Second, small businesses are disproportionately affected by Federal regulations compared to their larger counterparts.

The Reg Flex Act was enacted to reduce, where appropriate, the impact of Federal regulations on small business. The Reg Flex Act requires Federal agencies to assess the impact of their proposals on small businesses. Agencies have two options under the statute—performing a regulatory flexibility analysis or issuing a certification.

An agency certifies a rule if it determines the rule will not have a significant economic impact on a substantial number of small businesses. The certification must be announced in the—Federal Register and must be accompanied by ''a succinct statement explaining the reasons for such certification.'' Boilerplate statements that the rule will not have such an effect are inadequate under the Reg Flex Act.

An agency assessment that reveals the rule will have a significant economic impact on a substantial number of small businesses requires the agency to prepare a regulatory flexibility analysis. The analysis must contain: a description of the reasons why the action is being considered; a succinct statement of the objectives of and legal basis for the action; a description and estimate of the number of small businesses affected by the agency action; a detailed description of the reporting, recordkeeping, and other compliance requirements with special attention to the affected small businesses; and any duplicative Federal regulations.

Additionally, the analysis must describe and examine significant alternatives to the proposed rule which can accomplish the objectives of the agency, but which minimize the economic impact on small businesses. Significant alternatives may include but are not limited to: First establishment of differing compliance or reporting requirements that take into account the resources available to small businesses; second, the use of performance rather than design standards; and third, exemptions of small businesses from all or part of the rule. When an agency promulgates a final rule under section 553 of the Reg Flex Act, it must explain why it did not adopt other alternatives to minimize the effects on small businesses which were presented to the agency during the rulemaking process.

WHY AMEND THE REG FLEX ACT?

Unfortunately, too many Federal regulators fail to exercise their responsibilities under the Reg Flex Act. When government agencies fail to comply with the act, they impose significant and burdensome requirements on small businesses and thereby threaten their viability. All too often, these agencies view the act as nothing more than another procedural impediment to the adoption of a particular rule. As a result, agencies issue boilerplate certifications without performing the underlying assessment of impacts on small businesses required by the Reg Flex Act. As long as Federal departments and agencies continue to act in this manner, small businesses will be the big losers.

MEANS TO STRENGTHEN AGENCY COMPLIANCE WITH THE REG FLEX ACT

My Regulatory Flexibility Act Amendment has one critical element: repeal the prohibition against judicial review.

The Reg Flex Act requires Federal departments and agencies to consider the impact of their actions on small businesses. However, in 1980, the authors of the act were concerned a litigation explosion might result under this law. The rationale being that businesses would attempt to delay the implementation of regulations through court action. To prevent this problem, the sponsors included a provision excluding separate judicial challenges to agency compliance with the Reg Flex Act.

Today, we realize it is highly unlikely there would be a flood of litigation if judicial review is permitted under the Reg Flex Act. The fact is, most small businesses do not have the financial resources to bring frivolous, unfounded lawsuits. However, my bill will insure that small business have the opportunity to challenge regulators who attempt to avoid the Reg Flex Act. As a consequence, my colleagues should not be fooled by the ''red herring'' of a threat of litigation explosion.

The ability of agencies to ignore their responsibilities under the Reg Flex Act is enhanced by the conspicuous absence of judicial review under the act. Without judicial review, compliance rests upon each agency's voluntary commitment to utilize the Reg Flex Act in its quest for rational rulemaking mandated by the Administrative Procedure Act [APA].

Small businesses do not need voluntary commitments, they need concrete action. The primary means to accomplish mandatory compliance will be to authorize small businesses hurt by an agency's failure to comply with the Reg Flex Act to challenge that agency in federal court. That is what my bill does.

CONCLUSION

Mr. President, the Regulatory Flexibility Amendments Act of 1995 will help curtail excessive regulation by Government bureaucrats. Furthermore, it will add teeth to the Reg Flex Act and give small businesses a legal means for countering continued violations of the act. The Reg Flex Act, if properly implemented and appropriately strengthened, can help ease the regulatory burdens on small businesses. Regulatory relief will create greater opportunities for small businesses, more jobs for American workers, and will expand the U.S. economy.

I urge my colleagues to support this reform of the Reg Flex Act.●

ADDITIONAL COSPONSORS

S. 47

At the request of Mr. SARBANES, the name of the Senator from Maryland [Ms. MIKULSKI] was added as a cosponsor of S. 47, a bill to amend certain provisions of title 5, United States Code, in order to ensure equality between Federal firefighters and other employees in the civil service and other public sector firefighters, and for other purposes.

S. 50

At the request of Mr. LOTT, the name of the Senator from Delaware [Mr. ROTH] was added as a cosponsor of S. 50, a bill to repeal the increase in tax on social security benefits.

S. 205

At the request of Mrs. BOXER, the name of the Senator from Hawaii [Mr. AKAKA] was added as a cosponsor of S. 205, a bill to amend title 37, United States Code, to revise and expand the prohibition on accrual of pay and allowances by members of the Armed Forces who are confined pending dishonorable discharge.

S. 219

At the request of Mr. NICKLES, the name of the Senator from South Dakota [Mr. PRESSLER] was added as a cosponsor of S. 219, a bill to ensure economy and efficiency of Federal Government operations by establishing a moratorium on regulatory rulemaking actions, and for other purposes.

S. 233

At the request of Mr. MCCAIN, the name of the Senator from Mississippi [Mr. LOTT] was added as a cosponsor of S. 233, a bill to provide for the termination of reporting requirements of certain executive reports submitted to the Congress, and for other purposes.

S. 241

At the request of Mr. D'AMATO, the name of the Senator from Ohio [Mr. DEWINE] was added as a cosponsor of S. 241, a bill to increase the penalties for sexual exploitation of children, and for other purposes.

S. 256

At the request of Mr. DOLE, the name of the Senator from Mississippi [Mr. COCHRAN] was added as a cosponsor of S. 256, a bill to amend title 10, United States Code, to establish procedures for determining the status of certain missing members of the Armed Forces and certain civilians, and for other purposes.

S. 326

At the request of Mr. HATFIELD, the name of the Senator from Arkansas [Mr. PRYOR] was added as a cosponsor of S. 326, a bill to prohibit U.S. military assistance and arms transfers to foreign governments that are undemocratic, do not adequately protect human rights, are engaged in acts of armed aggression, or are not fully participating in the United Nations Register of Conventional Arms.

AMENDMENTS SUBMITTED

THE COMPREHENSIVE REGULATORY REFORM ACT OF 1995

DOLE (AND OTHERS) AMENDMENT NO. 229

(Ordered referred to the Committee on the Judiciary.)

Mr. DOLE (for himself, Mr. NICKLES, Mr. BOND, Mrs. HUTCHISON, Mr. MURKOWSKI, Mr. LOTT, Mr. COCHRAN, Mr. HATCH, Mr. DOMENICI, Mrs. KASSEBAUM, Mr. COATS, Mr. ABRAHAM, Mr. INHOFE, Mr. SMITH, Mr. SANTORUM, Mr. THOMPSON, Mr. WARNER, Mr. KYL) submitted an amendment intended to be proposed by them to the bill (S. 343) to reform the regulatory process, and for other purposes; as follows:

At the appropriate place add the following:

''SUBCHAPTER III—RISK ASSESSMENTS

''§ 631. Definitions

''For purposes of this subchapter:

''(1) The term 'best estimate' means an estimate that, to the extent feasible and scientifically appropriate, is based on one or more of the following:

''(A) Central estimates of risk using the most plausible assumptions.

''(B) An approach that combines multiple estimates based on different scenarios and weighs the probability of each scenario.

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

''(2) The term 'emergency' means a clearly imminent and substantial endangerment to public health, safety, or natural resources.

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

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

''(5) The term 'plausible' means realistic and scientifically probable.

''(6) The term 'risk assessment' means—

''(A) the process of identifying hazards, and quantifying (to the extent practicable) or describing the degree of toxicity, exposure, or other risk the hazards pose for exposed individuals, populations, or resources; and

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

''(7) The term 'risk characterization'—

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

''(B) includes discussions of uncertainties, conflicting data, estimates, extrapolations, inferences, and opinions.

''(8) The term 'substitution risk' means a potential increased risk to human health, safety, or the environment from a regulatory option designed to decrease other risks.

''§ 632. Applicability

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

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

''(A) a situation that the head of the agency considers to be an emergency;

''(B) a rule that authorizes the introduction into commerce, or recognizes the marketable status of a product; or

''(C) a screening analysis.

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

''(i) as the basis for imposing a restriction on a substance or activity; or

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

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

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

''§ 633. Rule of construction

''Nothing in this subchapter shall be construed to—

''(1) preclude the consideration of any data or the calculation of any estimate to more fully describe risk or provide examples of scientific uncertainty or variability; or

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

''§ 634. Requirement to prepare risk assessments

''(a) Except as provided in section 632, the head of each agency shall prepare for each major rule relating to human health, safety, or natural resources that is proposed by the agency after the date of enactment of this subchapter, is pending on the date of enactment of this subchapter, or is subject to a granted petition for cost-benefit analysis pursuant to section 625 or petition for review pursuant to section 637—

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

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

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

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

''§ 635. Principles for risk assessment

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

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

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

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

''(2) Discussions or explanations required under this section need not be repeated in each risk assessment document as long as there is a reference to the relevant discussion or explanation in another agency document.

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

''(1)(A) When assessing human health risks, a risk assessment shall be based on the most reliable laboratory, epidemiological, and exposure assessment data that finds, or fails to find, a correlation between a health risk and a potential toxin or activity. Other relevant data may be summarized.

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

''(2) When a risk assessment involves selection of any significant assumption, inference, or model, the agency shall—

''(A) describe the plausible and alternative assumptions, inferences, or models;

''(B) explain the basis for any choices among such assumptions, inferences, or models;

''(C) identify any policy or value judgments involved in choosing from among such alternative assumptions, inferences, or models;

''(D) fully describe any model used in the risk assessment and make explicit the assumptions incorporated in the model; and

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

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

''§ 636. Principles for risk characterization and communication

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

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

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

''(i) shall provide—

''(I) the best estimate or estimates for the specific populations or natural resources which are the subject of the characterization