citizens if there ever was a time when the public's health and safety was placed second to market revitalization or anything else.

The provisions requiring cost-benefit analysis appear to be biased against taking any regulatory action. "Costs" are defined to include a myriad of factors and must be measured both with respect to the implementation of a rule and compliance with it. "Benefits" are defined narrowly and may only be measured with respect to the implementation of a rule, and do not include the benefit to society of compliance with a regulation. Thus, the costs will be measured as if every business complied fully with a regulation, but the benefits will not.

Our concerns also relate to the amount of delay this bill would entail for developing necessary and beneficial regulations. Because S. 343 allows affected interests numerous opportunities to interrupt the rulemaking process, the bill will likely exacerbate—not diminish—problems related to regulatory uncertainty and delay. It does not provide a logical and coherent framework for the promulgation of regulations, instead, it would create a duplicative and cumbersome process that will not help distinguish between useful and unneeded regulation so much as to make regulations of any kind more difficult to promulgate. We all agree that safe drinking water is important and that measures should be taken to ensure the quality of the water. The steps outlined within this bill—especially the notice and comment procedures, the petition process, peer review, and judicial review—will cut against the primary goal of clean water by encouraging delay in implementing of such regulations.

The majority's superficial and subjective historical narrative attempts to portray the bill as the logical outcome of the evolution of the majority's "efficiency paradigm." However, the inefficient procedural steps of the bill, beginning with the first notice that an agency intends to propose a rule, and ending with judicial review of the final agency action, will lead to delay and uncertainty in the regulatory process. The majority characterizes as "reform" a measure that would roll back years of progress in protecting the environment and the safety and health of the American people. Ironically, S. 343 is far from efficient—the Congressional Budget Office's rather conservative estimate concluded the bill would lead to *at least* $180 million increase in agency expenditures *not including* the significant costs that will be incurred by the Department of Energy or the Department of Transportation.[2]

In 1982, the Senate passed S. 1080, the Leahy-Laxalt regulatory reform bill by a vote of 94–0. We would welcome the opportunity to return to the text and the bipartisan spirit of that effort. Regrettably, the majority has not offered the opportunity for meaningful bipartisan discussions, as was the case in the development of S. 1080, despite the majority's assertions to the contrary. Senator Kohl's bipartisan proposal was voted down on a party-line vote during subcommittee consideration. Senate bill 343 was never voted on by the committee, but was discharged summarily. Without adequate opportunity to offer amendments, we oppose S. 343 because it is unbalanced, unfair, illogical, poorly drafted, imprecise, overly prescriptive, dangerous, and short-sighted.

The minority views set out our objections and proposed solutions to the issues we have identified with regard to the bill. It is our sincere hope that these views can serve as the basis for a bipartisan approach to regulatory reform.

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[2] We believe that the CBO estimate should be much higher. The estimate did not take into account the costs that will accompany the expanded right of petition or the increase in the number of rules for which the bill will require a cost benefit analysis and risk assessment under the qualitative/narrative criteria for major rule designations. In addition, the CBO estimates assume that the cost-benefit analysis and risk assessment required under the bill will cost the same as the present analyses. This assumption is wrong as the procedures outlined in the bill will cost more.

II. S. 343's Cost-Benefit Analysis: "Costs the People, Benefits the Special Interests"

We have highlighted areas—the uncertain scope of the bill, the supermandate, the notice and comment period, the peer review process, the petition process, judicial review, exemptions to the criminal and civil sanctions, the Delaney Clause and the Court of Federal Claims jurisdiction—in which we believe S. 343 would place the concerns of well-financed special interests ahead of public health and safety. The regulatory framework proposed under S. 343 will lead to an uncertain regulatory scheme through its one size fits all approach and the repetitive procedural requirements it imposes.

A. S. 343's Scope: No Effort to Identify Where the Problems Exist

S. 343's proponents have been unable or unwilling to identify the existing statutes the bill would affect or how many more rules will be designated "major." As a consequence, we have no idea which congressionally approved policies will be changed by this legislation's imposition of cost-benefit analysis as the *determinative* criteria in every rulemaking. By default, these decisions will now be made by litigants and the Federal courts who hear their claims. By this fact alone, the proponents of the bill will ultimately cede significant congressional authority to the Federal courts.

1. The need to know which statutes will be impacted

Over the past several decades, we have worked to craft statutes to protect our health, safety and the environment. These laws have individualized standards that are intended to respond to specific threats. They have made our air cleaner, our water healthier and our workplaces safer. While not perfect, these statutes have greatly benefitted the majority of Americans.

S. 343 would override environmental and health and safety laws with a one-size-fits-all approach. We remain unsure which statutes will be affected by S. 343. While some statutes may be in need of reform, these matters are complex. Accordingly, substantive reforms should be undertaken in the context of the specific laws, not through a blanket rewrite of all environmental and health and safety laws.

In presenting support for S. 343, the majority ignores situations in which the industry and the agencies have been working well together. In these situations, enactment of S. 343 would upset the balance struck between the agency and industry.

For example, in the case of the Mine Safety and Health Act of 1969, Richard Lawson, the president of the industry group National Mining Association, said, "There is no question in my mind, and I don't know of anybody in the entire mining industry that would argue with this statement, that we wouldn't have achieved the results that we have in the past 25 years if we hadn't had a federal regulatory program and a state regulatory program." Prior to the Mine Act, in 1968, a coal miner was five times more likely to be killed while working than he would be today. Since 1968, coal mine productivity has increased approximately 80 percent.

The proponents do not offer any explanation for the need to expend agency resources and tax dollars in reevaluating statutes in which the Federal Government and the industry have reached agreement. Indeed, S. 343 would promote inefficiency in such cases by upsetting the balance which regulators and the regulated previously had reached.

On March 29, 1995, Senator Simon wrote a letter to Chairman Hatch asking him to provide a list of all the statutes that would be affected by S. 343. Specifically, Senator Simon wrote:

> * * * this legislation would dramatically alter the way our regulatory process works and appears to undercut many statutes that we have all labored long and hard to enact. Before we complete the markup of this legislation, I think it is critical that we know what statutes this will apply to and how it will change the authority created under those statutes.

Unfortunately, Senator Simon has not received a response to his letter.

At the committee markup, Senator Simon was not given the opportunity to offer his amendment that would require Congress to enact legislation specifying the laws and proposed regulations that would be affected before S. 343 would become effective. We believe this information is critical to a proper understanding of S. 343 and must be provided. To proceed in the dark is unfair to the millions of Americans who have been protected by these laws for many years and deserve to know how they will be changed. We wonder whether the proponents of S. 343 really intend to impede the development of safety standards for airlines, food products, medicine, children's toys or standards to rid drinking water of cryptosporidium by blindly passing this legislation.

The bill before us fails its own cost-benefit philosophy—we cannot determine how much it will increase the costs of writing and defending these safety standards—not simply the cost in dollars to taxpayers, but the costs to each citizen in health and safety as well as the costs to small business generated by an uncertain regulatory landscape. Unless we know how many, and which, regulations will have to be rewritten, we can't know if this is the best way to reform our regulatory system.

2. How many health and safety standards will be caught up in S. 343's red tape?

For the first time, S. 343 would codify the definition of a major rule. The major rule designation is the important first step in determining whether a rule will be subject to the rigorous cost-benefit analysis and risk assessment outlined in S. 343. We support the use of cost-benefit analysis and risk assessment in the promulgation of major rules. We, however, do not support the majority's definition of a major rule. The majority would define a "major rule" using two standards: (a) a rule that would have a $50 million dollar impact on the economy in direct and indirect costs, or (b) a rule that fits the description of certain qualitative criteria, a "significant impact on the economy" for example. Both standards present a number of problems.

Every administration since President Ford has issued Executive orders that define rules as "major" based upon the numerical threshold of a $100 million impact on the economy. The unfunded mandates bill uses the same $100 million threshold. The majority does not offer an explanation for the adoption of the lower threshold. They do not know how many current regulations will be subjected to challenge under this reduced economic threshold or the amount of scarce taxpayer dollars that will be spent by agencies to bring those regulations into compliance.

The $50 million threshold includes both direct and indirect costs. The indirect costs, by statutory definition, include "reduced consumer choice, substitution effects, and impeded technological advancement." In our $6.3 trillion economy, just a few such hypothetical "indirect" costs can add up to $50 million quickly. Indeed, virtually every rule could be a major rule under this definition, and, hence snared by the additional red tape required by S. 343.

The majority offers no explanation as to how lowering the threshold actually promotes regulatory efficiency. We understand that each administration since President Ford has chosen the $100 million threshold in the belief that the resources devoted to a regulatory analysis should be commensurate with the significance of the decision to be made. We favor the use of cost-benefit analysis but only in those instances where it will be most productive—setting the threshold at $50 million dilutes this distinction and will create additional paperwork, uncertainty and delay.

In addition to the uncertain number of major rules generated by the lower numerical threshold, S. 343 defines as "major" a rule that has "a significant impact on a sector of the economy" and includes a number of other equally open-ended and ill-defined qualitative terms to define a major rule that will create confusion. Scant indication is provided as to what constitutes a significant impact, or what constitutes a sector of the economy: is there a mohair sector? a buggy whip sector? Agencies would be provided with little direction as to how to make such decisions.

With a creative definition of "indirect costs," every regulation has an impact on some sector of the economy. "Significant" is certainly a relative term depending on the size of the sector. Combined with the lower numerical threshold, this definition will lead to an expansion of unknown proportion in the number of major rules. Ultimately, this important policy decision will be made by unelected judges.

We question whether the enormous number of regulations that could be swept in under these standards actually will benefit from a cost-benefit analysis and whether the resources that will be expended on such analyses will be well spent. Because a designation or failure to designate a rule as "major" under the various qualitative standards is judicially reviewable, agency determinations that a rule is not major will be subject to review under an ill-defined but very broad standard. Litigation over this issue will hardly constitute an efficient use of taxpayer resources.

Had we been given the chance, we would have offered an amendment to restore the $100 million threshold that has been used to define major rules in every Executive order for the past two decades. The numerical threshold should serve as a bright line test.

We would also place all the qualitative standards into one provision from which the President or the agency may be guided, but not required, to choose to designate a rule as "major."

B. S. 343'S "SUPERMANDATE": COSTS OVER SAFETY

S. 343 contains what has been called a "super-mandate." It creates supplementary decisional criteria for every agency action that permits the cost factors to trump safety factors in statutes in which Congress intended that safety should be the primary consideration. Without acknowledgement, the bill's supplementary decisional criteria effectively would amend the carefully considered criteria now in place in such landmark laws as the Food, Drug and Cosmetic Act, the Occupational Safety and Health Act, the Clean Air Act and an untold number of other laws.

The bill creates a new section 624 of title 5 of the United States Code. This new provision would subject every major rule promulgated by an administrative agency to cost-benefit analysis, and would prohibit the issuance of a major rule unless the agency affirmatively finds that the benefits of the rule justify its costs. That is a superficially appealing notion, but it is flawed in several respects, especially in regard to regulations dealing with public health, safety and the environment.

Many agencies dealing with public health and safety currently utilize cost-benefit analysis as a tool. But cost-benefit is not the ultimate test that those agencies use to decide whether to protect the public. Instead, each agency relies on the decisional criteria that appears in the legislation that establishes the agency. For example, The Food, Drug and Cosmetic Act prohibits the distribution of food that is "injurious to health" but permits tolerable levels of certain deleterious substances in food if they cannot be avoided by "good manufacturing practice."

The present standards represent a careful balancing of competing interests by Congress, and they have a well-defined meaning after years of agency practice and case law. There is a notion of cost-benefit analysis embedded in each standard, but in practice, a strict economic test does not overrule worker and consumer safety.

The House-passed regulatory reform bill would simply override existing standards with a cost-benefit test. S. 343, as reported by the committee, purports to soften the blow by saying that cost-benefit analysis would only "supplement" the standards in existing law. But that means that an agency action would still have to meet both the old standard and the new standard. The economist's veto over public health and safety would prevail, even under the seemingly more reasonable Judiciary Committee bill.

The problems with these procedural changes can be seen in the *Cotton Dust* case, in which the Supreme Court forbade the use of cost-benefit analysis as a decisional criterion in setting a particular health standard. Exposure to excessive levels of cotton dust had caused approximately 20 percent of the textile industry's workers to contract byssinosis or "brown lung" disease, a respiratory ailment that cripples and eventually kills many of its victims. In 1978, the industry sued to block the issuance of regulations, arguing that the standards had not been subjected to a cost-benefit test,

and that they would fail such a test. The Supreme Court rejected the industry's argument.

Since the issuance of the regulations, the number of workers with brown lung disease has dropped from 40,000 in 1978 to less than 2,000 in 1985. The rule turned out to be far less expensive than the industry had anticipated, costing less than a quarter of what the agency had estimated in its regulatory analysis (as is generally the case, the agency relies principally on cost data submitted for the record by the industry itself).

Because the proponents of the bill fail to squarely address this regulation and other health based standards, S. 343 would create uncertainty in areas where peoples health and lives are at risk.

During the markup, the committee unanimously adopted an amendment that created a special rule for agencies applying "the express decisional criteria in [a] statute." In such situations, agencies could promulgate a rule that does not satisfy this bill's cost-benefit test, but only if such a rule imposes

> (1) lower costs than any of the reasonable alternatives; or
>
> (2) the least costs taking into accounts benefits that the agency has discretion to adopt under the statute granting the rule-making authority.

This amendment improves the supermandate provision but does not adequately address the flaws in the provision. It still adds a new standard on top of legal standards that Congress has already determined are appropriate and necessary to protect public health and safety. Properly understood, this bill poses a substantial revision to the Occupational Safety and Health Act, the Food, Drug and Cosmetic Act, the Clean Air Act, the Clean Water Act and hundreds of other federal statutes.

It is, of course, the prerogative of the new majority in Congress to place revisions of these landmark statutes on the congressional agenda. But that should be accomplished in a straightforward manner, with full notice to interested citizens, and not cloaked in a veil of process reform. For example, the House of Representatives has passed H.R. 961, a bill to revise the Clean Water Act. Many of us disagree with that action on its merits, but it is at least the result of a process that fairly put before the Congress and the American public the question of whether that law should be amended. In contrast, S. 343 constitutes a substantial reexamination of the Clean Water Act and every other environmental statute without even mentioning those statutes.

In this manner, the bill also represents a circumvention of the committee process in the Senate. Ordinarily a bill that so profoundly implicates environmental laws would be considered by the Environment and Public Works Committee, just as a bill revising the Food, Drug and Cosmetic Act or the Occupational Safety and Health Act would come before the Committee on Labor and Human Resources.

But S. 343 has not been referred to those committees. This is more than a mere parliamentary nicety. The committee system is designed to ensure that a group of Senators with expertise in a particular subject have ongoing responsibility for overseeing the

implementation of and amending the laws relating to that subject. Typically, a bill is brought before the full Senate only after it has been considered and subjected to revision by those Members who have long-standing familiarity with the subject of the bill; Members of the Senate not on the relevant committee will often look to the views of their better informed colleagues on the committee as they formulate their own views on the bill.

Members of the Judiciary and Governmental Affairs Committees may possess expertise in administrative process, but this bill has too many implications for the substance of health, safety and environmental laws to justify its consideration in this manner. Instead, each statute sought to be amended by the proponents of S. 343 should be the subject of legislative consideration by the respective committees of jurisdiction.

The problem with considering a bill with ramifications on issues outside the committee's jurisdiction is further exemplified by the majority's discussion of the Supreme Court's *Cotton Dust* decision, *American Textile Manufacturers Institute* v. *Donovan*, 452 U.S. 490 (1981) in footnote 31. We believe the majority's understanding of the *Cotton Dust* decision based on a comment made by Justice Rehnquist in dissent is mistaken. The Supreme Court did preclude the use of cost-benefit tests in setting OSHA health standards.

The fifth circuit in *National Grain and Feed Association* v. *OSHA*, 866 F.2d 717,730 (1988), wrote that the Supreme Court in the *Cotton Dust* case held "that OSHA need not, indeed must not consider cost-benefit criteria in setting toxic substance standards." The Supreme Court's holding in the *Cotton Dust* case was not ambiguous. The Court held that the Secretary of Labor is precluded from performing cost-benefit analysis when setting health standards because Congress has already balanced costs and benefits and decided that the value of preserving the lives of workers outweighs any cost of regulation imposed on their employers, so long as the regulation is economically feasible. See *American Textile Manufacturers Institute* v. *Donovan*, 452 U.S. at 509.

To avoid such misunderstandings, we suggest that a full airing of issues related to statutes under the jurisdiction of other committees take place. Until the relevant committees act in the appropriate fashion, we should continue to let each agency accomplish the mission that Congress has already set out for it using the decisional criteria that Congress has created in each statute to guide the agency's discretion.

There are practical reasons why Congress has not set forth strict cost-benefit criteria for many agencies. In the context of health, safety and the environment, for example, costs may be easy to quantify, but benefits are not. We can determine with some specificity how much it will cost a factory to clean up a river, or how much it will cost business to provide safety gear to workers on a hazardous job site. But the benefits of a clean river, or clean air, or a hundred workers' lives are more intangible and often impossible to measure. To acknowledge that it is difficult to place a price tag on such things is not to say that they lack great value.

C. S. 343'S NOTICE AND COMMENT PERIOD: WORKS A LIMITLESS EXPANSION TO THE AGENCY RULEMAKING PROCESS

Under the present law, the opportunity to shape the agency determination of a final rule and the informal contacts between agencies and industry occur from the start of the rulemaking process. An agency must file a notice of rulemaking and allow a period for public comments on the proposed rules.

We believe that notice and comment serves to make the rulemaking process more informed. We also share the belief of many in industry that some agencies have been less than forthcoming in making these notice and comment periods true dialogues. We certainly would be supportive of measures designed to improve this area.

However, the bill contains a significant number of new provisions governing the notice and comment period that would convert what should be an informed exchange between interested parties and agencies into an exchange of papers to be carefully tabbed and filed. Because these new provisions are judicially reviewable, an agency would be forced to spend substantial resources crafting the content of notices and processing and filing paper instead of evaluating the merits of the information.

The majority makes a great deal out of the alleged growth in size of the Federal Register, yet we would note that S. 343 would certainly make the Register more voluminous—indeed the growth would probably be off the majority's chart provided. We question the cost-effectiveness of requiring the Treasury Department to publish in the Federal Register all 11,000 private letter rulings or include in the Federal Register the 60,000 requests for statutorily approved alcohol labels that the Bureau of Alcohol, Tobacco and Firearms grants annually. Requiring the Internal Revenue Service to publish private letter rulings not only seems inefficient but it would also conflict with laws intended to govern privacy. These requirements, however, represent only a few of the bureaucratic hoop agencies will be forced to jump through.

We wonder whether those provisions alone could survive cost-benefit analysis when considering the increased number of pages in the Federal Register they will require. This bill converts the rather straight-forward 1 page statute governing notice and comment into a 12-page, judicially reviewable, bureaucratic quagmire. Unfortunately, the present notice and comment period can extend for years and the provisions of this bill would certainly do little to shorten that process in order to bring important regulations into effect.

D. S. 343'S PETITION AND LOOK BACK PROVISIONS: PREVENTS A LOGICAL AND COMPREHENSIVE REVIEW OF THE AGENCY PROCESS

Presently, the Administrative Procedures Act contains a process whereby a private party can petition an agency with regard to a regulation. The majority's assertion during the markup that the provisions in this bill would narrow the petition process is incorrect. Senate bill 343 would expand dramatically the types and the number of private petitions seeking changes in existing regulations *at the same time* it would direct the agency to conduct a review of all existing rules.

We support the adoption of requirements that would direct each agency to review existing rules in a timely and logical fashion based upon a schedule established with the aid of interested parties. We fail to see the efficiency in allowing special interests to push their concerns to the front of the line while undermining a schedule established for the benefit of the entire public.

While the majority contends that the petition process should be open to all *interested* citizens, the bill allows only the regulated industry to challenge the regulation. That is to say, the majority wants to allow only those petitions alleging that a regulation is burdensome, but would preclude communities from challenging a regulation or practice that did not do enough to guarantee the safety of its citizens. The regulated community—not those protected by the regulations—would have the right to file separate petitions for the repeal of an existing major rule, the completion of a cost-benefit analysis of an existing major rule, the completion of a risk assessment of an existing major rule, and a variance or exemption from a major rule or guidance.

The petition process proposed in S. 343 would undermine the conventional wisdom that agencies should be directed by the President and Congress and allows unelected and unaccountable private interests to set priorities. As Chairman Robert Walker noted during the House debate on the petition process, we would prefer not "to pass a bill that is simply an employment policy for lawyers." The provisions of this bill make it more cost-efficient to frustrate rulemaking rather than comply with health and safety standards.

Of course, the S. 343 petition process poses problems for business as well. In situations in which industry and the agency have worked together to develop a set of regulations, the bill would provide no certainty that these regulations will not be undermined by a disaffected or irresponsible entity. Indeed, S. 343 would prevent businesses who seek to comply with the law from formulating a business plan that would include the necessary improvements or renovations to comply with the law. This type of uncertainty is hardly the hallmark of regulatory reform.

In addition to the petition process, the bill also would require agencies to establish their own schedule for reviewing existing rules within 5 to 7 years. Any regulation that is not reviewed would sunset automatically. We fail to see the efficiency in requiring an agency to establish a schedule for the review of existing rules at the same time an agency must respond within a set time frame to private parties who will be able to disrupt that schedule with their own special concerns—especially when private parties will be permitted to file a petition on each aspect of the rulemaking process.

The broad new petition right means the agency cannot plan a logical review of regulations required under the bill if bad actors can petition randomly for the review of rules. It means that well-financed bad actors can paralyze agencies by flooding the agency with petitions. We share Chairman Walker's views in which he noted that the flood of petitions would leave "agencies at a point where they will not be able to do some of the things we want them to do; namely to put into effect a process for good science and common sense." (CR, Feb. 28, 1995, H2352.) Agency resources would be

targeted to respond to petitions, rather than to promulgate rules that improve the quality of our lives.

The potential for abuse under S. 343 is not farfetched when one considers that any person subject to a rule can petition for its amendment or repeal. The agency must grant the petition and complete a cost-benefit analysis or risk assessment within one year if there is a reasonable likelihood that the rule will have the effect of a major rule.

Even worse, perhaps, are the two overlapping petition processes that allow an individual to compel an agency to respond, in writing, within 180 days, to a request for an exemption or waiver from the requirements of a regulation. The agency, because it must decide each petition on the basis of the petitioner's legal and factual claims (each of which will differ according to the individual circumstances of the petitioner), will have to investigate every petition individually. Because a decision to deny a petition becomes immediately reviewable in court, the agencies will face a hard decision—whether to grant petitions willy-nilly or devote enormous amounts of their resources to litigation.

Take a single agency and a single rule—OSHA's congressionally mandated standard for lead in construction. If only 1,000 of the tens of thousands of covered contractors petitioned for an exemption or variance, OSHA's compliance and legal staff would be completely overwhelmed. Repeat this for each of some 600 standards, and the absurdity of this provision becomes apparent. How does the rule of law mean anything if it cannot be enforced?

The problem is not forcing the agency to review regulations—we want a logical, exhaustive and complete review. We do question whether an agency is able to allocate resources, establish priorities for review, fulfill directives from Congress, and respond to widely varying special interest petitions. The majority has made much of the growth in the number of regulators. The petition process is one example where this bill would require more government employees and a greater allocation of taxpayer resources.

We think it would be preferable to establish a more systematic, unbiased approach. Senator Simon did not have the opportunity in committee to offer his amendment that would ensure an orderly and rational review of regulations under the supervision of a broadly representative advisory committee. The Simon amendment would provide for the creation of an agency-by-agency blue ribbon advisory committee to review all regulations. Under the Simon amendment, the head of each agency would appoint a 7- to 15-member regulatory review advisory committee comprised of a diverse group of individuals, including representatives of the regulated industry, small businesses, State and local governments, and public interest groups.

Not later than 1 year after the date of enactment of the act, the advisory committee would identify rules that warrant review by the head of the agency, and prioritize the order in which they should be reviewed. The agency head, upon receiving the priority list, would in turn conduct an analysis of the rules submitted by the advisory committee, identify which rules required re-analysis of the costs and benefits, and conduct these new analyses. The agency would make changes to regulations where appropriate. The agency

head would complete its review (of the rules identified by the advisory committee) within 1 year.

The Simon amendment would accomplish the same goal as the universal review and petition process dictated by S. 343, but would do it in an efficient, prioritized manner. Without this amendment, agencies will waste taxpayer dollars reviewing rules that are working perfectly well. Without this amendment, petitioners would be able to endlessly disrupt the rulemaking process, and make it impossible for agencies to respond, no matter how essential the regulation might be to protecting the public. With this amendment, careful and thorough scrutiny can be given to existing regulations to weed out unnecessary and overly burdensome regulations, at the same time allowing agencies the ability to continue protecting the health and safety of our constituents.

In addition to the petition process and the agency review of regulations, S. 343 would start the clock ticking for a number of other existing health and safety standards that would automatically sunset if an agency fails or is unable to review within the 5- to 7-year period outlined in the bill. Further, there is a stay of enforcement of any rule that cannot be rewritten to comply with the new decisional criteria of S. 343 within 2 years.

Of even more concern is that the development of new health and safety standards, head impact protections for example, might have to take a back seat to an agency's obligations to respond to petitions and to review of existing rules. The tragic irony in the case of the head impact standards for car passengers is that these regulations have already undergone cost-benefit analysis—just not the one outlined in the bill. S. 343, however, would require that its cost-benefit provisions be applied to rule-makings that are not yet complete.

As a consequence of S. 343's requirements, the National Highway Traffic Safety Administration (NHTSA) will have to redo the cost-benefit analysis. In the meantime, it will also have to answer petitions and review existing rules. For every year the implementation of the head impact standards is delayed, NHTSA calculates that more than 1,000 lives will be lost and more than 600 serious injuries will occur. The safety of our drivers, passengers, and children cannot afford the delay brought about by S. 343.

E. S. 343'S PEER REVIEW PANELS: WHO WILL REPRESENT THE PUBLIC'S INTEREST?

The operation and creation of peer review panels presently is under agency control. Peer review panels are established by agencies to evaluate and advise agencies concerning the methods and the science used to conduct cost-benefit analyses and risk assessments. The panels are comprised of scientists employed by the government, academics, and other independent experts. While we support the use of peer review panels to evaluate and make recommendations to agencies concerning the most applicable or up-to-date scientific methods, the provisions contained in the bill are ill-conceived and unbalanced.

S. 343 would require the President to set up a uniform peer review process for all agencies under which each major rule, clean up plan, risk assessment and risk characterization must be reviewed

by a panel. The bill would bestow significant power—veto authority—to the panel to dictate agency scientific procedures.

The legislation would open up the panels to special interest participation—the bill allows consultants employed by entities with a potential interest in the outcome to serve on the panels, if their interest is fully disclosed. Conversely, it would exclude from panels "experts who were associated with the generation of the specific work product either directly by substantial contribution. * * * Or indirectly by consultation and development of the specific product." The effect would be to include private parties with an interest in the litigation and exclude government scientists dedicated to protecting public health and safety.

The proposed conflict rules limit the number of available scientists by precluding government scientists, and failing to acknowledge that academic scientists have faculty meetings to attend, research to conduct, grants to renew, papers to write and classes to teach. That combination leaves a likelihood that only private consultants will be available to serve on peer review panels on any consistent basis.

As a group we differ on the advisability of allowing industry a role in the peer review process. However, we share the common view that this proposal would displace totally the people charged with ensuring the public's welfare with the narrow concerns of special interest groups and therefore is untenable.

The proposed limitations on panel membership would only exacerbate the problem that there are probably not enough scientists and experts to serve on the number of panels this bill would require. The legislation would increase by hundreds the number of major rules requiring peer review, in addition to the hundreds of risk assessments and risk characterizations completed each year that also would require a peer review.

The irrationality of this provision becomes more evident when we consider the bill's requirement to do a peer review on all risk characterizations. The Food and Drug Administration sometimes will request that a company issue a "Dear Doctor" letter to inform physicians about the dangerous side effects of a drug which may not be readily apparent on the label. These letters are "risk characterizations" and are one technique the FDA uses to communicate risk. Even though the risk from the drug is obvious and immediate, under S. 343, the FDA would have to conduct an exhaustive risk assessment, including a peer review, prior to issuing the letter—resulting in a delay in issuing the warning that could extend for years.

We do not believe that such requirements actually serve the public well-being.

F. S. 343'S JUDICIAL REVIEW: MISUNDERSTANDS THE PROPER ROLE OF THE JUDICIARY

Our objections to the concept of judicial review as contemplated in this legislation do not rest on an objection to allowing judges to review agency actions—the right to bring a suit in Federal court is an important check on the arbitrary and abusive exercise of Federal authority. The right to challenge an agency action exists now, in the current version of the Administrative Procedures Act, and

has provided an important check on agency discretion in the implementation of our health, safety, and environmental laws.

We, however, are concerned about the undefined scope of policymaking authority we will blindly cede to the Federal courts, and question whether inviting litigators and judges to second guess the scientific assumptions and procedures adopted by agencies during the course of a risk assessment or cost-benefit analysis will actually serve the goal of regulatory reform. Senate bill 343 would actually require judges to be the "judicial activists" many of the proponents of this bill have decried over the years.

1. S. 343 places the Judiciary in the role of Congress

In a previous section, we noted that the proponents of the bill do not know with any certainty all the statutes that will be affected by this legislation. As we also pointed out earlier, the legislation mandates the cost-benefit analysis as the determinative factor in whether a rule will be promulgated. No one can anticipate the kinds of issues that an agency will face in trying to reconcile the decisional criteria of this legislation with the decisional criteria of the underlying organic statute.

S. 343 relinquishes to the courts the congressional responsibility to develop and oversee government policy. The priorities and the discretion of the agencies would be set by special interests litigating in Federal court. Such policy making functions ought to remain reserved to Congress. However, S. 343 would require the Federal courts to reconcile more than 30 years of statutes, regulations, and judicial interpretation with its cost-benefit standard that was neither part of the debate on the underlying statute nor a part of the case establishing the precedent.

Senator Kennedy noted during the full committee hearing and the markup, many of the worker safety statutes have been interpreted not to require cost-benefit analysis as the determinative criteria for promulgating a rule. In those instances where the statute is unclear, the court will ultimately be left to decide the public policy matter about whether Congress intended that a cost-benefit analysis be the determinative measure.

If we want to codify the concepts of cost-benefit analysis and risk assessment, we, not the courts, should apply the decisional criteria to each statute—health, safety and environmental—and decide in each case if the result is one under which people will be able to live.

2. S. 343 will require judges to determine matters of science, not law

Our second concern about the scope of judicial review in S. 343 relates to the subject matter the proponents of the bill want to expose to judicial review—namely each procedural step of the rulemaking process. We question the wisdom of this legislation's invitation to litigators to reopen the entire rulemaking process after the substantial opportunity private parties will have to participate in that process.

Under this bill judicial review is simply another place for well-financed parties to inject themselves into the process. We have noted already that this bill greatly expands the agency's obligations to allow notice and comment, provides an expanded right of peti-

tion, creates a peer review process dominated by private interests which can dictate agency policy, and includes congressional review of all regulations. After an agency goes through all the procedures outlined in this bill, private parties can still litigate the validity of a regulation's compliance with this statute in Federal court—even after Congress has approved the regulation!

At the same time, the bill does not require the regulated parties to share information even though much of the information needed to determine whether a rulemaking will be "major" will be held by industry.

Ultimately, judges must focus on the cost-benefit analysis and risk assessment. A risk assessment and cost-benefit analysis must be completed in order to provide the necessary basis to apply S. 343's decisional criteria. Further, the bill is extremely prescriptive in outlining the procedures required for each type of analysis. Both the bill and the present Administrative Procedures Act provide for judicial review of all new procedures required under this bill.

Before codifying and opening to judicial review the procedural requirements of this bill, we must recognize that underlying each risk assessment and cost-benefit analysis are assumptions about which experts differ, often dramatically. Both cost-benefit analysis and risk assessment are valuable tools that agencies should continue to use when promulgating Federal regulations.

The judicial review provisions in S. 343 would require judges to determine which scientific or economic "models" over which experts disagree are the "most plausible" accounts of how a substance may harm people or the environment. Under S. 343, those same judges will be confronted with choices between esoteric statistical models that attempt to quantify probabilities of, for example, cancer deaths which are themselves based on statistical models that are subject to debate. Moreover, judges will be forced to balance the scientific principles with the economic principles in order to determine which safety standard should apply.

The majority neglects to confront situations in which an agency *cannot* comply with the cost-benefit or risk assessment requirements because there is not a sufficient understanding of the problem to be addressed. The Environmental Protection Agency is presently confronted with that problem in relation to safe drinking water regulations and cryptosporidium—a deadly water-borne parasite scientists do not understand but which made hundreds of thousands of people sick and killed more than a hundred in Milwaukee in 1993. The question remains under this bill whether a safe-drinking water regulation will pass judicial muster if the agency cannot quantify adequately the dangers of cryptosporidium. Further, the opportunities that the bill creates for bureaucratic delays will stall the promulgation of new standards necessary to protect against future appearances of deadly parasites like cryptosporidium.

On other grounds, the prescriptive criteria imposed on both the cost-benefit analyses and the risk assessments under this bill would drive the process toward a certain kind of result—a result that would make it much more difficult to justify rules that protect certain vulnerable groups of people—children or pregnant women. Under standard cost-benefit techniques, those sensitive groups are

"worth" fewer dollars to economists and may have lower tolerances than a hypothetical average citizen—represented by the "central estimate." The procedures in this bill would focus on that hypothetical average citizen and discount the value of sensitive subpopulations.

Contrary to the majority's assertion that the bill will encourage innovation, one obvious problem with a process that mandates certain procedures and funnels virtually all of these decisions into court is that once a particular scientific model and statistical method is approved by a court, there will be a tendency to freeze the science. It will be difficult to argue that another, equally plausible, model that may be closer to reality should be accepted when it is inevitably dragged into a future court by an aggrieved party.

As the majority points out, judges are often called upon to weigh complicated scientific questions. We question, however, whether Congress knowingly should provide the uncertainty that will be used by those who seek only to undermine the agency's position in court with any possible argument. We do not believe that such a scenario provides regulatory certainty.

The Administrative Office of the U.S. Courts noted "there could be substantial increases in actions seeking judicial review" and there would be "considerable increases in court time and resources necessary to review substantial expansions of the full agency record in each case." Certainly, the bill will require courts to delve into the scientific record.

These are not reasons to do away with cost-benefit analysis or with risk assessment. We should, however, be responsible in our deployment of these tools. We should recognize their limits as well as their merits, and we certainly should not expect the court system to resolve fundamental scientific disputes. Unfortunately, in an attempt to put some "teeth" into the cost-benefit and risk assessment requirements in this legislation, S. 343 will short-circuit the very scientific procedures that we all want to guide—but not to determine—our regulations.

Senator Biden's amendment would restrict judicial review to judgements about the reasonableness of the final rule itself, rather than expanding exponentially the grounds for future litigation. Making cost-benefit analysis and risk assessment part of the overall record open to the courts in their review of final agency action is sufficient to ensure the results we seek, without the problems we have described. Without these changes, no regulation written after the passage of S. 343 will be final—it will be open to endless litigation in which our courts will be asked to rule not just on the appropriate question of agency discretion under authorizing statutes, but on scientific models and statistical methods, as well.

G. S. 343'S CRIMINAL AND CIVIL EXCEPTIONS: WOULD PROVIDE A LOOPHOLE TO THOSE WHO VIOLATE THE LAW

We believe that people should not be prosecuted for activity an agency had previously advised was legal. But we also believe the laws should be enforced stringently, and not riddled with loopholes and defenses for those who would try to escape responsibility from complying with the law. The loopholes contained in S. 343 are not fair to the average citizen who relies on regulations to protect

health and safety. In addition, we note the unfairness S. 343 would entail for businesses that make capital improvements to make their facilities environmentally safe for their employees and their communities. We do not think that bad actors should be given a competitive advantage over progressive and law-abiding corporate citizens.

The costs of white collar-crimes are substantial. Consider, for example, health care fraud, which costs the U.S. economy over $100 billion per year. A number of us have been trying over the last several years to *strengthen* the prohibitions on fraudulent activity which costs each American family about $1,300 each year.

S. 343 moves in the opposite direction and would seriously hamper law enforcement efforts. Section 709 would give heart to every shady character trying to game Medicare and Medicaid—not to mention those who pollute our water or our air, or those responsible for selling us unsafe food or unsafe medicine. Current criminal law provides appropriate protections for those trying to comply with law, generally requiring that the violation be "willful." A person who in good faith gives the government complete information about what he is doing, and then receives government approval for his actions, cannot be prosecuted. The current law makes sense; someone who is trying to follow the law, but makes a mistake, should not be prosecuted.

But this bill goes beyond current law. This bill undermines incentives to obey the law and weakens the government's ability to enforce compliance. Effectively, this bill lets the *regulated person*, not the government, decide what the law requires. For example, someone trying to evade compliance with a law could manipulate the system to insulate himself from law enforcement. To invoke the defense, the defendant need not provide complete, accurate or honest information about what he is doing. What we will get are people shading the facts. For example, someone telling the government that the kickback payment to get Medicare business is actually a legitimate payment to the doctor to do a "study." If the government then tells that person that the arrangement is lawful, that is final. That individual can never be prosecuted under this bill, even though the individual was consciously trying to evade the law.

Further, the bill prevents the government from changing its interpretations of a statute or its factual assumptions, essentially freezing all regulations in place. For example, let us assume that an agency made a mistake in evaluating the level of emissions created by a particular production process and told the company its emissions would comply with the requirements of the law. Later, it is determined that the initial analysis of the emissions level was too low and that, in reality, the level of pollutants violates the law. We believe that the company should not face any criminal or civil sanction if it comes forward with the information, since presumably it acted in good faith. However, we would not prevent the agency from subsequently requiring the company to come into compliance as would section 709(c)(1) of this bill.

In addition, the bill in effect raises the level of proof required for civil enforcement actions to literally the same level as required for criminal prosecutions. Civil enforcement is a crucial tool for enforcing the health care fraud laws, the wage and hour laws, the immi-

gration employer sanctions laws, and others. While we do not know what the fiscal impact of this will be, it certainly will reduce fraud recoveries and penalty recoveries throughout the government.

The amendment Senator Biden would have proposed was better targeted and more responsible. It provided that in cases where intent must be proven, a defendant could assert a defense that he was relying on governmental advice. But it ensured that the defendant was required to do so responsibly by seeking advice from the government in good faith, before taking action, and after fully and accurately disclosing to the government all material facts. It did not tie the government's hands, and it did not turn over unprecedented authority to every government employee and every regulated party to determine what the law is.

H. THE PROPOSAL TO REPEAL THE DELANEY CLAUSE: REFORM RUN AMOK

One of the most serious flaws in S. 343 is the proposal to repeal the Delaney Clause. While Delaney reform may well be warranted, the current law should not be changed unless it is replaced with a scientific standard that sufficiently protects the public from cancer-causing chemicals.

The Delaney Clause has been part of Federal law for decades. It prohibits the approval of pesticide products, animal drugs, and food additives containing substances that may cause cancer. It was enacted to address the serious, legitimate concern about the impact on food safety of cancer-causing chemicals in pesticides and related products.

For many years, critics have argued that the Delaney Clause is sunscientific and overbroad. In the interest of guarding against cancer, these sections of the Food, Drug and Cosmetic Act require a zero tolerance level for certain chemicals, and that may be too strict a standard. But while a consensus has developed that Delaney is in need of reform, there has been an equally strong consensus that if Delaney is to be repealed, it must be replaced by a scientific safety standard that provides rigorous guidance to the Federal agencies that regulate potential carcinogens. Furthermore, the scientific community recognizes that any such guidance must take account of the need to protect vulnerable populations such as children.

The movement to reform the Delaney Clause began in earnest in 1987 with the publication of a National Academy of Sciences report entitled, "Regulation of Pesticides in Food: The Delaney Paradox." That report recommended that Congress consider replacing the Delaney Clause with a more scientifically based public health standard.

In the years since publication of this landmark National Academy report, several members of the Judiciary Committee have been active supporters of Delaney reform. Senators Kennedy and Leahy, for example, have each introduced detailed bills designed to repeal Delaney in a comprehensive fashion. *See, e.g.,* S. 331, a bill introduced by Senator Kennedy in the 103d Congress. That bill and others similar to it contain detailed standards that reflect and respond to a substantial body of scientific literature.

And Senator Hatch, the chairman of this committee and for many years the ranking member of the Senate Committee on Labor and Human Resources, has been a party to lengthy negotiations on a compromise standard to replace the Delaney Clause. Those negotiations never entertained the possibility that Delaney might be simply repealed.

We would be pleased to resume such negotiations at any time. But the bill reported by the committee simply wipes Delaney off the books. Rather than a comprehensive system of risk protection in place of the Delaney Clause, this bill just dispenses with Delaney, and makes no attempt to address the significant public health issues presented by that repeal. Such a stunning reversal of public policy would mean a sweeping reduction in public health protection.

Repeal of the Delaney Clause without a balanced effort to protect the American public would be a bad bargain for consumers and for parents who want to protect their children's health. Children are especially vulnerable to food-borne carcinogens because of their unique diet and metabolism.

It is especially strange that the Judiciary Committee would take this action without the benefit of careful consideration by the Committee on Labor and Human Resources, the Senate committee with jurisdiction over this issue. In fact, this legislation has been drafted and reported by the Judiciary Committee without any recent hearings or debate in the Labor Committee. Perhaps that committee has been bypassed because testimony before it in the past has so emphasized the need for a scientific standard in place of Delaney. *See, e.g.,* "Hearing on Safety of Pesticides in Food Act" (S. Hrg. 102–252) (July 10, 1991).

It is also disingenuous for the majority to suggest, as it does in its views, that FDA Commissioner David Kessler and EPA Administrator Carol Browner support the outright repeal of Delaney. Both officials may support reexamination of Delaney and possible replacement of it with a more scientific negligible risk standard, but neither supports the simple repeal of the Delaney Clause that appears in S. 343.

In its views, the majority also expresses support for the EPA's efforts to implement some of the recommendations of the 1993 National Academy of Sciences report on pesticides and children, *supra*. In particular, the majority suggests that the EPA is protecting children by utilizing hundred fold safety factors when interpreting animal data. But the NAS report explicitly challenged the hundredfold safety factor as inadequate to protect children, and recommended that an additional safety factor of up to tenfold be applied in order to protect children.

In sum, it is irresponsible to eliminate the black-letter protection of the current Delaney Clause unless we are prepared to replace it with a thoughtful, serious, sophisticated process for protecting children and other vulnerable populations. We hope that progress can be made on this issue before this ill-considered proposal is considered by the Senate.

I. S. 343'S COURT OF CLAIMS JURISDICTION: TURNING THE 5TH AMENDMENT TAKINGS CLAUSE ON ITS HEAD

Section 5 of S. 343, which relates to judicial review, contains in subsection (b) a grant of authority to the Court of Federal Claims that relates to the takings clause of the fifth amendment. The majority contends this provision will eliminate the so-called "Tucker Act Shuffle." While that may be true, it also turns on its head the fifth amendments takings clause jurisprudence.

There are several remarkable things about this provision. First is the fact that we even find it in the middle of a regulation reform bill at all. This provision relates to the fifth amendment of the Constitution—and the whole complicated issue of property rights, takings, eminent domain and just compensation. Indeed, the provision is contained, word for word, in the comprehensive takings legislation that we have just begun to consider in committee.

Both the regulatory reform bill and the takings legislation would make radical and major changes in separate and very complicated areas of the law. Both deserve our utmost care and attention. We should not complicate our consideration of regulation reform by rushing to judgment on one particular provision from the takings legislation.

More importantly, however, is that this short, 2-page takings provision—buried in more than a hundred pages of legislation—is no trivial matter. We must admit at the outset that we find the provision quite confusing as drafted. But if we look at the plain meaning of the words, it could work an enormous and profound change in takings jurisprudence.

The fifth amendment provides that "no private property may be taken for public use without just compensation." What this means is that if the government "takes" your property—either outright in a condemnation proceeding or through regulation—it must pay you and it must pay you fairly. This is a bedrock constitutional protection for property owners. But the fifth amendment does *not* in any way say that the government *can not* take property for the public good—only that it must pay just compensation if its action results in a "taking."

Indeed, the power of eminent domain is so firmly embedded in our nation's history and in our notion of what it means to be a sovereign nation, that it is not even mentioned in the Constitution. As the Supreme Court has said, the right of eminent domain "appertains to every independent government. It requires no constitutional recognition; it is an attribute of sovereignty." *Boom Co.* v. *Patterson*, 98 U.S. 403, 406 (1879).

S. 343 might very well change all that. It appears to declare that compensation—the time-honored constitutional remedy for a taking—is not sufficient. Rather, it authorizes the Court of Federal Claims to *invalidate* an act of government that "adversely affects private property rights in violation of the Fifth Amendment of the Constitution." The invalidation of an act is a remedy not contemplated in the fifth amendment. Indeed, the Supreme Court has on a number of occasions explicitly rejected that idea. As it said in *Ruckelshaus* v. *Monsanto* 467 U.S. 986, 1016 (1984):

> equitable relief is not available to enjoin an alleged taking of property for public use, duly authorized by law, when a suit for compensation can be brought against the government.

Or as then D.C. Circuit Judge Scalia once wrote:

> that money alone may not constitute just compensation for purposes of the Fifth Amendment is a principle of breathtaking novelty.

As drafted, this provision would thus rewrite a major chapter of takings law, and give a sweeping grant of authority to the Court of Federal Claims. Indeed, read literally, it can be seen as nothing short of a surrender of the government's sovereign right of eminent domain.

The provision also would give this new, sweeping grant of authority to an article I—or so-called "legislative"—court, the Court of Federal Claims. The judges who sit on this court do not have the protections of article III courts—protections of life tenure and protected salaries that are meant to safeguard their independence from the legislative branch and insulate them from political pressure.

The independence of article III judges is why we entrust those courts with the core judicial responsibility of interpreting the Constitution and invalidating acts of Congress and the Executive. In this provision, we would give this core article III power to article I judges who do not have the independence protections. Needless to say, this raises questions in our minds about the constitutionality of this provision.

On the merits, we believe that this provision's attempt to rewrite constitutional law and rearrange Federal court power are unwise and unwarranted, to say the least. Our view of the merits aside, we believe that it would be irresponsible for this committee to take such action without full and careful consideration—and certainly not in the middle of the already complicated debate we find ourselves in over regulatory reform.

The Judicial Conference of the United States has written to Chairman Hatch a letter urging that we defer consideration of this provision until it can be more carefully analyzed. The Conference's Committee on Federal-State Jurisdiction is now examining the provision, which we might add, includes other less expansive but certainly significant issues—such as expanding the Court of Claims' power to issue declaratory judgements and to hear ancillary claims arising under the Federal Tort Claims Act.

We have other major concerns regarding the costs of this takings provision to the Federal Government as well as the appropriateness of specifying compensation terms for regulatory actions. The compensation scheme of S. 343 is in complete contradiction to the judicial holdings under the takings clause of the U.S. Constitution.

We should not be rushing to judgment on issues as serious and significant as those raised by this provision. We urge that this provision be struck from the bill until there is a full opportunity to consider it at the right place and the right time—when we take up the comprehensive takings bill.

VIII. SUPPLEMENTAL VIEWS OF SENATOR LEAHY

The committee was never given an opportunity to vote on whether it supported this legislation. There are many reasons the committee should have rejected and the Senate should reject this legislation.

First, this legislation claims to be a regulatory reform bill. It is not. It is a regulatory policy bill. Unfortunately the policy assumptions of this legislation are contrary to both historic and contemporary American values.

Second, it does not make regulation more efficient. It is a "monkey wrench" bill that makes better regulations nearly impossible.

Third, this is not a bill that benefits the public or the middle class. The corporate clients of the big Washington law firms and beltway consultants, not the middle class, will be its beneficiaries. They will employ the scientists and attorneys to contest cost/benefit analyses, risk assessments, or file petitions for review of regulations.

Fourth, this bill does not protect the public from government. It is, instead, a profoundly anti-democratic, elitist bill.

CONTRARY TO SHARED AMERICAN VALUES

As Americans, we have a history of shared community values. The phrase, "your freedom ends, where my nose begins," expresses a commonly held view of the relationship between neighbors. This common value is now being challenged. Some are saying that property owners have a right to use their property in a way that harms their neighbors.

This is not the American tradition. A person has never had an unfettered right to use his property in a way that hurts his neighbors.

Before the American Revolution, community values were reflected in the "common law." The "common law" was the body of law that developed out of common community values without any need for legislative action. The common law "nuisance" action was the legal expression of the maxim, "your freedom ends where my nose begins."

As one commentator says:

> The beauty of a simple nuisance * * * case is that it reduces that case to terms a lay person can understand: "You dumped it, it hurt me or my property, and you should pay."

This regulatory "reform" bill is contrary to our shared community values. The bill's premise is that a person or his property should only be protected if that person's life or property is worth more than the activity of the person causing the damage. This is the essence of the cost/benefit requirement contained in the new section

624 of the Administrative Procedure Act proposed by this legislation.

The use of cost/benefit analysis as a *decisional criterion* in this legislation shows how this legislation contradicts traditional American values.

Americans do not believe that children, the poor or rural residents are of less value than adults, the wealthy or suburbanites. Unfortunately, the opposite premise is implicit in the use of cost/benefit analysis. The following chart is from a standard text book on cost/benefit analysis. It is included in a chapter entitled "The Value of Longevity." (*The Benefits of Environmental Improvement*, Freeman; p. 170.) This chart indicates that using standard cost/benefit analysis techniques, the value of a female infant is $30,000 and the value of a 25 year old male is $170,000.

TABLE 3. PRESENT VALUE OF LIFETIME EARNINGS, DISCOUNTED AT 6 PERCENT, BY AGE, SEX, AND RACE, 1972

[In dollars]

Years of age	Men			Women		
	Total	White	Other	Total	White	Other
Under 1	$48,720	$51,011	$31,232	$30,976	$31,557	$27,069
1–4	55,433	57,962	35,768	33,148	35,765	30,890
5–9	74,418	77,785	48,082	47,141	47,960	41,459
10–14	99,742	104,263	64,458	63,172	64,267	55,573
15–19	129,394	135,142	83,955	80,588	82,016	70,692
20–24	156,640	163,469	101,006	91,114	92,834	79,123
25–29	170,988	178,483	107,823	90,439	92,237	77,800
30–34	170,788	178,519	104,179	84,513	86,378	71,237
35–39	161,072	168,609	94,492	77,513	79,444	63,204
40–44	144,209	150,904	82,760	69,215	71,135	54,158
45–49	121,856	127,250	69,586	59,187	61,074	43,578
50–54	96,158	100,033	55,968	47,115	48,873	31,897
55–59	67,763	70,128	41,785	33,825	35,317	20,349
60–64	38,588	39,830	24,964	21,406	22,436	11,702
65–69	18,107	18,631	12,656	11,890	12,436	6,467
70–74	9,886	10,184	6,911	6,598	6,861	3,685
75–79	5,434	5,675	3,168	3,396	3,526	1,956
80–84	3,209	3,354	1,839	1,507	1,562	912
85 & over	519	543	291	194	200	128

Source: Cooper and Rice (1976), p. 28.

Why is there this disparity between the value of the adult male and the female infant? First, because this technique measures the value of a human life by the wages a person would receive in their life. Men normally earn more than women. Second, the disparity exists because cost/benefit analysis assumes that benefits that occur in the future have very little value.

After determining the value of a human life, cost/benefit analysis applies a "discount rate" to benefits that will occur in the future. Benefits of the lives saved in the future by a regulation are reduced by 6–7 percent per year. In business planning this makes sense. A dollar of economic return 10 years from now is worth less than a dollar of economic return earned today. This business evaluation tool does not make sense when applied to the protection of human life.

For example, in arguing that it is essential to balance the Federal Budget, the Chair of the House Budget Committee, John Ka-

sich recently stated, "mothers and fathers will do virtually anything for their children." (*Washington Post*, May 15, 1995, p. 1.) This legislation does not share the same assumption about the value of children.

While most of us would spend as much to save our infant child as we would to save our teenagers' life, cost/benefit analysis assumes the opposite. Babies do not earn wages for many years. The joy of childhood has no economic value. Thus, the value of saving their lives is reduced by discounting. Therefore, infants lives are worth less, according to this analysis.

A simple example shows the importance of this disparity.

Congress has told the Environmental Protection Agency to protect the public from toxic pollution. This legislation requires the EPA to look at a broad series of options. One option, will save 1,000 female infants. The second would save 1,000 adult males. The pollution control costs are the same.

If cost/benefit analysis is a *decisional criterion*, the agency would implement the option that saved the 25 year-old males simply because they are "worth more."

Adults' lives are worth more because the value of saving lives in the future is much less than saving lives in the present.

There are now some who want to revert to a 19th century Social Darwinism, in which it is every man for himself—and only the strongest men win. they want to revert to a theory of property and government that argues that child labor laws interfere with private property rights. The Supreme Court and our society have rejected this argument since the 1930's.

For example, a recent Harris poll asked if owners of private land should be able to develop their land in a way that would harm the environment. By a 79-to-20-percent margin, the interviewees responded that the Federal Government should have the right to stop pollution. The polls show clear support for a "good neighbor" philosophy.

Regulations are neither good, nor bad, in and of themselves. In a complex society they are, however, the only way that we establish the responsibility of neighbors to neighbors. If the neighbors are local, it is local regulations that make a "good neighbor" policy works. In a complex society of 240 million Americans, Federal regulations are necessary to make sure that the acid rain produced by our neighbors in Ohio does not hurt Vermonters, or that meat packed by our neighbors in California does not cause illness or death in Oregon.

Similarly, regulations make sure that responsible property owners are not at competitive disadvantage compared to irresponsible property owners.

We have a responsibility to preserve these American values while protecting the American people.

Our society does, and should, protect private property. It protects private property for two reasons. First, because it protects the liberty of those who own property. Second, protecting private property makes it possible to use that property to create the economic goods the society wants.

The majority report claims that regulation is interfering with the "creation of economic value" aspect of private property. The facts do not support this contention.

In a March 15, 1995, *Washington Post* article, the eminent economist, Robert Samuelson noted that "industrial productivity has increased at its fastest rate in decades." "Between 1980 and 1994, U.S. manufacturing output rose more than 50 percent." Even though proponents of S. 343 claim that existing regulations are excessively burdensome, Samuelson points out that "manufacturing output is now twice as high as in 1970 and five times as high as in 1950."

Many studies have assessed the effect of environmental regulation on our international competitiveness. On March 17, 1994, *The Washington Post* noted that a review of 100 separate studies found that "* * * there is little evidence that environmental compliance costs have adversely affected the competitiveness of U.S. manufacturing firms." Paul Portney of Resources for the Future explained that "* * * with pollution control costs running at between 1 and 3 percent of sales in most industries, they simply aren't big enough to sway major decisions."

The other evidence that existing regulations are crippling the economy is anecdotal. For instance, Representative McIntosh cited several anecdotes in his testimony before the committee on March 17, 1995.

His first anecdote involved a device which its proponents claim can be used to detect breast cancer. The second anecdote claimed that the Consumer Product Safety Commission was intending to require holes in buckets. Both stories are sensational and both stories were incorrect.

Representative McIntosh claimed that the sensor pad device was approved by the "equivalent of the Canadian equivalent of the Food and Drug Administration." Not only was Representative McIntosh wrong in claiming that the device had been approved in Canada, the sensor pad is banned in Canada. This was not the only misinformation Representative McIntosh shared with the public.

In the hearing he also testified that the Consumer Product Safety Commission had prepared a guideline requiring that all five gallon buckets have a hole in the bottom. This was not true and Representative McIntosh knew it. The Judiciary Committee hearing was not the first time Representative McIntosh had used this erroneous story and been corrected.

He used this story during the February 23, 1995, House floor debate and was immediately corrected by a letter from the Consumer Product Safety Commission. Then, on March 12, 1995, he used it again on the "One to One" television show, and was corrected by Congressman Kanjorski. An article appeared in the *New York Times* on February 29, 1995, again correcting this erroneous story. Finally, he used it at a public conference on food safety and was corrected publicly.

The tragic truth of the CPSC's inquiry into the design of 5-gallon buckets is that between 1984 and 1994, 228 children drowned after falling into the buckets. The CPSC issued an Advance Notice of Proposed Rulemaking on May 19, 1994. This notice sought to lay out the facts of the drownings in an attempt to solicit industry

opinions and possible solutions. Early in the process of developing the proposed regulation, a CPSC engineer suggested that a bucket with a hole in it would be exempt from any performance standard which the Commission might issue.

In fact, such a bucket is used by companies which collect waste products at curbside for recycling. In addition, less than 1 year after the Advance Notice was published, the bucket industry undertook a $500,000 public education campaign to warn parents about the dangers of children drowning in buckets. This campaign was done voluntarily by the bucket industry. The Commission voted to cancel the advance notice shortly after the public information campaign began.

NOT REGULATORY REFORM: A MONKEY WRENCH BILL

This is a "monkey wrench" bill that establishes a presumption against regulation, even where it protects a neighbor from an irresponsible neighbor. It includes so many roadblocks that it will be nearly impossible to issue new regulations in the face of a well-financed, determined opposition.

That this is a "monkey wrench" bill is clear from the fact that the business community has insisted that it be exempted from it. New product approvals are exempt from all of the "reforms" that apply to regulations designed to protect the public.

Before an agency can issue a public safety regulation, it must do both a peer-reviewed, judicially reviewable, cost/benefit analysis and a peer-reviewed, judicially reviewable, risk assessment. New product approvals are exempt from these "reforms."

This committee and its membership believe in regulatory reform. In 1982, the Laxalt-Leahy Regulatory Reform bill reported from this committee, S. 1080, passed the Senate unanimously. That was 13 years ago. The statement is often made that this bill—S. 343—is just an updated form of S. 1080.

This is not correct. It is different in four critical ways.

1. It includes judicial review of every element of a cost/benefit analysis and a risk assessment.
2. It is too broad. Many more regulations are covered because the threshold is $50 million instead of the $100 million threshold used in S. 1080.
3. It includes a retroactive petition that allows decade-old regulatory decisions to be reopened.
4. Cost benefit is a decisional criterion, not a tool to produce better decisions.

Of these points of difference between S. 1080 and S. 343, the most critical is the section which makes "cost/benefit analysis" a *decisional* criterion. S. 1080 required cost/benefit analysis. We all weigh the costs and benefits of optional courses of action and try to choose the most efficient means to reach that end. Making cost/benefit analysis a decisional criterion is very different.

Congress should decide what responsibility we have to avoid harming our neighbors and the values it wants to protect. Then the agencies should use cost/benefit anlaysis—and whatever other tools are available—to design the best method of achieving that protection.

This bill takes a fundamentally different approach to regulatory reform. As discussed earlier in these views, the use of cost/benefit analysis as a *decisional criterion* is contrary to shared American values.

Independent analyst have also strongly criticized cost/benefit analysis. A recent article by Professor Lester Lave of Carnegie Mellon University and Howard Gruenspecht of the President's Council of Economic Advisers summarizes these criticisms.

In spite of the loyalty of some economists to this tool, they warn that the "problem with benefit-cost analysis in both theory and practice seem overwhelming. * * *"

They note that:

> This tool grew out of utilitarianism in the 1810–1830 period in England. Utilitarians such as John Stuart Mill believed that society could and should maximize the greatest good for the greatest number. They myriad assumptions of utilitarianism as moral philosophy are rejected by modern philosophers, the economic assumptions are largely rejected by economists.

They further warn that "in practice, the analysts are either biased or directed to justify a particular answer."

They conclude:

> The difficulties with missing data, uncertainty, and too little time and resources for an exhaustive analysis combine with the theoretical difficulties to make ineffectual any serious claim that an applied study produces an optimal or theoretically justified outcome.

The proponents of this legislation have often quoted Philip Howard, the author of a book criticizing regulation. Ironically, in his testimony before the committee, Mr. Howard said that:

> Less procedure is vital for regulatory reform. First it is almost scandalous that it takes seven years for the FDA to pass a rule, or that decades go by without decisions on potentially harmful pesticides. * * *

The committee unfortunately did not follow Mr. Howard's suggestions. Instead it created a bill with layer after layer of new procedures.

One of the principal reasons that it is almost impossible for the Environmental Protection Agency to remove a pesticide from the market is that the pesticide statute makes cost/benefit analysis a *decisional criterion*. It is virtually the only health and safety statute based on a cost/benefit, rather than a health-based criteria.

The very legislation that Mr. Howard criticizes for excessive delay is the model for this so-called reform bill. In the end, this legislation is not a reform bill, it is a "monkey wrench" bill.

S. 1080 used cost/benefit analysis as a tool to make sure regulation is done right. This bill takes a *useful tool*, and turns it into a *rigid rule*. S. 1080 made sure that rules were sensible. This bill turns "reform" into a receipt for paralysis. Instead of making sure there are good decisions, it makes sure that there will be no decisions.

CONSULTANTS, NOT MIDDLE-CLASS BENEFIT

The chief beneficiaries of this so-called reform will be the big Washington law firms and beltway consultants, not the middle class. These law firms and consultants will be hired to contest cost/benefit analyses, risk assessments, or file petitions for review of regulations.

Indeed, in his testimony on the legislation, Professor Cass Sustein, a former Reagan Justice Attorney, called S. 343 a "Full Employment Act for both Lawyers and Accountants." The truth of this statement can be seen in the fact that this legislation will create over 100 new grounds for litigation. (List follows these views.)

These are not processes that the middle class can or will use.

ANTI-DEMOCRATIC ELITIST BILL

This bill does not protect the public from government. It is, instead, a profoundly anti-democratic elitist bill.

By making cost/benefit analysis a *decisional criterion*, this bill empowers an elite group of economists—using formulas we do not understand and values we do not share—to veto laws passed by Congress designed to protect the health and safety of the American people.

This bill is anti-democratic. As discussed in the first section of these additional views, the use of cost/benefit analysis involves value-laden decisions about the value of human life and the value of the future. Even the Reagan Department of Justice rejected putting the courts of cost/benefit analysis, according to Professor Cass Sunstein, an attorney at the Department of Justice. Professor Sunstein was an active participant in the Reagan administration's efforts to include cost/benefit analysis in the Federal regulatory process.

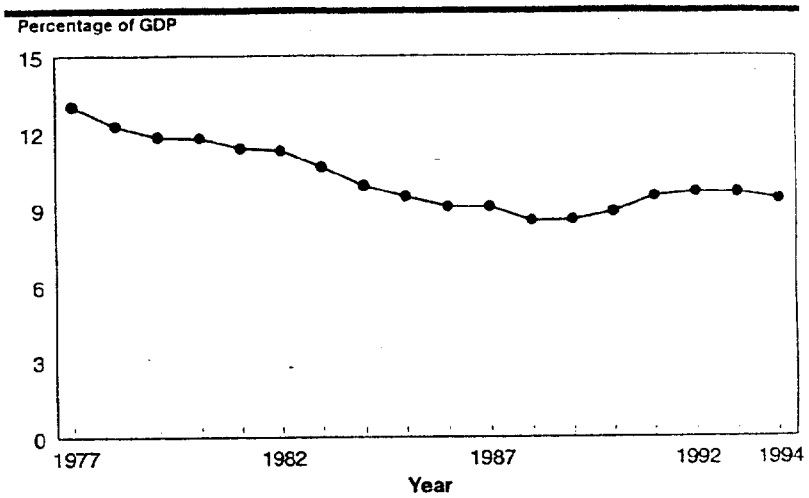
In the interagency process leading up to the issuance of Executive Order 12991, the Reagan administration considered whether judicial view of cost/benefit analysis was a sound idea. Early in the interagency process it decided that empowering appointed judges to make decisions about cost-benefit analysis was anti-democratic.

CONCLUSION

Regulations are tools used to protect commonly held American values about the proper relationship of neighbors to neighbors. The premises of this legislation are contrary to those commonly held values. It is also unworkable and anti-democratic. It is based on the incorrect premise that the regulatory burden on the public is increasing. (See Attachment 1)

REGULATORY REFORM: Information on Costs, Cost-Effectiveness, and Mandated Deadlines for Regulations (GAO/PEMD–95–18BR, March 1995, p.15)

GAO Hopkins' Estimates of Total Regulatory Costs



Source: Data derived from Hopkins, 1991, and Bureau of Economic Analysis, 1994; converted to constant 1995 dollars.

At the same time, GDP grew steadily; hence, the percent of GDP devoted to the costs of federal regulations decreased over the period.

120 Items to Litigate Under S. 343

1. Does a rule cost more than $50 million?
2. Does rule have significant impact on sector of economy?
3. Does rule substantially increase costs for wage earners?
4. Does rule substantially increase costs for consumers?
5. Does rule substantially increase costs for individual industry?
6. Does rule substantially increase costs for nonprofits?
7. Does rule substantially increase costs for government?
8. Does rule substantially increase costs for a geographic region?
9. Does rule adversely affect competition?
10. Does rule adversely affect employment?
11. Does rule adversely affect investment?
12. Does rule adversely affect productivity?
13. Does rule adversely affect innovation?
14. Does rule adversely affect the environment?
15. Does rule adversely affect public health or safety?
16. Does rule adversely affect U.S. business' ability to compete?
17. Is rule inconsistent or does it interfere with action of another agency?
18. Does rule materially alter budgetary impact or rights of recipients of entitlements, grants, user fees, or loan programs?
19. Does rule impose disproportionate and significant costs to class of persons within regulated sector?
20. Is rule closely related to other rules that aggregate into major rule?
21. Did agency adequately analyze benefits of rule?
22. Did agency adequately explain how rule achieves each benefit?
23. Did agency adequately identify recipients of benefits?
24. Did agency adequately analyze costs of rule?
25. Did agency adequately explain how rule results in costs?
26. Did agency adequately identify bearers of costs?
27. Did agency adequately identify alternatives that require no government action?
28. Did agency adequately assess costs/benefits of no-action alternatives?
29. Did agency adequately identify alternatives that accommodate differences among geographic regions?
30. Did agency adequately assess costs/benefits of geographic alternatives?
31. Did agency adequately identify alternatives that accommodate different compliance resources?
32. Did agency adequately assess costs/benefits of different compliance resource alternatives?
33. Did agency adequately identify market-based alternatives?
34. Did agency adequately assess cost/benefits of market-based alternatives?
35. Were alternatives examined authorized under statute granting rule-making authority?
36. Did agency adequately assess feasibility of market-based regulatory program?

37. Did agency adequately verify quality, reliability, and relevance of science?
38. Did agency adequately assess cumulative burden of compliance with rule and other existing regulations?
39. Did agency adequately assess effect of rule on small businesses?
40. Did agency adequately analyze whether benefits of rule justify costs?
41. Did agency adequately analyze whether rule achieves greater net benefits to society than alternatives?
42. Did quantify cost and benefits to extent feasible?
43. Did quantification adequately specify ranges of predictions?
44. Did quantification adequately explain margins of error?
45. Did agency adequately describe nature and extent of nonquantifiable costs and benefits?
46. Were costs and benefits broken down appropriately on industry-by-industry basis?
47. Did agency rely impermissibly on unsupported information?
48. Did non-agency employee participate in preparation of analysis?
49. Did agency adequately identify data or information gathered by non-agency employee?
50. Did agency adequately identify non-agency employee who gathered information?
51. Did agency adequately explain financial arrangement for procuring information?
52. Did agency correctly conclude that petition did not show that costs of rule likely exceed benefits?
53. Did agency correctly conclude that petition raised no reasonable question that alternative to rule might provide greater net benefits to society?
54. Did agency correctly conclude that guidance would not be major rule if adopted as rule?
55. Did agency correctly conclude that statute expressly forbids consideration of whether benefits justify costs?
56. Did agency correctly conclude that statute expressly forbids consideration of whether rule achieves greatest net societal benefits?
57. If statute ambiguous, did agency correctly identify range of permissible statutory constructions?
58. Is agency interpretation of statute within permissible range?
59. Did agency reasonably determine that interpretation maximizes agency ability to base rule on cost/benefit analysis or greatest net societal benefits?
60. Did agency adequately identify specific statutory authority for promulgating rule?
61. Did agency develop adequate regulatory flexibility analysis?
62. Does rulemaking record provide substantial support for asserted necessary factual basis for rule?
63. Is a risk assessment exempt because of an emergency (does risk pose an imminent and substantial endangerment to public health or environment)?
64. Is risk assessment related to rule authorizing a product's introduction into commerce?

65. Is risk assessment an exempt screening analysis?
66. Is screening analysis used as the basis for restricting an activities?
67. Is screening analysis used to characterize a positive finding of risk in document available to public?
68. Did agency appropriately assess incremental risk reduction associated with each significant regulatory alternative?
69. Did agency adequately compare risk with other relative risk regulated by agency?
70. Did agency adequately compare risk with other relevant risk with which public is familiar?
71. Does risk assessment adequately distinguish scientific findings from other considerations?
72. Is the science behind risk assessment objective?
73. Is the science behind risk assessment unbiased?
74. Does risk assessment include all relevant data?
75. Does risk assessment rely to extent practicable on scientific findings?
76. Does risk assessment adequately consider and discuss most reliable laboratory and epidemiological data?
77. Does risk assessment adequately summarize other data?
78. Does risk assessment adequately discuss reconciliation of conflicting information?
79. Does risk assessment adequately discuss differences in study designs?
80. Does risk assessment adequately discuss mechanisms of action?
81. Does risk assessment adequately discuss comparative physiology?
82. Does risk assessment adequately discuss routes of exposure?
83. Does risk assessment adequately discuss bioavailability?
84. Does risk assessment adequately discuss pharmacokinetics?
85. Does risk assessment adequately discuss availability of raw data?
86. Does risk assessment adequately discuss other relevant factors?
87. Does risk assessment place greatest emphasis on data indicating biological basis of harm in humans?
88. Does risk assessment appropriately discuss relevancy of animal data to humans?
89. Does risk assessment involve the selection of any significant assumption, inference, or model?
90. Does risk assessment adequately identify and explain all plausible and alternative assumptions, inferences, or models?
91. Does risk assessment adequately explain sensitivity of conclusions to alternative assumptions, inferences, or models?
92. Does risk assessment adequately explain the basis for selecting any assumption, inference, or model?
93. Does risk assessment adequately identify all policy or value judgments?
94. Does risk assessment sufficiently describe all models used?
95. Does risk assessment appropriately specify the assumptions incorporated in any models used?

96. Does risk assessment adequately explain the extent models have been validated by data?

97. Does risk assessment clearly separate hazard identification from risk characterization?

98. Does risk assessment adequately make clear the relationship between level of risk and level of exposure to potential hazard?

99. Was risk assessment prepared at appropriate level of detail?

100. Does risk characterization adequately describe the populations or resources at risk?

101. Are numerical estimates of risk in risk characterization scientifically appropriate?

102. Does risk characterization appropriately address the reasonable range of scientific uncertainties?

103. Does risk characterization provide appropriate best estimate of risk?

104. If no single best estimate of risk is given, does risk characterization include an appropriate discussion of multiple estimates?

105. If risk characterization includes multiple estimates of risks, are the assumptions, inferences, and models associated with such multiple estimates equally plausible?

106. Does risk characterization appropriately discuss the distribution and probability of risk estimates?

107. Are all safety factors used similar in degree to safety factors used to ensure safety in human activities?

108. Does risk characterization adequately explain exposure scenarios?

109. Does risk characterization appropriately identify population at risk under each exposure scenario?

110. Does risk characterization adequately discuss the relative likelihood of exposure scenarios?

111. Does risk characterization place in appropriate context the nature and magnitude of individual and population risks?

112. Does risk characterization adequately discuss substitution risks?

113. Does risk characterization adequately discuss risk summaries submitted by other persons?

114. In reviewing petition, did agency correctly conclude that risk assessment consistent with principles in Grassley Amendment to S. 343?

115. In reviewing petition, did agency correctly conclude that risk assessment would not produce substantially different results?

116. In reviewing petition, did agency correctly conclude that risk assessment is consistent with regulation governing risk assessments?

117. Is there material new scientific information which risk assessment should take into account?

118. Did peer review panel determine that rule is supported by best available scientific data?

119. Did agency adequately respond to peer review panel comments?

120. Does consent decree imposing rulemaking obligation divest agency of discretion to respond to changing circumstances, make policy or managerial changes, or protect rights of third parties?

IX. SUPPLEMENTAL VIEWS OF SENATOR KOHL

I generally agree with the minority views of the other Democrats but I write separately to emphasize my support for bipartisan regulatory reform. Indeed, I believe that cost-benefit analysis and risk assessment are vital to an effective, beneficial regulatory process. That is why I supported Senator Johnston's amendment to the Safe Drinking Water Act last year, offered Senator Roth's bill (S. 291) as a substitute for S. 343 at subcommittee, and drafted an amendment for full committee consideration that drew heavily from the bipartisan Leahy-Laxalt legislation of 1982 (S. 1080).

However, while S. 343 purports to streamline regulations, it would still undermine the very cost-benefit goals it professes to achieve. The petition process alone will open up a Pandora's Box of litigation. For example, a single bad actor could drown an agency in paperwork in order to delay the implementation of a rule—even if virtually the entire regulated industry supports the regulation itself. In general, the Federal Government should be promoting the efforts of progressive businesses, not bolstering the actions of renegades, as S. 343 could do.

Once S. 343 reaches the Senate floor, I look forward to working cooperatively with the proponents of the legislation to achieve a responsible and streamlined regulatory process.

X. SUPPLEMENTAL VIEWS OF SENATOR FEINGOLD

The need for meaningful reform of the Federal regulatory process is undeniable. Our farmers, our small businesses and our families too often become ensnared in a sea of burdensome and sometimes needless government red tape and regulation.

At the same time, we cannot ignore the need and the responsibility to protect our Nation's health, safety and environment. Just 2 years ago, a cryptosporidium outbreak in the city of Milwaukee's water supply left 104 people dead and over 100,000 people seriously ill.

The clear answer to this quandary—and one that has been agreed upon by a wide array of interested parties ranging from the Clinton administration to business advocacy groups—is to introduce a mix of common sense and sound science to the regulatory process. We must find the proper balance between adequately safeguarding health and safety protections that give us cleaner air, cleaner water and safer products, and granting greater relief to those who are being regulated by rules that have little or no rational and sensible basis.

Unfortunately, S. 343 as reported by the Judiciary Committee, does not strike that balance. The Minority Views accurately enumerate many of the problematic sections of this legislation, such as the excessive and unmanageable judicial review and overprescriptive "one-size-fits-all" peer review provisions.

It is my hope that when this legislation is brought to the Senate floor, the majority will recognize that there are Senators on both sides of the aisle who support making the regulatory process less bureaucratic and less problematic. As reflected by the Senate's actions in 1982, as well as the recent bipartisan work of the Government Affairs Committee, this issue has not been partisan in the past and should not be partisan in the future.

RUSSELL D. FEINGOLD.

XI. CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 343, as reported, are shown as follows (existing law proposed to be omitted is enclosed in brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

UNITED STATES CODE

* * * * * * *

TITLE 5—GOVERNMENT ORGANIZATION AND EMPLOYEES

PART I—THE AGENCIES GENERALLY

Chapter	Sec.
1. Organization	101
* * * * * * *	
7. Judicial Review	701
8. Congressional Review of Agency Rulemaking	801
9. Executive Reorganization	901
* * * * *	

CHAPTER 5—ADMINISTRATIVE PROCEDURE

* * * * * * *

Subchapter II—Administrative Procedure

§ 551. Definitions

For the purpose of [this subchapter] *this chapter and chapters 6, 7, and 8*—

(1) "agency" means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include—

* * * * * * *

(13) "agency action" includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act; [and]

(14) "ex parte communication" means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding covered by this subchapter[.]*; and*

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

§ 552. Public information; agency rules, opinions, orders, records, and proceedings

(a) Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the FEDERAL REGISTER for the guidance of the public—

(A) * * *

* * * * * * *

(E) each amendment, revision, or repeal of the foregoing. Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the FEDERAL REGISTER and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the FEDERAL REGISTER when incorporated by reference therein with the approval of the Director of the Federal Register. *In an action brought in a Federal court seeking a civil or criminal penalty for the alleged violation of a rule, including actions pending on the date of enactment of this sentence, no consideration shall be given to any interpretive rule, general statement of policy, or other agency guidance of general or specific applicability; relied upon by the agency in the action, that had not published in the Federal Register or otherwise directly and specifically communicated to the defendant by the agency, or by a State authority to which had been delegated the responsibility for ensuring compliance with the rule, prior to that alleged violation.*

* * * * * * *

[§ 553. Rule making]

§ 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, guidance, or rule of agency organization, procedure, or practice that is not generally applicable and 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(4);

(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 explanation 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;

(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 is 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 (1) and (2), 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)(i) an explanation of whether the specific statutory interpretation upon which the rule is based is expressly required by the text of the statute; or

(ii) if the specific statutory interpretation upon which the rule is based is not expressly required by the text of the statute, an explanation that the interpretation is within the range of permissible interpretations of the statute as identified by the agency, and why the agency has rejected other interpretations proposed in comments to the agency;

(D) 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

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

(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, interpretive rule, general statement of policy, or guidance; and

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

(3)(A) Any person subject to a rule, interpretive rule, general statement of policy, or guidance may petition an agency for the amendment or repeal of any rule, interpretive rule, general statement of policy, or guidance.

(B) If such petition presents a reasonable likelihood that, considering its future impact, the rule, interpretive rule, general statement of policy, or guidance is, or has the effect of, a major rule within the meaning of section 621(4), and its amendment or repeal is required to satisfy the decisional criteria of section 624, the agency shall grant the petition and shall, within one year, conduct a cost-benefit analysis under chapter 6.

(C) If, considering its future impact, the rule, interpretive rule, general statement of policy, or guidance does not satisfy the requirements of chapter 6, including the decisional criteria set forth in section 624, the agency shall take immediate action either to revoke or to amend the rule, interpretive rule, general statement of policy, or guidance to conform it to the requirements of chapter 6, including the decisional criteria in section 624.

(4) 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.

(5) Following a decision to grant or deny a petition to conduct a cost-benefit analysis for a rule, interpretive rule, general statement of policy, or guidance under this subsection, no further petition for such rule, interpretive rule, general statement of policy, or guidance, submitted by the same person, shall be considered by any agency unless such petition is based on a change in a fact, circumstance, or provision of law underlying or otherwise related to the rule, interpretive rule, general statement of policy, or guidance occurring since the initial petition was granted or denied, that warrants the amendment or repeal of the rule, interpretive rule, general statement of policy, or guidance.

(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.

(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, this section 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.

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CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS

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[§ 611. Judicial review

[(a) Except as otherwise provided in subsection (b), any determination by an agency concerning the applicability of any of the provisions of this chapter to any action of the agency shall not be subject to judicial review.

[(b) Any regulatory flexibility analysis prepared under sections 603 and 604 of the title and the compliance or noncompliance of the agency with the provisions of this chapter shall not be subject to judicial review. When an action for judicial review of the rule is instituted, any regulatory flexibility analysis for such rule shall constitute part of the whole record of agency action in connection with the review.

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

§ 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.

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SUBCHAPTER II—ANALYSIS OF AGENCY RULES

§ 621. Definitions

For purposes of this subchapter—

(1) the term "benefit" means the reasonably identifiable significant incremental 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;

(2) the term "cost" means the reasonably identifiable significant incremental 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;

(3) 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;

(4)(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, health, safety, or the environment, 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;

(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 re-

ceive 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 freely 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;

(6) the term ''performance-based standards'' means requirements, expressed in terms of outcomes or goals rather than mandatory means of achieving outcomes or goals, that permit the regulated entity discretion to determine how best to meet specific requirements in particular circumstances;

(7) the term ''reasonable alternatives'' means the range of regulatory options that the agency has discretion to consider under the text of the statute granting rulemaking authority, interpreted, to the maximum extent possible, to embrace the broadest range of options that satisfy the decisional criteria of section 624(b); and

(8) the term ''rule'' has the same meaning as in section 551(4), 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—

(i) 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;

(ii) a rule relating to monetary policy or to the safety or soundness of Federally insured depository institutions or any affiliate of such an institution (as defined in section 2(k) of the Bank Holding Company Act of 1956), credit unions, Federal Home Loan Banks, government sponsored housing enterprises, farm credit institutions, foreign banks that operate in the United States and their affiliates, branches, agencies, commercial lending companies, or representative offices, (as those terms are defined in section 1 of the International Banking Act of 1978); or

(iii) a rule relating to the payment system or the protection of deposit insurance funds or the farm credit insurance fund.

§ 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(4)(A)(i) and, if it is not, whether it should be designated a major rule under section 621(4)(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(4)(A)(i) and has not designated the rule a major rule within the meaning of section 621(4)(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 in the same manner as if the initial 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 that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority, as supplemented by the decisional criteria in section 624, for achieving identified benefits, including, where appropriate, 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 or performance-based standards, market-based mechanisms, or other flexible regulatory alternatives that permit the greatest flexibility in achieving the identified benefits of the proposed rule;

(D) an assessment of the feasibility of establishing a regulatory program that operates through the application of vol-

untary programs, voluntary consensus standards, performance-based standards, market-based mechanisms, or other flexible regulatory alternatives;

(E) in any case in which the proposed rule is based on one or more scientific evaluations, scientific information, or a risk assessment, or is subject to the risk assessment requirements of subchapter III, a description of the actions undertaken by the agency to verify the quality, reliability, and relevance of such scientific evaluations or scientific information in accordance with the 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 or, where applicable, lower net costs, than any of the alternatives to the proposed rule, including alternatives identified in accordance with subparagraphs (C) and (D).

(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 flexible regulatory alternatives identified pursuant to subsection (c)(2) (C) and (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 or, where section 624(c) applies, lower net costs, than any of the reasonable alternatives that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority, as supplemented by the decisional criteria in section 624, for achieving identified benefits, including, where appropriate, alternatives referred to in subsection (c)(2) (C) and (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 pre-

cise 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 and appropriate, 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 relevant information 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.

§ 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 and the amendment or repeal requested.

(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, considering the future impact of the rule—

(A) the rule is a major rule; and

(B) the proposed amendment or repeal of the rule is required to satisfy the decisional criteria of section 624.

(4) A decision to grant, or final agency action to deny, a petition under this subsection shall be made not later than 180 days after submittal.

(5) Following a decision to grant or deny a petition to conduct a cost-benefit analysis for a rule under this subsection, no further petition for such rule, submitted by the same person, shall be considered

by any agency, the Director, or a designee of the President, unless such petition is based on a change in a fact, circumstance, or provision of law underlying or otherwise related to the rule occurring since the initial petition was granted or denied, that warrants the amendment or repeal of the rule.

(b) Not later than 1 year after the date on which a petition has been granted for a major rule under subsection (a), the agency shall conduct a cost-benefit analysis in accordance with this subchapter, and shall propose amendments to, or repeal of, the rule if required by the decisional criteria set forth in 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 interpretive rule, guidance, or general statement of policy that would have the effect of a major rule if the interpretive rule, guidance, or general statement of policy had been adopted as a rule.

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

(4) A decision to grant, or final agency action to deny, a petition under this subsection shall be made not later than 180 days after the petition is submitted.

(e) For each interpretative rule, guidance, or general statement of policy for which a petition has been granted under subsection (d), the agency shall—

(1) immediately withdraw the interpretive rule, guidance, or general statement of policy; or

(2) within one year, propose a rule in compliance with this subchapter incorporating, with such modifications as the agency considers appropriate, the regulatory standards or criteria contained in such interpretive rule, general statement of policy, or guidance.

(f) Upon withdrawing an interpretive rule, guidance, or general statement of policy, or where such interpretive rule, guidance, or general statement of policy is not withdrawn and a final rule is not promulgated within 2 years of granting a petition under subsection (d), the agency shall be prohibited from enforcing against any person the regulatory standards or criteria contained in such interpretive rule, guidance, or general statement of policy, unless and until they are included in a rule promulgated in accordance with this subchapter.

(g)(1) Any person subject to a major rule may petition the relevant agency to modify or waive the specific requirements of the major rule and to authorize such person to demonstrate compliance through alternative means not otherwise permitted by the major rule. The petition shall identify with reasonable specificity the requirements for which the waiver is sought and the alternative means of compliance being proposed.

(2) The agency shall grant the petition if the petition shows that there is a reasonable likelihood that the proposed alternative means of compliance would achieve the specific benefits of the major rule with an equivalent or greater level of protection of health, safety, and the environment than would be provided by the major rule, and would not impose an undue burden on the agency that would be responsible for enforcing such alternative means of compliance.

(3) Following a decision to grant or deny a petition under this subsection, no further petition for such rule, submitted by the same person, shall be considered by any agency unless such petition is based on a change in a fact, circumstance, or provision of law underlying or otherwise related to the rule occurring since the initial petition was granted or denied, that warrants the granting of such further petition.

§ 624. Decisional criteria

(a) The requirements of this section shall supplement any other decisional criteria otherwise provided by law.

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

(1) the potential benefits from the rule justify the potential costs of the rule; and

(2) the rule will produce the most cost-effective result of any of the reasonable alternatives that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority.

(c) If a statute requires or permits that a rule be promulgated and that rule cannot, applying the express decisional criteria in the statute, satisfy the criteria provided in subsection (b), the agency shall not promulgate the rule unless the rule imposes—

(1) lower costs than any of the reasonable alternatives; or

(2) the least costs taking into account benefits that the agency has discretion to adopt under the decisional criteria of the statute granting the rulemaking authority.

(d) If an agency promulgates a rule that is subject to subsection (c), the agency shall prepare a written explanation of why the agency was required to promulgate a rule with potential costs that were not justified by the potential benefits and shall transmit that explanatio nalong with 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 agency action under this subchapter.

(b)(1) 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 and shall be considered by a court in determining the legality of the agency action, but only to the extent that it relates to the agency''s decisional responsibilities under section 624 or the statute granting the agency authority to take the agency action.

(2) No analysis required by this subchapter shall be subject to judicial review separate or apart from judicial review of the agency action to which it relates.

(3) 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 take the action.

(4) The court shall set aside agency action that fails to satisfy the decisional criteria of section 624, applying the applicable judicial review standards.

§ 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 by another deadline, the deadline for such regulation 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, considering its future impact, would be a major rule under this subchapter;

(ii) each rule of the agency that is inconsistent or incompatible with, or duplicative of, 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(4)(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(4) 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 in subsection (f)—

(A) in the case of a regulation that takes effect after the date of enactment of this section, the regulation shall terminate on the date that is 5 years after the date on which the regulation takes effect, unless the review required by this section has been completed by the date that is 5 years after the date on which the regulation takes effect; and

(B) in the case of a regulation in effect on the date of enactment of this section, the regulation shall terminate on the date that is 7 years after the date of enactment of the Regulatory Reform Act of 1995, unless the review required by this section has been completed by the date that is 7 years after the date of enactment of the Regulatory Reform Act of 1995.

(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, an explanation 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;

(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 re-

quirement 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(4), an explanation of how 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) is contrary to an important public interest, may request the President, or an officer designated by the President, to establish a period longer than 5 years, in the case of a regulation that takes effect after the date of enactment of this section, or 7 years, in the case of a regulation in effect on the date of enactment of this section, 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 10 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 issue 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.

§ 628. Special rule

Notwithstanding any other provision of the Comprehensive Regulatory Reform Act of 1995, or the amendments made by such Act, for purposes of this subchapter and subchapter IV, the head of each appropriate Federal banking agency (as defined in section 3(q) of

the Federal Deposit Insurance Act), the National Credit Union Administration, the Federal Housing Finance Board, the Office of Federal Housing Enterprise Oversight, and the Farm Credit Administration, shall have authority with respect to such agency that otherwise would be provided under such subchapters to the Director, a designee of the President, Vice President, or any officer designated or delegated with authority under such subchapters.

SUBCHAPTER III—RISK ASSESSMENTS

§ 631. Definitions

For purposes of this subchapter—

(1) the term "benefit" has the meaning given such term in section 621(1);

(2) 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 and realistic 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 plausible and realistic level of risk, given the current scientific information available to the agency concerned;

(3) the term "cost" has the meaning given such term in section 621(2);

(4) the term "cost-benefit analysis" has the meaning given such term in section 621(3);

(5) the term "emergency" means an actual, immediate, and substantial endangerment to health, safety, or the human environment;

(6) the term "hazard identification" means identification of a substance, activity, or condition that may cause to health, 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 combined degree of toxicity and actual exposure, or other risk the hazards pose for individuals, populations, or natural resources; and

(7) the term "major cleanup plan" means any proposed or final environmental cleanup plan for a facility, or Federal guidelines for the issuance of any such plan, the expected costs, expenses, and damages of which are likely to exceed, in the aggregate, $10,000,000, including a corrective action requirement under the Solid Waste Disposal Act (notwithstanding section 4(b)(1)(C) of such Act, but only to the extent of such requirement), a removal or remedial action under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, and any other environmental restoration or damage assessment carried out by, on behalf of, or as required or ordered by, an agency or Federal court, or pursuant to the authority of a Federal statute with respect to any substance;

(8) the term "major rule" has the meaning given such term in section 621(4);

(9) the term "negative data" means data that fail to show that a given substance or activity induces an adverse effect under certain conditions;

(10) the term "risk assessment" means—

(A) the process of identifying hazards, and of quantifying (to the maximum extent practicable) or describing the combined degree of toxicity and actual exposure, or other risk the hazards pose for individuals, populations, or natural resources; and

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

(11) 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) may include discussions of uncertainties, conflicting data, estimates, extrapolations, inferences, and opinions, as appropriate;

(12) the term "rule" has the meaning given such term in section 621(7); and

(13) the term "substitution risk" means a potential increased risk to 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 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 initiation of manufacture, of a substance, mixture, or product, or recognizes the marketable status of a product;

(C) a health, safety, or environmental inspection, compliance or enforcement action, 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 previously authorized substance, product, or activity after its initial introduction into manufacture or commerce; or

(ii) to characterize a finding of risk 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 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. 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 for a major rule 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, plausible, and realistic, and inclusive of all relevant data;

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

(D) use situation- or decision-specific information to the maximum extent practicable.

(2) An agency shall not be required to repeat discussions or explanations required under this section in each risk assessment document if there is an unambiguous reference to the relevant discussion or explanation in another reasonably available agency document that was prepared in accordance with this subchapter.

(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, including negative data, and summarize the remaining data that finds, or fails to find, a correlation between a health risk and a substance 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. 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) give preference to the model, assumption, input parameter that represents the most plausible or realistic inference from supporting scientific information;

(C) identify any science policy or value judgments and employ those judgments only where the policy determination has been approved by the head of the agency, after notice and opportunity for public involvement, as appropriate for the circumstance under consideration;

(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) Risk assessments that provide a quantification or numerical output shall be calculated using the best estimate for each input parameter and shall use, as available, probabilistic descriptions of the uncertainty and variability associated with each input parameter.

(4) 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.

(5) 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.

(6) Where relevant, practicable, and appropriate, data shall be developed consistent with standards for the development of test data promulgated pursuant to section 4 of the Toxic Substances Control Act, and standards for data requirements promulgated pursuant to section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(c)(1) The head of each agency shall promote early involvement by all stakeholders in the development of risk assessments that may support or affect agency rules, guidance, and other significant actions, by publishing as part of its semiannual regulatory agenda, required under section 602—

(A) a list of risk assessments and supporting assessments, including hazard, dose or exposure assessments, under preparation or planned by the agency;

(B) a brief summary of relevant issues addressed or to be addressed by each listed risk assessment or supporting assessment;

(C) an approximate schedule for completing each listed risk assessment and supporting assessment;

(D) an identification of potential rules, guidance, or other agency actions supported or affected by each listed risk assessment and supporting assessment; and

(E) the name, address, and telephone number of an agency official knowledgeable about each listed risk assessment and supporting assessment.

(2)(A) The head of each agency shall provide an opportunity for meaningful public participation and comment on any risk assessment throughout the regulatory process commensurate with the consequences of the decision to be made.

(B) In cases where the risk assessment will support a major rule, the agency shall publish, at the earliest opportunity in the process,

an advanced notice of relevant risk assessment related information that includes, at a minimum, an identification of—

(i) all relevant hazard, dose, exposure, and other risk related documents that the agency plans to consider;

(ii) all risk related guidance that the agency considers relevant;

(iii) all hazard, dose, exposure, and other risk assumptions on which the agency plans to relay and the bases therefor; and

(iv) all data and information deficiencies that could affect agency decisionmaking.

(d)(1) No agency shall automatically incorporate or adopt any recommendation or classification made by an entity described in paragraph (2) concerning the health effects or value of a substance without an opportunity for notice and comment. Any risk assessment or risk characterization document adopted by an agency on the basis of such a recommendation or classification shall comply with this title.

(2) An entity referred to in paragraph (1) includes—

(A) any foreign government and its agencies;

(B) the United Nations or any of its subsidiary organizations;

(C) any international governmental body or standards-making organization; and

(D) any other organization or private entity without that does not have a place of business located in the United States or its territories.

§ 634. Principles for risk characterization and communication

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

(1) The head of the agency shall describe the exposure scenarios used in any risk assessment, and, to the extent feasible, provide an estimate of the size of the corresponding population or natural resource at risk and the likelihood of such exposure scenarios.

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

(A) the range and distribution of exposures derived from exposure scenarios used in a risk assessment, including, where appropriate, central and high-end estimates, but always including a best estimate of the risk to the general population;

(B) the range and distribution of risk estimates, including best estimates and, where quantitative estimates of the range of distribution of risk estimates are not possible, a list of qualitative factors influencing the range of possible risks; and

(C) a statement of the major sources of uncertainties in the hazard identification, dose-response, and exposure as-

sessment phases of risk assessment and their influence on the results of the assessment.

(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.

§ 635. Requirement to prepare assessment

(a) Except as provided in section 632 and in addition to any requirements applicable under subchapter II, the head of each agency shall prepare—

(1) for each major rule relating to health, safety, or the environment, and for each major cleanup plan, that is proposed by the agency after the date of enactment of this subchapter, 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 623, a risk assessment in accordance with this subchapter;

(2) for each such proposed or final plan, and each reasonable alternative within the statutory authority of the agency taking action, a cost-benefit analysis equivalent to that which would be required under subchapter II if subchapter II were applicable; and

(3) for each such proposed or final plan, quantified to the extent feasible, a comparison of any 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 major cleanup plan is subject to this subchapter if—

(1) construction has not commenced on a significant portion of the work required by the plan; or

(2) if construction has commenced on a significant portion of the work required by the plan, unless—

(A) it is more cost-effective to complete construction of the work than to apply the provisions of this subchapter; or

(B) the application of the provisions of this subchapter, including any delays caused thereby, will result in an actual and immediate risk to human health or welfare.

(c) A risk assessment prepared pursuant to this subchapter shall be a component of and used to develop any cost-benefit analysis re-

quired by this subchapter or subchapter II, and shall, along with any cost-benefit analysis required by this subchapter, be made part of the administrative record for judicial review of any final agency action.

§ 636. Requirements for assessments

(a) The head of the agency, subject to review by the Director or a designee of the President, shall make a determination that, notwithstanding any other provision of law—

(1) for each major rule and major cleanup plan subject to this subchapter, the risk assessment required under section 635 is based on a scientific, plausible, and realistic evaluation, reflecting reasonable exposure scenarios, of the risk addressed by the major rule and is supported by the best available scientific data, as determined by a peer review panel in accordance with section 640; and

(2) for each major cleanup plan subject to this subchapter, the plan has benefits that justify its costs and that there is no alternative that is allowed by the statute under which the plan 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 agency shall prohibit or refuse to approve a substance or product on the basis of safety where the substance or product presents a negligible or insignificant human risk under the intended conditions of use.

(c) Notwithstanding any other provision of law, issuance of a record of decision or a final permit condition or administrative order containing a major cleanup plan, or denial of, or completion of agency review pursuant to, a petition for review of a major cleanup plan under section 637(c), shall constitute final agency action subject to judicial review at the time this action is taken.

§ 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 risk characterization principles set forth in sections 633 and 634; 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) Review of a risk assessment or any entry (or the evaluation underlying the entry) on an agency-developed database (including, but not limited to, the Integrated Risk Information System), shall be conducted by the head of the agency on the written petition of a person showing a reasonable likelihood that—

(1) the risk assessment or entry is inconsistent with the principles set forth in sections 633 and 634;

(2) the risk assessment or entry contains different results than if it had been properly conducted under sections 633 and 634;

(3) the risk assessment or entry is inconsistent with a rule issued under subsection (a); or

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

(c) Review of a risk assessment, a cost-benefit analysis, or both, for a major cleanup plan shall be conducted by the head of the agency on the written petition of a person showing a reasonable likelihood that—

(1) the risk assessment warrants revision under any of the criteria set forth in subsection (b); or

(2) the cost-benefit analysis warrants revision under any of the criteria set forth in section 624.

(d)(1) Not later than 90 days after receiving a petition under subsection (b), the head of the agency shall respond to the petition by agreeing or declining to review the risk entry, the cost-benefit analysis, or both, referred to in the petition, and shall state the basis for the decision.

(2) 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 (1), unless the Director agrees in writing with an agency determination that an extension is necessary in view of limitations on agency resources. Prior to completion of the agency review, the agency's written conclusions concerning the review shall be subjected to peer review pursuant to section 640.

(3) A risk assessment review completed pursuant to a petition may be the basis for initiating a petition pursuant to any other provision of law.

(4) Following a decision to grant or deny a petition under subsection (b) or (c), no further petition for such risk assessment, entry, or cost-benefit analysis, submitted by the same person, shall be considered by any agency unless such petition is based on a change in a fact, circumstance, or provision of law underlying or otherwise related to the matters covered by the initial petition, occurring since the initial petition was granted or denied, that warrants the granting of such further petition.

(e) 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.

(f) 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. 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.

§ 639. Regulatory priorities

(a)(1) Not later than 180 days after the date of enactment of this section, the Director of the Office of Management and Budget, in consultation with the Office of Science and Technology Policy, shall enter into appropriate arrangements with an accredited scientific body to—

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

(B) to conduct a comparative risk analysis in accordance with paragraph (2).

(2) The study of the methodologies under paragraph (1)(A) shall be conducted as part of the first comparative risk analysis under paragraph (1)(B). The study shall—

(A) seek to develop and rigorously test methods of comparative risk analysis;

(B) have sufficient scope and breadth to test approaches for improving comparative risk analysis and its use in setting priorities for health, safety, and environmental risk prevention and reduction; and

(C) review and evaluate the experience of States that have conducted comparative risk analyses.

(3)(A) The comparative risk analysis under paragraph (1)(B) shall compare and rank, to the extent feasible, health, safety, and environmental risks potentially regulated across the spectrum of programs relating to health, safety, and the environment administered by the departments, agencies, and instrumentalities of the Federal Government.

(B) In carrying out the comparative risk analysis under this paragraph, the Director shall ensure that—

(i) the scope and specificity of the analysis are sufficient to provide the President and the heads of agencies guidance in allocating resources across agencies and among programs in agencies to achieve the greatest degree of risk prevention and reduction for the public and private resources expended;

(ii) the analysis is conducted through an open process, by individuals with relevant expertise, including, as appropriate—

(I) toxicologists;

(II) biologists;

(III) engineers; and

(IV) experts in the fields of medicine, industrial hygiene, and environmental effects;

(iii) the analysis is conducted, to the extent feasible, consistent with the risk assessment and risk characterization principles described in sections 633 and 634;

(iv) the methodologies and principal scientific determinations made in the analysis are subjected to peer review under section 640 and the conclusions of the peer review are made publicly available as part of the final report;

(v) there is an opportunity for public comments on the results of the analysis prior to making them final; and

(vi) the results of the analysis are presented in a manner that distinguishes between the scientific conclusions and any policy or value judgments embodied in the comparisons.

(4) The comparative risk analysis shall be completed, and a report submitted to Congress not later than 3 years after the date of enactment of this section. The analysis shall be reviewed and revised not less often than every 5 years thereafter for a minimum of 15 years following the release of the initial analysis.

(b) Not later than 180 days after the date of enactment of this section, the Director of the Office of Management and Budget, in collaboration with the head of each Federal agency, shall enter into a contract with the National Research Council to provide technical guidance to the agencies on approaches to using comparative risk analysis in setting health, safety, and environmental priorities to assist the agencies in complying with subsection (c).

(c)(1) In exercising authority under any laws protecting health, safety, or the environment, the head of an agency shall prioritize the use of the resources available under such laws to address the risks to health, safety, and the environment that—

(A) the agency determines are the most serious; and

(B) can be addressed in a cost-effective manner, with the goal of achieving the greatest overall net reduction in risks with the public and private sector resources to be expended.

(2) In identifying the sources of the most serious risks under paragraph (1), the head of the agency shall consider, at a minimum—

(A) the plausible likelihood and severity of the effect; and

(B) the plausible number and groups of individuals potentially affected.

(3) The head of the agency shall incorporate the priorities identified in paragraph (1) into the budget, strategic planning, and research activities of the agency by, in the agency's annual budget request to Congress—

(A) identifying which risks the agency has determined are the most serious and can be addressed in a cost-effective manner under paragraph (1), and the basis for that determination;

(B) explicitly identifying how the agency's requested funds will be used to address those risks;

(C) identifying any statutory, regulatory, or administrative obstacles to allocating agency resources in accordance with the priorities established under paragraph (1); and

(D) explicitly considering the requirements of paragraph (1) when preparing the agency's regulatory agenda or other strategic plan, and providing an explanation of how the agenda or plan reflects those requirements and the comparative risk analysis when publishing any such agenda or strategic plan.

(4) In March of each year, the head of each agency shall submit to Congress specific recommendations for repealing or modifying laws that would better enable the agency to prioritize its activities to address the risks to health, safety, and the environment that are the most serious and can be addressed in a cost-effective manner consistent with the requirements of paragraph (1).

§ 640. Establishment of program

(a) The Director of the Office of Science and Technology or the Director, as appropriate, shall develop a systematic program for the peer review of work products covered by subsection (c), which pro-

gram shall be used, in as uniform a manner as is practicable, 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 experts who were associated with the generation of the specific work product either directly by substantial contribution to its development, or indirectly by consultation and development of the specific product;

(4) shall provide for differing levels of peer review depending on the significance or complexity of the issue or the need for expedition;

(5) shall contain balanced presentations of all considerations, including minority reports and an agency response to all significant peer review comments; and

(6) shall provide an opportunity for interested parties to submit issues for consideration by peer review panels.

(c) Matters requiring peer review shall include—

(1) risk assessments and cost-benefit analyses for major rules;

(2) quantitative estimates of risk or hazard that are used in making regulatory determinations, including all entries into the Integrated Risk Information System;

(3) risk assessment and risk characterization regulations and cost-benefit guidelines; and

(4) any other significant or technical work product, as designated by the head of each agency, the Director of the Office of Science and Technology, or the Director.

(d) All underlying data shall be submitted to peer reviewers, except to the extent necessary to protect confidential business information and trade secrets. To ensure such protections, the head of the agency may require that peer reviewers enter into confidentiality agreements.

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

(f) The proceedings of peer review panels under this section shall be subject to the applicable provisions of the Federal Advisory Committee Act.

Subchapter IV—Executive Oversight

§ 641. Procedures

(a) 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.

(b) Not later than 12 months after the date of enactment of this subchapter the Office of Management and Budget shall issue regu-

lations to assist agencies in preparing the cost-benefit analyses required by this subchapter. The regulations shall—

(1) ensure that cost and benefit evaluations are consistent with this subchapter and, to the extent feasible, represent realistic and plausible estimates;

(2) be adopted following public notice and adequate opportunity for comment; and

(3) be used consistently by all agencies covered by this subchapter.

§ 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.

CHAPTER 7—JUDICIAL REVIEW

Sec.
701. Application; definitions.

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706. Scope of review.

707. Consent decrees.
708. Affirmative defense.
709. Agency interpretations in civil and criminal actions.

* * * * * * *

[§ 706. Scope of review]

§ 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 of an agency hearing provided by statute;

(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; or

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

(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, 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.

§ 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.

§ 708. Affirmative defense

Notwithstanding any other provision of law, it shall be an affirmative defense in any enforcement action brought by an agency that the regulated person or entity is complying with a rule, regulation, adjudication, directive, or order of such agency or any other agency that is inconsistent, incompatible, contradictory, or otherwise cannot be reconciled with the agency rule, regulation, adjudication, directive, or order being enforced.

§ 709. Agency interpretations in civil and criminal actions

(a)(1) No civil or criminal penalty shall be imposed in any action brought in a Federal court, including an action pending on the date of enactment of this section, for the alleged violation of a rule, if the defendant, prior to the alleged violation—

(A) reasonably determined, based upon a description, explanation, or interpretation of the rule contained in the rule's statement of basis and purpose, that the defendant was in compliance with, exempt from, or otherwise not subject to, the requirements of the rule; or

(B) was informed by the agency that promulgated the rule, or by a State authority to which had been delegated the responsibility for ensuring compliance with the rule, that the defendant was in compliance with, exempt from, or otherwise not subject to, the requirements of the rule.

(2) In determining, for purposes of paragraph (1)(A), whether a defendant reasonably relied upon a description, explanation, or interpretation of the rule contained in the rule's statement of basis and purpose, the court shall not give deference to any subsequent agency description, explanation, or interpretation of the rule relied on by the agency in the action that had not been published in the Federal Register or otherwise directly and specifically communicated to the defendant by the agency, or by a State authority to which had been delegated the responsibility for ensuring compliance with the rule, prior to the alleged violation.

(b)(1) In a civil or criminal action in Federal court to redress an alleged violation of a rule, including an action pending on the date

of enactment of this section, if the court determines that the rule in question is ambiguous, the court shall not give deference to an agency interpretation of the rule if the defendant relied upon an interpretation of the rule to the effect that the defendant was in compliance with or was exempt or otherwise not subject to the requirement of the rule, and the court determines that such determination is reasonable.

(2) Without regard to whether the defendant relied upon an interpretation that the court determines is reasonable under paragraph (1), if the court determines that the rule failed to give the defendant fair warning of the conduct that the rule prohibits or requires, no civil or criminal penalty shall be imposed.

(c)(1) No agency action shall be taken, or any action or other proceeding maintained, seeking the retroactive application of a requirement against any person that is based upon—

(A) an interpretation of a statute, rule, guidance, agency statement of policy, or license requirement or condition; or

(B) a determination of fact,

if such interpretation or determination is different from a prior interpretation or determination by the agency or by a State or local government exercising authority delegated or approved by the agency, and if such person relied upon the prior interpretation or determination.

(2) This subsection shall take effect on the date of enactment of the Comprehensive Regulatory Reform Act of 1995 and shall apply to any matter for which a final unappealable judicial order has not been issued.

(d) This section shall apply to the review by a Federal court of any order of an agency assessing civil administrative penalties.

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, 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(4), 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.

(h) This section shall not apply to rules that concern monetary policy proposed or implemented by the Board of Governors of the Federal Reserve System or the Federal Open Market Committee.

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Title 28—JUDICIARY AND JUDICIAL PROCEDURE

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PART IV. JURISDICTION AND VENUE

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CHAPTER 91—COURT OF CLAIMS

Sec.
1491. Claims against United States generally; actions involving Tennessee Valley Authority.

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[1500. Pendency of claims in other courts.]

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§ 1491. Claims against United States generally; actions involving Tennessee Valley Authority

(a)(1) [The United States Claims Court shall have jurisdiction to render judgment upon any claim against the United States founded either upon the Constitution, or any Act of Congress or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort.] *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 or action of an agency, 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. For the purpose of this paragraph, an express or implied contract with the Army and Air Force Exchange Service, Navy Exchanges, Marine Corps Exchanges, Coast Guard Exchanges, or Exchange Councils of the National Aeronautics and Space Administration shall be considered an express or implied contract with the United States.

(2) *In any case within its jurisdiction, the Court of Federal Claims shall have the power to grant injunctive and declaratory relief when appropriate.* To provide an entire remedy and to complete the relief afforded by the judgment, the court may, as an incident of and collateral to any such judgment, issue orders directing restoration to office or position, placement in appropriate duty or retirement status, and correction of applicable records, and such orders may be issued to any appropriate official of the United States. In any case within its jurisdiction, the court shall have the power to remand appropriate matters to any administrative or executive body or official with such direction as it may deem proper and just. The Claims Court shall have jurisdiction to render judgment upon any claim by or against, or dispute with, a contractor arising under section 10(a)(1) of the Contract Disputes Act of 1978.

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(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.

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[§ 1500. Pendency of claims in other courts

[The United States Claims Court shall not have jurisdiction of any claim for or in respect to which the plaintiff or his assignee has pending in any other court any suit or process against the United States or any person who, at the time when the cause of action alleged in such suit or process arose, was, in respect thereto, acting or professing to act, directly or indirectly under the authority of the United States.**]**

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