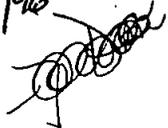


NLWJC - Kagan

Counsel - Box 028 - Folder 002

**Regulatory Reform-Legislative
Materials [1]**

Latest Levin
S.L.C. 3/13/96


104TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mr. LEVIN introduced the following bill: which was read twice and referred to the Committee on _____

A BILL

To provide for comprehensive regulatory reform.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Regulatory Reform Act
5 of 1996".

6 **SEC. 2. DEFINITIONS.**

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

9 (1) in the matter preceding paragraph (1), by
10 striking "this subchapter" and inserting "this chap-
11 ter and chapters 7 and 8";

1 mental, economic, and distributional effects that are
2 expected to result directly or indirectly from imple-
3 mentation of, or compliance with, a rule;

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

14 “(4) the term ‘flexible regulatory options’
15 means regulatory options that permit flexibility to
16 regulated persons in achieving the objective of the
17 rulemaking including regulatory options that employ
18 market-based mechanisms, performance standards,
19 or voluntary programs;

20 “(5) the term ‘major rule’ means a rule or a
21 group of closely related rules that the agency pro-
22 posing the rule or the Director ^{pursuant to} reasonably deter- 622(b)(1)
23 mines is likely to have an annual effect on the econ-
24 omy of \$100,000,000 or more in reasonably quan-
25 tifiable costs and such \$100,000,000 amount shall

1 “(8) the term ‘reasonable alternative’ means a
2 reasonable regulatory option ~~within the reasonable~~
3 ~~range of options~~ that would achieve the objective of
4 the rulemaking and that the agency has authority to
5 adopt under the statute granting rulemaking author-
6 ity, including flexible regulatory options; ~~unless such~~
7 ~~flexible regulatory options are precluded by the stat-~~
8 ~~ute granting the rulemaking authority.~~

9 “(9) the term ‘risk assessment’ has the same
10 meaning as such term is defined under section
11 631⁵(~~8~~); and

12 “(10) the term ‘rule’ has the same meaning as
13 in section 551(4) of this title, and shall not in-
14 clude—

15 “(A) a rule exempt from notice and public
16 comment procedure under section 553 of this
17 title;

18 “(B) a rule that involves the internal reve-
19 nue laws of the United States, or the assess-
20 ment and collection of taxes, duties, or other
21 revenue or receipts;

22 ~~“(C) a rule or agency action that author-~~
23 ~~izes the introduction into, or removal from,~~
24 ~~commerce, or recognizes the marketable status,~~
25 ~~of a product;~~

1 tem or the protection of deposit insurance funds
2 or Farm Credit Insurance Fund;

3 “~~(F)~~^F a rule or order relating to the finan-
4 cial responsibility of brokers and dealers or fu-
5 tures commission merchants, the safeguarding
6 of investor securities and funds or commodity
7 future or options customer securities and funds,
8 the clearance and settlement of securities, fu-
9 tures, or options transactions, or the suspension
10 of trading under the Securities Exchange Act of
11 1934 (15 U.S.C. 78a et seq.) or emergency ac-
12 tion taken under the Commodity Exchange Act
13 (7 U.S.C. 1 et seq.), or a rule relating to the
14 protection of the Securities Investor Protection
15 Corporation, that is promulgated under the Se-
16 curities Investor Protection Act of 1970 (15
17 U.S.C. 78aaa et seq.);

18 “~~(G)~~^G a rule issued by the Federal Election
19 Commission or a rule issued by the Federal
20 Communications Commission pursuant to sec-
21 tions 312(a)(7) and 315 of the Communications
22 Act of 1934 (47 U.S.C. 312(a)(7) and 315);

23 “~~(H)~~^H a rule required to be promulgated ~~at~~ ^{at regular}
24 ^{intervals} least annually pursuant to statute;

INSERT **A**

622 (a)(2). Notwithstanding the provision of paragraph 621(5), the Director may designate up to 25 rules in any calendar year as major rules if the Director determines that the rule is likely to adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities.

1 of the persons or classes of persons likely to
2 bear such costs; and

3 “(iii) an evaluation of the relationship of
4 the benefits of the proposed rule to its costs;

5 “(B) an evaluation of a reasonable number of
6 reasonable alternatives, including, where appropriate, alternatives that—

reflecting the range of regulatory options that could achieve the objective of the rulemaking

7 “(i) require no government action;

8 “(ii) accommodate differences among geo-
9 graphic regions and among persons with differ-
10 ing levels of resources with which to comply;
11 and
12

13 “(iii) employ flexible regulatory options;

14 “(C) a description of the ~~reliability~~ of scientific
15 or economic evaluations or information upon which
16 the agency substantially relied in the cost-benefit
17 analysis and any risk assessment required under this
18 chapter; and

19 “(D) if required under this chapter, a risk as-
20 sessment in accordance with subchapter III.

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

INSERT **B**

The agency evaluations of the relationships of the benefits of a proposed and final rule to its costs required by this section shall be clearly articulated in accordance with the provisions of this section.

INSERT **B**

Where a risk assessment has been prepared pursuant to subchapter III, the analysis of costs and benefits shall take into account the results of that risk assessment.

1 “(ii) either maximize net benefits or achieve
2 benefits in a more cost-effective manner than the
3 other reasonable alternatives evaluated by the agen-
4 cy that achieve the same or a substantially similar
5 level of benefits; and

*Insert D
(Next page)*

6 “(iii) provide benefits which justify the costs of
7 the rule unless scientific, technical, or economic un-
8 certainties identified by the agency in the rule-
9 making record make such a determination ~~infeasible~~
10 and the President determines it is appropriate and
11 in the public interest to issue the rule.

impracticable

12 “(B) Nothing in subparagraph (A)(iii) provides au-
13 thority for the agency to act when not otherwise author-
14 ized by law.

15 “(C) Any determination under this paragraph shall
16 be based upon the rulemaking record as a whole, including
17 the regulatory analysis required by section 622.

18 “(2) The agency shall publish in the Federal Register
19 at the time of promulgation of the final rule an expla-
20 nation of the determinations made with respect to this
21 subsection, and any required Presidential determination.

*and forward
to Congress*

22 “(3) The President may delegate the authority to
23 make a determination under this subsection only to the
24 Director of the Office of Management and Budget.

1 “(b) If the agency is unable to make the determina-
2 tion required under subsection (a)(1)(A)(iii) that the bene-
3 fits of the reasonable alternative it selected justify the
4 costs because the selection of ^{such}~~that~~ alternative is otherwise
5 required by law, the agency shall at the time the final rule
6 is published in the Federal Register, place in the Federal
7 Register and forward to Congress—

8 “(1) an explanation of the reason why such a
9 determination cannot be made; and

10 “(2) a statement regarding the statutory provi-
11 sions that required the agency to select an alter-
12 native for which the benefits do not justify the costs,
13 including any recommendation for amendments to
14 the statutory provisions and identification of other
15 possible regulatory options which could have benefits
16 that justify the costs and meet the objectives of the
17 statute.

18 “(c) The procedures for congressional review under
19 chapter 8 for a final major rule subject to subsection (b)
20 shall be modified as follows:

21 “(1) The time period under section
22 801(b)(2)(A) shall be 90 days instead of the 45-day
23 period specified under such subparagraph.

24 “(2) The time period of 20 calendar days under
25 section 801(i)(3) shall be 30 calendar days.

JUDICIAL REVIEW

(e) In any proceeding involving judicial review under section 706 or under the statute granting the rulemaking authority, the information contained in any cost-benefit analysis or risk assessment required under subchapter II or III may be considered by the court as part of the rulemaking record solely for the purpose of determining whether the final agency action is arbitrary, capricious or an abuse of discretion (or unsupported by substantial evidence where that standard is otherwise provided by law). The adequacy of compliance or the failure to comply with subchapter II or III shall not be grounds for remanding or invalidating a final agency action, unless the agency entirely failed to perform a required cost-benefit analysis or risk assessment or to conduct a peer review under section 642.

1 “(h) Nothing in this chapter is intended to modify
2 the rules of statutory construction applied by the courts.

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

4 “(a) All deadlines in statutes that require agencies
5 to propose or promulgate any major rule subject to section
6 622 or subchapter III during the 2-year period beginning
7 on the effective date of this section shall be suspended
8 until the earlier of—

9 “(1) the date on which the requirements of sec-
10 tion 622 or subchapter III are satisfied; or

11 “(2) the date occurring 6 months after the date
12 of the applicable deadline.

13 “(b) All deadlines imposed by any court of the United
14 States that would require an agency to propose or promul-
15 gate a major rule subject to section 622 or sub-
16 III during the 2-year period beginning on the effective
17 date of this section shall be suspended until the earlier
18 of—

19 “(1) the date on which the requirements of sec-
20 tion 622 or subchapter III are satisfied; or

21 “(2) the date occurring 6 months after the date
22 of the applicable deadline.

23 “(c) In any case in which the failure to promulgate
24 a major rule by a deadline occurring during the 2-year
25 period beginning on the effective date of this section would

1 Membership on the committee shall represent a balanced
2 cross-section of public and private interests affected by the
3 regulations of the agency, including small businesses and
4 small governments. No employee of the ~~Federal Govern~~ *agency convening the*
5 ment shall serve as a member of a committee under this *committee*
6 section.

7 “(2) Each member shall be appointed for the life of
8 the advisory committee. The advisory committee shall ter-
9 minate 1 year after the date on which the committee is
10 established.

11 “(3) A vacancy on a committee shall be filled in the
12 same manner as the original appointment.

13 “(4) Each committee shall solicit public participation
14 through appropriate means including hearings, written
15 comments, public meetings, and electronic mail.”

16 “(5) Members of each committee shall receive travel
17 expenses, including per diem in lieu of subsistence, in ac-
18 cordance with sections 5702 and 5703 of this title.

19 “(6) Each committee shall be subject to the provi-
20 sions of the Federal Advisory Committee Act (5 U.S.C.
21 App.).

22 **“§ 627. Agency regulatory review**

23 “(a) Each advisory committee appointed under sec-
24 tion 626 shall develop a list of rules promulgated by the
25 agency ~~which~~ *that* the committee serves, which the committee

1 “(8) the resources are expected to be available
2 to the agency to carry out the reviews under this
3 section.

4 “(8) No later than 6 months after an advisory com-
5 mittee is established, such committee shall deliver to the
6 agency the committee’s recommended list of rules to be
7 reviewed in order of priority. The agency shall immediately
8 publish the list in the Federal Register and forward a copy
9 of the list to the appropriate committees of jurisdiction
10 in the House of Representatives and the Senate.

11 “(9)(1) No later than 60 days after receiving and re-
12 viewing the list of rules from its committee, the agency
13 shall publish in the Federal Register a preliminary sched-
14 ule for review of rules based on such list. The agency shall
15 give deference to the recommendations of its advisory com-
16 mittee but may modify the list of rules to be reviewed,
17 taking into account the factors contained in subsection
18 (a).

19 “(2) The agency shall provide in the Federal Register
20 at the time the preliminary schedule is published an expla-
21 nation of each modification to the list provided by the ad-
22 visory committee and shall invite public comment on the
23 preliminary schedule for a period of no less than 60 days.

24 “(10) The preliminary schedule under this subsection
25 shall propose deadlines for review of each rule listed there-

*b) In developing
the list required
by subsection
a) each advisory
committee
shall obtain
comments
and suggestions
from the
public.*

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

4 “(i) addresses public comments generated
5 by the notice in subparagraph (A);

6 “(ii) contains a preliminary analysis by the
7 agency with respect to subsection (a) (1), (2),
8 (3), (4), and (5);

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

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

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

17 “(i) addresses public comments generated
18 by the notice in subsection (c);

19 “(ii) contains a determination to continue,
20 amend, or repeal the rule and an explanation of
21 such determination with respect to subsection
22 (a) (1), (2), (3), (4), and (5); and

23 “(iii) if the agency determines to amend or
24 repeal the rule, contains a notice of proposed
25 rulemaking under section 553.

1 or that would substantially decrease costs or increase ben-
2 efits while meeting the objectives of the rulemaking.

3 "SUBCHAPTER III—RISK ASSESSMENTS

4 "§ 631. Definitions

5 "For purposes of this subchapter, the definitions
6 under sections 551 and 621 shall apply, and—

7 "(1) the term 'assumption' means a reasonably
8 accepted principle, theory, or assertion that is reli-
9 able, relevant, and objective, ~~which may reasonably~~
10 ~~be used when relevant and adequate information~~
11 ~~about the specific site or substance is unavailable,~~

12 "(2) the term 'covered agency' means each
13 agency required to comply with this subchapter, as
14 provided in section 632;

15 ~~"(3) the term 'emergency' means an imminent~~
16 ~~or substantial endangerment to human health, safe-~~
17 ~~ty, or the environment.~~

*(already
in
cost-benefit
analysis
section)*

18 ³~~(2)~~ the term 'exposure assessment' means the
19 scientific determination of the intensity, frequency,
20 distribution, and duration of actual or reasonably
21 foreseeable exposures to the hazard in question;

22 ⁴~~(3)~~ the term 'hazard assessment' means the
23 scientific determination of whether a substance, ac-
24 tivity, or condition can cause an increased incidence
25 of one or more significant adverse effects, and a sci-

²⁷ the primary purpose of which is

1 connection with a major rule ~~addressing~~ health, safety,
2 and environmental risks by—

3 “(1) the Secretary of Defense, for environ-
4 mental restoration and waste management pro-
5 grams, and for programs and responsibilities of the
6 United States Army Corps of Engineers:

7 “(2) the Secretary of the Interior, for programs
8 and responsibilities of the Office of Surface Mining
9 Reclamation and Enforcement;

10 “(3) the Secretary of Agriculture, for programs
11 and responsibilities of—

12 “(A) the Animal and Plant Health Inspec-
13 tion Service;

14 “(B) the Grain Inspection, Packers, and
15 Stockyards Administration;

16 “(C) the Food Safety and Inspection Serv-
17 ice;

18 “(D) the Forest Service; and

19 “(E) the Natural Resources Conservation
20 Service;

21 “(4) the Secretary of Commerce, for programs
22 and responsibilities of the National Marine Fisheries
23 Service;

24 “(5) the Secretary of Labor, for programs and
25 responsibilities of—

1 rector of the Office of Management and Budget, shall de-
2 termine whether any other Federal agency or specific pro-
3 gram under a Federal agency should be considered a cov-
4 ered agency. Such determination, with respect to a par-
5 ticular Federal agency or program, shall be based on the
6 importance of risk assessment and risk characterization
7 to—

8 “(A) regulatory programs administered by that
9 agency; and

10 “(B) the communication of risk information by
11 that agency to the public.

12 “(2) If the President makes a determination under
13 paragraph (1), the requirements of this subchapter shall
14 apply to any agency determined to be a covered agency
15 beginning on a date set by the President. Such date shall
16 be no later than 6 months after the date of such deter-
17 mination.

18 “(c)(1) This subchapter shall not apply to risk assess-
19 ments performed with respect to—

20 “(A) an emergency ^{under 622(g); or} ~~determined by the head of~~
21 ~~an agency;~~

22 “(B) a health, safety, or environmental inspec-
23 tion, compliance or enforcement action, or individual
24 facility permitting action; ~~or,~~

25 ~~“(C) a screening analysis.~~

1 **“§ 634. Principles for risk assessments**

2 “(a) Each agency shall design and conduct risk as-
3 ~~sessments for each proposed and final major rule~~ *in accordance with this chapter* in a
4 manner that promotes rational and informed risk manage-
5 ment decisions and informed public input into and under-
6 standing of the process of making agency decisions.

7 “(b) Each agency shall consider in each risk assess-
8 ment reliable and reasonably available scientific informa-
9 tion and shall describe the basis for selecting such sci-
10 entific information.

11 “(c)(1) Each agency may use assumptions, ~~including~~
12 ~~inferences, models, or safety factors~~; unless relevant and
13 adequate scientific information, including site-specific or
14 substance-specific information, is available, ~~which materi-~~
15 ~~ally affects the agency decision.~~

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

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

22 “(B) explain the basis for any choices among
23 assumptions and, where applicable, the basis for
24 combining multiple assumptions; and

25 “(C) describe reasonable alternative assump-
26 tions that were not selected by the agency for use

1 ^f~~(e)~~ To the extent scientifically appropriate, each
2 agency shall—

3 “(1) express the overall estimate of risk as ~~one~~
4 ^{a reasonable}~~or more~~ ranges or probability distributions that re-
5 flects variabilities and uncertainties in the analysis;

6 “(2) provide the range and distribution of risks
7 and the corresponding exposure scenarios, identify-
8 ing the range and distribution and likelihood of risk
9 to the general population and to more highly ex-
10 posed or sensitive subpopulations; and

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

14 “(f) When scientific information that permits rel-
15 evant comparisons of risk is reasonably available, the
16 agency shall use the information to place the nature and
17 magnitude of a risk to human health, safety, and the envi-
18 ronment being analyzed in relationship to other risks.
19 Such comparisons should consider relevant distinctions
20 among risks, such as the voluntary or involuntary nature
21 of risks.

22 “(g) When scientifically appropriate information ^{of}~~of~~
23 significant substitution risks to human health, safety, or
24 the environment is reasonably available to the agency, the
25 agency shall describe such risks in the risk assessment.

1 representatives of industry, universities, agriculture,
2 labor consumers, conservation organizations, or
3 other public interest groups and organizations;

4 “(2) may exclude any person with substantial
5 and relevant expertise as a panel member ^{or participant} on the
6 basis that such person represents ^{another person} ~~an entity~~ that may
7 have a potential financial interest in the outcome, or
8 may include such person if such interest is fully dis-
9 closed to the agency, and in the case of a regulatory
10 decision affecting a single ^{person} ~~entity~~, no peer reviewer
11 representing such ^{person} ~~entity~~ may be included; ~~on the~~
12 ~~panel~~;

*and included
in the
rulemaking
file,*

13 “(3) shall provide for a timely completed peer
14 review, meeting agency deadlines, that contains a
15 balanced presentation of all considerations, including
16 minority reports and an agency response to all sig-
17 nificant peer review comments; and

18 “(4) shall provide adequate protections for con-
19 fidential business information and trade secrets, in-
20 cluding requiring panel members ^{or participants} to enter into con-
21 fidentiality agreements.

22 “(b)(1) Each covered agency shall provide for peer
23 review in accordance with this section of any ^{cost-benefit analysis or} risk assess-
24 ment that forms the basis of any major rule ^{the primary purpose} that addresses
25 ~~risks to the environment, health, safety, and energy~~

77

1 tion 622, and the risk assessment principles under section
2 634.

3 “(b) The development, issuance, and publication of
4 guidelines under this section shall not be subject to judi-
5 cial review.

6 “(c) Each covered agency shall publish, after notice
7 and public comment, guidelines for the conduct of risk as-
8 sessments not required by this subchapter that adapt the
9 principles of this subchapter in a manner consistent with
10 section 634(a)(2) and the risk assessment and risk man-
11 agement needs of the agency.

12 **“§ 644. Research, training, and coordination**

13 “(a) To promote the conduct, application, and prac-
14 tice of cost-benefit analysis and risk assessment in a con-
15 sistent manner and to identify agency data and research
16 needs, the Director, in consultation with the Office of
17 Science and Technology Policy, shall—

18 “(1) oversee periodic evaluations of Federal
19 agency cost-benefit analysis and risk assessment in-
20 cluding, where relevant and appropriate, research
21 needs to—

22 “(A) reduce generic data gaps, to address
23 modeling needs (including improved model sen-
24 sitivity), and to validate assumptions, particu-

1 in the development and application of cost-benefit
2 analysis and risk assessment.

3 **“§ 645. Judicial review**

4 *Except for the provisions of section 624(c),*
5 *“There shall be no judicial review of agency decisions*
6 *or actions made under this subchapter.*

6 **“SUBCHAPTER V—EXECUTIVE OVERSIGHT**

7 **“§ 651. Definitions**

8 “For purposes of this subchapter—

9 “(1) the definitions under sections 551 and 621
10 shall apply; and

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

13 “(A) An agenda or schedule for
14 rulemakings.

15 “(B) Advance notice of proposed
16 making.

17 “(C) Notice of proposed rulemaking.

18 “(D) Proposed final rulemaking and in-
19 terim final rulemaking.

20 **“§ 652. Presidential regulatory review**

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

1 **“§ 653. Public disclosure of information**

2 “The Director, in carrying out the provisions of sec-
3 tion 652, shall establish procedures to provide public and
4 agency access to information concerning regulatory review
5 actions, including—

6 “(1) disclosure to the public on an ongoing
7 basis of information regarding the status of regu-
8 latory actions undergoing review;

9 “(2) disclosure to the public, no later than pub-
10 lication of a regulatory action, of—

11 “(A) all written communications, regard-
12 less of form or format, including drafts of all
13 proposals and associated analyses, between the
14 Director or employees of the Director and the
15 regulatory agency;

16 “(B) all written communications, regard-
17 less of form or format, between the Director or
18 employees of the Director and any person not
19 employed by the executive branch of the Fed-
20 eral Government relating to the substance of a
21 regulatory action;

22 “(C) a record of all oral communications
23 relating to the substance of a regulatory action
24 between the Director or employees of the Direc-
25 tor and any person not employed by the execu-
26 tive branch of the Federal Government; and

1 ~~thorized by section 611(a) of title 5, United States~~
 2 Code (as added by subsection (a)), shall apply only
 3 to final agency rules issued after such effective date.

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

10 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

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

15 **“CHAPTER 6—THE ANALYSIS OF**
 16 **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. Regulatory analysis.
- “623. Decisional criteria.

1 ~~efficiently reduce risks to human health, safety, and the~~
2 ~~environment.~~

3 (f) SAVINGS PROVISION AND JUDICIAL REVIEW.—

4 (1) IN GENERAL.—Nothing in this section shall
5 be construed to modify any statutory standard or re-
6 quirement designed to protect human health, safety,
7 or the environment.

8 (2) JUDICIAL REVIEW.—Compliance or non-
9 compliance by an agency with the provisions of this
10 ~~section shall not be subject to judicial review.~~

11 **SEC. 7. EFFECTIVE DATE.**

12 Except as otherwise provided in this Act, this Act
13 shall take effect 180 days after the date of the enactment
14 of this Act, but shall not apply to any agency rule for
15 which a general notice of proposed rulemaking is published
16 on or before such date.

AMENDMENT NO. _____

Calendar No. _____

IN THE SENATE OF THE UNITED STATES—104th Cong., 2d Sess.

S. _____

To amend subchapter IV of chapter 5 of title 5, United States Code, relating to alternative means of dispute resolution in the administrative process, and for other purposes.

AMENDMENT intended to be proposed by Mr. JOHNSTON (for himself and _____)

1 Viz:

2 At the end of the Committee amendment add the following:

3 **SEC. __. ELIMINATION OF REDUNDANT ADMINISTRATIVE**
4 **REQUIREMENTS AFFECTING NEGOTIATED RULEMAKING**

5 (a) Section 564 of title 5, United States Code, is amended
6 by adding at the end the following:

7 “(d) The publication of notice under subsection (a) and the
8 period for comment under subsection (c) shall be in lieu of any
9 requirement for notice or for filing an advisory committee
10 charter under sections 9 or 14 of the Federal Advisory
11 Committee Act.”

12 (b) Section 567 of title 5, United States Code, is amended
13 to read as follows:

14 “Notwithstanding section 14 of the Federal Advisory
15 Committee Act, a negotiated rulemaking committee shall

1 terminate upon promulgation of the final rule under
2 consideration, unless the agency, after consulting the committee,
3 or the committee itself specifies an earlier termination date."

EXPLANATION OF THE AMENDMENT

SECTION __

Section __, added by this amendment, eliminates two points of redundancy between the Negotiated Rulemaking Act of 1990 (NRA) and the Federal Advisory Committee Act (FACA).

Subsection __ (a) deals with the redundancy between the mechanisms in the NRA for public notification at the establishment of a negotiated rulemaking committee and the advisory committee chartering process in the FACA. The requirement of FACA to prepare and publish charters, every two years, for advisory committees is made redundant by the requirement in section 564 for extensive notification of the public regarding the establishment of a negotiated rulemaking committee (including publication "in the Federal Register and, as appropriate, in trade or other specialized publications" and for a public comment period of at least 30 days. Further, since it is envisioned by the NRA that negotiated rulemaking committees routinely remain in existence until the publication of a final rule (which may take several years), there would seem to be little point in forcing a rechartering of the negotiated rulemaking committee on an arbitrary two-year schedule. Finally, the formal chartering process under FACA, in practice, involves numerous levels of review within agencies and is often a time-consuming bureaucratic step. Since the purpose of the NRA is to encourage this innovative form of rulemaking, any such bureaucratic step (and particularly one that must be accomplished before the committee can meet or take any substantive action) needs to play a unique and valuable role, which is not the case for chartering. Thus, the carrying out of the requirements of section 564(a) and (c) are made to be in lieu of any requirement for an advisory committee charter, and negotiated rulemaking committees can thus begin to meet once the public comment period under section 564(c) has expired.

Section __ (b) deals with the automatic sunset, every two years, of advisory committees under FACA (unless rechartering takes place). As noted above, section 567 of title 5 envisions a limitation on the life of the negotiated rulemaking committee that is organically related to the rulemaking process itself, and also provides for the agency to specify another termination date, after consultation with the committee. The sunset provision in section 14 of FACA (which may be appropriate for advisory committees that do not have their scope and activities tied to a fixed agency decision) does not serve a useful purpose in the context of the NRA, and so section 567 is amended and made to apply in lieu of section 14 of FACA.

AMENDMENT NO. _____

Calendar No. _____

IN THE SENATE OF THE UNITED STATES—104th Cong., 2d Sess.

S. _____

AMENDMENT intended to be proposed by Mr. JOHNSTON (for himself and _____)

1 Viz:

2 At the end of the [bill] [Committee amendment] add the
3 following:

4 SEC. __. RULE MAKING.

5 Section 553(b)(A) of title 5, United States Code, is
6 amended to read as follows:

7 "(A) to interpretative rules, general statements of policy,
8 guidance, or rules of agency organization, procedure, or practice
9 (and such rules, statements, or guidance shall not have general
10 applicability and substantially alter or create rights or
11 obligations of persons outside the agency); or"

EXPLANATION OF THE AMENDMENT

SECTION __

Section __, added by this amendment, amends section 553 of title 5, United States Code, governing informal (notice and comment) rulemaking. Section 553 was initially enacted as section 4 of the Administrative Procedure Act, or APA (P.L. 79-404, June 11, 1946, 60 Stat. 237), and was recodified to section 553 by Public Law 89-554 (September 6, 1966, 80 Stat. 383).

The current section 553(b)(A) contains an exemption for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." This exemption does not apply to the entire section 553, but only to the requirement for general notice of proposed rulemaking (and the related requirements governing informal rulemaking procedure in section 553(c)).

This amendment clarifies that the "interpretative rules, general statements of policy, guidance, or rules of agency organization, procedure" which are exempt from notice-and-comment procedures under section 553(b)(A) cannot have "general applicability and substantially alter or create rights or obligations of persons outside the agency." It reinforces, in statutory language, the distinctions that have evolved in administrative case law between such agency statements and rules with the force and effect of law that must be promulgated, under section 553, using notice-and-comment procedures.

The following discussion treats each part of this key phrase, focusing first on the principle of general applicability, then on the principle of creation of rights or obligations (or "binding effect"), and finally on considerations of the difference between binding effects within the agency and outside the agency. These principles are discussed specifically in relation to interpretative rules, general statements of policy, and guidance. Rules of agency organization, procedure, or practice are discussed separately at the end of this section.

General applicability. The language in this section allows an agency to issue interpretations, policy statements, or guidance, that is applicable to a particular person for a particular regulated situation without following section 553 rulemaking procedures. The agency is not able to use that process of individualized interpretations, though, to address matters of general applicability to a larger number of individuals or groups if such an "interpretation" will be applied so as to substantially alter or create a right of such a larger number of persons outside the agency. It is intended that a person affected by the sort of "interpretation" described in the

preceding sentence would be entitled to assert that such "interpretation" was in fact a legislative rule. But that person would have to demonstrate that the rule had general applicability and that a class of persons beyond the individual and outside the agency, after adoption of that interpretation or policy statement, had been given substantially new rights or obligations or had rights or obligations which had been substantially altered.

Legislative and non-legislative rules. The distinction between (1) rules that have the force and effect of law and hence are subject to notice-and-comment rule making under section 553 (hereinafter referred to as "legislative rules") and (2) other kinds of agency statements about laws and their requirements has been the subject of extensive case law and legal commentary over the years. The APA does not explicitly invoke the term "legislative rule" to describe what must be subject to notice and comment rulemaking, but rather discusses the types of "rules" (under the broad definition in section 551(4)) that should be exempt from notice and comment. Current case law has exhaustively probed the distinctions among legislative rules, interpretative rules, and general statements of policy and guidance. See K.C. Davis and R.J. Pierce, Jr., *Administrative Law Treatise*, Third Edition, 225-248 (hereinafter referred to as the "*Treatise*").

Legislative rules vs. interpretative rules. There are three important differences between legislative rules, which are subject to notice and comment rulemaking, and interpretative rules, which are exempt from the notice and comment requirement. The distinctions have been well established in Supreme Court decision making for more than half a century. Cf. *American Telephone & Telegraph Co. v. United States*, 299 U.S. 232 (1936) and *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). These distinctions are preserved in this amendment. First, a legislative rule has the same binding effect as a statute. It binds members of the public, the agency, and even the courts, in the sense that courts must affirm a legislative rule as long as it represents a valid exercise of agency authority. By contrast, an interpretative rule that interprets a statute is not binding, of itself, on courts or the public. A court may give binding effect to a position taken by an agency in such an interpretative rule, but in such a case it is the court that provides the binding effect, and the agency's position only serves as a potentially persuasive position for the court to adopt. Second, an agency has the power to issue a legislative rule only if and to the extent Congress has authorized it to do so. By contrast, any agency has the inherent power to issue interpretative rules. Third, a legislative rule can impose distinct obligations on members of the public in addition to those imposed by statute, as long as the rule is within the scope of rulemaking authority conferred on the agency by statute. By contrast, an interpretative rule cannot impose obligations on citizens that exceed those fairly attributable to Congress through

the process of statutory interpretation. (In the case of an interpretative rule that explains a statutory provision containing a mandate, the language of the interpretative rule might use mandatory language in spelling out the pre-existing duty contained in legislation, without thereby becoming a legislative rule—while the use of mandatory language in a purported statement of general policy or guidance might indicate that the agency statement is actually a legislative rule.)

These considerations are consistent with a number of tests used by the court in *American Mining Congress v. Mine Safety and Health Administration*, 995 F.2d 1106 (D.C. Cir. 1993). In distinguishing between interpretative rules and legislative rules, the court concluded that an agency statement is a legislative rule, and not an interpretative rule, if any of the following questions can be answered in the affirmative: “whether in the absence of the rule there would not be an adequate legal basis for enforcement action or other agency action to confer benefits or ensure the performance of duties” (i.e., whether there are distinct obligations in addition to those in the statute), “whether the agency has explicitly invoked its general legislative authority” (i.e., whether the agency, in making the statement, is invoking its power to issue legislative rules), or “whether the rule effectively amends a prior legislative rule” (i.e., an alteration to a legislative rule can only be made by another legislative rule). 995 F.2d at 1112. A fourth test mentioned in *American Mining Congress*, whether the agency has published the rule in the Code of Federal Regulations (drawing on the authority in 44 U.S.C. 1510 for the publication of a Code of Federal Regulations containing “the documents of each agency of the Government having general applicability and legal effect”), was subsequently qualified in large measure by the same circuit in *Health Insurance Association v. Shalala*, 23 F.3d 412, 423 (D.C. Cir. 1994) (publication in the Code of Federal Regulations is no more than “a snippet of evidence of agency intent”), and a close reading of 44 U.S.C. 1510 shows that even this qualified test is not persuasive. Nothing in section 1510 prohibits or discourages the publication of interpretative rules or other agency statements in the Code of Federal Regulations, and many agencies use the Code to publish their most important interpretative rules and policy statements. Such publication facilitates the access of affected members of the public to the most important agency interpretations and policies, and should be encouraged. In distinguishing between legislative rules and interpretative rules (or other agency statements) under the changes to section 553(b) made by this amendment, it is not intended that courts apply the test that any rule published in the Code is *ipso facto* a legislative rule (see the next section for related comments about the lack of usefulness of “form” tests for distinguishing between legislative rules and other agency statements). Such a test will prevent agencies from publishing their most important interpretative rules and policy statements in the

Code out of a concern that such publication will expose those agency statements to invalidation on the basis that they were actually legislative rules issued without notice and comment.

Revenue rulings issued by the Internal Revenue Service are common examples of what this amendment conceives of as genuine interpretative rules, exempted from normal rulemaking procedures under this new section 553(b)(A). Where a Revenue Ruling assists citizens in complying with the tax laws, but does not create new rights or obligations, or alter those that exist, it will be exempted from notice and comment procedures as an interpretative rule.

Legislative rules vs. general statements of policy and guidance. The notion of "binding effect" is also useful in distinguishing legislative rules from general statements of policy and guidance, although in a slightly different way than for the case of distinguishing legislative rules from interpretative rules (*Cf.*, the discussion of mandatory language in interpretative rules to the following discussion). Many agency statements cause considerable confusion to the public and the courts because of the agency's choice of language to characterize the effect that the agency intends to have. An agency sometimes characterizes the intended effect of its statement in the language of command in one passage, e.g., "regulatees must," and in the language of preference in other passages, e.g., "regulatees should." Sometimes, the mixture of such language is simply a reflection of pre-existing rights and obligations contained in the law or legislative rule being described in the agency statement. Sometimes, though, such ambiguity is due to sloppiness or indecision, and sometimes such ambiguities are created intentionally for strategic purposes. For example, a statement labeled as (or in the "form" of) a general statement of policy or a guidance document can have coercive effects, to the extent that an agency possesses significant discretionary power over a class of regulatees who "comply voluntarily" with an agency's nonbinding, statement of its preferred policies. As the *Treatise* notes, in these and similar cases:

"An agency might want to issue a statement that has binding effect without following the notice and comment procedures mandated for legislative rulemaking and without subjecting its statement to the kind of "searching and careful" judicial review courts typically apply to legislative rules. To further these illegitimate strategic goals, an agency might intentionally use ambiguous or inconsistent language in the hope that its regulatees will give its statement binding effect while the courts will characterize the statement as an unreviewable general statement of policy exempt from notice and comment procedures.

"The beauty of the 'binding effect' test lies in its ability to frustrate agency attempts to use ambiguity to further illegitimate strategic goals. A court may interpret an ambiguous

statement as binding or not binding, but the agency cannot have it both ways. If the court concludes that the agency statement is binding in some important respect, it will hold that the statement is a 'rule' that can be promulgated only through the use of rulemaking procedures and that is potentially reviewable to the same extent as any other rule. If instead the court concludes that the statement is a general statement of policy, courts will not permit the agency to give its statement binding effects on members of the public."

(Treatise at 229)

This amendment takes the view that the practical impact intended by an agency in making its statement is the appropriate guide to use in determining whether that statement is a legislative rule or a statement of general policy or guidance. The mere fact that an agency describes a rule as an interpretative rule or as guidance or as a general statement of policy, or the mere fact that the "form" of the rule is that of some other kind of agency statement, cannot serve as a standard for determining whether or not it is a legislative rule. If the court concludes that an agency statement is intended to have binding effects outside the agency, and is serving as an independent source of those binding effects, the court should review the statement with reference to the same substantive and procedural criteria that would apply if it were promulgated as a legislative rule.

This view is supported by ACUS Recommendation No. 92-2, "Agency Policy Statements." As in this amendment, ACUS decided that the "binding effect" test should be keyed to the practical impact of the agency statement: "A document that was not issued pursuant to section 553, and therefore cannot be binding legally, may nevertheless be binding as a practical matter if the agency treats it as dispositive of the issue that it addresses." ACUS, "Agency Policy Statements (Recommendation No. 92-2)," 1 C.F.R. §305-92-2 (1993), n.3. In the commentary on its recommendation, ACUS stated:

"The Conference is concerned, however, about situations where agencies issue policy statements which they treat or which are reasonably regarded by the public as binding and dispositive of the issues that they address. The issuance of such binding pronouncements as policy statements does not offer the opportunity for public comment which is normally afforded during the notice-and-comment rulemaking process for rules which have the force of law. Courts have frequently overruled agency reliance on policy statements as binding on affected persons.

"Where the policy statement is treated by the agency as binding, it operates effectively as a legislative rule but without the notice-and-comment protection of section 553. It may be difficult or impossible for affected persons to challenge the policy statement

within the agency's own decisional process; they may be foreclosed from an opportunity to contend that the policy statement is unlawful or unwise, or that an alternative policy should be adopted.... The public is therefore denied the opportunity to comment and the agency is denied the educative value of any facts or arguments the party may have tendered. The Conference believes that this outcome should be avoided...."

In *Pacific Gas & Electric Co. v. Federal Power Commission*, 506 F.2d 33, 38 (D.C. Cir. 1974), the court provided a useful test of whether a agency statement is "binding and dispositive": "when the agency applies the policy in a particular situation, it must be prepared to support the policy just as if the policy statement had never been issued." If the agency provides a reasonably accessible and credible forum for affected persons to challenge both a policy statement (or guidance) and its application, *de novo*, when the policy statement is applied, it will probably avoid situations in which the agency statement is "reasonably regarded by the public as binding and dispositive of the issues."

The Administrative Conference specifically recommended that agencies specifically state in agency statements of general policy that they wish to promulgate under the exemption in section 553(b)(A) that such statements are not binding, and that this nonbinding nature be, to the extent practicable, "communicated to all persons who apply them or advise on the basis of them, including agency staff, counsel, administrative law judges, and relevant state officials." This sound suggestion would be an excellent way in which to implement this section.

The preceding discussion is not meant to imply that general statements of policy or guidance need have no effect at all. As the court observed in *Pacific Gas & Electric Co.*, nonbinding agency statements may have many effects:

"As an informational device, the general statement of policy encourages public dissemination of the agency's policies prior to their actual application in particular situations. Thus, the agency's initial views do not remain secret but are disclosed well in advance of their actual application. Additionally, the publication of a general statement of policy facilitates long range planning within the regulated industry and promotes uniformity in areas of national concern." *Id.*

These same considerations would be true of other forms of agency guidance, as well.

Binding Effect Required to Be Outside the Agency. Additionally, the language in the revised section 553(b)(A) stipulates that these binding effects take place on persons outside the agency. This is intended to permit statements of general policy to "bind," or affect the discretion of, an agency or its staff without triggering the notice and comment provisions of section 553. A

binding by the agency of its own discretion does not, by itself, "substantially alter or create rights or obligations of persons outside the agency" within the meaning of this revision of section 553(b)(A). This point is generally consistent with contemporary administrative case law, but intentionally runs counter to one circuit court opinion, in *Community Nutrition Institute v. Young*, 818 F.2d 943 (D.C. Cir. 1987), which held that policy statements that purport to "bind" agency staff could only be issued through use of notice and comment rulemaking. This amendment is in accordance with the view expressed in the *Treatise* that:

"That holding would create horrible incentives for agencies if it were followed generally...If agencies are allowed to establish policies that limit their discretion and that of their employees only through use of expensive and time-consuming notice and comment procedure, they rarely will choose to limit their discretion at all or to limit the discretion of their employees charged with enforcement and prosecutorial responsibilities. Thus, the holding in *Community Nutrition* inevitably would yield an administrative law system in which tens of thousands of individual agency employees have virtually unconstrained discretion and in which neither affected members of the public nor politically accountable government officials would be able to predict the action of those employees." *Treatise* at 232-233.

The Administrative Conference also supports the intent of this amendment on this point, in its recommendation on "Agency Policy Statements," by stating that agencies should not be precluded:

"from making a policy statement which is authoritative for staff officials in the interest of administrative uniformity or policy coherence. Indeed, agencies are encouraged to provide guidance to staff in the form of manuals and other management directives as a means to regularize employee action that directly affects the public. However, they should advise staff that while instructive to them, such policy guidance does not constitute a standard where noncompliance may form an independent basis for action in matters that determine the rights and obligations of any person outside the agency."

ACUS, *Id.*

This ACUS recommendation also includes a number of other provisions that are commended to the attention of agencies, as it will help them to better implement the principles underlying section 553(b)(A), as amended here.

Rules of Agency Organization, Procedure, or Practice. This amendment retains the existing exemption in the APA for rules of agency organization, procedure, or practice. This

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exemption has proved difficult for courts to apply in the past, particularly in the gray area comprising rules that could be characterized equally as well as being substantive, and hence legislative, or as being procedural. As the *Treatise* notes: "There are scores of lower court opinions that apply the procedure[-]substance distinction to a wide variety of agency rules that are difficult to classify. They form an untidy body of law that defies accurate summary treatment." *Treatise* at 250. In applying the exemption for rules of agency organization, procedure, and practice, it is intended that agencies and courts apply the standard contained in the Administrative Conference's recommendation on "The Procedural and Practice Rule Exemption from the APA Notice and Comment Rulemaking Requirements (Recommendation No. 92-1)," 1 C.F.R. §305-92-1 (1993):

"A rule is within the terms of the exception when it both (a) relates solely to agency methods of internal operations or of interacting with regulated parties or the public, and (b) does not (i) significantly affect conduct, activity, or a substantive interest that is the subject of agency jurisdiction, or (ii) affect the standards for eligibility for a government program."

ACUS further defined the term "program" in the above standard as being "meant to be interpreted broadly to include, among others, those involving benefits, contracts, licenses, permits, and loan guarantees."

This amendment supports this scope for the exemption from the requirements of section 553. For example, then, rules such as those governing conduct of formal hearings or appeals, ex parte rules, and rules concerning the business hours of the agency would be exempt. In contrast, rules setting criteria for determining the severity of enforcement sanctions, levels of civil money penalties, or application requirements that serve to limit eligibility for a government benefit program would not be able to use this exemption from notice and comment procedures.

AMENDMENT NO. _____

Calendar No. _____

IN THE SENATE OF THE UNITED STATES—104th Cong., 2d Sess.

S. _____

AMENDMENT intended to be proposed by Mr. JOENSTON (for himself and _____)

1 Viz:

2 At the end of the [bill] [Committee amendment] add the
3 following:

4 **SEC. __. RESPONSE TO PETITIONS:**

5 Section 553(e) of title 5, United States Code, is amended—

6 (1) by inserting “(1)” before “Each”; and

7 (2) by adding at the end the following paragraphs—

8 “(2) The agency shall take final agency action to grant
9 or deny a petition made under paragraph (1), and give
10 written notice of its action to the petitioner, including an
11 explanation of its reasons for granting or denying the
12 petition, with reasonable promptness, but in no event later
13 than 18 months after the petition was received by the
14 agency.

15 “(3) In acting on a petition made under paragraph (1),
16 the agency shall consider the availability of its resources

- 1 and evaluate the effect of granting the petition on achieving
- 2 statutory objectives.”

EXPLANATION OF THE AMENDMENT

SECTION __

Section __, added by this amendment, amends section 553(e) of title 5, United States Code, governing petitions for informal (notice and comment) rulemaking, to provide requirements governing agency handling of petitions received under section 553(e).

Section 553(e) states that "Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule." Subsection (e) does not apply to categories of rules made exempt from notice and public comment procedure by section 553(a), but other than rules in the topical areas listed in section 553(a), section 553(e) generally applies to "rules" as defined in section 551(4), including legislative rules, interpretative rules, general statements of policy, and organizational and procedural rules.

Inherent in the right to petition is the right to a response to the merits of the petition. In this regard, it appears that the drafters of the original APA intended that the identical requirements in section 555(e) ("Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person made in connection with any agency proceeding. Except in affirming a prior denial or when the denial is self-explanatory, the notice shall be accompanied by a simple statement of procedural or other grounds." 60 Stat. 240) apply to denials of petitions for rule making under section 553(e). Sen. Report No. 97-305, 97th Cong., 1st Sess., 31 (1981). It also appears that the original APA envisioned some degree of judicial involvement. "The facts or considerations brought to the attention by the agency by such a petition might be such as to require the agency to act to prevent the rule from continuing or becoming vulnerable upon judicial review." Sen. Doc. No. 248, 79th Cong., 2d Sess., 201-202 (1946).

Thus, under current case law, the "rejection" of a petition on a summary basis may be remanded with instructions that the agency deny the petition on the merits and state the reasons for doing so. *National Organization for the Reform of Marijuana Laws v. Ingersoll*, 497 F.2d 292 (D.C. Cir. 1971). The D.C. Circuit has also held that agency denials of petitions for rule making are generally subject to judicial review, but with an "extremely narrow" scope of review. *WWHT v. FCC*, 656 F.2d 807, 818 (D.C. Cir. 1981). The courts have generally applied a deferential standard when reviewing agency denials of petitions or when reviewing agency decisions not to issue rules, after conducting a rule making in response to a petition. For

example, in the latter situation, the D.C. Circuit has held that this degree of deference to the agency, "while not extreme, is very substantial." *Consumer Federation v. Consumer Product Safety Commission*, 990 F.2d 1298, 1305 (D.C. Cir. 1993).

The purpose of this amendment, then, is to clarify and codify the case law in this area, to prevent further occurrences of instances where petitions have languished for years awaiting an agency response. Thus, agencies are instructed to provide a dispositive response to petitions under section 553(e) within 18 months, along with a statement of the reasons for granting or denying the petition. The existing right to judicial review of such agency action, under the prevailing standard of review, is affirmed. Availability of agency resources or other statutory mandates are explicitly named as factors that agencies may take into account in responding to petitions.

These changes are not intended to permit the harassment of agencies with petitions and lawsuits. As Judge Leventhal stated in *Oljato Chapter of the Navajo Tribe v. Train*, 515 F.2d 654, 666-667 n. 19 (D.C. Cir. 1975), "We are by no means demanding comprehensive responses to frivolous petitions, but nor are we sanctioning summary dismissals of meritorious claims...." These changes are premised on the belief that agencies should respond seriously, and within a reasonable time, to petitions from the public.

AMENDMENT NO. _____

Calendar No. _____

IN THE SENATE OF THE UNITED STATES—104th Cong., 2d Sess.

S. _____

AMENDMENT intended to be proposed by Mr. JOHNSTON (for himself and _____)

1 Viz:

2 At the end of the [bill] [Committee amendment] add the
3 following:

4 SEC. ____ REASONABLE AND GOOD-FAITH RELIANCE ON
5 AGENCY INTERPRETATIONS AND DETERMINATIONS

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

8 "§ 707. Agency interpretations in civil and criminal actions.

9 "(a) No civil or criminal sanction shall be imposed by a
10 court, and no civil administrative sanction shall be imposed by
11 an agency, for the violation of a rule if the court or agency, as
12 appropriate, finds that—

13 "(1) the rule, other information published by the
14 agency under section 552(a)(1) or section 553 of this title
15 (or other applicable rule making authority), and other
16 written agency information directly and specifically
17 communicated to the defendant prior to the violation, failed

1 to give the defendant fair warning that the conduct engaged
2 in by the defendant violates the rule;

3 "(2) the defendant, reasonably and in good faith
4 determined, prior to the alleged violation, based on the
5 information described in paragraph (1), that the defendant
6 was in compliance with, exempt from, or not otherwise
7 subject to, the requirements of the rule;

8 "(3) the defendant engaged in the conduct alleged to
9 violate the rule in reasonable reliance upon a written
10 statement from an appropriate agency official, or from an
11 appropriate official of a State authority to which had been
12 delegated responsibility for implementing or ensuring
13 compliance with the rule, after good-faith disclosure of the
14 facts that were material at the time of the determination
15 (including any facts requested at the time by the agency or
16 State authority) and after appropriate review, stating that
17 the action was in compliance with, or that the defendant
18 was exempt from, or otherwise not subject to, the
19 requirements of the rule; or

20 "(4) the proposed sanction is based upon--

21 "(A) an interpretation of a statute, rule, guidance,
22 agency statement of policy, or license requirement or
23 condition which is materially different from a prior
24 interpretation; or

1 “(B) a determination of fact made by an
2 appropriate agency official, or a State official
3 described in paragraph (3), which is materially
4 different from a prior determination of fact made by
5 the agency or the State authority, after good-faith
6 disclosure of the facts that were material at the time of
7 the determination (including any facts requested at the
8 time by the agency or State authority) and after
9 appropriate review; and—

10 the defendant, having taken into account all information
11 described in paragraph (1) that was reasonably available at
12 the time of the original interpretation or determination,
13 reasonably and in good faith relied upon the prior
14 interpretation or determination.

15 “(b) In determining whether a defendant’s determination or
16 reliance under subsection (a) was reasonable, the court or
17 agency shall consider, as appropriate, whether—

18 “(1) the defendant was qualified to make a
19 determination under subsection (a)(2) or sought competent
20 advice from a qualified person;

21 “(2) the defendant sought a determination under
22 subsection (a)(3) or subsection (a)(4)(B) in good faith; or

23 “(3) the agency or State official who provided a
24 determination under subsection (a)(3) or subsection
25 (a)(4)(B) had the authority to do so.

1 “(c) Nothing in this section shall be construed—

2 “(1) to preclude an agency from revising a rule or
3 changing its interpretation of a rule in accordance with
4 section 552(a)(1) or section 553 of this title (or other
5 applicable rule making authority) and, subject to the
6 provisions of this section, from prospectively enforcing the
7 requirements of such rule, as revised or reinterpreted, and
8 imposing or seeking civil or criminal penalty for any
9 subsequent violation of such rule, as revised or
10 reinterpreted; or

11 “(2) to preclude an agency from making a new
12 determination of fact and, based on such determination,
13 from prospectively applying a particular legal
14 requirement.”

15 (b) TECHNICAL AND CONFORMING AMENDMENTS.—

16 (1) The analysis for chapter 7 of title 5, United States
17 Code, is amended by inserting the following new item:

18 “707. Agency interpretations in civil and criminal actions.”

19 (2) Section 701(b)(2) of title 5, United States Code, is
20 amended by striking “‘sanction’”.

EXPLANATION OF THE AMENDMENT

SECTION __

Section __, added by this amendment, is a modified form of the Modified Hutchison Amendment No. 1539, adopted by the Senate by a vote of 80-0 on July 14, 1995. The purpose of this section is the same as the Hutchison Amendment—to prevent agencies from bringing enforcement actions seeking civil or criminal sanctions when due process and fair notice are not followed. In some cases, agencies have sought to impose sanctions retroactively based on new agency interpretations or determinations of fact, even when the person against whom the action is brought has reasonably relied, in good faith, on a prior agency interpretation or determination. The principles underlying this section are generally accepted in administrative case law, and generally upheld by courts, as will be discussed below. Yet, the time and expense involved in litigation in such circumstances is burdensome, particularly to small businesses, who are often forced to settle a case and pay a reduced fine because to fight for their rights under administrative case law would be more expensive. The codification of these principles is intended to deter agencies from pursuing these cases in the first place, by reminding them through a clear statutory pronouncement of their obligations to provide regulated persons with clear and adequate notice of their regulatory responsibilities.

SUBSECTION __ (a)

Subsection __ (a) adds a new section 707 to title 5, United States Code. The provisions of the new section 707 are as follows:

Subsection 707(a)

This subsection enumerates four situations in which "no civil or criminal sanction shall be imposed by a court, and no civil administrative sanction shall be imposed by an agency, for violation of a rule." These four situations, contained in the four paragraphs of subsection 707(a), are a disjunctive test and require a finding by the court or agency, as appropriate to the situation.

Paragraph 707(a)(1)

The first situation in which civil or criminal sanctions for violation of a rule are precluded is if the court or agency finds that the rule, other agency published by the agency under section 552(a)(1) or section 553 of title 5 (or other applicable rule making authority), and other written agency information directly and specifically communicated to the defendant prior to the violation, failed to give the defendant fair warning that the conduct engaged in by the defendant violates the rule. This provision reflects an array of Federal court decisions on the principles of basic fairness and due process. For example, in *Diamond Roofing v. OSHRC*, 528 F.2d 645, 649 (5th Cir. 1976), the court found that 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 regulations cannot be construed to mean what an agency intended but did not adequately express." This is in accord with the finding of the court in *Gates & Fox Co. v. OSHRC*, 790 F.2d 154, 156 (D.C. Cir. 1986) that "Where the imposition of penal sanctions is at issue...the due process clause prevents [deference to agency interpretation] from validating the application of a regulation that fails to give fair warning of the conduct it prohibits or requires." This is also consistent with the finding of the court in *Director, Office of Worker's Compensation v. Magnifest*, 826 F.2d 1318, 1325 (3d Cir. 1987), stating that "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."

The principle of fair warning has been applied by the courts in both criminal and civil contexts, as explained by Judge Tatel in *General Electric Co. v. EPA*, 53 F.3d 1324, 1329 (D.C. Cir. 1995):

"Of course, it is in the context of criminal liability that this 'no punishment without notice' rule is most commonly applied. See, e.g., *United States v. National Dairy Corp.*, 372 U.S. 29, 32-33, 9 L. Ed. 2d 561, 83 S. Ct. 594 (1963) ('Criminal responsibility should not attach where one could not reasonably understand that his contemplated conduct is proscribed.'). But as long ago as 1968, we recognized that this 'fair notice' requirement in the civil administrative context. In *Radio Athens, Inc. v. FCC*, we held that when sanctions are drastic—in that case, the FCC dismissed the petitioner's application for a radio station license—'elementary fairness compels clarity' in the statements and regulations setting forth the actions with which the agency expects the public to comply. 130 U.S. App D.C. 333, 401 F.2d 398, 404 (D.C. Cir. 1968); see also

Maxcell Telecom Plus Inc. v. FCC, 259 U.S. App. D.C. 350, 815 F.2d 1551, 1558 (D.C. Cir. 1987) (Describing FCC's legal duty to provide adequate notice of requirements). This requirement has now been thoroughly 'incorporated into administrative law.' *Satellite Broadcasting Co. v. FCC*, 262 U.S. App. D.C. 274, 824 F.2d 1, 3 (D.C. Cir. 1987); see also *Rollins (Envtl. Serv., Inc. v. EPA)*, 937 F.2d at 654 n.1, 655 (Edwards, J., dissenting in part and concurring in part) (principle is not constitutional, but 'basic hornbook law in the administrative context,' and 'simple principle of administrative law')."

There are several ways in which the agency may provide fair warning under paragraph 707(a)(1). The agency may do so in the context of its publication of the rule, either plainly in the text of the rule or in the material accompanying its promulgation. It may do so as part of "statements of general policy or interpretations of general applicability formulated and adopted by the agency" and published in the Federal Register under section 552(a)(1) of title 5, United States Code. The connection between this requirement and fair warning is provided by the statement at the end of section 552(a)(1) that "Except to the extent that a person has actual and timely notice of the terms thereof, a person may not be in any manner required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published." Finally, as stated in paragraph 707(a)(1), the agency may provide fair warning through "written agency information directly and specifically communicated to the defendant prior to the violation," provided that that written communication meet the standards of "actual and timely notice" contained in section 552(a)(1). What an agency may not do is to use a sanction, without prior warning in the rule itself, in any other interpretative statement published in the Federal Register, or in any other "actual and timely" statement to the defendant, as the initial means of announcing a particular interpretation of a rule.

Paragraph 707(a)(2)

The second situation in which the imposition of sanctions is not permitted is where the court or agency, as appropriate, finds that the defendant "reasonably and in good faith determined, prior to the alleged violation, based on the information described in paragraph (1), that the defendant was in compliance with, exempt from, or not otherwise subject to, the requirements of the rule." This test is subject to the requirement in subsection 707(b)(1) that the defendant be qualified to make such a determination or that the defendant seek competent advice

from a qualified person (and act on the advice given). This paragraph is not intended to "reward ignorance," as it might be construed to do if this qualification were not included (see, e.g., the statement of Senator Biden, July 14, 1995, CONGRESSIONAL RECORD at S 9957.) It is intended to preclude the imposition of civil or criminal sanctions in cases where a qualified or competently advised defendant, after consulting all of the agency information described in paragraph 707(a)(1), concludes that the action that the defendant is about to undertake is within the law. This is intended to be an incentive for agencies to write clear regulations and interpretations of regulations, for the courts have held that where "the regulations and other policy statements are unclear, where the [defendant's] interpretation is reasonable, and where the agency itself struggles to provide a definitive reading of the regulatory requirements, a regulated party is not 'on notice' of the agency's ultimate interpretation of the regulations, and may not be punished." 53 F.3d at 1334.

Paragraph 707(a)(3)

The third situation in which the imposition of sanctions is not permitted is where the court or agency, as appropriate, finds that the defendant "engaged in the conduct alleged to violate the rule in reasonable reliance upon a written statement from an appropriate agency official, or from an appropriate official of a State authority to which had been delegated responsibility for implementing or ensuring compliance with the rule, after good-faith disclosure of the facts that were material at the time of the determination (including any facts requested at the time by the agency or State authority) and after appropriate review, stating that the action was in compliance with, or that the defendant was exempt from, or not otherwise subject to, the requirements of the rule."

This section is intended to hold harmless from sanctions a person: (1) who goes to a Federal agency, or to a State authority to which a Federal agency has delegated its authority for compliance and enforcement; (2) who discloses the person's planned actions along with all the facts that are deemed material at the time; and (3) who then receives from the agency or State authority a written statement that the person's intended action is in compliance with, exempt from, or not otherwise subject to a particular regulation. If there is a change in the agency's or State authority's rules, interpretations, or determinations of fact, then the person can be made to prospectively comply with new requirements, but the person cannot be penalized for past actions based on good-faith disclosure and reliance.

There are several important caveats contained in this paragraph. The written statement from the agency or State official must precede the conduct alleged to violate the rule. All of the facts that were material at the time that the determination was sought and made must be disclosed—"good faith" disclosure precludes any attempt by a defendant to conceal such material facts. An appropriate review of the determination may be incorporated into the process of providing the determination by the relevant agency or State authority.

In addition to these considerations, several qualifications in subsection 707(b) are relevant here. First, the "appropriate official" of an agency or a State authority must be an official with the authority to provide a determination, and the official must know that he or she is, in fact, providing such a determination. A court should not find "reasonable reliance" on statements from low-level agency or State employees that cannot be reasonably be considered to be able to "speak for the agency." At the same time, this qualification does not mean that each statement relied on under this paragraph must be issued by the head of the agency or the State authority. It is expected that the court will take into account such factors as the level of authority of the person within the agency as well as the defendant's own reasonable belief as to the nature of that person's authority. Second, the actions of the defendant in seeking a determination must be in good faith. Thus, for example, any determination obtained by a defendant through collusion or by suborning an official of an agency or State authority would be invalid.

This paragraph (and the following paragraph 707(a)(4)) elevates the importance of interpretations and determinations of fact made by State authorities under delegated authority from Federal agencies. Where a Federal agency makes a State authority its agent for matters of compliance or enforcement, it must resolve intergovernmental differences in interpretation or factual analysis with the State authority (and perhaps through the terms of its delegation), not by seeking criminal or civil sanctions against parties that are bystanders to the intergovernmental dispute. The focus should be on the appropriate Federal exercise of authority over the State agency, as provided by law.

Paragraph 707(a)(4)

The final situation in which a criminal or civil sanction may not be imposed is if the court or agency, as appropriate, finds that the proposed sanction is based on an interpretation or determination of fact that is materially different from a prior interpretation or determination of fact that the defendant reasonably and in good faith relied upon, having taken into account all of

the information described in paragraph 707(a)(1). Such retroactive sanctions, based on reinterpretations or new determinations of fact disclosed in an enforcement proceeding, violate the principle of fair warning and due process.

This paragraph 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 new determination to actions taken after the agency's change in position, as is made explicit in subsection 707(c).

Subsection 707(b)

This subsection contains a number of important qualifications to the concepts of reasonable reliance and reasonable determination in subsection 707(a). These qualifications have been discussed, above, in connection with section 707(a).

Subsection 707(c)

This subsection clarifies that nothing in section 707 precludes agencies from revising rules under applicable rule making authority, from revising interpretations of rule under section 552(a)(1), or from making new determinations of fact. In such cases, agencies may prospectively enforce the requirements of a rule, as revised or reinterpreted or prospectively apply a particular legal requirement, based on the new fact determination, and seeking civil or criminal sanctions for any subsequent violation of such rule, subject to the provisions of section 707. This section is not intended to, nor does it, lock agencies into particular interpretations or determinations of fact for all time. It merely prevents the unfair situation in which agencies retroactively penalize parties for interpretations or determinations of fact that did not exist (or were unknown outside the agency) at the time of the alleged violation.

SUBSECTION __ (b)

Paragraph __ (b)(1) amends the chapter analysis for chapter 7 of title 5 to reflect the addition of the new section 707.

Paragraph __ (b)(2) removes the term "sanction" from the list of defined terms in section 702(b)(2) of title 5. The matter in chapter 7 of title 5 was originally enacted as section 10 of the

Administrative Procedure Act (APA; 60 Stat. 243), and all of the definitions in section 2 of that Act were applicable to section 10 (including "sanction"). However, the term "sanction" was not used in section 10. When title 5 was recodified and enacted into positive law by P.L. 89-554 (80 Stat. 392), a selection of the terms from the original section 2 of the APA were referenced in section 702, providing definitions for chapter 7, including "sanction," again, despite the fact that the term was not used in chapter 7. This amendment employs the term "sanction" for the first time in chapter 7 of title 5, and so it is worth examining whether the definition in 5 U.S.C. 551(10), made applicable here by 5 U.S.C. 702(b)(2), is compatible with the way in which "sanction" is used in the court cases that form the basis for this section. The definition in section 551(10), which includes essentially any agency restriction in the definition of sanction, could be read as including prospective requirements of agencies after fair warning is given—a type of "sanction" expressly allowed by section 707. To avoid confusion, then, the definition of "sanction" in section 551 is made inapplicable to section 707 by removing the term from the list in section 702(b)(2). The term "sanction" should thus be understood in the broad manner that is used in the case law that this section is codifying, including both penalties and findings of liability (*Cf.*, 53 F.3d at 1334), and in the sense that is defined in standard dictionaries of legal terms (i.e., "penalty or other mechanism of enforcement used to provide incentives for obedience with the law or with rules and regulations" 6 BLACK'S LAW DICTIONARY 1341 (1990)), instead of the more specialized definition in 5 U.S.C. 551(10).

AMENDMENT TO H.R. 3136

OFFERED BY MR. HYDE

Strike title III and insert the following:

1 **TITLE III—SMALL BUSINESS**
2 **REGULATORY FAIRNESS**

3 SEC. 301. SHORT TITLE.

4 This title may be cited as the “Small Business Regu-
5 latory Enforcement Fairness Act of 1996”.

6 SEC. 302. FINDINGS.

7 Congress finds that—

8 (1) a vibrant and growing small business sector
9 is critical to creating jobs in a dynamic economy;

10 (2) small businesses bear a disproportionate
11 share of regulatory costs and burdens;

12 (3) fundamental changes that are needed in the
13 regulatory and enforcement culture of Federal agen-
14 cies to make agencies more responsive to small busi-
15 ness can be made without compromising the statu-
16 tory missions of the agencies;

17 (4) three of the top recommendations of the
18 1995 White House Conference on Small Business in-
19 volve reforms to the way government regulations are
20 developed and enforced, and reductions in govern-
21 ment paperwork requirements;

1 (5) the requirements of chapter 6 of title 5,
2 United States Code, have too often been ignored by
3 government agencies, resulting in greater regulatory
4 burdens on small entities than necessitated by statute;
5 and

6 (6) small entities should be given the opportunity
7 to seek judicial review of agency actions required
8 by chapter 6 of title 5, United States Code.

9 SEC. 303. PURPOSES.

10 The purposes of this title are—

11 (1) to implement certain recommendations of
12 the 1995 White House Conference on Small Business
13 regarding the development and enforcement of
14 Federal regulations;

15 (2) to provide for judicial review of chapter 6
16 of title 5, United States Code;

17 (3) to encourage the effective participation of
18 small businesses in the Federal regulatory process;

19 (4) to simplify the language of Federal regulations
20 affecting small businesses;

21 (5) to develop more accessible sources of information
22 on regulatory and reporting requirements for
23 small businesses;

1 (6) to create a more cooperative regulatory en-
2 vironment among agencies and small businesses that
3 is less punitive and more solution-oriented; and

4 (7) to make Federal regulators more account-
5 able for their enforcement actions by providing small
6 entities with a meaningful opportunity for redress of
7 excessive enforcement activities.

8 **Subtitle A—Regulatory Compliance** 9 **Simplification**

10 SEC. 311. DEFINITIONS.

11 For purposes of this subtitle—

12 (1) the terms “rule” and “small entity” have
13 the same meanings as in section 601 of title 5, Unit-
14 ed States Code;

15 (2) the term “agency” has the same meaning as
16 in section 551 of title 5, United States Code; and

17 (3) the term “small entity compliance guide”
18 means a document designated as such by an agency.

19 SEC. 312. COMPLIANCE GUIDES.

20 (a) **COMPLIANCE GUIDE.**—For each rule or group of
21 related rules for which an agency is required to prepare
22 a final regulatory flexibility analysis under section 604 of
23 title 5, United States Code, the agency shall publish one
24 or more guides to assist small entities in complying with
25 the rule, and shall designate such publications as “small

1 entity compliance guides". The guides shall explain the ac-
2 tions a small entity is required to take to comply with a
3 rule or group of rules. The agency shall, in its sole discre-
4 tion, taking into account the subject matter of the rule
5 and the language of relevant statutes, ensure that the
6 guide is written using sufficiently plain language likely to
7 be understood by affected small entities. Agencies may
8 prepare separate guides covering groups or classes of simi-
9 larly affected small entities, and may cooperate with asso-
10 ciations of small entities to develop and distribute such
11 guides.

12 (b) COMPREHENSIVE SOURCE OF INFORMATION.—

13 Agencies shall cooperate to make available to small enti-
14 ties through comprehensive sources of information, the
15 small entity compliance guides and all other available in-
16 formation on statutory and regulatory requirements af-
17 fecting small entities.

18 (c) LIMITATION ON JUDICIAL REVIEW.—An agency's

19 small entity compliance guide shall not be subject to judi-
20 cial review, except that in any civil or administrative ac-
21 tion against a small entity for a violation occurring after
22 the effective date of this section, the content of the small
23 entity compliance guide may be considered as evidence of
24 the reasonableness or appropriateness of any proposed
25 fines, penalties or damages.

1 SEC. 313. INFORMAL SMALL ENTITY GUIDANCE.

2 (a) GENERAL.—Whenever appropriate in the interest
3 of administering statutes and regulations within the juris-
4 diction of an agency which regulates small entities, it shall
5 be the practice of the agency to answer inquiries by small
6 entities concerning information on, and advice about, com-
7 pliance with such statutes and regulations, interpreting
8 and applying the law to specific sets of facts supplied by
9 the small entity. In any civil or administrative action
10 against a small entity, guidance given by an agency apply-
11 ing the law to facts provided by the small entity may be
12 considered as evidence of the reasonableness or appro-
13 priateness of any proposed fines, penalties or damages
14 sought against such small entity.

15 (b) PROGRAM.—Each agency regulating the activities
16 of small entities shall establish a program for responding
17 to such inquiries no later than 1 year after enactment of
18 this section, utilizing existing functions and personnel of
19 the agency to the extent practicable.

20 (c) REPORTING.—Each agency regulating the activi-
21 ties of small business shall report to the Committee on
22 Small Business and Committee on Governmental Affairs
23 of the Senate and the Committee on Small Business and
24 Committee on the Judiciary of the House of Representa-
25 tives no later than 2 years after the date of the enactment
26 of this section on the scope of the agency's program, the

1 number of small entities using the program, and the
2 achievements of the program to assist small entity compli-
3 ance with agency regulations.

4 SEC. 314. SERVICES OF SMALL BUSINESS DEVELOPMENT
5 CENTERS.

6 (a) Section 21(c)(3) of the Small Business Act (15
7 U.S.C. 648(c)(3)) is amended—

8 (1) in subparagraph (O), by striking “and” at
9 the end;

10 (2) in subparagraph (P), by striking the period
11 at the end and inserting a semicolon; and

12 (3) by inserting after subparagraph (P) the fol-
13 lowing new subparagraphs:

14 “(Q) providing information to small busi-
15 ness concerns regarding compliance with regu-
16 latory requirements; and

17 “(R) developing informational publications,
18 establishing resource centers of reference mate-
19 rials, and distributing compliance guides pub-
20 lished under section 312(a) of the Small Busi-
21 ness Regulatory Enforcement Fairness Act of
22 1996.”.

23 (b) Nothing in this Act in any way affects or limits
24 the ability of other technical assistance or extension pro-

1 grams to perform or continue to perform services related
2 to compliance assistance.

3 **SEC. 315. COOPERATION ON GUIDANCE.**

4 Agencies may, to the extent resources are available
5 and where appropriate, in cooperation with the states, de-
6 velop guides that fully integrate requirements of both Fed-
7 eral and state regulations where regulations within an
8 agency's area of interest at the Federal and state levels
9 impact small entities. Where regulations vary among the
10 states, separate guides may be created for separate states
11 in cooperation with State agencies.

12 **SEC. 316. EFFECTIVE DATE.**

13 This subtitle and the amendments made by this sub-
14 title shall take effect on the expiration of 90 days after
15 the date of enactment of this subtitle.

16 **Subtitle B—Regulatory**
17 **Enforcement Reforms**

18 **SEC. 321. DEFINITIONS.**

19 For purposes of this subtitle—

20 (1) the terms “rule” and “small entity” have
21 the same meanings as in section 601 of title 5, Unit-
22 ed States Code;

23 (2) the term “agency” has the same meaning as
24 in section 551 of title 5, United States Code; and

1 (3) the term "small entity compliance guide"
2 means a document designated as such by an agency.

3 **SEC. 322. SMALL BUSINESS AND AGRICULTURE ENFORCE-**
4 **MENT OMBUDSMAN.**

5 The Small Business Act (15 U.S.C. 631 et seq.) is
6 amended—

7 (1) by redesignating section 30 as section 31;
8 and

9 (2) by inserting after section 29 the following
10 new section:

11 **"SEC. 30. OVERSIGHT OF REGULATORY ENFORCEMENT.**

12 "(a) **DEFINITIONS.**—For purposes of this section, the
13 term—

14 "(1) "Board" means a Regional Small Business
15 Regulatory Fairness Board established under sub-
16 section (c); and

17 "(2) "Ombudsman" means the Small Business
18 and Agriculture Regulatory Enforcement Ombuds-
19 man designated under subsection (b).

20 **"(b) SBA ENFORCEMENT OMBUDSMAN.**—

21 "(1) Not later than 180 days after the date of
22 enactment of this section, the Administrator shall
23 designate a Small Business and Agriculture Regu-
24 latory Enforcement Ombudsman, who shall report
25 directly to the Administrator, utilizing personnel of

1 the Small Business Administration to the extent
2 practicable. Other agencies shall assist the Ombuds-
3 man and take actions as necessary to ensure compli-
4 ance with the requirements of this section. Nothing
5 in this section is intended to replace or diminish the
6 activities of any Ombudsman or similar office in any
7 other agency.

8 “(2) The Ombudsman shall—

9 “(A) work with each agency with regu-
10 latory authority over small businesses to ensure
11 that small business concerns that receive or are
12 subject to an audit, on-site inspection, compli-
13 ance assistance effort, or other enforcement re-
14 lated communication or contact by agency per-
15 sonnel are provided with a means to comment
16 on the enforcement activity conducted by such
17 personnel;

18 “(B) establish means to receive comments
19 from small business concerns regarding actions
20 by agency employees conducting compliance or
21 enforcement activities with respect to the small
22 business concern, means to refer comments to
23 the Inspector General of the affected agency in
24 the appropriate circumstances, and otherwise
25 seek to maintain the identity of the person and

1 small business concern making such comments
2 on a confidential basis to the same extent as
3 employee identities are protected under section
4 7 of the Inspector General Act of 1978 (5
5 U.S.C.App.);

6 “(C) based on substantiated comments re-
7 ceived from small business concerns and the
8 Boards, annually report to Congress and af-
9 fected agencies evaluating the enforcement ac-
10 tivities of agency personnel including a rating of
11 the responsiveness to small business of the var-
12 ious regional and program offices of each agen-
13 cy;

14 “(D) coordinate and report annually on the
15 activities, findings and recommendations of the
16 Boards to the Administrator and to the heads
17 of affected agencies; and

18 “(E) provide the affected agency with an
19 opportunity to comment on draft reports pre-
20 pared under subparagraph (C), and include a
21 section of the final report in which the affected
22 agency may make such comments as are not
23 addressed by the Ombudsman in revisions to
24 the draft.

1 “(c) REGIONAL SMALL BUSINESS REGULATORY
2 FAIRNESS BOARDS.—

3 “(1) Not later than 180 days after the date of
4 enactment of this section, the Administrator shall
5 establish a Small Business Regulatory Fairness
6 Board in each regional office of the Small Business
7 Administration.

8 “(2) Each Board established under paragraph
9 (1) shall—

10 “(A) meet at least annually to advise the
11 Ombudsman on matters of concern to small
12 businesses relating to the enforcement activities
13 of agencies;

14 “(B) report to the Ombudsman on sub-
15 stantiated instances of excessive enforcement
16 actions of agencies against small business con-
17 cerns including any findings or recommenda-
18 tions of the Board as to agency enforcement
19 policy or practice; and

20 “(C) prior to publication, provide comment
21 on the annual report of the Ombudsman pre-
22 pared under subsection (b).

23 “(3) Each Board shall consist of five members,
24 who are owners, operators, or officers of small busi-
25 ness concerns, appointed by the Administrator, after

1 receiving the recommendations of the chair and
2 ranking minority member of the Committees on
3 Small Business of the House of Representatives and
4 the Senate. Not more than three of the Board mem-
5 bers shall be of the same political party. No member
6 shall be an officer or employee of the Federal Gov-
7 ernment, in either the executive branch or the Con-
8 gress.

9 “(4) Members of the Board shall serve at the
10 pleasure of the Administrator for terms of three
11 years or less.

12 “(5) The Administrator shall select a chair
13 from among the members of the Board who shall
14 serve at the pleasure of the Administrator for not
15 more than 1 year as chair.

16 “(6) A majority of the members of the Board
17 shall constitute a quorum for the conduct of busi-
18 ness, but a lesser number may hold hearings.

19 “(d) POWERS OF THE BOARDS.

20 “(1) The Board may hold such hearings and
21 collect such information as appropriate for carrying
22 out this section.

23 “(2) The Board may use the United States
24 mails in the same manner and under the same con-

1 ditions as other departments and agencies of the
2 Federal Government.

3 “(3) The Board may accept donations of serv-
4 ices necessary to conduct its business, provided that
5 the donations and their sources are disclosed by the
6 Board.

7 “(4) Members of the Board shall serve without
8 compensation, provided that, members of the Board
9 shall be allowed travel expenses, including per diem
10 in lieu of subsistence, at rates authorized for em-
11 ployees of agencies under subchapter I of chapter 57
12 of title 5, United States Code, while away from their
13 homes or regular places of business in the perform-
14 ance of services for the Board.”.

15 **SEC. 323. RIGHTS OF SMALL ENTITIES IN ENFORCEMENT**
16 **ACTIONS.**

17 (a) **IN GENERAL.**—Each agency regulating the activi-
18 ties of small entities shall establish a policy or program
19 within 1 year of enactment of this section to provide for
20 the reduction, and under appropriate circumstances for
21 the waiver, of civil penalties for violations of a statutory
22 or regulatory requirement by a small entity. Under appro-
23 priate circumstances, an agency may consider ability to
24 pay in determining penalty assessments on small entities.

1 (b) CONDITIONS AND EXCLUSIONS.—Subject to the
2 requirements or limitations of other statutes, policies or
3 programs established under this section shall contain con-
4 ditions or exclusions which may include, but shall not be
5 limited to—

6 (1) requiring the small entity to correct the vio-
7 lation within a reasonable correction period;

8 (2) limiting the applicability to violations dis-
9 covered through participation by the small entity in
10 a compliance assistance or audit program operated
11 or supported by the agency or a state;

12 (3) excluding small entities that have been sub-
13 ject to multiple enforcement actions by the agency;

14 (4) excluding violations involving willful or
15 criminal conduct;

16 (5) excluding violations that pose serious
17 health, safety or environmental threats; and

18 (6) requiring a good faith effort to comply with
19 the law.

20 (c) REPORTING.—Agencies shall report to the Com-
21 mittee on Small Business and Committee on Govern-
22 mental Affairs of the Senate and the Committee on Small
23 Business and Committee on Judiciary of the House of
24 Representatives no later than 2 years after the date of
25 enactment of this section on the scope of their program

1 or policy, the number of enforcement actions against small
2 entities that qualified or failed to qualify for the program
3 or policy, and the total amount of penalty reductions and
4 waivers.

5 **SEC. 324. EFFECTIVE DATE.**

6 This subtitle and the amendments made by this sub-
7 title shall take effect on the expiration of 90 days after
8 the date of enactment of this subtitle.

9 **Subtitle C—Equal Access to Justice**
10 **Act Amendments**

11 **SEC. 331. ADMINISTRATIVE PROCEEDINGS.**

12 (a) Section 504(a) of title 5, United States Code, is
13 amended by adding at the end the following new para-
14 graph:

15 “(4) If, in an adversary adjudication brought by an
16 agency, the demand by the agency is substantially in ex-
17 cess of the decision of the adjudicative officer and is un-
18 reasonable when compared with such decision, under the
19 facts and circumstances of the case, the adjudicative offi-
20 cer shall award to the party the fees and other expenses
21 related to defending against the excessive demand, unless
22 the party has committed a willful violation of law or other-
23 wise acted in bad faith, or special circumstances make an
24 award unjust.”.

1 (b) Section 504(b) of title 5, United States Code, is
2 amended—

3 (1) in paragraph (1)(A), by striking "\$75" and
4 inserting "\$125";

5 (2) at the end of paragraph (1)(B), by inserting
6 before the semicolon "or for purposes of subsection
7 (a)(4), a small entity as defined in section 601";

8 (3) at the end of paragraph (1)(D), by striking
9 "and";

10 (4) at the end of paragraph (1)(E), by striking
11 the period and inserting "; and"; and

12 (5) at the end of paragraph (1), by adding the
13 following new subparagraph:

14 "(F) 'demand' means the express demand of
15 the agency which led to the adversary adjudication,
16 but does not include a recitation by the agency of
17 the maximum statutory penalty (i) in the adminis-
18 trative complaint, or (ii) elsewhere when accom-
19 panied by an express demand for a lesser amount."

20 **SEC. 332. JUDICIAL PROCEEDINGS.**

21 (a) Section 2412(d)(1) of title 28, United States
22 Code, is amended by adding at the end the following new
23 subparagraph:

24 "(D) If, in a civil action brought by the United
25 States, the demand by the United States is substantially

1 in excess of the judgment finally obtained by the United
2 States and is unreasonable when compared with such
3 judgment, under the facts and circumstances of the case,
4 the court shall award to the party the fees and other ex-
5 penses related to defending against the excessive demand,
6 unless the party has committed a willful violation of law
7 or otherwise acted in bad faith, or special circumstances
8 make an award unjust.”.

9 (b) Section 2412(d) of title 28, United States Code,
10 is amended—

11 (1) in paragraph (2)(A), by striking “\$75” and
12 inserting “\$125”;

13 (2) at the end of paragraph (2)(B), by inserting
14 before the semicolon “or for purposes of subsection
15 (d)(1)(D), a small entity as defined in section 601
16 of title 5”;

17 (3) at the end of paragraph (2)(G), by striking
18 “and”;

19 (4) at the end of paragraph (2)(H), by striking
20 the period and inserting “; and”; and

21 (5) at the end of paragraph (2), by adding the
22 following new subparagraph:

23 “(I) ‘demand’ means the express demand of the
24 United States which led to the adversary adjudica-
25 tion, but shall not include a recitation of the maxi-

1 mum statutory penalty (i) in the complaint, or (ii)
2 elsewhere when accompanied by an express demand
3 for a lesser amount.”.

4 **SEC. 333. EFFECTIVE DATE.**

5 The amendments made by sections 331 and 332 shall
6 apply to civil actions and adversary adjudications com-
7 menced on or after the date of the enactment of this sub-
8 title.

9 **Subtitle D—Regulatory Flexibility**
10 **Act Amendments**

11 **SEC. 341. REGULATORY FLEXIBILITY ANALYSES.**

12 **(a) INITIAL REGULATORY FLEXIBILITY ANALYSIS.—**

13 (1) **SECTION 603.—**Section 603(a) of title 5,
14 United States Code, is amended—

15 (A) by inserting after “proposed rule”, the
16 phrase “, or publishes a notice of proposed rule-
17 making for an interpretative rule of general ap-
18 plicability involving the internal revenue laws of
19 the United States”; and

20 (B) by inserting at the end of the sub-
21 section, the following new sentence: “In the
22 case of an interpretative rule involving the in-
23 ternal revenue laws of the United States, this
24 chapter applies to interpretative rules published
25 in the Federal Register for codification in the

1 Code of Federal Regulations, but only to the
2 extent that such interpretative rules impose on
3 small entities a collection of information re-
4 quirement.”.

5 (2) SECTION 601.—Section 601 of title 5, Unit-
6 ed States Code, is amended by striking “and” at the
7 end of paragraph (5), by striking the period at the
8 end of paragraph (6) and inserting “; and”, and by
9 adding at the end the following:

10 “(7) the term ‘collection of information’—

11 “(A) means the obtaining, causing to be
12 obtained, soliciting, or requiring the disclosure
13 to third parties or the public, of facts or opin-
14 ions by or for an agency, regardless of form or
15 format, calling for either—

16 “(i) answers to identical questions
17 posed to, or identical reporting or record-
18 keeping requirements imposed on, 10 or
19 more persons, other than agencies, instru-
20 mentalities, or employees of the United
21 States; or

22 “(ii) answers to questions posed to
23 agencies, instrumentalities, or employees of
24 the United States which are to be used for
25 general statistical purposes; and

1 “(B) shall not include a collection of infor-
2 mation described under section 3518(c)(1) of
3 title 44, United States Code.

4 “(8) RECORDKEEPING REQUIREMENT.—The
5 term ‘recordkeeping requirement’ means a require-
6 ment imposed by an agency on persons to maintain
7 specified records.

8 (b) FINAL REGULATORY FLEXIBILITY ANALYSIS.—
9 Section 604 of title 5, United States Code, is amended—

10 (1) in subsection (a) to read as follows:

11 “(a) When an agency promulgates a final rule under
12 section 553 of this title, after being required by that sec-
13 tion or any other law to publish a general notice of pro-
14 posed rulemaking, or promulgates a final interpretative
15 rule involving the internal revenue laws of the United
16 States as described in section 603(a), the agency shall pre-
17 pare a final regulatory flexibility analysis. Each final regu-
18 latory flexibility analysis shall contain—

19 “(1) a succinct statement of the need for, and
20 objectives of, the rule;

21 “(2) a summary of the significant issues raised
22 by the public comments in response to the initial
23 regulatory flexibility analysis, a summary of the as-
24 sessment of the agency of such issues, and a state-

1 ment of any changes made in the proposed rule as
2 a result of such comments;

3 “(3) a description of and an estimate of the
4 number of small entities to which the rule will apply
5 or an explanation of why no such estimate is avail-
6 able;

7 “(4) a description of the projected reporting,
8 record keeping and other compliance requirements of
9 the rule, including an estimate of the classes of
10 small entities which will be subject to the require-
11 ment and the type of professional skills necessary
12 for preparation of the report or record; and

13 “(5) a description of the steps the agency has
14 taken to minimize the significant economic impact
15 on small entities consistent with the stated objectives
16 of applicable statutes, including a statement of the
17 factual, policy, and legal reasons for selecting the al-
18 ternative adopted in the final rule and why each one
19 of the other significant alternatives to the rule con-
20 sidered by the agency which affect the impact on
21 small entities was rejected.”; and

22 (2) in subsection (b), by striking “at the time”
23 and all that follows and inserting “such analysis or
24 a summary thereof.”.

1 SEC. 342. JUDICIAL REVIEW.

2 Section 611 of title 5, United States Code, is amend-
3 ed to read as follows:

4 "§ 611. Judicial review

5 "(a)(1) For any rule subject to this chapter, a small
6 entity that is adversely affected or aggrieved by final agen-
7 cy action is entitled to judicial review of agency compliance
8 with the requirements of sections 601, 604, 605(b),
9 608(b), and 610 in accordance with chapter 7. Agency
10 compliance with sections 607 and 609(a) shall be judicially
11 reviewable in connection with judicial review of section
12 604.

13 "(2) Each court having jurisdiction to review such
14 rule for compliance with section 553, or under any other
15 provision of law, shall have jurisdiction to review any
16 claims of noncompliance with sections 601, 604, 605(b),
17 608(b), and 610 in accordance with chapter 7. Agency
18 compliance with sections 607 and 609(a) shall be judicially
19 reviewable in connection with judicial review of section
20 604.

21 "(3)(A) A small entity may seek such review during
22 the period beginning on the date of final agency action
23 and ending one year later, except that where a provision
24 of law requires that an action challenging a final agency
25 action be commenced before the expiration of one year,

1 such lesser period shall apply to an action for judicial re-
2 view under this section.

3 “(B) In the case where an agency delays the issuance
4 of a final regulatory flexibility analysis pursuant to section
5 608(b) of this chapter, an action for judicial review under
6 this section shall be filed not later than—

7 “(i) one year after the date the analysis is made
8 available to the public, or

9 “(ii) where a provision of law requires that an
10 action challenging a final agency regulation be com-
11 menced before the expiration of the 1-year period,
12 the number of days specified in such provision of law
13 that is after the date the analysis is made available
14 to the public.

15 “(4) In granting any relief in an action under this
16 section, the court shall order the agency to take corrective
17 action consistent with this chapter and chapter 7, includ-
18 ing, but not limited to—

19 “(A) remanding the rule to the agency, and

20 “(B) deferring the enforcement of the rule
21 against small entities unless the court finds that
22 continued enforcement of the rule is in the public in-
23 terest.

24 “(5) Nothing in this subsection shall be construed to
25 limit the authority of any court to stay the effective date

1 of any rule or provision thereof under any other provision
2 of law or to grant any other relief in addition to the re-
3 quirements of this section.

4 “(b) In an action for the judicial review of a rule,
5 the regulatory flexibility analysis for such rule, including
6 an analysis prepared or corrected pursuant to paragraph
7 (a)(4), shall constitute part of the entire record of agency
8 action in connection with such review.

9 “(c) Compliance or noncompliance by an agency with
10 the provisions of this chapter shall be subject to judicial
11 review only in accordance with this section.

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

16 **SEC. 343. TECHNICAL AND CONFORMING AMENDMENTS.**

17 (a) Section 605(b) of title 5, United States Code, is
18 amended to read as follows:

19 “(b) Sections 603 and 604 of this title shall not apply
20 to any proposed or final rule if the head of the agency
21 certifies that the rule will not, if promulgated, have a sig-
22 nificant economic impact on a substantial number of small
23 entities. If the head of the agency makes a certification
24 under the preceding sentence, the agency shall publish
25 such certification in the Federal Register at the time of

1 publication of general notice of proposed rulemaking for
2 the rule or at the time of publication of the final rule,
3 along with a statement providing the factual basis for such
4 certification. The agency shall provide such certification
5 and statement to the Chief Counsel for Advocacy of the
6 Small Business Administration.”.

7 (b) Section 612 of title 5, United States Code is
8 amended—

9 (1) in subsection (a), by striking “the commit-
10 tees on the Judiciary of the Senate and the House
11 of Representatives, the Select Committee on Small
12 Business of the Senate, and the Committee on Small
13 Business of the House of Representatives” and in-
14 serting “the Committees on the Judiciary and Small
15 Business of the Senate and House of Representa-
16 tives”.

17 (2) in subsection (b), by striking “his views
18 with respect to the” and inserting in lieu thereof,
19 “his or her views with respect to compliance with
20 this chapter, the adequacy of the rulemaking record
21 with respect to small entities and the”.

22 **SEC. 344. SMALL BUSINESS ADVOCACY REVIEW PANELS.**

23 (a) **SMALL BUSINESS OUTREACH AND INTERAGENCY**
24 **COORDINATION.**— Section 609 of title 5, United States
25 Code is amended—

1 (1) before “techniques,” by inserting “the rea-
2 sonable use of”;

3 (2) in paragraph (4), after “entities” by insert-
4 ing “including soliciting and receiving comments
5 over computer networks”;

6 (3) by designating the current text as sub-
7 section (a); and

8 (4) by adding the following:

9 “(b) Prior to publication of an initial regulatory flexi-
10 bility analysis which a covered agency is required to con-
11 duct by this chapter—

12 “(1) a covered agency shall notify the Chief
13 Counsel for Advocacy of the Small Business Admin-
14 istration and provide the Chief Counsel with infor-
15 mation on the potential impacts of the proposed rule
16 on small entities and the type of small entities that
17 might be affected;

18 “(2) not later than 15 days after the date of re-
19 ceipt of the materials described in paragraph (1),
20 the Chief Counsel shall identify individuals rep-
21 resentative of affected small entities for the purpose
22 of obtaining advice and recommendations from those
23 individuals about the potential impacts of the pro-
24 posed rule;

1 “(3) the agency shall convene a review panel for
2 such rule consisting wholly of full time Federal em-
3 ployees of the office within the agency responsible
4 for carrying out the proposed rule, the Office of In-
5 formation and Regulatory Affairs within the Office
6 of Management and Budget, and the Chief Counsel;

7 “(4) the panel shall review any material the
8 agency has prepared in connection with this chapter,
9 including any draft proposed rule, collect advice and
10 recommendations of each individual small entity rep-
11 resentative identified by the agency after consulta-
12 tion with the Chief Counsel, on issues related to sub-
13 sections 603(b), paragraphs (3), (4) and (5) and
14 603(c);

15 “(5) not later than 60 days after the date a
16 covered agency convenes a review panel pursuant to
17 paragraph (3), the review panel shall report on the
18 comments of the small entity representatives and its
19 findings as to issues related to subsections 603(b),
20 paragraphs (3), (4) and (5) and 603(c), provided
21 that such report shall be made public as part of the
22 rulemaking record; and

23 “(6) where appropriate, the agency shall modify
24 the proposed rule, the initial regulatory flexibility

1 analysis or the decision on whether an initial regu-
2 latory flexibility analysis is required.

3 “(c) An agency may in its discretion apply subsection
4 (b) to rules that the agency intends to certify under sub-
5 section 605(b), but the agency believes may have a greater
6 than de minimis impact on a substantial number of small
7 entities.

8 “(d) For purposed of this section, the term covered
9 agency means the Environmental Protection Agency and
10 the Occupational Safety and Health Administration of the
11 Department of Labor.

12 “(e) The Chief Counsel for Advocacy, in consultation
13 with the individuals identified in subsection (b)(2), and
14 with the Administrator of the Office of Information and
15 Regulatory Affairs within the Office of Management and
16 Budget, may waive the requirements of subsections (b)(3),
17 (b)(4), and (b)(5) by including in the rulemaking record
18 a written finding, with reasons therefor, that those re-
19 quirements would not advance the effective participation
20 of small entities in the rulemaking process. For purposes
21 of this subsection, the factors to be considered in making
22 such a finding are as follows:

23 “(1) In developing a proposed rule, the extent
24 to which the covered agency consulted with individ-
25 uals representative of affected small entities with re-

1 spect to the potential impacts of the rule and took
2 such concerns into consideration; or in developing a
3 final rule, the extent to which the covered agency
4 took into consideration the comments filed by the in-
5 dividuals identified in subsection (b)(2).

6 “(2) Special circumstances requiring prompt is-
7 suance of the rule.

8 “(3) Whether the requirements of subsection
9 (b) would provide the individuals identified in sub-
10 section (b)(2) with a competitive advantage relative
11 to other small entities.”.

12 (b) **SMALL BUSINESS ADVOCACY CHAIRPERSONS.—**

13 Not later than 30 days after the date of enactment of this
14 Act, the head of each covered agency that has conducted
15 a final regulatory flexibility analysis shall designate a
16 small business advocacy chairperson using existing person-
17 nel to the extent possible, to be responsible for implement-
18 ing this section and to act as permanent chair of the agen-
19 cy’s review panels established pursuant to this section.

20 **SEC. 345. EFFECTIVE DATE.**

21 This subtitle shall become effective on the expiration
22 of 90 days after the date of enactment of this subtitle,
23 except that such amendments shall not apply to interpre-
24 tative rules for which a notice of proposed rulemaking was
25 published prior to the date of enactment.

1 **Subtitle E—Congressional Review**

2 **SEC. 351. CONGRESSIONAL REVIEW OF AGENCY RULE-**
3 **MAKING.**

4 Title 5, United States Code, is amended by inserting
5 immediately after chapter 7 the following new chapter:

6 **“CHAPTER 8—CONGRESSIONAL REVIEW**
7 **OF AGENCY RULEMAKING**

“Sec.

“801. Congressional review.

“802. Congressional disapproval procedure.

“803. Special rule on statutory, regulatory, and judicial deadlines.

“804. Definitions.

“805. Judicial review.

“806. Applicability; severability.

“807. Exemption for monetary policy.

“808. Effective date of certain rules.

8 **“§ 801. Congressional review**

9 “(a)(1)(A) Before a rule can take effect, the Federal
10 agency promulgating such rule shall submit to each House
11 of the Congress and to the Comptroller General a report
12 containing—

13 “(i) a copy of the rule;

14 “(ii) a concise general statement relating to the
15 rule, including whether it is a major rule; and

16 “(iii) the proposed effective date of the rule.

17 “(B) On the date of the submission of the report
18 under subparagraph (A), the Federal agency promulgating
19 the rule shall submit to the Comptroller General and make
20 available to each House of Congress—

1 “(i) a complete copy of the cost-benefit analysis
2 of the rule, if any;

3 “(ii) the agency’s actions relevant to sections
4 603, 604, 605, 607, and 609;

5 “(iii) the agency’s actions relevant to sections
6 202, 203, 204, and 205 of the Unfunded Mandates
7 Reform Act of 1995; and

8 “(iv) any other relevant information or require-
9 ments under any other Act and any relevant Execu-
10 tive Orders.

11 “(C) Upon receipt of a report submitted under sub-
12 paragraph (A), each House shall provide copies of the re-
13 port to the Chairman and Ranking Member of each stand-
14 ing committee with jurisdiction under the rules of the
15 House of Representatives or the Senate to report a bill
16 to amend the provision of law under which the rule is is-
17 sued.

18 “(2)(A) The Comptroller General shall provide a re-
19 port on each major rule to the committees of jurisdiction
20 in each House of the Congress by the end of 15 calendar
21 days after the submission or publication date as provided
22 in section 802(b)(2). The report of the Comptroller Gen-
23 eral shall include an assessment of the agency’s compli-
24 ance with procedural steps required by paragraph (1)(B).

1 “(B) Federal agencies shall cooperate with the Comp-
2 troller General by providing information relevant to the
3 Comptroller General’s report under subparagraph (A).

4 “(3) A major rule relating to a report submitted
5 under paragraph (1) shall take effect on the latest of—

6 “(A) the later of the date occurring 60 days
7 after the date on which—

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

10 “(ii) the rule is published in the Federal
11 Register, if so published;

12 “(B) if the Congress passes a joint resolution of
13 disapproval described in section 802 relating to the
14 rule, and the President signs a veto of such resolu-
15 tion, the earlier date—

16 “(i) on which either House of Congress
17 votes and fails to override the veto of the Presi-
18 dent; or

19 “(ii) occurring 30 session days after the
20 date on which the Congress received the veto
21 and objections of the President; or

22 “(C) the date the rule would have otherwise
23 taken effect, if not for this section (unless a joint
24 resolution of disapproval under section 802 is en-
25 acted).

1 “(4) Except for a major rule, a rule shall take effect
2 as otherwise provided by law after submission to Congress
3 under paragraph (1).

4 “(5) Notwithstanding paragraph (3), the effective
5 date of a rule shall not be delayed by operation of this
6 chapter beyond the date on which either House of Con-
7 gress votes to reject a joint resolution of disapproval under
8 section 802.

9 “(b)(1) A rule shall not take effect (or continue), if
10 the Congress enacts a joint resolution of disapproval, de-
11 scribed under section 802, of the rule.

12 “(2) A rule that does not take effect (or does not
13 continue) under paragraph (1) may not be reissued in sub-
14 stantially the same form, and a new rule that is substan-
15 tially the same as such a rule may not be issued, unless
16 the reissued or new rule is specifically authorized by a law
17 enacted after the date of the joint resolution disapproving
18 the original rule.

19 “(c)(1) Notwithstanding any other provision of this
20 section (except subject to paragraph (3)), a rule that
21 would not take effect by reason of subsection (a)(3) may
22 take effect, if the President makes a determination under
23 paragraph (2) and submits written notice of such deter-
24 mination to the Congress.

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

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

6 “(B) necessary for the enforcement of criminal
7 laws;

8 “(C) necessary for national security; or

9 “(D) issued pursuant to any statute implement-
10 ing an international trade agreement.

11 “(3) An exercise by the President of the authority
12 under this subsection shall have no effect on the proce-
13 dures under section 802 or the effect of a joint resolution
14 of disapproval under this section.

15 “(d)(1) In addition to the opportunity for review oth-
16 erwise provided under this chapter, in the case of any rule
17 for which a report was submitted in accordance with sub-
18 section (a)(1)(A) during the period beginning on the date
19 occurring—

20 “(A) in the case of the Senate, 60 session days,
21 or

22 “(B) in the case of the House of Representa-
23 tives, 60 legislative days,

24 before the date the Congress adjourns a session of Con-
25 gress through the date on which the same or succeeding

1 Congress first convenes its next session, section 802 shall
2 apply to such rule in the succeeding session of Congress.

3 “(2)(A) In applying section 802 for purposes of such
4 additional review, a rule described under paragraph (1)
5 shall be treated as though—

6 “(i) such rule were published in the Federal
7 Register (as a rule that shall take effect) on—

8 “(I) in the case of the Senate, the 15th
9 session day, or

10 “(II) in the case of the House of Rep-
11 resentatives, the 15th legislative day,
12 after the succeeding session of Congress first con-
13 venes; and

14 “(ii) a report on such rule were submitted to
15 Congress under subsection (a)(1) on such date.

16 “(B) Nothing in this paragraph shall be construed
17 to affect the requirement under subsection (a)(1) that a
18 report shall be submitted to Congress before a rule can
19 take effect.

20 “(3) A rule described under paragraph (1) shall take
21 effect as otherwise provided by law (including other sub-
22 sections of this section).

23 “(e)(1) For purposes of this subsection, section 802
24 shall also apply to any major rule promulgated between

1 March 1, 1996, and the date of the enactment of this
2 chapter.

3 “(2) In applying section 802 for purposes of Congres-
4 sional review, a rule described under paragraph (1) shall
5 be treated as though—

6 “(A) such rule were published in the Federal
7 Register on the date of enactment of this chapter;
8 and

9 “(B) a report on such rule were submitted to
10 Congress under subsection (a)(1) on such date.

11 “(3) The effectiveness of a rule described under para-
12 graph (1) shall be as otherwise provided by law, unless
13 the rule is made of no force or effect under section 802.

14 “(f) Any rule that takes effect and later is made of
15 no force or effect by enactment of a joint resolution under
16 section 802 shall be treated as though such rule had never
17 taken effect.

18 “(g) If the Congress does not enact a joint resolution
19 of disapproval under section 802 respecting a rule, no
20 court or agency may infer any intent of the Congress from
21 any action or inaction of the Congress with regard to such
22 rule, related statute, or joint resolution of disapproval.

23 **“§ 802. Congressional disapproval procedure**

24 “(a) For purposes of this section, the term ‘joint res-
25 olution’ means only a joint resolution introduced in the

1 period beginning on the date on which the report referred
2 to in section 801(a)(1)(A) is received by Congress and
3 ending 60 days thereafter (excluding days either House
4 of Congress is adjourned for more than 3 days during a
5 session of Congress), the matter after the resolving clause
6 of which is as follows: 'That Congress disapproves the rule
7 submitted by the ____ relating to ____, and such rule
8 shall have no force or effect.' (The blank spaces being ap-
9 propriately filled in).

10 “(b)(1) A joint resolution described in subsection (a)
11 shall be referred to the committees in each House of Con-
12 gress with jurisdiction.

13 “(2) For purposes of this section, the term ‘submis-
14 sion or publication date’ means the later of the date on
15 which—

16 “(A) the Congress receives the report submitted
17 under section 801(a)(1); or

18 “(B) the rule is published in the Federal Reg-
19 ister, if so published.

20 “(c) In the Senate, if the committee to which is re-
21 ferred a joint resolution described in subsection (a) has
22 not reported such joint resolution (or an identical joint
23 resolution) at the end of 20 calendar days after the sub-
24 mission or publication date defined under subsection
25 (b)(2), such committee may be discharged from further

1 consideration of such joint resolution upon a petition sup-
2 ported in writing by 30 Members of the Senate, and such
3 joint resolution shall be placed on the calendar.

4 “(d)(1) In the Senate, when the committee to which
5 a joint resolution is referred has reported, or when a com-
6 mittee is discharged (under subsection (c)) from further
7 consideration of a joint resolution described in subsection
8 (a), it is at any time thereafter in order (even though a
9 previous motion to the same effect has been disagreed to)
10 for a motion to proceed to the consideration of the joint
11 resolution, and all points of order against the joint resolu-
12 tion (and against consideration of the joint resolution) are
13 waived. The motion is not subject to amendment, or to
14 a motion to postpone, or to a motion to proceed to the
15 consideration of other business. A motion to reconsider the
16 vote by which the motion is agreed to or disagreed to shall
17 not be in order. If a motion to proceed to the consideration
18 of the joint resolution is agreed to, the joint resolution
19 shall remain the unfinished business of the Senate until
20 disposed of.

21 “(2) In the Senate, debate on the joint resolution,
22 and on all debatable motions and appeals in connection
23 therewith, shall be limited to not more than 10 hours,
24 which shall be divided equally between those favoring and
25 those opposing the joint resolution. A motion further to

1 limit debate is in order and not debatable. An amendment
2 to, or a motion to postpone, or a motion to proceed to
3 the consideration of other business, or a motion to recom-
4 mit the joint resolution is not in order.

5 “(3) In the Senate, immediately following the conclu-
6 sion of the debate on a joint resolution described in sub-
7 section (a), and a single quorum call at the conclusion of
8 the debate if requested in accordance with the rules of the
9 Senate, the vote on final passage of the joint resolution
10 shall occur.

11 “(4) Appeals from the decisions of the Chair relating
12 to the application of the rules of the Senate to the proce-
13 dure relating to a joint resolution described in subsection
14 (a) shall be decided without debate.

15 “(e) In the Senate the procedure specified in sub-
16 section (c) or (d) shall not apply to the consideration of
17 a joint resolution respecting a rule—

18 “(1) after the expiration of the 60 session days
19 beginning with the applicable submission or publica-
20 tion date, or

21 “(2) if the report under section 801(a)(1)(A)
22 was submitted during the period referred to in sec-
23 tion 801(d)(1), after the expiration of the 60 session
24 days beginning on the 15th session day after the
25 succeeding session of Congress first convenes.

1 “(f) If, before the passage by one House of a joint
2 resolution of that House described in subsection (a), that
3 House receives from the other House a joint resolution
4 described in subsection (a), then the following procedures
5 shall apply:

6 “(1) The joint resolution of the other House
7 shall not be referred to a committee.

8 “(2) With respect to a joint resolution described
9 in subsection (a) of the House receiving the joint
10 resolution—

11 “(A) the procedure in that House shall be
12 the same as if no joint resolution had been re-
13 ceived from the other House; but

14 “(B) the vote on final passage shall be on
15 the joint resolution of the other House.

16 “(g) This section is enacted by Congress—

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

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

6 **“§ 803. Special rule on statutory, regulatory, and judi-**
7 **cial deadlines**

8 “(a) In the case of any deadline for, relating to, or
9 involving any rule which does not take effect (or the effec-
10 tiveness of which is terminated) because of enactment of
11 a joint resolution under section 802, that deadline is ex-
12 tended until the date 1 year after the date of enactment
13 of the joint resolution. Nothing in this subsection shall be
14 construed to affect a deadline merely by reason of the
15 postponement of a rule’s effective date under section
16 801(a).

17 “(b) The term ‘deadline’ means any date certain for
18 fulfilling any obligation or exercising any authority estab-
19 lished by or under any Federal statute or regulation, or
20 by or under any court order implementing any Federal
21 statute or regulation.

22 **“§ 804. Definitions**

23 “For purposes of this chapter—

24 “(1) The term ‘Federal agency’ means any
25 agency as that term is defined in section 551(1).

1 “(2) The term “major rule” means any rule
2 that the Administrator of the Office of Information
3 and Regulatory Affairs of the Office of Management
4 and Budget finds has resulted in or is likely to re-
5 sult in—

6 “(A) an annual effect on the economy of
7 \$100,000,000 or more;

8 “(B) a major increase in costs or prices for
9 consumers, individual industries, Federal,
10 State, or local government agencies, or geo-
11 graphic regions; or

12 “(C) significant adverse effects on competi-
13 tion, employment, investment, productivity, in-
14 novation, or on the ability of United States-
15 based enterprises to compete with foreign-based
16 enterprises in domestic and export markets.

17 The term does not include any rule promulgated
18 under the Telecommunications Act of 1996 and the
19 amendments made by that Act.

20 “(3) The term ‘rule’ has the meaning given
21 such term in section 551, except that such term does
22 not include—

23 “(A) any rule of particular applicability,
24 including a rule that approves or prescribes for
25 the future rates, wages, prices, services, or al-

1 lowances therefor, corporate or financial struc-
2 tures, reorganizations, mergers, or acquisitions
3 thereof, or accounting practices or disclosures
4 bearing on any of the foregoing;

5 “(B) any rule relating to agency manage-
6 ment or personnel; or

7 “(C) any rule of agency organization, pro-
8 cedure, or practice that does not substantially
9 affect the rights or obligations of non-agency
10 parties.

11 **“§ 805. Judicial review**

12 “No determination, finding, action, or omission under
13 this chapter shall be subject to judicial review.

14 **“§ 806. Applicability; severability**

15 “(a) This chapter shall apply notwithstanding any
16 other provision of law.

17 “(b) If any provision of this chapter or the applica-
18 tion of any provision of this chapter to any person or cir-
19 cumstance, is held invalid, the application of such provi-
20 sion to other persons or circumstances, and the remainder
21 of this chapter, shall not be affected thereby.

22 **“§ 807. Exemption for monetary policy**

23 “Nothing in this chapter shall apply to rules that con-
24 cern monetary policy proposed or implemented by the

1 Board of Governors of the Federal Reserve System or the
2 Federal Open Market Committee.

3 **“§ 808. Effective date of certain rules**

4 **“Notwithstanding section 801—**

5 **“(1) any rule that establishes, modifies, opens,**
6 **closes, or conducts a regulatory program for a com-**
7 **mercial, recreational, or subsistence activity related**
8 **to hunting, fishing, or camping, or**

9 **“(2) any rule which an agency for good cause**
10 **finds (and incorporates the finding and a brief state-**
11 **ment of reasons therefor in the rule issued) that no-**
12 **tice and public procedure thereon are impracticable,**
13 **unnecessary, or contrary to the public interest,**
14 **shall take effect at such time as the Federal agency pro-**
15 **mulgating the rule determines.”.**

16 **SEC. 352. EFFECTIVE DATE.**

17 **The amendment made by section 351 shall take effect**
18 **on the date of enactment of this Act.**

19 **SEC. 353. TECHNICAL AMENDMENT.**

20 **The table of chapters for part I of title 5, United**
21 **States Code, is amended by inserting immediately after**
22 **the item relating to chapter 7 the following:**

“8. Congressional Review of Agency Rulemaking 801”.

REGULATORY REFORM AMENDMENT

The amendment assumes enactment of S.942, a Small Business Committee bill providing for judicial review of "regulatory flexibility analyses" and other small-business-friendly changes to rule making, and some form of S.219, the Reid-Nickles bill providing for congressional review of rules. For this reason, these topics are not included in the amendment.

What the Amendment Does

1. Regulatory Analyses (Sec. 622)

Requires risk assessments and cost-benefit analyses of "major rules" (rules with over \$100 million/year in increased economic costs, plus up to 25 additional rules per year picked by OMB)

2. Definitions and Procedures (Sec. 621, Sec. 631-636, Sec. 641-645, Sec. 651-654)

Sets forth definitions and procedures for conducting these assessments and analyses (for example, provides for peer review, OMB regulatory review);

3. Decisional Criteria (Sec. 623)

Provides decisional criteria that apply unless otherwise required by the underlying statute (i.e., no supermandate). In issuing a major rule, an agency must select the alternative likely to—

- (i) employ to the extent practicable flexible options;
- (ii) either maximize net benefits or achieve benefits in a more cost-effective manner than the alternatives; and
- (iii) provide benefits that justify the costs.

Two important "outs" from the above tests—

The agency can issue a major rule that does not meet the above tests if required to do so by the law underlying the rulemaking.

The President may order a major rule issued if he determines that it is appropriate and in the public interest to do so and it is infeasible to meet the test of (iii) because of scientific, technical or economic uncertainties.

There is an explicit savings clause that these provisions do not "override any statutory requirement, including health, safety, and environmental requirements."

4. Judicial Review (Sec. 624)

No judicial review of a major rule apart from judicial review of final agency action. Judicial review is based on the whole rule making record.

Judicial review of the decisional criteria is limited to whether the agency determinations required under the decisional criteria either (1) were omitted or (2) were arbitrary, capricious or an abuse of discretion.

Failure to comply with other requirements do not provide grounds for setting aside or remanding the rule unless the failure was reasonably likely materially to affect the outcome of the final rule and the rule, based on the record as a whole, is arbitrary, capricious or an abuse of discretion.

5. Review of Rules (Sec. 625)

Requires review of existing rules under a 5-year schedule established by the agency. Deadlines are set by the agency. Content of the schedule is not subject to judicial review. The agency must continue the rule, or conduct a rule making to amend or repeal the rule, before the deadline is reached. If a deadline is reached without agency action, the agency must propose a rule making to repeal the rule.

6. Administrative Procedure (Sec. 504)

Codifies current case law that “interpretative rules, general statements of policy, guidance, and rules of agency organization, procedure or practice” are rules subject to notice and comment under the Administrative Procedure Act (APA), if they substantially create or alter rights or obligations of persons outside the agency (creation of a binding legal effect is considered the hallmark of an APA notice-and-comment rule). This change is endorsed by the American Bar Association (ABA).

Requires agencies to respond to petitions allowed under existing law within 18 months. Allows agencies to consider the availability of their resources in deciding whether to grant or deny petitions. No new petitions are created anywhere in this amendment. This change is also endorsed by the ABA.

7. Risk-Based Priorities (Sec. 505)

The Roth-Biden-Johnston-Glenn amendment to S.343. Requires a set of “covered agencies” to set priorities in addressing risks based on the seriousness of the risk and cost-effectiveness of the remedy in achieving the greatest risk reduction for the dollars expended.

8. Effective Date (Sec. 506)

Phased-in approach, based on the date of promulgation of the final rule (not date of NOPR). After 90 days after enactment, a final major rule must comply with the decisional criteria, but can use analyses already required by the Clinton Executive Order (or other appropriate analyses) for this purpose. After 3 years, a final major rule must comply with the decisional criteria using analyses that meet the requirements established by the amendment.

The effective date of other sections of the amendment is 180 days after enactment.

9. Exclusions from Requirements for Risk Assessment and Cost-Benefit Analysis (Sec. 621, 622)

All exclusions to risk assessment and cost-benefit analysis adopted during the floor debate on S.343 (mammography standards, poisoning threats to children, food safety / E. coli) are in the amendment.

What is Not in the Amendment

No Toxic Release Inventory provisions.

No change to the Delaney clause.

No override of existing consent decrees.

No language affecting the Chevron precedent—a savings clause affirmatively states that nothing in the amendment “is intended to modify the rules of statutory construction applied by the courts.”

No Superfund provisions.

No takings provisions.

No alternative compliance provision.

DRAFT AMENDMENT – 3/14/96

Amendment No. _____

Calendar No. _____

Purpose: To provide for improvement in regulatory procedures and analyses.

**IN THE SENATE OF THE UNITED STATES
104th Congress, 2nd Session**

S. _____

Amendment intended to be proposed by MR. JOHNSTON
(for himself, MR. ROBB, _____
_____)

Viz:

1 At the end of the bill, add the following new title:

2 **TITLE II**
3 **IMPROVEMENT OF REGULATORY**
4 **DECISION MAKING**

5 **SEC. 201. SHORT TITLE.**

6 This title may be cited as the "Regulatory Reform Act of
7 1996".

8 **SEC. 202. DEFINITIONS.**

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

10 (1) in the matter preceding paragraph (1), by
11 striking "this subchapter" and inserting "this chapter and
12 chapters 7 and 8";

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

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

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

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

7 **SEC. 203. ANALYSIS OF AGENCY RULES.**

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

10 **"SUBCHAPTER II—ANALYSIS OF**
11 **AGENCY RULES**

12 **"§ 621. Definitions**

13 "For purposes of this subchapter, the definitions under
14 section 551 shall apply and—

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

21 "(2) the term 'cost' means the reasonably identifiable
22 significant adverse effects, quantifiable and
23 nonquantifiable, including social, health, environmental,
24 economic, and distributional effects that are expected to

1 result directly or indirectly from implementation of, or
2 compliance with, a rule or an alternative to a rule;

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

12 "(4) the term 'flexible regulatory options' means
13 regulatory options for a rule that are not precluded by the
14 statute authorizing the rule and that permit maximum
15 flexibility to regulated persons in achieving the
16 regulatory result that the statute authorizing a rule is
17 designed to produce, including regulatory options that
18 employ market-based mechanisms, performance
19 standards, or voluntary programs;

20 "(5) the term 'major rule' means a rule or a group of
21 closely related rules that—

22 "(A) the agency proposing the rule reasonably
23 determines under section 622(a), or the Director
24 reasonably determines under section 622(b), is

DRAFT AMENDMENT – 3/14/96

1 likely to have a gross annual effect on the economy
2 of \$100,000,000 or more in reasonably quantifiable
3 increased costs and such \$100,000,000 amount shall
4 be adjusted periodically by the Director to account
5 for inflation; or

6 “(B) the Director otherwise designates as a
7 major rule under section 622(b);

8 “(6) the term 'market-based mechanism' means a
9 regulatory approach that—

10 “(A) maintains the legal accountability of each
11 regulated person for achievement of an explicit
12 regulatory objective; and

13 “(B) affords maximum flexibility to each
14 regulated person in complying with such regulatory
15 objective, including, where feasible and appropriate,
16 the opportunity to transfer to, or receive from, other
17 persons (including for cash or other legal
18 consideration) increments of compliance
19 responsibility established by the program;

20 “(7) the term 'performance standard' means a
21 requirement that imposes legal accountability for the
22 achievement of an explicit regulatory objective, without
23 prescribing the particular method or procedures, for
24 achieving such objective;

1 “(8) the term ‘reasonable alternative’ means a
2 reasonable regulatory option that—

3 “(A) would achieve the objectives of the statute
4 that are relevant to the rule making; and

5 “(B) the agency has authority to adopt under
6 the statute granting rule making authority, including
7 a flexible regulatory option (unless such flexible
8 regulatory option is precluded by the statute
9 granting the rule making authority);

10 “(9) the term ‘risk assessment’ has the same
11 meaning as in section 631(6); and

12 “(10) the term ‘rule’ has the same meaning as in
13 section 551(4) of this title, except that the term shall not
14 include any rule otherwise described in section 551(4)
15 that is—

16 “(A) an agency statement of particular
17 applicability that approves or prescribes for the
18 future rates, corporate or financial structures or
19 reorganizations thereof, prices, facilities, appliances,
20 services or allowances therefor or valuations, costs,
21 or accounting, or practices bearing on any of the
22 foregoing;

DRAFT AMENDMENT – 3/14/96

6

1 “(B) a rule exempt from notice and public
2 comment procedure under section 553(a), section
3 553(b)(A), or section 553(b)(B) of this title;

4 “(C) a rule that involves the internal revenue
5 laws of the United States, or the assessment and
6 collection of taxes, duties, or other revenues or
7 receipts;

8 “(D) a rule or agency action relating to the
9 public debt;

10 “(E) a rule relating to monetary policy proposed
11 or promulgated by the Board of Governors of the
12 Federal Reserve System or by the Federal Open
13 Market Committee;

14 “(F) a rule relating to the safety or soundness of
15 federally insured depository institutions or any
16 affiliate of such an institution (as defined in section
17 2(k) of the Bank Holding Company Act of 1956 (12
18 U.S.C. 1841(k))); credit unions; Federal Home Loan
19 Banks; government sponsored housing enterprises; a
20 Farm Credit System institution; foreign banks, and
21 their branches, agencies, commercial lending
22 companies or representative offices that operate in
23 the United States and any affiliate of such foreign
24 banks (as those terms are defined in the

1 International Banking Act of 1978 (12 U.S.C.
2 3101)); or a rule relating to the payments system or
3 the protection of deposit insurance funds or the
4 Farm Credit Insurance Fund;

5 “(G) a rule or order relating to the financial
6 responsibility of brokers and dealers or futures
7 commission merchants, the safeguarding of investor
8 securities and funds or commodity future or options
9 customer securities and funds, the clearance and
10 settlement of securities, futures, or options
11 transactions, or the suspension of trading under the
12 Securities Exchange Act of 1934 (15 U.S.C. 78a et
13 seq.) or emergency action taken under the
14 Commodity Exchange Act (7 U.S.C. 1 et seq.), or a
15 rule relating to the protection of the Securities
16 Investor Protection Corporation, that is promulgated
17 under the Securities Investor Protection Act of 1970
18 (15 U.S.C. 78aaa et seq.);

19 “(H) a rule that the Federal Energy Regulatory
20 Commission certifies would increase reliance on
21 competitive market forces or reduce regulatory
22 burdens, or an order issued in a rate or certificate
23 proceeding by the Federal Energy Regulatory
24 Commission;

1 “(I) a rule issued by the Federal Election
2 Commission or a rule issued by the Federal
3 Communications Commission pursuant to section
4 312(a)(7) and 315 of the Communications Act of
5 1934 (47 U.S.C. 312(a)(7) and 315);

6 “(J) a rule required to be promulgated at least
7 annually pursuant to statute;

8 “(K) a rule intended to implement section 354
9 of the Public Health Service Act (42 U.S.C. 263b)
10 (as added by section 2 of the Mammography Quality
11 Standards Act of 1992); or

12 “(L) a rule or agency action intended to protect
13 children against poisoning by ingestion, including a
14 rule—

15 “(i) relating to iron toxicity poisoning;

16 “(ii) relating to lead poisoning from food
17 products; or

18 “(iii) promulgated under the Poison
19 Prevention Packaging Act of 1970 (15 U.S.C.
20 1471 et seq.).

21 **“§ 622. Regulatory analysis**

22 “(a) Before publishing notice of a proposed rule making
23 for any rule, each agency shall determine whether the rule is
24 or is not a major rule under section 621(5)(A). For the

1 purpose of any such determination, a group of closely related
2 rules shall be considered as one rule.

3 "(b)(1) If an agency has determined that a rule is not a
4 major rule under section 621(5)(A), the Director may, no later
5 than 30 days after the close of the comment period for the
6 rule,—

7 "(A) determine that the rule is a major rule under
8 section 621(5)(A), or

9 "(B) designate the rule as a major rule under section
10 621(5)(B), except that the Director shall not designate
11 more than 25 rules under this subparagraph in any one
12 calendar year.

13 "(2) No later than 15 days after the close of the
14 comment period for the rule, the Chief Counsel for Advocacy
15 of the Small Business Administration may recommend to the
16 Director that a rule which would have a significant impact on
17 a substantial number of small entities be designated as a
18 major rule. The recommendation shall include a statement of
19 the supporting factual reasons, including reasons why the
20 regulatory analysis under this section is appropriate. If the
21 Director is permitted to make a designation under paragraph
22 (1)(B) and does not accept the recommendation of the Chief
23 Counsel for Advocacy, the Director shall publish a notice in
24 the Federal Register containing the recommendation of the

1 Chief Counsel together with a statement of the supporting
2 factual reasons for the Director's action.

3 "(3) A determination or designation under this subsection
4 shall be published in the Federal Register, together with a
5 succinct statement of the basis for the Director's action.

6 "(c)(1)(A) When the agency publishes a notice of
7 proposed rule making for a major rule, the agency shall issue
8 and place in the rule making record an initial regulatory
9 analysis, and shall include a summary of such analysis in the
10 notice of proposed rule making.

11 "(B)(i) When the Director has published a determination
12 or designation that a rule is a major rule after the publication
13 of the notice of proposed rule making for the rule, the agency
14 shall promptly issue and place in the rule making record an
15 initial regulatory analysis for the rule and shall publish in the
16 Federal Register a summary of such analysis.

17 "(ii) Following the issuance of an initial regulatory
18 analysis under clause (i), the agency shall give interested
19 persons an opportunity to comment pursuant to section 553 of
20 this title in the same manner as if the initial regulatory
21 analysis had been issued with the notice of proposed rule
22 making.

23 "(2) Each initial regulatory analysis shall contain—

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

3 “(i) a succinct analysis of the benefits of the
4 proposed rule, including any benefits that cannot be
5 quantified, and an explanation of how the agency
6 anticipates that such benefits will be achieved by the
7 proposed rule, including a description of the persons
8 or classes of persons likely to receive such benefits;

9 “(ii) a succinct analysis of the costs of the
10 proposed rule, including any costs that cannot be
11 quantified, and an explanation of how the agency
12 anticipates that such costs will result from the
13 proposed rule, including a description of the persons
14 or classes of persons likely to bear such costs; and

15 “(iii) an evaluation of the relationship of the
16 benefits of the proposed rule to its costs;

17 “(B) an evaluation of the benefits and costs of a
18 reasonable number of reasonable alternatives, reflecting
19 the range of regulatory options that would achieve the
20 objectives of the statute that are relevant to the rule
21 making, including, where appropriate, alternatives that—

22 “(i) require no government action;

23 “(ii) accommodate differences among geo-
24 graphic regions; or

1 "(iii) are flexible regulatory options;

2 “(C) a description of the basis for scientific or
3 economic evaluations or information upon which the
4 agency substantially relied in the cost-benefit analysis
5 and in any risk assessment required under this chapter;
6 and

7 “(D) if required under section 632 of this title, a risk
8 assessment in accordance with section 634 of this title.

9 “(d)(1) When the agency publishes a final major rule, the
10 agency shall also issue and place in the rule making record a
11 final regulatory analysis, and shall include a summary of the
12 analysis in the statement of basis and purpose.

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

16 “(A) any material changes made to the proposed
17 rule by the agency after publication of the notice of
18 proposed rule making; and

19 “(B) agency consideration of significant comments
20 received regarding the proposed rule and the initial
21 regulatory analysis, including regulatory review
22 communications under subchapter V.

23 “(e) The cost-benefit analysis of a proposed and a final
24 rule required under this section shall include, to the extent

1 feasible, a quantification or numerical estimate of the
2 quantifiable benefits and costs. Such quantification or
3 numerical estimate shall be made in the most appropriate unit
4 of measurement, using comparable assumptions, specify the
5 ranges of predictions, and explain the margins of error
6 involved in the quantification methods and the uncertainties
7 and variabilities in the estimates used. An agency shall
8 describe the nature and extent of the nonquantifiable benefits
9 and costs of a final rule under this section in as precise and
10 succinct a manner as possible. If a risk assessment is required
11 under section 632, the cost-benefit analysis under this section
12 shall rely on the risk assessment. The agency evaluation of
13 the relationships of the benefits of a proposed and final rule to
14 its costs required by this section and section 623 shall be
15 clearly articulated in accordance with the provisions of this
16 section. An agency shall not be required to make such
17 evaluation primarily on a mathematical or numerical basis.

18 “(f)(1) A major rule may be adopted without prior
19 compliance with this subchapter or subchapter III if—

20 “(A) the agency for good cause finds that
21 conducting the regulatory analysis under this section or
22 subchapter III is contrary to the public interest due to an
23 emergency, or an imminent threat to health or safety or
24 food safety (including an imminent threat from E. coli

1 bacteria) that is likely to result in significant harm to the
2 public or to natural resources; and

3 “(B) the agency publishes in the Federal Register,
4 together with such finding, a succinct statement of the
5 basis for the finding and a deadline for compliance with
6 the provisions of subsections (a) through (e) of this
7 section. Such deadline shall occur as soon as reasonably
8 practicable after the promulgation of the rule.

9 “(2) The agency shall comply with the provisions of
10 subsections (a) through (e) of this section by the deadline
11 established in paragraph (1)(B) of this subsection and shall
12 revise the rule under section 553 of this title, if necessary, to
13 meet the requirements of section 623.

14 **“§ 623. Decisional criteria**

15 “(a)(1)(A) In promulgating a final major rule subject to
16 this subchapter, an agency shall, unless otherwise required by
17 law, select the reasonable alternative that it determines is
18 likely to—

19 “(i) employ to the extent practicable flexible
20 regulatory options;

21 “(ii) either maximize net benefits or achieve benefits
22 in a more cost-effective manner than the other reasonable
23 alternatives evaluated by the agency; and

1 “(iii) provide benefits which justify the costs of the
2 rule unless scientific, technical, or economic
3 uncertainties identified by the agency in the rule making
4 record make such a determination infeasible and the
5 President determines that it is appropriate and in the
6 public interest to issue the rule.

7 “(B) Nothing in subparagraph (A)(iii) provides authority
8 for the agency to act when not otherwise authorized by law.

9 “(C) Any determination under this paragraph shall be
10 based on the rule making record as a whole, including the
11 regulatory analysis required by section 622.

12 “(2) The agency shall publish in the Federal Register at
13 the time of promulgation of the final rule an explanation of
14 the determinations made with respect to this subsection, and
15 any required Presidential determination.

16 “(3) Notwithstanding section 301 of title 3, United
17 States Code, the President may not delegate the authority to
18 make a determination under this subsection to any other
19 person.

20 “(b) If the agency is unable to make the determination
21 required under subsection (a)(1)(A)(iii) that the benefits of
22 the reasonable alternative it selected justify the costs because
23 the selection of that alternative is otherwise required by law,
24 the agency shall, at the time the final rule is published in the

1 Federal Register, place in the Federal Register and forward to
2 Congress—

3 “(1) an explanation of the reason why such a
4 determination cannot be made; and

5 “(2) a statement regarding the statutory provision
6 that required the agency to select an alternative for which
7 the benefits do not justify the costs, including any
8 recommendation for amendments to the statutory
9 provisions and identification of other possible regulatory
10 options which could have benefits that justify the costs
11 and meet the objectives of the statute.

12 “(c) The procedures for congressional review under
13 chapter 8 of this title for a final major rule promulgated under
14 subsection (a)(1)(A)(iii) or subsection (b) shall be modified
15 as follows:

16 “(1) The time period under section 801(a)(3)(A)
17 shall be 90 days instead of the 45-day period specified
18 under such subparagraph.

19 “(2) The time period of 20 calendar days under
20 section 802(c) shall be 30 calendar days.

21 “(3) The requirement under section 802(c) for 30
22 Senators on a discharge petition shall be 20 Senators.

1 “(d) Nothing in this section shall be construed to
2 override any statutory requirement, including health, safety,
3 and environmental requirements.

4 **“§ 624. Judicial review**

5 “(a) Compliance or noncompliance by an agency with
6 the provisions of this subchapter and subchapter III shall be
7 subject to judicial review only in accordance with this
8 section.

9 “(b) The provisions of section 706(1) shall apply to the
10 provisions of this subchapter and subchapter III.

11 “(c) The periodic adjustment by the Director of the
12 \$100,000,000 amount in section 621(5)(A), to account for
13 inflation, shall not be subject to judicial review.

14 “(d)(1) The determination by an agency under section
15 622(a) that a rule is, or is not, a major rule shall be set aside
16 by a reviewing court only if the court finds that the
17 determination is arbitrary, capricious, or an abuse of
18 discretion in light of the information available to the agency
19 at the time the agency made the determination.

20 “(2) No determination or designation by the Director
21 under section 622(b) that a rule is a major rule, or failure to
22 make such a determination or designation, shall be subject to
23 judicial review.

1 “(e) No claim of noncompliance with this subchapter or
2 subchapter III shall be reviewed separate or apart from
3 judicial review of the final agency action to which it relates.

4 “(f) Judicial review of agency action under section
5 623(a) shall be limited to whether—

6 “(1) the agency determination under section 623(a),
7 based on the rule making record as a whole, was
8 arbitrary, capricious, or an abuse of discretion (or
9 unsupported by substantial evidence where that standard
10 is otherwise provided by law); or

11 “(2) the agency failed to make a determination
12 required by section 623(a).

13 “(g) A major rule for which the cost-benefit analysis or
14 risk assessment required by this chapter has been omitted in
15 its entirety shall be deemed arbitrary or capricious.

16 “(h) Except as otherwise provided in this section, failure
17 of an agency to comply with the requirements of this
18 subchapter or subchapter III shall not provide grounds for
19 setting aside or remanding the rule under review unless the
20 court finds that there is a reasonable likelihood that the
21 agency’s failure to comply with such requirements materially
22 affected the outcome of the final rule and that such rule,
23 based on the rule making record as a whole, is arbitrary,
24 capricious, or an abuse of discretion (or unsupported by

1 substantial evidence where that standard is otherwise
2 provided by law).

3 “(i) Nothing in this chapter is intended to modify the
4 rules of statutory construction applied by the courts.

5 **“§ 625. Advisory committee on regulations**

6 “(a)(1) No later than 90 days after the date of enactment
7 of this section and every 5 years thereafter, each executive
8 department (as that term is defined in section 101 of this
9 title), the Environmental Protection Agency, and each
10 independent regulatory commission shall establish an
11 advisory committee for the review of rules.

12 “(2) An agency listed in paragraph (1) may establish
13 panels under its advisory committee to facilitate review of
14 rules if the different parts of the agency affected by this
15 section are so dissimilar that it is impracticable to assemble
16 the required expertise on a single advisory committee. Such
17 panels shall be governed by the requirements of subsection
18 (b) and section 626 pertaining to advisory committees.

19 “(b)(1) Each such agency head shall appoint 9 members
20 to serve on the agency’s advisory committee and shall
21 designate a chairman from the members of the committee.
22 Membership on the committee shall represent a balanced
23 cross-section of public and private interests affected by the
24 regulations of the agency, including small businesses and

1 small governments. No person who would otherwise be an
2 employee of the Federal government serve as a member of an
3 advisory committee under this section.

4 “(2) Each member shall be appointed for the life of the
5 advisory committee. The advisory committee shall terminate
6 1 year after the date on which the committee is established.

7 “(3) A vacancy on a committee shall be filled in the same
8 manner as the original appointment.

9 “(4) Each committee shall solicit public participation
10 through appropriate means including hearings, written
11 comments, public meetings, and electronic mail.

12 “(5) Members of the committee shall receive travel
13 expenses, including per diem in lieu of subsistence, in
14 accordance with section 5703 of this title.

15 “(6) Each committee shall be subject to the provisions of
16 the Federal Advisory Committee Act (5 U.S.C. Appendix).

17 **“§ 626. Agency regulatory review**

18 “(a) Each advisory committee appointed under section 625
19 shall develop a list of rules promulgated by the agency which
20 the committee serves, which the committee determines should
21 be reviewed by the agency and can reasonably be reviewed
22 by the agency within a 5-year period. In selecting rules for
23 review, each committee shall consider the extent to which—

24 “(1) a rule may be unnecessary;

1 “(2) a rule is duplicative of other rules of the agency
2 or could be coordinated or consolidated with similar
3 rules of other agencies;

4 “(3) the benefits of a rule may not justify the costs
5 of a rule;

6 “(4) a rule may not be achieving the objectives of
7 the statute on which the rule is based in a cost-effective
8 manner; and

9 “(5) a rule could be revised to achieve the objective
10 of the statute on which the rule is based with
11 substantially—

12 “(A) less costs;

13 “(B) more benefits; or

14 “(C) greater flexibility for regulated entities.

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

22 “(c)(1) No later than 90 days after receiving and
23 reviewing the list of rules from its advisory committee, the
24 agency head shall publish in the Federal Register a

1 preliminary schedule for review of rules based on such list.
2 The agency shall give deference to the recommendations of
3 its advisory committee but may modify the list of rules to be
4 reviewed, taking into account the factors contained in
5 subsection (a)(1), (2), (3), (4), and (5), and

6 “(A) the extent to which the agency has discretion
7 under the statute authorizing the rule to modify or repeal
8 the rule;

9 “(B) the importance of the rule relative to other
10 rules being reviewed under this section; and

11 “(C) the resources expected to be available to the
12 agency to carry out the reviews under this section.

13 “(2) The agency shall provide in the Federal Register at
14 the time the preliminary schedule is published an explanation
15 of each modification to the list provided by the committee and
16 shall invite public comment on the preliminary schedule for a
17 period of no less than 60 days.

18 “(d) The preliminary schedule under subsection (c) shall
19 propose deadlines for review of each rule listed thereon, and
20 such deadlines shall occur no later than 5 years from the
21 estimated date of publication of the final schedule.

22 “(e)(1) No later than 120 days after publication of a
23 preliminary schedule under subsection (c), the agency shall

1 publish a final schedule of rules to be reviewed by the agency
2 under this section.

3 “(2) The final schedule shall establish a deadline for
4 completion of the review of each rule listed on the schedule,
5 taking into account the criteria in subsection (a) and
6 subsection (c)(1) and the comments received under subsection
7 (c)(2). Each deadline shall occur no later than 5 years after
8 the date of publication of the final schedule under paragraph
9 (1) of this subsection.

10 “(f)(1) The President’s annual budget proposal under
11 section 1105(a) of title 31, United States Code, for each
12 agency subject to this section shall identify as a separate
13 sum—

14 “(A) the amount requested to be appropriated for
15 implementation of this section during the upcoming
16 fiscal year; and

17 “(B) the amount necessary to complete the review of
18 each rule listed on the final schedule by the deadline
19 specified on the schedule;

20 and shall identify any rules for which a deadline on the final
21 schedule shall occur during the upcoming fiscal year.

22 “(2)(A) Amendments to the final schedule that add or
23 delete a rule or change a deadline for the review of a rule may

1 be included in annual appropriations Acts for the relevant
2 agencies.

3 “(B) An authorizing committee with jurisdiction may
4 submit, to the Committee on Appropriations of the Senate or
5 the House of Representatives (as the case may be),
6 amendments to a final agency schedule. The appropriations
7 committee to which such amendments have been submitted
8 may include or propose the amendments in the annual
9 appropriations Act for the relevant agency.

10 “(C) Each amendment that adds a rule to the schedule or
11 changes a deadline on the schedule shall establish a deadline
12 that provides sufficient time to accomplish the requirements
13 of subsection (h);

14 “(D) Each agency shall modify its final schedule in
15 accordance with amendments that are enacted into law.

16 “(E) An agency may revise a final schedule to extend one
17 or more deadlines for review if an appropriations Act for the
18 agency provides a sum less than the appropriation requested by
19 the President under paragraph (1) for implementation of this
20 section.

21 “(g) Notwithstanding section 624, agency failure to take
22 actions required by subsections (a) through (f) shall be
23 subject to judicial review only under section 706(1) of this

1 title. There shall be no other judicial review of the
2 preliminary or final schedule.

3 “(h)(1) For each rule on a final schedule, the agency
4 shall—

5 “(A) no later than 2 years before the deadline in such
6 schedule, publish in the Federal Register a notice that
7 solicits public comment regarding whether the rule
8 should be continued, amended, or repealed;

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

11 “(i) addresses public comments generated by
12 the notice in subparagraph (A);

13 “(ii) contains a preliminary analysis provided
14 by the agency with respect to subsection (a)(1), (2),
15 (3), (4), and (5);

16 “(iii) contains a preliminary determination
17 whether the rule should be continued, amended, or
18 repealed; and

19 “(iv) solicits public comment on the
20 preliminary determination for the rule; and

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

1 "(i) addresses public comments generated by
2 the notice in subparagraph (B);

3 "(ii) contains a determination to continue,
4 amend, or repeal the rule and an explanation of such
5 determination with respect to subsection (a)(1), (2),
6 (3), (4), and (5); and

7 "(iii) if the agency determines to amend or repeal
8 the rule, contains a notice of proposed rule making
9 under section 553 of this title.

10 “(2) If the final determination of the agency is to
11 continue the rule, such determination shall constitute final
12 agency action 60 days after the publication in the Federal
13 Register of the notice in subparagraph (C).

14 “(i) If an agency makes a determination to amend or
15 repeal a major rule under subsection (h)(1)(C), the agency
16 shall complete final agency action with regard to such rule no
17 later than 2 years of the date of publication of the notice in
18 subsection (h)(1)(C) containing such determination. Nothing
19 in this subsection shall limit the discretion of an agency to
20 decide, after having proposed to modify or repeal a rule, not
21 to promulgate such modification or repeal. Such decision
22 shall constitute final agency action for the purposes of
23 judicial review.

1 “(j) If an agency has not completed review of a rule by the
2 deadline on the final schedule, the agency shall immediately
3 commence a rule making action under section 553 of this title
4 to repeal the rule. The agency shall complete such rule
5 making no later than 2 years after the deadline on the final
6 schedule.

7 “(k) A court may remand a determination under
8 subsection (h)(1)(C) only upon a clear and convincing
9 showing that the agency could have adopted a reasonable
10 alternative that is substantially more flexible or cost-effective,
11 or that would substantially decrease costs or increase benefits,
12 while meeting the objectives of the statute that are relevant to
13 the rule under review.

14 **“SUBCHAPTER III—RISK ASSESSMENTS**

15 **“§ 631. Definitions**

16 “For purposes of this subchapter, the definitions under
17 sections 551 and 621 shall apply, and—

18 “(1) the term ‘covered agency program’ means each
19 agency program required to comply with this subchapter,
20 as provided in section 632;

21 “(2) the term ‘default inference option’ means the
22 predetermined choice for a specific inference option that,
23 in the agency’s judgment, represents the most
24 appropriate generic combination of scientific knowledge

1 and policy considerations, that serves as a starting point
2 in a risk assessment, and that is subject to modification
3 or replacement as other valid situation-specific or
4 substance-specific information is available;

5 “(3) the term 'exposure assessment' means the
6 scientific determination of the intensity, frequency,
7 distribution, and duration of actual or potential exposures
8 to the hazard in question;

9 “(4) the term 'hazard assessment' means the
10 scientific determination of whether a substance, activity,
11 or condition can cause an increased incidence of one or
12 more significant adverse effects, and a scientific
13 evaluation of the relationship between the degree of
14 exposure to the substance, activity, or condition and the
15 incidence and severity of the effect;

16 “(5) the term 'inference option' means the explicit
17 statement of an assumption, inference, or choice of
18 model, which may incorporate both scientific judgments
19 and policy considerations and which is used when
20 scientific information for inferring risk is not fully
21 adequate or is not fully drawn from experience;

22 “(6) the term 'risk assessment' means the systematic
23 process of organizing and analyzing scientific
24 information on potential hazards, including as

1 appropriate for the specific risk involved, hazard
2 assessment, exposure assessment, and risk
3 characterization;

4 “(7) the term 'risk characterization' means the
5 integration and organization of hazard and exposure
6 assessment to estimate the potential for specific harm to
7 an exposed population or natural resources including, to
8 the extent feasible, a characterization of the distribution
9 of risk as well as an analysis of uncertainties,
10 variabilities, conflicting information, and inference
11 options in the assessment;

12 “(8) the term 'screening analysis' means an analysis
13 using simple conservative inference options to arrive at
14 an estimate of upper bounds of risk to allow an agency to
15 eliminate risks from further consideration and analysis or
16 to establish priorities for action; and

17 “(9) the term 'substitution risk' means an increased
18 risk to human health, safety, or the environment
19 reasonably likely to result from a regulatory option.

20 **“§ 632. Applicability**

21 "(a) Except as provided in section 622(f) or in subsection
22 (c) of this section, a risk assessment shall be prepared
23 according to section 634 for each proposed and final major
24 rule, a primary purpose of which is to protect human health,

1 safety, or the environment, or a consequence of which is a
2 substantial substitution risk, by—

3 “(1) the Secretary of Defense, for environmental
4 restoration and waste management programs, and for
5 programs and responsibilities of the United States Army
6 Corps of Engineers;

7 “(2) the Secretary of the Interior, for programs and
8 responsibilities of the Office of Surface Mining
9 Reclamation and Enforcement;

10 “(3) the Secretary of Agriculture, for programs and
11 responsibilities of—

12 “(A) the Animal and Plant Health Inspection
13 Service;

14 “(B) the Food Safety and Inspection Service;

15 “(C) the Forest Service; and

16 “(D) the Natural Resources Conservation
17 Service;

18 “(4) the Secretary of Commerce, for programs and
19 responsibilities of the National Marine Fisheries Service;

20 “(5) the Secretary of Labor, for programs and
21 responsibilities of—

22 “(A) the Occupational Safety and Health
23 Administration; and

1 “(B) the Mine Safety and Health Adminis-
2 tration;

3 “(6) the Secretary of Health and Human Services,
4 for programs and responsibilities assigned to the Food
5 and Drug Administration;

6 “(7) the Secretary of Transportation, for programs
7 and responsibilities assigned to—

8 “(A) the Federal Aviation Administration; and

9 “(B) the National Highway Traffic Safety
10 Administration;

11 “(8) the Secretary of Energy, for programs and
12 responsibilities related to nuclear safety, occupational
13 safety and health, and environmental restoration and
14 waste management;

15 “(9) the Chairman of the Consumer Product Safety
16 Administration;

17 “(10) the Administrator of the Environmental
18 Protection Agency; and

19 “(11) the Chairman of the Nuclear Regulatory
20 Commission.

21 “(b)(1) No later than 18 months after the effective date of
22 this section, the President, acting through the Director, shall
23 determine whether any other Federal agency or specific
24 program under a Federal agency should be considered a

1 covered agency program. Such determination, with respect to
2 a particular Federal agency or program, shall be based on the
3 importance of risk assessment and risk characterization to—

4 “(A) regulatory programs administered by that
5 agency; and

6 “(B) the communication of risk information by that
7 agency to the public.

8 “(2) If the President makes a determination under
9 paragraph (1), the requirements of this subchapter shall apply
10 to any agency program determined to be a covered agency
11 program beginning on a date set by the President. Such date
12 may be no later than 6 months after the date of such
13 determination.

14 “(c)(1) The requirements of section 634 shall not apply
15 to risk assessments performed with respect to agency action
16 other than major rules described in subsection (a),
17 including—

18 “(A) the determination of an emergency or the
19 carrying out of emergency response action;

20 “(B) a health, safety, or environmental inspection,
21 compliance or enforcement action, or individual facility
22 permitting action; or

23 “(C) a screening analysis.

1 “(2) The requirements of section 634 shall not apply to
2 any food, drug, or other product label, or to any risk
3 characterization appearing on any such label.

4 “(3) If a risk assessment under section 634 is otherwise
5 required by this section, but the agency determines that—

6 “(A) a final rule subject to this subchapter is
7 substantially similar to the proposed rule with respect to
8 the risk being addressed;

9 “(B) a risk assessment for the proposed rule has
10 been carried out in accordance with section 634; and

11 “(C) a new risk assessment for the final rule is not
12 required in order to respond to comments received
13 during the period for comment on the proposed rule;

14 the agency may publish such determination along with the
15 final rule in lieu of preparing a new risk assessment for the
16 final rule.

17 **“§ 633. Savings provisions**

18 “Nothing in this subchapter shall be construed to—

19 “(1) modify any statutory standard or requirement
20 designed to protect human health, safety, or the
21 environment; or

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

1 **“§ 634. Principles for risk assessments**

2 “(a)(1) Each agency shall design and conduct risk
3 assessments in a manner that promotes rational and informed
4 risk management decisions and informed public input into
5 and understanding of the process of making agency decisions.

6 “(2) In conducting a risk assessment under this section,
7 each agency shall employ the level of detail and rigor that is
8 appropriate and practicable for reasoned decision making in
9 the matter involved, and that is proportionate to the
10 significance and complexity of the potential agency action
11 and the need for expedition.

12 “(b)(1) Each agency shall consider in each risk assessment
13 all reliable and reasonably available scientific information
14 and shall describe the basis for selecting such scientific
15 information.

16 “(2) When material conflicts among scientific
17 information appear to exist, the risk assessment shall include
18 a discussion of all relevant information including the
19 likelihood of alternative interpretations of scientific
20 information.

21 “(3) An agency shall not automatically incorporate or
22 adopt any recommendations or classification made by any
23 foreign government, the United Nations, any international
24 governmental body or standards-making organization

1 concerning the health-effects value of a substance. An
2 agency may use such recommendation or classification in a
3 risk assessment, based on a reasoned analysis of the quality
4 and relevance of the underlying data, if it describes such basis
5 under paragraph (1) of this subsection.

6 “(c)(1) Each agency shall rely on inference options alone
7 only to the extent that relevant and reliable scientific
8 information, including situation-specific or substance-specific
9 information, is not available.

10 “(2) When a risk assessment involves choice of an
11 inference option, the agency shall—

12 “(A) identify the inference option and its scientific
13 or policy basis, including the extent to which it has been
14 validated by, or conflicts with, empirical data;

15 “(B) describe, and explain the basis for, any choices
16 among inference options, including a description of
17 reasonable alternative inference options that were not
18 selected by the agency for use in the risk assessment, and
19 the sensitivity of the conclusions of the risk assessment
20 to the choice of inference options; and

21 “(C) where applicable, explain the basis for
22 compounding multiple inference options.

23 “(3) An agency shall not inappropriately combine
24 multiple inference options.

1 “(4) Each agency shall, after notice and public comment,
2 publish the agency’s default inference options, the principles
3 and rationale governing their selection, and the agency’s
4 guidelines for deciding when and how in a specific risk
5 assessment to adopt alternative inference options or to use
6 available scientific information to modify or replace a default
7 inference option.

8 “(d) The head of each agency shall provide appropriate
9 opportunities for public participation and comment during the
10 development of a risk assessment.

11 “(e) Each risk assessment shall include in the risk
12 characterization, as appropriate, each of the following:

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

14 “(2) A description of the populations or natural
15 resources that are the subject of the risk assessment.

16 “(3) An explanation of the exposure scenarios used
17 in the risk assessment, including an estimate of the
18 corresponding population at risk and the likelihood of
19 such exposure scenarios.

20 “(4) A description of the nature and severity of the
21 harm that could reasonably occur.

22 “(5) A description of the major uncertainties in each
23 component of the risk assessment and their influence on
24 the results of the assessment.

1 “(f) To the extent feasible and scientifically appropriate,
2 each agency shall—

3 “(1) express the overall estimate of exposures and
4 risk as one or more ranges or probability distributions
5 that reflect variabilities and uncertainties in the analysis;

6 “(2) for each range and distribution of exposures
7 and risks in paragraph (1), provide the corresponding
8 exposure scenarios and identify the range, distribution,
9 and likelihood of risk to the general population and,
10 where appropriate, to more highly exposed or sensitive
11 subpopulations; and

12 “(3) where quantitative estimates of the range and
13 distribution of risk estimates are not available, describe
14 the qualitative factors influencing the range, distribution,
15 and likelihood of possible risks.

16 “(g) When scientific information that permits relevant
17 comparisons of risk is reasonably available, the agency shall
18 use such information to place the nature and magnitude of a
19 risk to human health, safety, and the environment being
20 analyzed in relationship to other risks. Such comparisons
21 should consider relevant distinctions among risks, such as the
22 voluntary or involuntary nature of risks.

23 “(h) When scientifically appropriate information on
24 significant substitution risks to human health, safety, or the

1 environment is reasonably available to the agency, the agency
2 shall describe such risks in the risk assessment.

3 **“§ 635. Plan for review of risk assessments**

4 “(a) No later than 18 months after the effective date of
5 this section, the head of each agency with a covered agency
6 program shall publish a plan to review and revise any risk
7 assessment published before the expiration of such 18-month
8 period if the agency determines that significant new
9 information or methodologies are available that could
10 significantly alter the results of the prior risk assessment and
11 materially affect 1 or more major rules or policies with the
12 economic impact of a major rule.

13 “(b) A plan under subsection (a) shall—

14 “(1) provide procedures for receiving and
15 considering new information and risk assessments from
16 the public; and

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

20 **“§ 636. Judicial review**

21 “The provisions of section 624 relating to judicial review
22 shall apply to this subchapter.

1 **“SUBCHAPTER IV—QUALITY ASSURANCE AND**
2 **RESEARCH PROGRAMS**

3 **“§ 641. Definitions**

4 “For purposes of this subchapter, the definitions under
5 sections 551, 621, and 631 shall apply.

6 **“§ 642. Peer review**

7 “(a) Each covered agency program shall develop a
8 systematic program for independent and external peer review
9 required under subsection (b). Such peer review program—

10 “(1) shall provide for the creation or utilization of
11 peer review panels, expert bodies, or other formal or
12 informal devices that are broadly representative and
13 balanced and that consist of panel members or
14 participants, as the case may be, with expertise relevant
15 to the sciences involved in regulatory decisions,
16 including risk assessment and cost-benefit analysis, and
17 who are independent of the covered agency program;

18 “(2) may exclude any person with substantial and
19 relevant expertise as a panel member or participant on
20 the basis that such person represents an entity that may
21 have a potential financial interest in the outcome, or may
22 include such person if such interest is fully disclosed to
23 the agency and the agency includes such disclosure in
24 the rule making record, except that, in the case of a

1 regulatory decision affecting a single entity, no peer
2 reviewer representing such entity may be included;

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

8 “(4) shall provide adequate protections for
9 confidential business information and trade secrets,
10 including requiring panel members or participants to
11 enter into confidentiality agreements.

12 “(b)(1) Except as provided in paragraph (2), each
13 covered agency program shall provide for peer review in
14 accordance with this section of any risk assessment or cost-
15 benefit analysis that forms the basis of any major rule made
16 subject to section 634 by section 632.

17 “(2) For a major rule made subject to section 634 by
18 section 632 and that is also subject to sections 556 and 557 of
19 this title, the agency shall, as part of the record—

20 “(A) provide for peer review in accordance with this
21 section of a risk assessment or cost benefit analysis that
22 forms the basis of its decision; or

1 “(B) certify that the record otherwise contains
2 adequate scientific and technical review of a risk
3 assessment or cost-benefit analysis.

4 “(3) The Director, in consultation with the Director of
5 the Office of Science and Technology Policy, may order that
6 peer review be provided for any risk assessment or cost-
7 benefit analysis that is likely to have a significant impact on
8 public policy decisions or that would establish an important
9 precedent.

10 “(c) Each peer review under this section shall include a
11 report on the scientific and technical merit of data and the
12 methods used for the risk assessments or cost-benefit
13 analyses, and each report shall identify significant peer
14 review comments.

15 “(d) All peer review comments or conclusions and the
16 agency’s responses to significant peer review comments shall
17 be included in the rule making record.

18 “(e) No peer review shall be required under this section
19 for any data, method, document, assessment, or any
20 component thereof, which has been previously subjected to
21 peer review external to the covered agency program, unless
22 there has been a change in the relevant underlying scientific
23 information that is reasonably likely to materially affect the
24 outcome of the rule making.

1 **“§ 643. Guidelines**

2 “(a) As soon as practicable, and no later than 1 year after
3 the date of enactment of this section, each covered agency
4 program shall adopt, after notice and public comment,
5 guidelines to implement the cost-benefit analysis
6 requirements under section 622 and the risk assessment
7 principles under section 634.

8 “(b)(1) No later than 3 years after the date of enactment
9 of this section, each covered agency program shall publish,
10 after notice and public comment, guidelines for the conduct of
11 risk assessments for agency action other than major rules
12 described in subsection 632(a).

13 “(2) The guidelines under paragraph (1) shall apply the
14 principles of section 634 to the extent feasible and
15 scientifically appropriate, adapting such principles in a
16 manner that takes into account the nature of agency actions,
17 agency resources, and the risk assessment and risk
18 management needs of the agency.

19 “(3) In conducting a risk assessment under the guide-
20 lines in this subsection, the agency shall develop and use a
21 progressive analytical process, beginning with a screening
22 analysis, or with streamlined forms of risk characterization, to
23 identify issues needing more detailed analysis.

1 “(c) The development, issuance, and publication of
2 guidelines under this section shall not be subject to judicial
3 review, except for section 706(1) of this title.

4 **“§ 644. Research, training, and coordination**

5 “(a) To promote the conduct, application, and practice of
6 cost-benefit analysis and risk assessment and to identify
7 agency data and research needs, the Director of the Office of
8 Science and Technology Policy shall—

9 “(1) oversee periodic evaluations of Federal agency cost-
10 benefit analysis and risk assessment including, where relevant
11 and appropriate, the identification of and setting of priorities
12 for research needs to—

13 “(A) reduce generic data gaps, to address modeling
14 needs (including improved model sensitivity), and to
15 improve default inference options;

16 “(B) improve methods to quantify and communicate
17 uncertainty and variability among individuals, species,
18 populations, and ecological communities;

19 “(C) examine emerging and future areas of research
20 in cost-benefit analysis; and

21 “(D) examine emerging and future areas of research
22 in risk assessment;

23 “(2) oversee periodic evaluations of Federal agency
24 needs to train individuals in cost-benefit analysis and risk

1 assessment, including estimates of the resources needed to
2 provide training;

3 “(3) provide advice and recommendations to the
4 President and Congress based on the evaluations conducted
5 under paragraphs (1) and (2);

6 “(4) establish interagency mechanisms to improve the
7 consistency of cost-benefit analysis and risk assessment
8 among Federal agencies, where scientifically appropriate; and

9 “(5) establish mechanisms between Federal and State
10 agencies to improve cooperation in the development and
11 application of cost-benefit analysis and risk assessment.

12 “(b) The Director of the Office of Science and
13 Technology Policy shall coordinate the support, by agencies,
14 of research and training in risk assessment and cost-benefit
15 analysis, to ensure that the research needs and priorities
16 identified under subsection (a) are addressed adequately and
17 that an adequate supply of trained personnel in risk
18 assessment and cost-benefit analysis is maintained.

19 **“645. Judicial review.**

20 “Except as otherwise provided in this subchapter,
21 judicial review under this subchapter shall be in accordance
22 with section 624.

1 **SUBCHAPTER V—EXECUTIVE OVERSIGHT**

2 **“§ 651. Definitions**

3 “For purposes of this subchapter—

4 “(1) the definitions under sections 551 and 621 shall
5 apply; and

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

8 “(A) An agenda or schedule for rule makings.

9 “(B) Advance notice of proposed rule making.

10 “(C) Notice of proposed rule making.

11 “(D) Proposed final rule making and interim
12 final rule making.

13 **“§ 652. Presidential regulatory review**

14 “(a) The President shall establish a process for the
15 centralized review and coordination of Federal agency
16 regulatory actions. Such process shall be the responsibility of
17 the Director.

18 “(b) For the purpose of carrying out the review
19 established under subsection (a), the Director shall—

20 “(1) develop and oversee uniform regulatory
21 policies and procedures, including those by which each
22 agency shall comply with the requirements of this
23 chapter;

1 “(2) develop policies and procedures for review of
2 regulatory actions by the Director;

3 “(3) develop and oversee an annual governmentwide
4 regulatory planning process that shall include review of
5 planned agency major rules and other significant
6 regulatory actions and publication of—

7 “(A) a summary of and schedule for
8 promulgation of planned agency major rules;

9 “(B) agency schedules for review of existing
10 rules under section 625; and

11 “(C) a summary of regulatory review actions
12 undertaken in the prior year.

13 “(c) The review established under subsection (a) shall be
14 conducted as expeditiously as practicable and shall be limited
15 to no more than 90 days.

16 **“§ 653. Public disclosure of information**

17 “(a) The Director, in carrying out the provisions of
18 section 652, shall establish procedures to provide public and
19 agency access to information concerning regulatory review
20 actions, including—

21 “(1) disclosure to the public on an ongoing basis of
22 information regarding the status of regulatory actions
23 undergoing review;

1 “(2) disclosure to the public, no later than
2 publication of a regulatory action, of—

3 “(A) all written communications, regardless of
4 form or format, including drafts of all proposals and
5 associated analyses, between the Director, or
6 employees of the Director, and the regulatory
7 agency;

8 “(B) all written communications, regardless of
9 form or format, between the Director, or employees
10 of the Director, and any person not employed by the
11 executive branch of the Federal government relating
12 to the substance of a regulatory action;

13 “(C) a record of all oral communications
14 relating to the substance of a regulatory action
15 between the Director, or employees of the Director,
16 and any person not employed by the executive
17 branch of the Federal government; and

18 “(D) a written explanation of any review action
19 and the date of such action; and

20 “(3) disclosure to the regulatory agency, on a timely
21 basis, of—

22 “(A) all written communications between the
23 Director or employees of the Director and any
24 person not employed by the executive branch of the

1 Federal government, relating to the substance of an
2 agency regulatory action;

3 “(B) a record of all oral communications, and
4 an invitation to participate in meetings, relating to
5 the substance of an agency regulatory action,
6 between the Director or employees of the Director
7 and any person not employed by the executive
8 branch of the Federal government; and

9 “(C) a written explanation of any review action
10 taken concerning an agency regulatory action.

11 **“§ 654. Judicial review**

12 “(a) The exercise of the authority granted under this
13 subchapter by the Director or the President shall not be
14 subject to judicial review in any manner.

15 “(b) Judicial review of agency compliance or
16 noncompliance with any rule promulgated under this
17 subchapter shall be in accordance with section 624.”

18 (b) DEADLINES FOR RULE MAKING.—

19 (1) All deadlines in statutes that require agencies to
20 propose or promulgate any rule subject to section 622 or
21 subchapter III of title 5, United States Code (as amended by
22 this Act) during the 2-year period beginning on the effective
23 date of this section shall be suspended until the earlier of—

1 (A) the date on which the requirements of section
2 622 or subchapter III of title 5, United States Code (as
3 amended by this Act) are satisfied; or

4 (B) the date occurring 6 months after the date of the
5 applicable deadline.

6 (2) All deadlines imposed by any court of the United
7 States that would require an agency to propose or promulgate
8 a rule subject to section 622 or subchapter III of title 5,
9 United States Code (as amended by this Act) during the 2-
10 year period beginning on the effective date of this section
11 shall be suspended until the earlier of—

12 (A) the date on which the requirements of section
13 622 or subchapter III of title 5, United States Code (as
14 amended by this Act) are satisfied; or

15 (B) the date occurring 6 months after the date of the
16 applicable deadline.

17 (3) In any case in which the failure to promulgate a rule
18 by a deadline occurring during the 2-year period beginning on
19 the effective date of this section would create an obligation to
20 regulate through individual adjudications, the deadline shall
21 be suspended until the earlier of—

22 (A) the date on which the requirements of section
23 622 or subchapter III of title 5, United States Code (as
24 amended by this Act) are satisfied; or

1 (B) the date occurring 6 months after the date of the
2 applicable deadline.

3 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

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

7 **“CHAPTER 6—THE ANALYSIS OF**
8 **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. Regulatory analysis.

“623. Decisional criteria.

“624. Judicial review.

“625. Advisory committee on regulations.

“626. Agency regulatory review.

“SUBCHAPTER III—RISK ASSESSMENTS

“631. Definitions.

“632. Applicability.

“633. Savings provisions.

“634. Principles for risk assessments.

“635. Plan for review of risk assessments.

“636. Judicial review.

“SUBCHAPTER IV—QUALITY ASSURANCE AND
RESEARCH PROGRAMS

“641. Definitions.

“642. Peer review.

“643. Guidelines.

“644. Judicial review.

“645. Research, training, and coordination.

“SUBCHAPTER V—EXECUTIVE OVERSIGHT

“651. Definitions.

“652. Presidential regulatory review.

“653. Public disclosure of information.

“654. Judicial review.”.

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

4 “SUBCHAPTER I—REGULATORY ANALYSIS”.

5 (3) The Part analysis for Part I of title 5 is amended
6 by striking:

“5. Administrative Procedure..... 501”

7 and inserting:

“5. Administrative Procedure..... 500

“6. The Analysis of Regulatory Functions.. 601”.

8 **SEC. 204. RULE MAKING.**

9 (a) Section 553(b)(A) of title 5, United States Code, is
10 amended to read as follows:

11 “(A) to interpretative rules, general statements of policy,
12 guidance, or rules of agency organization, procedure, or

1 practice, unless such rules, statements, or guidance have
2 general applicability and substantially alter or create rights or
3 obligations of persons outside the agency; or”

4 (b) Section 553(e) of title 5, United States Code, is
5 amended—

6 (1) by inserting “(1)” before “Each”; and

7 (2) by adding at the end the following paragraphs—

8 “(2) The agency shall take final agency action to
9 grant or deny a petition made under paragraph (1), and
10 give written notice of its action to the petitioner,
11 including an explanation of its reasons for granting or
12 denying the petition, with reasonable promptness, but in
13 no event later than 18 months after the petition was
14 received by the agency.

15 “(3) In acting on a petition made under paragraph
16 (1), the agency shall consider the availability of its
17 resources and evaluate the effect of granting the petition
18 on achieving statutory objectives.”

19 **SEC. 205. RISK-BASED PRIORITIES**

20 (a) **PURPOSES.**—The purposes of this section are to—

21 (1) encourage Federal agencies engaged in
22 regulating risks to human health, safety, and the
23 environment to achieve the greatest risk reduction at the
24 least cost practical;

1 sion.

2 (I) The National Oceanic and Atmospheric
3 Administration.

4 (J) The United States Army Corps of
5 Engineers.

6 (K) The Nuclear Regulatory Commission.

7 (3) EFFECT.—The term 'effect' means a deleterious
8 change in the condition of—

9 "(A) a human or other living thing (including death,
10 cancer, or other chronic illness, decreased reproductive
11 capacity, or disfigurement); or

12 "(B) an inanimate thing important to human welfare
13 (including destruction, degeneration, the loss of
14 intended function, and increased costs for
15 maintenance).

16 (4) IRREVERSIBILITY.—The term 'irreversibility' means
17 the extent to which a return to conditions before the
18 occurrence of an effect are either very slow or will never
19 occur.

20 (5) LIKELIHOOD.—The term 'likelihood' means the
21 estimated probability that an effect will occur.

22 (6) MAGNITUDE.—The term 'magnitude' means the
23 number of individuals or the quantity of ecological
24 resources or other resources that contribute to human

1 welfare that are affected by exposure to a stressor.

2 (7) SERIOUSNESS.—The term 'seriousness' means the
3 intensity of effect, the likelihood, the irreversibility, and
4 the magnitude.

5 (c) DEPARTMENT AND AGENCY PROGRAM GOALS.—

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

12 (A) the covered agency determines to be most
13 serious; and

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

18 (2) DETERMINING THE MOST SERIOUS RISKS.—In
19 identifying the greatest risks under paragraph (1) of this
20 subsection, each covered agency shall consider, at a
21 minimum—

22 (A) the likelihood, irreversibility, and severity
23 of the effect; and

24 (B) the number and classes of individuals

1 potentially affected,
2 and shall explicitly take into account the results of the
3 comparative risk analysis conducted under subsection (d)
4 of this section.

5 (3) OMB REVIEW.—The covered agency's
6 determinations of the most serious risks for purposes of
7 setting priorities shall be reviewed and approved by the
8 Director of the Office of Management and Budget before
9 submission of the covered agency's annual budget
10 requests to Congress.

11 (4) INCORPORATING RISK-BASED PRIORITIES INTO
12 BUDGET AND PLANNING.—The head of each covered
13 agency shall incorporate the priorities identified under
14 paragraph (1) into the agency budget, strategic planning,
15 regulatory agenda, enforcement, and research activities.
16 When submitting its budget request to Congress and
17 when announcing its regulatory agenda in the Federal
18 Register, each covered agency shall identify the risks that
19 the covered agency head has determined are the most
20 serious and can be addressed in a cost-effective manner
21 under paragraph (1), the basis for that determination, and
22 explicitly identify how the covered agency's requested
23 budget and regulatory agenda reflect those priorities.

24 (5) EFFECTIVE DATE.—This subsection shall take

1 effect 12 months after the date of enactment of this Act.

2 (d) COMPARATIVE RISK ANALYSIS.—

3 (1) REQUIREMENT.—(A)(i) No later than 6 months
4 after the effective date of this Act, the Director of the
5 Office of Management and Budget shall enter into
6 appropriate arrangements with a nationally recognized
7 scientific institution or scholarly organization—

8 (I) to conduct a study of the methodologies for
9 using comparative risk to rank dissimilar human
10 health, safety, and environmental risks; and

11 (II) to conduct a comparative risk analysis.

12 (ii) The comparative risk analysis shall compare and
13 rank, to the extent feasible, human health, safety, and
14 environmental risks potentially regulated across the
15 spectrum of programs administered by all covered
16 agencies.

17 (B) The Director shall consult with the Office of
18 Science and Technology Policy regarding the scope of
19 the study and the conduct of the comparative risk
20 analysis.

21 (C) Nothing in this subsection should be construed
22 to prevent the Director from entering into a sole-source
23 arrangement with a nationally recognized scientific
24 institution or scholarly organization.

1 (2) CRITERIA.—The Director shall ensure that the
2 arrangement under paragraph (1) provides that—

3 (A) the scope and specificity of the analysis are
4 sufficient to provide the President and agency heads
5 guidance in allocating resources across agencies and
6 among programs in agencies to achieve the greatest
7 degree of risk prevention and reduction for the
8 public and private resources expended;

9 (B) the analysis is conducted through an open
10 process, including opportunities for the public to
11 submit views, data, and analyses and to provide
12 public comment on the results before making them
13 final;

14 (C) the analysis is conducted by a balanced
15 group of individuals with relevant expertise,
16 including toxicologists, biologists, engineers, and
17 experts in medicine, industrial hygiene, and
18 environmental effects, and the selection of members
19 for such study shall be at the sole discretion of the
20 scientific institution or scholarly organization;

21 (D) the analysis is conducted, to the extent
22 feasible and relevant, consistent with the risk
23 assessment principles in section 634 of this title;

24 (E) the methodologies and principal scientific

1 determinations made in the analysis are subjected to
2 independent peer review consistent with section
3 642, and the conclusions of the peer review are
4 made publicly available as part of the final report
5 required under subsection (e); and

6 (F) the results are presented in a manner that
7 distinguishes between the scientific conclusions and
8 any policy or value judgments embodied in the
9 comparisons.

10 (3) COMPLETION AND REVIEW.—No later than 3
11 years after the effective date of this Act, the comparative
12 risk analysis required under paragraph (1) shall be
13 completed. The comparative risk analysis shall be
14 reviewed and revised at least every 5 years thereafter for
15 a minimum of 15 years following the release of the first
16 analysis. The Director shall arrange for such review and
17 revision by an accredited scientific body in the same
18 manner as provided under paragraphs (1) and (2).

19 (4) STUDY.—The study of methodologies provided
20 under paragraph (1) shall be conducted as part of the first
21 comparative risk analysis and shall be completed no later
22 than 180 days after the completion of that analysis. The
23 goal of the study shall be to develop and rigorously test
24 methods of comparative risk analysis. The study shall

1 have sufficient scope and breadth to test approaches for
2 improving comparative risk analysis and its use in setting
3 priorities for human health, safety, and environmental
4 risk prevention and reduction.

5 (5) TECHNICAL GUIDANCE.—No later than 180 days
6 after the effective date of this Act, the Director, in
7 collaboration with other heads of covered agencies shall
8 enter into a contract with the National Research Council
9 to provide technical guidance to agencies on approaches
10 to using comparative risk analysis in setting human
11 health, safety, and environmental priorities to assist
12 agencies in complying with subsection (c) of this section.

13 (e) REPORTS AND RECOMMENDATIONS TO CONGRESS AND
14 THE PRESIDENT.—No later than 24 months after the effective
15 date of this Act, each covered agency shall submit a report to
16 Congress and the President—

17 (1) detailing how the agency has complied with
18 subsection (c) and describing the reason for any
19 departure from the requirement to establish priorities to
20 achieve the greatest overall net reduction in risk;

21 (2) recommending—

22 (A) modification, repeal, or enactment of laws
23 to reform, eliminate, or enhance programs or
24 mandates relating to human health, safety, or the

1 environment; and

2 (B) modification or elimination of statutory or
3 judicially mandated deadlines,

4 that would assist the covered agency to set priorities in
5 activities to address the risks to human health, safety, or
6 the environment in a manner consistent with the
7 requirements of subsection (c)(1);

8 (3) evaluating the categories of policy and value
9 judgment used in risk assessment, risk characterization,
10 or cost-benefit analysis; and

11 (4) discussing risk assessment research and training
12 needs, and the agency's strategy and schedule for meeting
13 those needs.

14 (f) SAVINGS PROVISION AND JUDICIAL REVIEW.—

15 (1) IN GENERAL.—Nothing in this section shall be
16 construed to modify any statutory standard or
17 requirement designed to protect human health, safety, or
18 the environment.

19 (2) JUDICIAL REVIEW.—Compliance or noncompli-
20 ance by an agency with the provisions of this section
21 shall not be subject to judicial review.

22 (3) AGENCY ANALYSIS.—Any analysis prepared
23 under this section shall not be subject to judicial
24 consideration separate or apart from the requirement,

1 rule, program, or law to which it relates. When an action
2 for judicial review of a covered agency action is
3 instituted, any analysis for, or relating to, the action shall
4 constitute part of the whole record of agency action for
5 the purpose of judicial review of the action and shall, to
6 the extent relevant, be considered by a court in
7 determining the legality of the covered agency action.

8 **SEC. 206. EFFECTIVE DATE**

9 (a) Except as otherwise provided in this title, this title and
10 the amendments made by this title shall take effect 180 days
11 after the date of enactment of this Act.

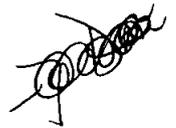
12 (b)(1) Except as provided in paragraph (2), section 203 of
13 this title shall take effect on the date that is 90 days after the date
14 of enactment of this Act.

15 (2) For a final rule that is a major rule under section
16 621(5)(A) of title 5, United States Code (as amended by this
17 Act), and that is promulgated after the effective date of section
18 203 and no later than 3 years after the date of enactment of this
19 Act, an agency may, in lieu of the requirements of sections 622
20 and subchapter III of title 5, United States Code (as amended by
21 this Act), comply with the requirements of section 623 using
22 other appropriate analyses (such as analyses performed pursuant
23 to Executive Order 12866), provided that such analyses are
24 placed in the rule making record for all purposes, including

DRAFT AMENDMENT – 3/14/96

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- 1 judicial review of the final agency action to which the analyses
- 2 relate.



104TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mr. LEVIN introduced the following bill: which was read twice and referred to the Committee on _____

A BILL

To provide for comprehensive regulatory reform.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Regulatory Reform Act
5 of 1996".

6 **SEC. 2. DEFINITIONS.**

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

9 (1) in the matter preceding paragraph (1), by
10 striking "this subchapter" and inserting "this chap-
11 ter and chapters 7 and 8";

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

2 (3) in paragraph (14), by striking the period at

3 the end and inserting “; and”; and

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

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

8 **SEC. 3. ANALYSIS OF AGENCY RULES.**

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

12 “SUBCHAPTER II—ANALYSIS OF AGENCY
13 RULES

14 “§ 621. Definitions

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

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

23 “(2) the term ‘cost’ means the reasonably iden-
24 tifiable significant adverse effects, quantifiable and
25 nonquantifiable, including social, health, environ-

1 mental, economic, and distributional effects that are
2 expected to result directly or indirectly from imple-
3 mentation of, or compliance with, a rule;

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

14 “(4) the term ‘flexible regulatory options’
15 means regulatory options that permit flexibility to
16 regulated persons in achieving the objective of the
17 rulemaking including regulatory options that employ
18 market-based mechanisms, performance standards,
19 or voluntary programs;

20 “(5) the term ‘major rule’ means a rule or a
21 group of closely related rules that the agency pro-
22 posing the rule or the Director [↑] reasonably deter-
23 mines is likely to have an annual effect on the econ-
24 omy of \$100,000,000 or more in reasonably quan-
25 tifiable costs and such \$100,000,000 amount shall

pursuant to
622(b)(1)

for inflation

1 be adjusted periodically by the Director ~~to account~~
 2 ~~for inflation~~ ^{but only} in increments of \$20,000,000, and such
 3 adjustment shall not be subject to judicial review;

4 “(6) the term ‘market-based mechanism’ means
 5 a regulatory approach that—

6 “(A) ^{uses in whole or in part} ~~permits regulated persons to respond~~
 7 ^{market forces, such as} ~~automatically to changes in general economic~~
 8 ~~conditions directly pertinent to the regulatory~~
 9 ~~program without affecting the achievement of~~
 10 ~~the objective of the rulemaking;~~

11 “(B) ~~affords flexibility to each regulated~~
 12 ~~person in complying with regulatory objectives,~~
 13 ~~including, where appropriate, the opportunity to~~
 14 ~~transfer to, or receive from, other persons (in-~~
 15 ~~cluding for cash or other legal consideration)~~

16 increments of compliance responsibility estab-
 17 lished by the program ~~and~~ ^{to achieve the objective of}
 18 ^{imposes} ~~maintains the~~ legal accountability ^{of} ~~on~~

19 each regulated person for the achievement of
 20 the objective of the rulemaking;

21 “(7) the term ‘performance standard’ means a
 22 requirement that imposes legal accountability ^{on each regulated person} for the
 23 achievement of ^{the} ~~an explicit regulatory~~ objective ^{of the rulemaking,} with-
 24 out prescribing the particular method or procedures,
 25 for achieving such objective;

1 “(8) the term ‘reasonable alternative’ means a
2 reasonable regulatory option ~~within the reasonable~~
3 ~~range of options~~ that would achieve the objective of
4 the rulemaking and that the agency has authority to
5 adopt under the statute granting rulemaking author-
6 ity, including flexible regulatory options; ~~unless such~~
7 ~~flexible regulatory options are precluded by the stat-~~
8 ~~ute granting the rulemaking authority;~~

9 “(9) the term ‘risk assessment’ has the same
10 meaning as such term is defined under section
11 631⁵(~~8~~); and

12 “(10) the term ‘rule’ has the same meaning as
13 in section 551(4) of this title, and shall not in-
14 clude—

15 “(A) a rule exempt from notice and public
16 comment procedure under section 553 of this
17 title;

18 “(B) a rule that involves the internal reve-
19 nue laws of the United States, or the assess-
20 ment and collection of taxes, duties, or other
21 revenue or receipts;

22 ~~“(C) a rule or agency action that author-~~
23 ~~izes the introduction into, or removal from,~~
24 ~~commerce, or recognizes the marketable status,~~
25 ~~of a product;~~

1 ^C
2 “(~~D~~) a rule of particular applicability that
3 approves or prescribes for the future rates,
4 wages, prices, services, corporate or financial
5 structures, reorganizations, mergers, acquisi-
6 tions, accounting practices, or disclosures bear-
7 ing on any of the foregoing;

8 ^D
9 “(~~E~~) a rule relating to monetary policy
10 proposed or promulgated by the Board of Gov-
11 ernors of the Federal Reserve System or by the
12 Federal Open Market Committee;

13 ^E
14 “(~~F~~) a rule relating to the safety or sound-
15 ness of federally insured depository institutions
16 or any affiliate of such an institution (as de-
17 fined in section 2(k) of the Bank Holding Com-
18 pany Act of 1956 (12 U.S.C. 1841(k)); credit
19 unions; the Federal Home Loan Banks; govern-
20 ment-sponsored housing enterprises; a Farm
21 Credit System Institution; foreign banks, and
22 their branches, agencies, commercial lending
23 companies or representative offices that operate
24 in the United States and any affiliate of such
25 foreign banks (as those terms are defined in the
26 International Banking Act of 1978 (12 U.S.C.
27 3101)); or a rule relating to the payments sys-

1 tem or the protection of deposit insurance funds
2 or Farm Credit Insurance Fund;

3 "^F~~(5)~~ a rule or order relating to the finan-
4 cial responsibility of brokers and dealers or fu-
5 tures commission merchants, the safeguarding
6 of investor securities and funds or commodity
7 future or options customer securities and funds,
8 the clearance and settlement of securities, fu-
9 tures, or options transactions, or the suspension
10 of trading under the Securities Exchange Act of
11 1934 (15 U.S.C. 78a et seq.) or emergency ac-
12 tion taken under the Commodity Exchange Act
13 (7 U.S.C. 1 et seq.), or a rule relating to the
14 protection of the Securities Investor Protection
15 Corporation, that is promulgated under the Se-
16 curities Investor Protection Act of 1970 (15
17 U.S.C. 78aaa et seq.);

18 "^E~~(1)~~ a rule issued by the Federal Election
19 Commission or a rule issued by the Federal
20 Communications Commission pursuant to sec-
21 tions 312(a)(7) and 315 of the Communications
22 Act of 1934 (47 U.S.C. 312(a)(7) and 315);

23 "^H~~(1)~~ a rule required to be promulgated ~~at~~ *at regular*
24 *intervals* least annually pursuant to statute;

1 “~~(J)~~^J a rule or agency action relating to the
2 public debt; or

3 “~~(K)~~^J a rule that involves the international
4 trade laws of the United States.
~~contract, or loan.~~

5 “§ 622. Regulatory analysis

6 “(a)⁽¹⁾ Before publishing notice of a proposed rule-
7 making for any rule, each agency shall determine whether
8 the rule is or is not a major rule. For the purpose of any
9 such determination, a group of closely related rules shall
10 be considered as one rule.

(2)
SEE
insert A
(next page)

11 “(b)(1) If an agency has determined that a rule is
12 not a major rule, the Director may determine under sec-
13 tion 621^{5 or 622(a)(2)}(A) that the rule is a major rule no later than
14 30 days after the close of the comment period for the rule.

15 “(2) A determination under paragraph (1) shall be
16 published in the Federal Register, together with a succinct
17 statement of the basis for the determination.

18 “(c)(1)(A) When the agency publishes a notice of pro-
19 posed rulemaking for a major rule, the agency shall issue
20 and place in the rulemaking file an initial regulatory anal-
21 ysis, and shall include a summary of such analysis in the
22 notice of proposed rulemaking.

23 “(B)(i) When the Director has published a deter-
24 mination that a rule is a major rule after the publication
25 of the notice of proposed rulemaking for the rule, the

INSERT **A**

622 (a)(2). Notwithstanding the provision of paragraph 621(5), the Director may designate up to 25 rules in any calendar year as major rules if the Director determines that the rule is likely to adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities.

1 agency shall promptly issue and place in the rulemaking
2 file an initial regulatory analysis for the rule and shall
3 publish in the Federal Register a summary of such analy-
4 sis.

5 “(ii) Following the issuance of an initial regulatory
6 analysis under clause (i), the agency shall give interested
7 persons an opportunity to comment pursuant to section
8 553 of this title in the same manner as if the initial regu-
9 latory analysis had been issued with the notice of proposed
10 rulemaking.

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

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

14 “(i) a succinct analysis of the benefits of
15 the proposed rule, including any benefits that
16 cannot be quantified, and an explanation of how
17 the agency anticipates that such benefits will be
18 achieved by the proposed rule, including a de-
19 scription of the persons or classes of persons
20 likely to receive such benefits;

21 “(ii) a succinct analysis of the costs of the
22 proposed rule, including any costs that cannot
23 be quantified, and an explanation of how the
24 agency anticipates that such costs will result
25 from the proposed rule, including a description

1 of the persons or classes of persons likely to
2 bear such costs; and

3 “(iii) an evaluation of the relationship of
4 the benefits of the proposed rule to its costs;

5 “(B) an evaluation of a reasonable number of
6 reasonable alternatives, including, where appropriate, alternatives that—

reflecting the range of regulatory options that could achieve the objective of the rulemaking

7 “(i) require no government action;

8 “(ii) accommodate differences among geo-
9 graphic regions and among persons with differ-
10 ing levels of resources with which to comply;
11 and
12

13 “(iii) employ flexible regulatory options;

14 “(C) a description of the ~~reliability~~ of scientific
15 or economic evaluations or information upon which
16 the agency substantially relied in the cost-benefit
17 analysis and any risk assessment required under this
18 chapter; and

19 “(D) if required under this chapter, a risk as-
20 sessment in accordance with subchapter III.

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

1 “(2) Each final regulatory analysis shall address each
 2 of the requirements for the initial regulatory analysis
 3 under subsection (c)(2), revised to reflect—

4 “(A) any material changes made to the pro-
 5 posed rule by the agency after publication of the no-
 6 tice of proposed rulemaking; and

7 “(B) agency consideration of significant com-
 8 ments received regarding the proposed rule and the
 9 initial regulatory analysis, including regulatory re-
 10 view communications under subchapter V.

11 “(e) The analysis of the benefits and costs of a pro-
 12 posed and a final rule required under this section shall
 13 include, to the extent feasible, a quantification or numeri-
 14 cal estimate of the quantifiable benefits and costs. Such
 15 quantification or numerical estimate shall be made in the
 16 most appropriate units of measurement, using comparable
 17 assumptions, specify the ranges of predictions, and explain
 18 the margins of error involved in the quantification meth-
 19 ods and in the estimates used. An agency shall describe
 20 the nature and extent of the nonquantifiable benefits and
 21 costs of a final rule pursuant to this section in as precise
 22 and succinet a manner as possible. [An agency shall not
 23 be required to make such evaluation primarily on a mathe-
 24 matical or numerical basis.

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(Next page)*

(f) Insert C (Next page)

INSERT **B**

The agency evaluations of the relationships of the benefits of a proposed and final rule to its costs required by this section shall be clearly articulated in accordance with the provisions of this section.

INSERT **B**

Where a risk assessment has been prepared pursuant to subchapter III, the analysis of costs and benefits shall take into account the results of that risk assessment.

1 ⁹~~(7)~~(1) A major rule may be adopted without prior
2 compliance with this subchapter or subchapter III if—

3 “(A) the agency for good cause finds that con-
4 ducting the cost-benefit analysis under this section
5 or risk assessment under subchapter III is contrary
6 to the public interest due to an emergency ~~of~~ health
7 or safety threat that is likely to result in significant
8 harm to the public, ^{to plants or animals} or to natural resources; and

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

12 “(2) If a major rule is adopted under paragraph (1),
13 the agency shall ~~promptly~~ comply with the provisions of

14 subsections (a) through (e) of this section ^{as promptly as possible unless}
15 ~~“(g) The requirements of this subchapter shall not~~ ^{compliance would be}
16 ~~alter the criteria for rulemaking otherwise applicable~~ ^{unreasonable because the rule}
17 ~~under other statutes.~~ ^{is, or soon will be, no longer in effect.}

18 “§ 623. Decisional criteria

19 “(a)(1)(A) In promulgating a final major rule subject
20 to this subchapter, an agency shall, unless otherwise re-
21 quired by law, ~~or subject to the provisions of subsection~~
22 ~~(d)~~, select the reasonable alternative that it determines is
23 likely to—

24 “(i) employ to the extent practicable flexible
25 regulatory options;

1 “(ii) either maximize net benefits or achieve
2 benefits in a more cost-effective manner than the
3 other reasonable alternatives evaluated by the agen-
4 cy that achieve the same or a substantially similar
5 level of benefits; and

*Insert D
(next page)*

6 “(iii) provide benefits which justify the costs of
7 the rule unless scientific, technical, or economic un-
8 certainties identified by the agency in the rule-
9 making record make such a determination ~~infeasible~~
10 and the President determines it is appropriate and
11 in the public interest to issue the rule.

impracticable

12 “(B) Nothing in subparagraph (A)(iii) provides au-
13 thority for the agency to act when not otherwise author-
14 ized by law.

15 “(C) Any determination under this paragraph shall
16 be based upon the rulemaking record as a whole, including
17 the regulatory analysis required by section 622.

18 “(2) The agency shall publish in the Federal Register
19 at the time of promulgation of the final rule an expla-
20 nation of the determinations made with respect to this
21 subsection, and any required Presidential determination.

*and forward
to Congress*

22 “(3) The President may delegate the authority to
23 make a determination under this subsection only to the
24 Director of the Office of Management and Budget.

INSERT ~~D~~

unless the consideration of other significant factors, authorized by the statute under which the rule is being promulgated and specifically identified by the agency in the rulemaking record, makes another reasonable alternative appropriate and in the public interest;

1 “(b) If the agency is unable to make the determina-
2 tion required under subsection (a)(1)(A)(iii) that the bene-
3 fits of the reasonable alternative it selected justify the
4 costs because the selection of ^{such}~~that~~ alternative is otherwise
5 required by law, the agency shall at the time the final rule
6 is published in the Federal Register, place in the Federal
7 Register and forward to Congress—

8 “(1) an explanation of the reason why such a
9 determination cannot be made; and

10 “(2) a statement regarding the statutory provi-
11 sions that required the agency to select an alter-
12 native for which the benefits do not justify the costs,
13 including any recommendation for amendments to
14 the statutory provisions and identification of other
15 possible regulatory options which could have benefits
16 that justify the costs and meet the objectives of the
17 statute.

18 “(c) The procedures for congressional review under
19 chapter 8 for a final major rule subject to subsection (b)
20 shall be modified as follows:

21 “(1) The time period under section
22 801(b)(2)(A) shall be 90 days instead of the 45-day
23 period specified under such subparagraph.

24 “(2) The time period of 20 calendar days under
25 section 801(i)(3) shall be 30 calendar days.

1 “(3) The requirement under section 801(i)(3)
2 for 30 Senators on a discharge petition shall be 20
3 Senators.

4 “(d) Nothing in this section shall be construed to
5 override any statutory requirement, including health, safe-
6 ty, and environmental requirements.

7 **“§ 624. Judicial review**

8 “(a) Compliance or noncompliance by an agency with
9 the provisions of this subchapter and subchapter III shall
10 be subject to judicial review only in accordance with this
11 section.

12 “(b) Any determination by the Director that a rule
13 is, or is not, a major rule shall not be subject to judicial
14 review in any manner.

15 “(c) The determination by an agency that a rule is,
16 or is not, a major rule shall be set aside by a reviewing
17 court only upon a clear and convincing showing that the
18 determination is erroneous in light of the information
19 available to the agency at the time the agency made the
20 determination.

21 “(d) No claim of noncompliance with this subchapter
22 or subchapter III shall be reviewed separate or apart from
23 judicial review of the final agency action to which it re-
24 lates.

JUDICIAL REVIEW

(e) In any proceeding involving judicial review under section 706 or under the statute granting the rulemaking authority, the information contained in any cost-benefit analysis or risk assessment required under subchapter II or III may be considered by the court as part of the rulemaking record solely for the purpose of determining whether the final agency action is arbitrary, capricious or an abuse of discretion (or unsupported by substantial evidence where that standard is otherwise provided by law). The adequacy of compliance or the failure to comply with subchapter II or III shall not be grounds for remanding or invalidating a final agency action, unless the agency entirely failed to perform a required cost-benefit analysis or risk assessment or to conduct a peer review under section 642.

1 ~~“(e) A major rule may be set aside or remanded only~~
2 if the court finds that—

3 ~~“(1) the agency determination under section~~
4 ~~623(a), based on the rulemaking file as a whole, was~~
5 ~~arbitrary or capricious or an abuse of discretion (or~~
6 ~~unsupported by substantial evidence where that~~
7 ~~standard is otherwise provided by law); or~~

8 ~~“(2) the agency failed to make a determination~~
9 ~~required by that subsection.~~

10 ~~“(f) Any rule determined to be a major rule under~~
11 ~~section 622 (a) or (b) for which the cost-benefit analysis~~
12 ~~or risk assessment required under this chapter has been~~
13 ~~omitted in its entirety, shall be deemed arbitrary or capri-~~
14 ~~cious.~~

15 ~~“(g) Except as otherwise provided in this section, fail-~~
16 ~~ure of an agency to comply with the procedural require-~~
17 ~~ments of this subchapter or subchapter III shall not pro-~~
18 ~~vide grounds for setting aside or remanding the rule under~~
19 ~~review unless the court finds that there is a substantial~~
20 ~~likelihood that the agency’s failure to comply with such~~
21 ~~procedural requirements materially affected the outcome~~
22 ~~of the final rule and that such rule, based on the rule-~~
23 ~~making record as a whole, is arbitrary, capricious, or an~~
24 ~~abuse of discretion (or unsupported by substantial evi-~~
25 ~~dence where that standard is otherwise provided by law).~~

[Handwritten signature]

1 “(h) Nothing in this chapter is intended to modify
2 the rules of statutory construction applied by the courts.

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

4 “(a) All deadlines in statutes that require agencies
5 to propose or promulgate any major rule subject to section
6 622 or subchapter III during the 2-year period beginning
7 on the effective date of this section shall be suspended
8 until the earlier of—

9 “(1) the date on which the requirements of sec-
10 tion 622 or subchapter III are satisfied; or

11 “(2) the date occurring 6 months after the date
12 of the applicable deadline.

13 “(b) All deadlines imposed by any court of the United
14 States that would require an agency to propose or promul-
15 gate a major rule subject to section 622 or subchapter
16 III during the 2-year period beginning on the effective
17 date of this section shall be suspended until the earlier
18 of—

19 “(1) the date on which the requirements of sec-
20 tion 622 or subchapter III are satisfied; or

21 “(2) the date occurring 6 months after the date
22 of the applicable deadline.

23 “(c) In any case in which the failure to promulgate
24 a major rule by a deadline occurring during the 2-year
25 period beginning on the effective date of this section would

1 create an obligation to regulate through individual adju-
2 dications, the deadline shall be suspended until the earlier
3 of—

4 “(1) the date on which the requirements of sec-
5 tion 622 or subchapter III are satisfied; or

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

8 **“§ 626. Advisory committee on regulations**

9 “(a)(1) No later than 90 days after the date of enact-
10 ment of this section and every 5 years thereafter, the head
11 of each department described under section 632(a) (1)
12 through (8) and each agency under section 632(a) (9)
13 through (11) shall establish an advisory committee for the
14 review of rules.

15 “(2) The head of a department or agency described
16 under paragraph (1) may establish panels under its advi-
17 sory committee to facilitate review of rules if the different
18 parts of the agency affected by this section are so dissimi-
19 lar that it is impracticable to assemble the required exper-
20 tise on a single advisory committee. Such panels shall be
21 governed by the requirements of subsection (b) and section
22 626 pertaining to advisory committees.

23 “(b)(1) Each such agency head shall appoint *a reasonable number of* mem-
24 bers to serve on the agency’s advisory committee and shall
25 designate a chairman from the members of the committee.

1 Membership on the committee shall represent a balanced
2 cross-section of public and private interests affected by the
3 regulations of the agency, including small businesses and
4 small governments. No employee of the ~~Federal Govern~~ *agency concerning the*
5 ment shall serve as a member of a committee under this *committee*
6 section.

7 “(2) Each member shall be appointed for the life of
8 the advisory committee. The advisory committee shall ter-
9 minate 1 year after the date on which the committee is
10 established.

11 “(3) A vacancy on a committee shall be filled in the
12 same manner as the original appointment.

13 “(4) Each committee shall solicit public participation
14 through appropriate means including hearings, written
15 comments, public meetings, and electronic mail.

16 “(5) Members of each committee shall receive travel
17 expenses, including per diem in lieu of subsistence, in ac-
18 cordance with sections 5702 and 5703 of this title.

19 “(6) Each committee shall be subject to the provi-
20 sions of the Federal Advisory Committee Act (5 U.S.C.
21 App.).

22 **“§ 627. Agency regulatory review**

23 “(a) Each advisory committee appointed under sec-
24 tion 626 shall develop a list of rules promulgated by the
25 agency ~~which~~ *that* the committee serves, which the committee

1 determines should be reviewed by the agency and can rea-
2 sonably be reviewed by the agency within a 5-year period.

3 In selecting rules for review, each committee shall consider
4 the extent to which—

5 “(1) a rule may be unnecessary;

6 “(2) a rule is duplicative of other rules of the
7 agency or other agencies;

8 “(3) the benefits of a rule may not justify the
9 costs of the rule;

10 “(4) a rule may not be ^{adequately} achieving the objective
11 of the statute on which the rule is based in a cost-
12 effective manner;

13 “(5) a rule could be revised to achieve the ob-
14 jective of the statute on which the rule is based with
15 substantially—

16 “(A) less costs;

17 “(B) more benefits; or

18 “(C) greater flexibility for regulated enti-
19 ties;

20 “(6) the agency has discretion under the statute
21 authorizing the rule to modify or repeal the rule;

22 “(7) the rule is important relative to other rules
23 being reviewed under this section; and

1 “(8) the resources are expected to be available
 2 to the agency to carry out the reviews under this
 3 section.

*(b) In developing
 the list required
 by subsection
 (a), each advisory
 committee
 shall obtain
 comments
 and suggestions
 from the
 public.*

4 “(b) No later than 6 months after an advisory com-
 5 mittee is established, such committee shall deliver to the
 6 agency the committee’s recommended list of rules to be
 7 reviewed in order of priority. The agency shall immediately
 8 publish the list in the Federal Register and forward a copy
 9 of the list to the appropriate committees of jurisdiction
 10 in the House of Representatives and the Senate.

11 “(c)(1) No later than 60 days after receiving and re-
 12 viewing the list of rules from its committee, the agency
 13 shall publish in the Federal Register a preliminary sched-
 14 ule for review of rules based on such list. The agency shall
 15 give deference to the recommendations of its advisory com-
 16 mittee but may modify the list of rules to be reviewed,
 17 taking into account the factors contained in subsection
 18 (a).

19 “(2) The agency shall provide in the Federal Register
 20 at the time the preliminary schedule is published an expla-
 21 nation of each modification to the list provided by the ad-
 22 visory committee and shall invite public comment on the
 23 preliminary schedule for a period of no less than 60 days.

24 “(d) The preliminary schedule under this subsection
 25 shall propose deadlines for review of each rule listed there-

1 on, and such deadlines shall occur no later than 5 years
2 from the date of publication of the final schedule.

3 “^f(~~e~~)⁶⁰(1) No later than ~~150~~ days after ^{the close of the} publication of
4 ~~a preliminary schedule under subsection (e)~~, the agency
5 shall publish a final schedule of rules to be reviewed by
6 the agency pursuant to this section.

7 “(2) The schedule shall establish a deadline for com-
8 pletion of the review of each rule listed on the schedule,
9 taking into account the criteria in subsection (a) and com-
10 ments received in the rulemaking. Each deadline shall
11 occur no later than 5 years from the date of publication
12 of the final schedule.

13 “^g(~~e~~) Notwithstanding section 624, agency failure to
14 take the actions required by this section shall be subject
15 to judicial review only under section 706(1) of this title.
16 There shall be no judicial review of the preliminary or final
17 schedule.

18 “^h(~~e~~)¹(1) For each rule on the schedule under sub-
19 section (e), the agency shall—

20 “(A) no later than 2 years before the deadline
21 in such schedule, publish in the Federal Register a
22 notice that solicits public comment regarding wheth-
23 er the rule should be continued, amended, or re-
24 pealed;

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

4 “(i) addresses public comments generated
5 by the notice in subparagraph (A);

6 “(ii) contains a preliminary analysis by the
7 agency with respect to subsection (a) (1), (2),
8 (3), (4), and (5);

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

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

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

17 “(i) addresses public comments generated
18 by the notice in subsection (c);

19 “(ii) contains a determination to continue,
20 amend, or repeal the rule and an explanation of
21 such determination with respect to subsection
22 (a) (1), (2), (3), (4), and (5); and

23 “(iii) if the agency determines to amend or
24 repeal the rule, contains a notice of proposed
25 rulemaking under section 553.

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

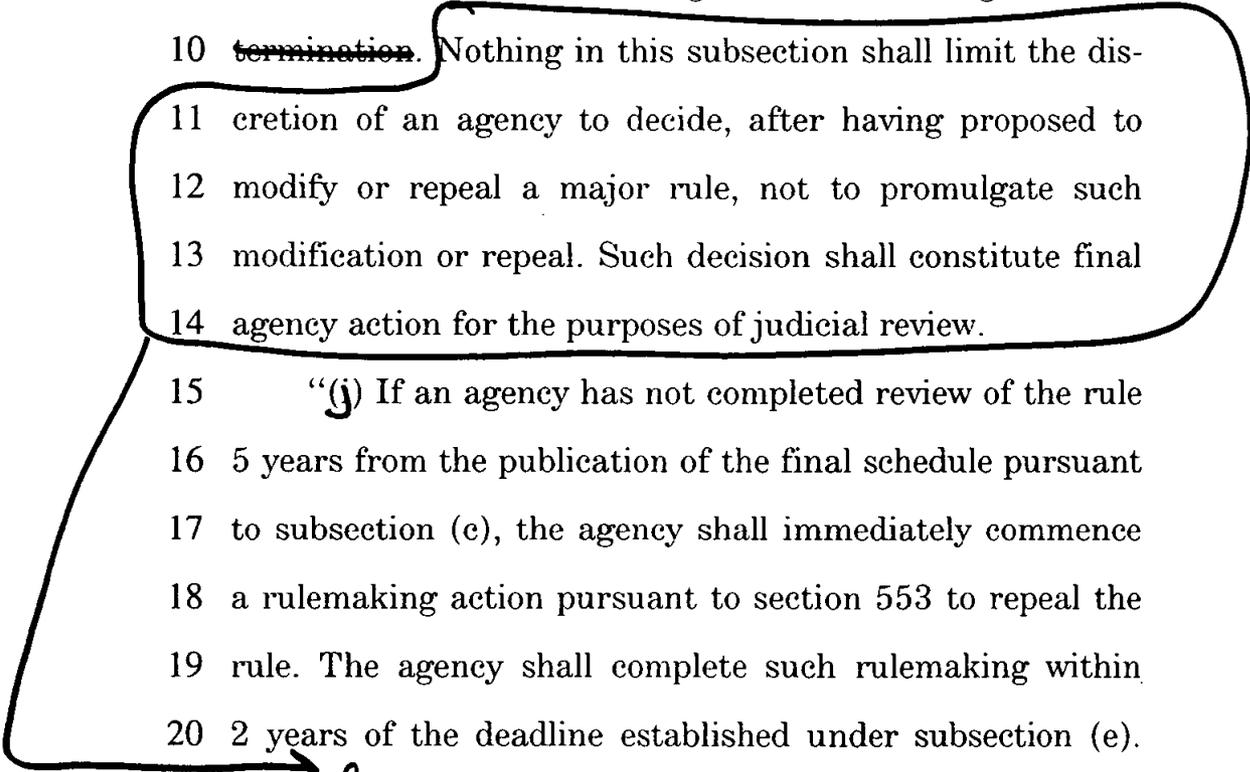
5 “(h) If an agency makes a determination to amend
 6 or repeal a major rule under subsection (g)(1)(C), the
 7 agency shall complete final agency action with regard to
 8 such rule no later than 2 years of the ~~date of publication~~ *deadline established*
 9 *under subsection (e).* ~~of the notice in subsection (g)(1)(C) containing such de-~~

10 ~~termination.~~ Nothing in this subsection shall limit the dis-
 11 cretion of an agency to decide, after having proposed to
 12 modify or repeal a major rule, not to promulgate such
 13 modification or repeal. Such decision shall constitute final
 14 agency action for the purposes of judicial review.

15 “(j) If an agency has not completed review of the rule
 16 5 years from the publication of the final schedule pursuant
 17 to subsection (c), the agency shall immediately commence
 18 a rulemaking action pursuant to section 553 to repeal the
 19 rule. The agency shall complete such rulemaking within
 20 2 years of the deadline established under subsection (e).

21 “(k) A court may remand a determination under sub-
 22 section (g)(1)(C) only upon a clear and convincing show-
 23 ing that the agency could have adopted a reasonable alter-
 24 native that is substantially more flexible or cost-effective

*New
(k)*



1 or that would substantially decrease costs or increase ben-
2 efits while meeting the objectives of the rulemaking.

3 "SUBCHAPTER III—RISK ASSESSMENTS

4 "§ 631. Definitions

5 "For purposes of this subchapter, the definitions
6 under sections 551 and 621 shall apply, and—

7 "(1) the term 'assumption' means a reasonably
8 accepted principle, theory, or assertion that is reli-
9 able, relevant, and objective, ~~which may reasonably~~
10 ~~be used when relevant and adequate information~~
11 ~~about the specific site or substance is unavailable,~~

12 "(2) the term 'covered agency' means each
13 agency required to comply with this subchapter, as
14 provided in section 632;

15 "~~(3) the term 'emergency' means an imminent~~
16 ~~or substantial endangerment to human health, safe-~~
17 ~~ty, or the environment.~~

(already
in
cost-benefit
analysis
section)

18 "³~~(2)~~ the term 'exposure assessment' means the
19 scientific determination of the intensity, frequency,
20 distribution, and duration of actual or reasonably
21 foreseeable exposures to the hazard in question;

22 "⁴~~(3)~~ the term 'hazard assessment' means the
23 scientific determination of whether a substance, ac-
24 tivity, or condition can cause an increased incidence
25 of one or more significant adverse effects, and a sci-

1 entific evaluation of the relationship between the de-
2 gree of exposure to the substance, activity, or condi-
3 tion and the incidence and severity of the effect;

4 “~~(5)~~⁵ the term ‘risk assessment’ means the sys-
5 tematic process of organizing hazard and exposure
6 assessments to estimate the potential for specific
7 harm to an exposed individual, population, or natu-
8 ral resource;

9 “~~(7)~~⁶ the term ‘risk characterization’ means the
10 presentation of risk assessment results including, to
11 the extent feasible, a characterization of the dis-
12 tribution of risk as well as an analysis of uncertain-
13 ties, variabilities, conflicting information, and infer-
14 ences and assumptions in the assessments;

15 “~~(8) the term ‘screening analysis’ means an~~
16 ~~analysis using simple assumptions to arrive at an es-~~
17 ~~timate of upper and lower bounds of risk as appro-~~
18 ~~priate, and~~

(unnecessary)

19 “~~(9)~~⁷ the term ‘substitution risk’ means an in-
20 creased risk to human health, safety, or the environ-
21 ment reasonably likely to result directly from a regu-
22 latory option.

23 **“§ 632. Applicability**

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

²⁷ *the primary purpose of which is*

1 connection with a major rule ^{addressing} health, safety,
2 and environmental risks by—

3 “(1) the Secretary of Defense, for environ-
4 mental restoration and waste management pro-
5 grams, and for programs and responsibilities of the
6 United States Army Corps of Engineers;

7 “(2) the Secretary of the Interior, for programs
8 and responsibilities of the Office of Surface Mining
9 Reclamation and Enforcement;

10 “(3) the Secretary of Agriculture, for programs
11 and responsibilities of—

12 “(A) the Animal and Plant Health Inspec-
13 tion Service;

14 “(B) the Grain Inspection, Packers, and
15 Stockyards Administration;

16 “(C) the Food Safety and Inspection Serv-
17 ice;

18 “(D) the Forest Service; and

19 “(E) the Natural Resources Conservation
20 Service;

21 “(4) the Secretary of Commerce, for programs
22 and responsibilities of the National Marine Fisheries
23 Service;

24 “(5) the Secretary of Labor, for programs and
25 responsibilities of—

1 “(A) the Occupational Safety and Health
2 Administration; and

3 “(B) the Mine Safety and Health Adminis-
4 tration;

5 “(6) the Secretary of Health and Human Serv-
6 ices, for programs and responsibilities assigned to
7 the Food and Drug Administration;

8 “(7) the Secretary of Transportation, for pro-
9 grams and responsibilities assigned to—

10 “(A) the Federal Aviation Administration;
11 and

12 “(B) the National Highway Traffic Safety
13 Administration;

14 “(8) the Secretary of Energy, for programs and
15 responsibilities related to nuclear safety, occupa-
16 tional safety and health, and environmental restora-
17 tion and waste management;

18 “(9) the Chairman of the Consumer Product
19 Safety Commission;

20 “(10) the Administrator of the Environmental
21 Protection Agency; and

22 “(11) the Chairman of the Nuclear Regulatory
23 Commission.

24 “(b)(1) No later than 18 months after the effective
25 date of this section, the President, acting through the Di-

1 rector of the Office of Management and Budget, shall de-
 2 termine whether any other Federal agency or specific pro-
 3 gram under a Federal agency should be considered a cov-
 4 ered agency. Such determination, with respect to a par-
 5 ticular Federal agency or program, shall be based on the
 6 importance of risk assessment and risk characterization
 7 to—

8 “(A) regulatory programs administered by that
 9 agency; and

10 “(B) the communication of risk information by
 11 that agency to the public.

12 “(2) If the President makes a determination under
 13 paragraph (1), the requirements of this subchapter shall
 14 apply to any agency determined to be a covered agency
 15 beginning on a date set by the President. Such date may
 16 be no later than 6 months after the date of such deter-
 17 mination.

18 “(c)(1) This subchapter shall not apply to risk assess-
 19 ments performed with respect to—

20 “(A) an emergency ^{under 622(g); or} ~~determined by the head of~~
 21 ~~an agency;~~

22 “(B) a health, safety, or environmental inspec-
 23 tion, compliance or enforcement action, or individual
 24 facility permitting action; ~~or~~

25 “(C) ~~a screening analysis.~~

1 “(2) This subchapter shall not apply to the require-
2 ments of any food, drug, or other product label, or to any
3 risk characterization appearing on any such label.

4 “(3) If a risk assessment under this subchapter is
5 otherwise required by this section, but the agency deter-
6 mines that—

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

10 “(B) a risk assessment for the proposed rule
11 has been carried out in a manner substantially con-
12 sistent with this subchapter; and

13 “(C) a new risk assessment for the final rule is
14 not required in order to respond to comments re-
15 ceived during the period for comment on the pro-
16 posed rule, the agency may publish such determina-
17 tion along with the final rule in lieu of preparing a
18 new risk assessment for the final rule.

19 **“§ 633. Savings provisions**

20 “Nothing in this subchapter shall be construed to—

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

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

1 **“§ 634. Principles for risk assessments**

2 “(a) Each agency shall design and conduct risk as-
3 ~~sessments for each proposed and final major rule~~ *in accordance with this chapter* in a
4 manner that promotes rational and informed risk manage-
5 ment decisions and informed public input into and under-
6 standing of the process of making agency decisions.

7 “(b) Each agency shall consider in each risk assess-
8 ment reliable and reasonably available scientific informa-
9 tion and shall describe the basis for selecting such sci-
10 entific information.

11 “(c)(1) Each agency may use assumptions, ~~including~~
12 ~~inferences, models, or safety factors~~, unless relevant and
13 adequate scientific information, including site-specific or
14 substance-specific information, is available, ~~which materi-~~
15 ~~ally affects the agency decision.~~

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

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

22 “(B) explain the basis for any choices among
23 assumptions and, where applicable, the basis for
24 combining multiple assumptions; and

25 “(C) describe reasonable alternative assump-
26 tions that were not selected by the agency for use

1 in the risk assessment, and the rationale for not
2 using such alternatives.

3 "(3) An agency shall not inappropriately combine
4 multiple assumptions.

5 "(4) Each ^{covered} agency shall, after notice and public com-
6 ment, publish guidelines for choosing assumptions and for
7 deciding when and how in a specific risk assessment to
8 adopt alternative assumptions or to use available scientific
9 information to modify or replace an assumption.

(d) Each covered agency shall provide appropriate opportunity for public participation during the development of a risk assessment.

10 ~~(d)~~ Each risk assessment supporting a major rule,
11 shall include, as appropriate, each of the following:

12 "(1) A description of the hazard of concern.

13 "(2) A description of the populations or natural
14 resources that are the subject of the risk assess-
15 ment.

16 "(3) An explanation of the exposure scenarios
17 used in the risk assessment, including an estimate of
18 the corresponding population at risk and the likeli-
19 hood of such exposure scenarios.

20 "(4) A description of the nature and severity of
21 the harm that could reasonably occur.

22 "(5) A description of the major uncertainties in
23 each component of the risk assessment and their in-
24 fluence on the results of the assessment.

1 ^f~~(e)~~ To the extent scientifically appropriate, each
2 agency shall—

3 “(1) express the overall estimate of risk as ~~one~~
4 ^{a reasonable} ~~or more~~ ranges or probability distributions that re-
5 flects variabilities and uncertainties in the analysis;

6 “(2) provide the range and distribution of risks
7 and the corresponding exposure scenarios, identify-
8 ing the range and distribution and likelihood of risk
9 to the general population and to more highly ex-
10 posed or sensitive subpopulations; and

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

14 “(f) When scientific information that permits rel-
15 evant comparisons of risk is reasonably available, the
16 agency shall use the information to place the nature and
17 magnitude of a risk to human health, safety, and the envi-
18 ronment being analyzed in relationship to other risks.
19 Such comparisons should consider relevant distinctions
20 among risks, such as the voluntary or involuntary nature
21 of risks.

22 “(g) When scientifically appropriate information ^{of}~~of~~
23 significant substitution risks to human health, safety, or
24 the environment is reasonably available to the agency, the
25 agency shall describe such risks in the risk assessment.

1 **“§ 635. Judicial review**

2 “The provisions of section 624 relating to judicial re-
3 view shall apply to this subchapter.

4 **“§ 636. Deadlines for rulemaking**

5 “The provisions of section 625 relating to deadlines
6 for rulemaking shall apply to this subchapter.

7 **“SUBCHAPTER IV—QUALITY ASSURANCE AND**
8 **RESEARCH PROGRAMS**

9 **“§ 641. Definitions**

10 “For purposes of this subchapter, the definitions
11 under sections 551 and 621 shall apply.

12 **“§ 642. Peer review**

13 “(a) Each covered agency shall develop a systematic
14 program for independent and external peer review re-
15 quired under subsection (b). Such ^{peer reviewed} program shall ~~be appli-~~
16 ~~cable throughout each covered agency and~~

17 “(1)(A) ~~shall~~ provide for the creation or utiliza-
18 tion of peer review panels, expert bodies, or other
19 formal or informal devices that are balanced and
20 that consist of ^{panel} members ^{or participants} with expertise relevant to
21 the sciences involved in regulatory decisions and who
22 are independent of the covered agency; ^{program} and

23 “(B) be broadly representative and balanced
24 and, to the extent relevant and appropriate, may in-
25 clude persons affiliated with Federal, State, local, or
26 tribal governments, small businesses, other rep-

1 representatives of industry, universities, agriculture,
 2 labor consumers, conservation organizations, or
 3 other public interest groups and organizations;

4 “(2) may exclude any person with substantial
 5 and relevant expertise as a panel member^{or participant} on the
 6 basis that such person represents ^{another person} ~~an entity~~ that may
 7 have a potential financial interest in the outcome, or
 8 may include such person if such interest is fully dis-
 9 closed to the agency, and in the case of a regulatory
 10 decision affecting a single ^{person} ~~entity~~, no peer reviewer
 11 representing such ^{person} ~~entity~~ may be included; ~~on the~~
 12 ~~panel,~~

13 “(3) shall provide for a timely completed peer
 14 review, meeting agency deadlines, that contains a
 15 balanced presentation of all considerations, including
 16 minority reports and an agency response to all sig-
 17 nificant peer review comments; and

18 “(4) shall provide adequate protections for con-
 19 fidential business information and trade secrets, in-
 20 cluding requiring panel members^{or participants} to enter into con-
 21 fidentiality agreements.

22 “(b)(1) Each covered agency shall provide for peer
 23 review in accordance with this section of any ^{cost-benefit analysis or} risk assess-
 24 ment that forms the basis of any major rule ^{the primary purpose} that addresses
 25 ~~risks to the environment, health, safety and~~ ~~environment~~

*and included
 in the
 rulemaking
 file,*

of which is

cost-benefit analysis or
36

1 “(2) The Director may order that peer review be pro-
2 vided for any risk assessment that is likely to have a sig-
3 nificant impact on public policy decisions or would estab-
4 lish an important precedent.

5 “(c) All peer review written comments or conclusions
6 and the agency’s written responses shall be made available
7 to the public and shall be made part of the ~~administrative~~
8 record for purposes of judicial review of any final agency
9 action.

*to significant peer review
comments*

rulemaking

10 “(d) No peer review shall be required under this sec-
11 tion for any ~~data, method, document, or assessment~~
12 any component thereof, which has been previously sub-
13 jected to peer review.

analysis

14 “(e) The requirements of this subsection shall not
15 apply to a rulemaking where the head of an agency has
16 published a determination, with the concurrence of the Ad-
17 ministrators of the Office of Information and Regulatory
18 Affairs, and notified the Congress, that the rulemaking
19 process followed by that agency provides sufficient oppor-
20 tunity for scientific or technical review of risk assessments
21 required by this chapter.

independent

cost-benefit analysis or

22 “§ 643. Guidelines

23 “(a) As soon as practicable, each covered agency shall
24 adopt, after notice and public comment, guidelines to im-
25 plement the cost-benefit analysis requirements under sec-

1 tion 622, and the risk assessment principles under section
2 634.

3 “(b) The development, issuance, and publication of
4 guidelines under this section shall not be subject to judi-
5 cial review.

6 “(c) Each covered agency shall publish, after notice
7 and public comment, guidelines for the conduct of risk as-
8 sessments not required by this subchapter that adapt the
9 principles of this subchapter in a manner consistent with
10 section 634(a)(2) and the risk assessment and risk man-
11 agement needs of the agency.

12 **“§ 644. Research, training, and coordination**

13 “(a) To promote the conduct, application, and prac-
14 tice of cost-benefit analysis and risk assessment in a con-
15 sistent manner and to identify agency data and research
16 needs, the Director, in consultation with the Office of
17 Science and Technology Policy, shall—

18 “(1) oversee periodic evaluations of Federal
19 agency cost-benefit analysis and risk assessment in-
20 cluding, where relevant and appropriate, research
21 needs to—

22 “(A) reduce generic data gaps, to address
23 modeling needs (including improved model sen-
24 sitivity), and to validate assumptions, particu-

1 larly those common to multiple cost-benefit
2 analyses and risk assessments;

3 “(B) improve methods to quantify and
4 communicate uncertainty and variability among
5 individuals, species, populations and ecological
6 communities;

7 “(C) examine emerging and future areas of
8 research in cost-benefit analysis; and

9 “(D) examine emerging and future areas
10 of research in risk assessment;

11 “(2) oversee periodic evaluations of Federal
12 agency needs to adequately train individuals in cost-
13 benefit analysis and risk assessment, including esti-
14 mates of the resources needed to provide necessary
15 training;

16 “(3) provide advice and recommendations to the
17 President and Congress based on the evaluations
18 conducted under paragraphs (1) and (2);

19 “(4) establish appropriate interagency mecha-
20 nisms to improve the consistency of cost-benefit
21 analysis and risk assessment among Federal agen-
22 cies; and

23 “(5) establish appropriate mechanisms between
24 Federal and State agencies to improve cooperation

1 in the development and application of cost-benefit
2 analysis and risk assessment.

3 **“§ 645. Judicial review**
4 *Except for the provisions of section 624(c),*
5 *“There shall be no judicial review of agency decisions*
6 *or actions made under this subchapter.*

6 **“SUBCHAPTER V—EXECUTIVE OVERSIGHT**

7 **“§ 651. Definitions**

8 “For purposes of this subchapter—

9 “(1) the definitions under sections 551 and 621
10 shall apply; and

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

13 “(A) An agenda or schedule for
14 rulemakings.

15 “(B) Advance notice of proposed rule-
16 making.

17 “(C) Notice of proposed rulemaking.

18 “(D) Proposed final rulemaking and in-
19 terim final rulemaking.

20 **“§ 652. Presidential regulatory review**

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

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

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

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

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

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

16 “(B) agency specific schedules for review
17 of existing rules under section 627; and

18 “(C) a summary of regulatory review ac-
19 tions undertaken in the prior year.

20 “(c) The review established under subsection (a) shall
21 be conducted as expeditiously as practicable and the re-
22 view of any regulatory action shall be limited to no more
23 than 90 days.

1 **“§ 653. Public disclosure of information**

2 “The Director, in carrying out the provisions of sec-
3 tion 652, shall establish procedures to provide public and
4 agency access to information concerning regulatory review
5 actions, including—

6 “(1) disclosure to the public on an ongoing
7 basis of information regarding the status of regu-
8 latory actions undergoing review;

9 “(2) disclosure to the public, no later than pub-
10 lication of a regulatory action, of—

11 “(A) all written communications, regard-
12 less of form or format, including drafts of all
13 proposals and associated analyses, between the
14 Director or employees of the Director and the
15 regulatory agency;

16 “(B) all written communications, regard-
17 less of form or format, between the Director or
18 employees of the Director and any person not
19 employed by the executive branch of the Fed-
20 eral Government relating to the substance of a
21 regulatory action;

22 “(C) a record of all oral communications
23 relating to the substance of a regulatory action
24 between the Director or employees of the Direc-
25 tor and any person not employed by the execu-
26 tive branch of the Federal Government; and

1 “(D) a written explanation of any review
2 action and the date of such action; and

3 “(3) disclosure to the regulatory agency, on a
4 timely basis, of—

5 “(A) all written communications between
6 the Director or employees of the Director and
7 any person who is not employed by the execu-
8 tive branch of the Federal Government;

9 “(B) a record of all oral communications,
10 and an invitation to participate in meetings, re-
11 lating to the substance of a regulatory action
12 between the Director or employees of the Direc-
13 tor and any person not employed by the execu-
14 tive branch of the Federal Government; and

15 “(C) a written explanation of any review
16 action taken concerning an agency regulatory
17 action.

18 **“§ 654. Judicial review**

19 “The exercise of the authority granted under this
20 subchapter by the Director or the President shall not be
21 subject to judicial review in any manner.”.

22 ~~(b) REGULATORY FLEXIBILITY ANALYSIS.—~~

23 ~~(1) IN GENERAL. Section 611 of title 5, Unit~~

24 ~~ed States Code, is amended to read as follows.~~

*Reg Flex is
in the
Bond bill.*

1 ~~thorized by section 611(a) of title 5, United States~~
2 Code (as added by subsection (a)), shall apply only
3 to final agency rules issued after such effective date.

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

10 ~~(c)~~ TECHNICAL AND CONFORMING AMENDMENTS.—

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

15 **“CHAPTER 6—THE ANALYSIS OF**
16 **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. Regulatory analysis.

“623. Decisional criteria.

- “624. Judicial review.
- “625. Deadlines for rulemaking.
- “626. Advisory committee on regulations.
- “627. Agency regulatory review.

“SUBCHAPTER III—RISK ASSESSMENTS

- “631. Definitions.
- “632. Applicability.
- “633. Savings provisions.
- “634. Principles for risk assessments.
- “635. Judicial review.
- “636. Deadlines for rulemaking.

“SUBCHAPTER IV—QUALITY ASSURANCE AND RESEARCH PROGRAMS FOR COST-BENEFIT ANALYSIS AND RISK ASSESSMENT

- “641. Definitions.
- “642. Peer review.
- “643. Guidelines.
- “644. Research, training, and coordination.
- “645. Judicial review.

“SUBCHAPTER V—EXECUTIVE OVERSIGHT

- “651. Definitions.
- “652. Presidential regulatory review.
- “653. Public disclosure of information.
- “654. Judicial review.”.

1 (2) Chapter 6 of title 5, United States Code, is
 2 amended by inserting immediately before section
 3 601, the following subchapter heading:
 4 “SUBCHAPTER I—REGULATORY ANALYSIS”.

5 **SEC. 5. CONGRESSIONAL REVIEW.**

6 (a) IN GENERAL.—Part I of title 5, United States
 7 Code, is amended by inserting after chapter 7 the follow-
 8 ing new chapter:

9 **“CHAPTER 8—CONGRESSIONAL REVIEW**
 10 **OF AGENCY RULEMAKING**

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

12 “(a) For purposes of this chapter, the term—

*Congressional
 Review is
 in Bond
 bill.*

1 ciently reduce risks to human health, safety, and the
2 environment.

3 (f) SAVINGS PROVISION AND JUDICIAL REVIEW.—

4 (1) IN GENERAL.—Nothing in this section shall
5 be construed to modify any statutory standard or re-
6 quirement designed to protect human health, safety,
7 or the environment.

8 (2) JUDICIAL REVIEW.—Compliance or non-
9 compliance by an agency with the provisions of this
10 section shall not be subject to judicial review.

11 **SEC. 7. EFFECTIVE DATE.**

12 Except as otherwise provided in this Act, this Act
13 shall take effect 180 days after the date of the enactment
14 of this Act, but shall not apply to any agency rule for
15 which a general notice of proposed rulemaking is published
16 on or before such date.