

105TH CONGRESS  
2D SESSION

# S. 1728

To provide for the conduct of a risk assessment for certain Federal agency rules, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

MARCH 6, 1998

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

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## A BILL

To provide for the conduct of a risk assessment for certain Federal agency rules, and for other purposes.

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

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Federal Regulatory  
5       Risk Assessment Act of 1997”.

6       **SEC. 2. RISK ASSESSMENTS.**

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

1 “SUBCHAPTER II—RISK ASSESSMENTS

2 “§ 621. Definitions

3 “For purposes of this subchapter the definitions  
4 under section 551 shall apply and—

5 “(1) the term ‘cost’ means the reasonably iden-  
6 tifiable significant adverse effects, including social,  
7 health, safety, environmental, economic, and dis-  
8 tributional effects that are expected to result directly  
9 or indirectly from implementation of, or compliance  
10 with, a rule;

11 “(2) the term ‘Director’ means the Director of  
12 the Office of Management and Budget, acting  
13 through the Administrator of the Office of Informa-  
14 tion and Regulatory Affairs;

15 “(3) the term ‘flexible regulatory options’  
16 means regulatory options that permit flexibility to  
17 regulated persons in achieving the objective of the  
18 statute as addressed by the rule making, including  
19 regulatory options that use market-based mecha-  
20 nisms, outcome oriented performance-based stand-  
21 ards, or other options that promote flexibility;

22 “(4) the term ‘major rule’ means a rule or a  
23 group of closely related rules that—

24 “(A) the agency proposing the rule or the  
25 Director reasonably determines is likely to have

1           an annual effect on the economy of  
2           \$100,000,000 or more in reasonably quantifi-  
3           able costs; or

4           “(B) is otherwise designated a major rule  
5           by the Director on the ground that the rule is  
6           likely to adversely affect, in a material way, the  
7           economy, a sector of the economy, including  
8           small business, productivity, competition, jobs,  
9           the environment, public health or safety, or  
10          State, local or tribal governments, or commu-  
11          nities;

12          “(5) the term ‘reasonable alternative’ means a  
13          reasonable regulatory option that would achieve the  
14          objective of the statute as addressed by the rule  
15          making and that the agency has authority to adopt  
16          under the statute granting rule making authority,  
17          including flexible regulatory options;

18          “(6) the term ‘risk assessment’ means the sys-  
19          tematic process of organizing hazard and exposure  
20          assessments to estimate the potential for specific  
21          harm to exposed individuals, populations, or natural  
22          resources;

23          “(7) the term ‘rule’ has the same meaning as  
24          in section 551(4), and shall not include—

1           “(A) a rule exempt from notice and public  
2 comment procedure under section 553;

3           “(B) a rule that involves the internal reve-  
4 nue laws of the United States, or the assess-  
5 ment and collection of taxes, duties, or other  
6 revenue or receipts;

7           “(C) a rule of particular applicability that  
8 approves or prescribes for the future rates,  
9 wages, prices, services, corporate or financial  
10 structures, reorganizations, mergers, acquisi-  
11 tions, accounting practices, or disclosures bear-  
12 ing on any of the foregoing;

13           “(D) a rule relating to monetary policy  
14 proposed or promulgated by the Board of Gov-  
15 ernors of the Federal Reserve System or by the  
16 Federal Open Market Committee;

17           “(E) a rule relating to the safety or sound-  
18 ness of federally insured depository institutions  
19 or any affiliate of such an institution (as de-  
20 fined in section 2(k) of the Bank Holding Com-  
21 pany Act of 1956 (12 U.S.C. 1841(k)); credit  
22 unions; the Federal Home Loan Banks; govern-  
23 ment-sponsored housing enterprises; a Farm  
24 Credit System Institution; foreign banks, and  
25 their branches, agencies, commercial lending

1 companies or representative offices that operate  
2 in the United States and any affiliate of such  
3 foreign banks (as those terms are defined in the  
4 International Banking Act of 1978 (12 U.S.C.  
5 3101)); or a rule relating to the payments sys-  
6 tem or the protection of deposit insurance funds  
7 or Farm Credit Insurance Fund;

8 “(F) a rule or order relating to the finan-  
9 cial responsibility, recordkeeping, or reporting  
10 of brokers and dealers (including Government  
11 securities brokers and dealers) or futures com-  
12 mission merchants, the safeguarding of investor  
13 securities and funds or commodity future or op-  
14 tions customer securities and funds, the clear-  
15 ance and settlement of securities, futures, or  
16 options transactions, or the suspension of trad-  
17 ing under the Securities Exchange Act of 1934  
18 (15 U.S.C. 78a et seq.) or emergency action  
19 taken under the Commodity Exchange Act (7  
20 U.S.C. 1 et seq.), or a rule relating to the pro-  
21 tection of the Securities Investor Protection  
22 Corporation, that is promulgated under the Se-  
23 curities Investor Protection Act of 1970 (15  
24 U.S.C. 78aaa et seq.), or a rule relating to the  
25 custody of Government securities by depository

1 institutions under section 3121 or 9110 of  
2 title 31;

3 “(G) a rule issued by the Federal Election  
4 Commission or a rule issued by the Federal  
5 Communications Commission under sections  
6 312(a)(7) and 315 of the Communications Act  
7 of 1934 (47 U.S.C. 312(a)(7) and 315);

8 “(H) a rule required to be promulgated at  
9 least annually pursuant to statute; or

10 “(I) a rule or agency action relating to the  
11 public debt; and

12 “(8) the term ‘substitution risk’ means an in-  
13 creased risk to health, safety, or the environment  
14 reasonably likely to result from a regulatory option.

15 **“§ 622. Applicability**

16 “Except as provided in section 623(d), this sub-  
17 chapter shall apply to all proposed and final major rules  
18 the primary purpose of which is to address health, safety,  
19 or environmental risk.

20 **“§ 623. Risk assessments**

21 “(a)(1) Before publishing a notice of a proposed rule  
22 making for any rule, each agency shall determine whether  
23 the rule is or is not a major rule covered by this sub-  
24 chapter.

1       “(2) The Director may designate any rule to be a  
2 major rule under section 621(4)(B), if the Director—

3               “(A) makes such designation no later than 30  
4 days after the close of the comment period for the  
5 rule; and

6               “(B) publishes such determination in the Fed-  
7 eral Register together with a succinct statement of  
8 the basis for the determination within 30 days after  
9 such determination.

10       “(b)(1) When an agency publishes a notice of pro-  
11 posed rule making for a major rule to which section 624(a)  
12 applies, the agency shall prepare and place in the rule  
13 making file an initial risk assessment, and shall include  
14 a summary of such assessment in the notice of proposed  
15 rule making.

16       “(2)(A) When the Director has published a deter-  
17 mination that a rule is a major rule to which section  
18 624(a) applies, after the publication of the notice of pro-  
19 posed rule making for the rule, the agency shall promptly  
20 prepare and place in the rule making file an initial risk  
21 assessment for the rule and shall publish in the Federal  
22 Register a summary of such assessment.

23       “(B) Following the issuance of an initial risk assess-  
24 ment under subparagraph (A), the agency shall give inter-  
25 ested persons an opportunity to comment under section

1 553 in the same manner as if the initial risk assessment  
 2 had been issued with the notice of proposed rule making.

3 “(c)(1) When the agency publishes a final major rule  
 4 to which section 624(a) applies, the agency shall also pre-  
 5 pare and place in the rule making file a final risk assess-  
 6 ment, and shall prepare a summary of the assessment.

7 “(2) Each final risk assessment shall address each  
 8 of the requirements for the initial risk assessment under  
 9 subsection (b), revised to reflect—

10 “(A) any material changes made to the pro-  
 11 posed rule by the agency after publication of the no-  
 12 tice of proposed rule making;

13 “(B) any material changes made to the risk as-  
 14 sessment; and

15 “(C) agency consideration of significant com-  
 16 ments received regarding the proposed rule and the  
 17 risk assessment.

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

20 “(A) the agency for good cause finds that con-  
 21 ducting the risk assessment under this subchapter is  
 22 contrary to the public interest due to an emergency,  
 23 or an imminent threat to health or safety that is  
 24 likely to result in significant harm to the public or  
 25 the environment; and



1           “(B) the agency publishes in the Federal Reg-  
 2           ister, together with such finding, a succinct state-  
 3           ment of the basis for the finding.

4           “(2) If a major rule is adopted under paragraph (1),  
 5           the agency shall comply with this subchapter as promptly  
 6           as possible unless compliance would be unreasonable be-  
 7           cause the rule is, or soon will be, no longer in effect.

8           **“§ 624. Principles for risk assessments**

9           “(a)(1) Subject to paragraph (2), each agency shall  
 10          design and conduct risk assessments in accordance with  
 11          this subchapter for each proposed and final major rule ,  
 12          or that results in a significant substitution risk, in a man-  
 13          ner that promotes rational and informed risk management  
 14          decisions and informed public input into and understand-  
 15          ing of the process of making agency decisions.

16          “(2) If a risk assessment under this subchapter is  
 17          otherwise required by this section, but the agency deter-  
 18          mines that—

19                 “(A) a final rule subject to this subchapter is  
 20                 substantially similar to the proposed rule with re-  
 21                 spect to the risk being addressed;

22                 “(B) a risk assessment for the proposed rule  
 23                 has been carried out in a manner consistent with  
 24                 this subchapter; and

1           “(C) a new risk assessment for the final rule is  
2       not required in order to respond to comments re-  
3       ceived during the period for comment on the pro-  
4       posed rule,  
5       the agency may publish such determination along with the  
6       final rule in lieu of preparing a new risk assessment for  
7       the final rule.

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

12          “(c)(1) Each agency may use reasonable assumptions  
13      to the extent that relevant and reliable scientific informa-  
14      tion, including site-specific or substance-specific informa-  
15      tion, is not reasonably available.

16          “(2) When a risk assessment involves a 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

1           “(C) describe reasonable alternative assump-  
2           tions that were considered but not selected by the  
3           agency for use in the risk assessment, how such al-  
4           ternative assumptions would have changed the con-  
5           clusions of the risk assessment, and the rationale for  
6           not using such alternatives.

7           “(d) Each agency shall provide appropriate oppor-  
8           tunity for public comment and participation during the de-  
9           velopment of a risk assessment.

10          “(e) Each risk assessment supporting a major rule  
11          under this subchapter shall include, as appropriate, each  
12          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 assess-  
16               ment.

17               “(3) An explanation of the exposure scenarios  
18               used in the risk assessment, including an estimate of  
19               the corresponding population at risk and the likeli-  
20               hood of such exposure scenarios.

21               “(4) A description of the nature and severity of  
22               the harm that could reasonably occur as a result of  
23               exposure to the hazard.

1           “(5) A description of the major uncertainties in  
2           each component of the risk assessment and their in-  
3           fluence on the results of the assessment.

4           “(f) To the extent scientifically appropriate, each  
5           agency shall—

6           “(1) express the overall estimate of risk as a  
7           reasonable range or probability distribution that re-  
8           flects variabilities, uncertainties, and lack of data in  
9           the analysis;

10          “(2) provide the range and distribution of risks  
11          and the corresponding exposure scenarios, identify-  
12          ing the range and distribution and likelihood of risk  
13          to the general population and, as appropriate, to  
14          more highly exposed or sensitive subpopulations, in-  
15          cluding the most plausible estimates of the risks;  
16          and

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

20          “(g) When scientific information that permits rel-  
21          evant comparisons of risk is reasonably available, each  
22          agency shall use the information to place the nature and  
23          magnitude of a risk to health, safety, or the environment  
24          being analyzed in relationship to other reasonably com-  
25          parable risks familiar to and routinely encountered by the

1 general public. Such comparisons should consider relevant  
 2 distinctions among risks, such as the voluntary or involun-  
 3 tary nature of risks.

4 “(h) When scientifically appropriate information on  
 5 significant substitution risks to health, safety, or the envi-  
 6 ronment is reasonably available to the agency, the agency  
 7 shall describe such risks in the risk assessment.

8 **“§ 625. Deadlines for rule making**

9 “(a) All deadlines in statutes or imposed by a court  
 10 of the United States, that require an agency to propose  
 11 or promulgate any major rule to which section 624(a) ap-  
 12 plies, during the 2-year period beginning on the effective  
 13 date of this section shall be suspended until the earlier  
 14 of—

15 “(1) the date on which the requirements of this  
 16 subchapter are satisfied; or

17 “(2) the date occurring 6 months after the date  
 18 of the applicable deadline.

19 “(b) In any case in which the failure to promulgate  
 20 a major rule to which section 624(a) applies by a deadline  
 21 occurring during the 2-year period beginning on the effec-  
 22 tive date of this section would create an obligation to regu-  
 23 late through individual adjudications, the deadline shall be  
 24 suspended until the earlier of—

1           “(1) the date on which the requirements of this  
2           subchapter are satisfied; or

3           “(2) the date occurring 6 months after the date  
4           of the applicable deadline.

5   **“§ 626. Judicial review**

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

9           “(b) Any determination of an agency whether a rule  
10          is or is not a major rule under section 621(4)(A) shall  
11          be set aside by a reviewing court only upon a clear and  
12          convincing showing that the determination is erroneous in  
13          light of the information available to the agency at the time  
14          the agency made the determination.

15          “(c) Any determination by the Director that a rule  
16          is a major rule under section 621(4), or any failure to  
17          make such determination, shall not be subject to judicial  
18          review in any manner.

19          “(d) Any risk assessment required under this sub-  
20          chapter shall not be subject to judicial review separate  
21          from review of the final rule to which the assessment ap-  
22          plies. Any risk assessment shall be part of the whole rule  
23          making record for purposes of judicial review of the rule  
24          and shall be considered by a court in determining whether  
25          the final rule is arbitrary or capricious unless the agency

1 can demonstrate that the assessment would not be mate-  
 2 rial to the outcome of the rule.

3 “(e) If an agency fails to perform the risk assess-  
 4 ment, a court shall remand or invalidate the rule.”.

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

11 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

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

15 **“CHAPTER 6—THE ANALYSIS OF**  
 16 **REGULATORY FUNCTIONS**

**“SUBCHAPTER I—ANALYSIS OF REGULATORY FLEXIBILITY**

- “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—RISK ASSESSMENTS**

- “621. Definitions.
- “622. Applicability.
- “623. Risk assessments.

4 “SUBCHAPTER I—ANALYSIS OF REGULATORY  
5 FLEXIBILITY”.

7        Except as otherwise provided in this Act, this Act  
8 shall take effect 180 days after the date of enactment of  
9 this Act, but shall not apply to any agency rule for which  
10 a notice of proposed rulemaking is published on or before  
11 August 1, 1997.

