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Introduction

The 103rd, 104th and 105th Congresses considered whether to require risk analysis of environmental regulatory proposals by the U.S. Environmental Protection Agency (EPA) and other agencies. The House and Senate each approved at least one such proposal (see below). However, no Congress has enacted a requirement for risk analysis that would change the way all environmental, or health and safety, regulations are developed. It is not clear whether any comprehensive requirement for risk analysis of environmental regulations will be considered by the 106th Congress. Some believe that recent proposals lack most of the provisions that historically have been stumbling blocks to passage, and they see a gathering momentum for a legislative mandate. While others percieve the waning of congressional interest.

At some point, however, Congress is expected to again debate an overarching mandate for risk analysis of environmental regulations. Many believe that environmental programs could be more efficient, flexible, and less costly to the regulated community, if the EPA considered the results of risk analysis. Others disagree, arguing that such analyses use scarce agency resources, delay rulemaking, and force decisions to conform to the analytic results, regardless of the quality of underlying data and models.

This report describes and compares selected provisions related to risk analysis in key legislative proposals introduced from the 103rd through the 105th Congresses, including:

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* The views expressed in this paper are the author's own and do not necessarily represent those of the Congressional Research Service.

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- the Johnston amendments to S. 171, a bill to confer cabinet-level status on the EPA, and to S. 2019, a bill to reauthorize the Safe Drinking Water Act, both as passed by the Senate in the 103rd Congress;
- S. 343, as reported by the Committee on the Judiciary, in the 104th Congress;
- Divisions C and D of H.R. 9, as passed by the House, in the 104th Congress;
- S. 981, as reported by the Committee on Governmental Affairs, in the 105th Congress; and
- S. 1728, as introduced, in the 105th Congress.

The comparison emphasizes differences among provisions related to risk analysis and cost-benefit analysis and mechanisms such as judicial review or peer review that make agencies more accountable for the quality of such analyses.

This report also focuses on the general provisions of highlighted sections oflarge and complex bills; specific provisions that modify the general requirements of the highlighted sections may be omitted.

Key Legislative Proposals

103rd Congress

More than a dozen bills and amendments on environmental risk analysis were introduced in the 103rd Congress. One, H.R. 4217, was enacted, but it applied only to the Department of Agriculture. Nine other bills were passed by one chamber or reported by the committees of jurisdiction.

Arguably, the most influential risk proposals in the 103rd Congress were two amendments offered by Senator J. Bennett Johnston. The original "Johnston amendment" was the first risk legislation debated on the Senate floor, and it was adopted on April 29, 1993, by a vote of 95 to 3. The amendment was incorporated as § 123 in S. 171, a bill to raise the EPA to department (cabinet) status. In the House, however, a proposal to similarly amend a bill to elevate the EPA to the cabinet (H.R. 3425) proved unsuccessful. The rule for consideration of the reported House bill was defeated on the floor, reportedly in part because the rule would have prevented introduction of non-germane amendments, such as one on risk and cost-benefit analysis.

During the second session of the 103rd Congress, Senator Johnston addressed some of the key concerns of members when he introduced a revised version of his amendment. It was adopted by the Senate during the May 18, 1994 floor debate on Senate-passed S. 2019, a bill to amend and reauthorize the Safe Drinking Water Act. The amendment became Section 18 of the Senate-passed bill. Section 15, S. 2019, as passed by the Senate, also included a revised version of a bill originally introduced by Senator Moynihan (S. 110) that would have required the EPA to rank pollution sources based on risk. These bills did not receive House action.

104th Congress

Three risk-related bills were reported to the Senate in the 104th Congress (S. 291, S. 333, and S. 343). In June, 1995, the three were merged and presented on the Senate floor by Senator Dole as a substitute amendment for S. 343, as reported by the Committee on Judiciary. After two weeks of debate and three failed votes to invoke closure, the Senate turned to other issues. The reported bill, also known as the Dole bill, is summarized in this report.

The House Republican Contract with America promised that within the first 100 days of the 104th Congress, risk legislation would be introduced, debated, and voted upon in the House. Title III of the "Job Creation and Wage Enhancement Act of 1995" (JCWEA), one of the draft bills distributed with the House Republican contract, appeared to integrate several of the proposals related to risk analysis involved in the 103rd Congress; including a slightly modified version of the original Johnston amendment with coverage expanding beyond the EPA to include all Federal agencies that promulgate regulations concerning human health and safety or the environment. The House amended and passed these provisions in H.R. 9 on March 3, 1995.

H.R. 9, as passed by the House, contained four divisions, A–D. Each contained the text of a bill that had passed the House prior to consideration of H.R. 9. Division C and Division D had provisions related to risk analysis. Division C contained the text of H.R. 926, the Regulatory Reform and Relief Act, while Division D had the text of H.R. 1022, the Risk Assessment and Cost-Benefit Act of 1995. The Senate did not act on H.R. 9.

Although the 104th Congress adjourned without enacting comprehensive requirements for risk analysis, Congress did enact risk-based provisions that was included in major legislation addressing drinking water (P.L. 104-182) and food safety (P.L. 104-170). The provisions also incorporated requirements for economic analysis, which for environmental regulations requires some analysis of risks as a basis for calculating risk reduction benefits (P.L. 104-4; P.L. 104-121, Title II). None of these mandates for risk analysis is compared in this report.

105th Congress

The 105th Congress considered various proposals that would have mandated analysis of environmental risks, but adjourned without approving any comprehensive regulatory reform legislation or other provisions that would have increased use of risk analysis by the EPA The most comprehensive, S. 981, as reported by the Senate Committee on Governmental Affairs, contained bipartisan support (S. Rept. 105-188), but also faced significant opposition. The Senate Committee on Governmental Affairs reported S. 981, the Regulatory Improvement Act of 1998, as amended, on May 11, 1998, but the bill received no floor action. The Majority Leader introduced a risk-only version, S. 1728, that would have applied only to proposed and final regulations to protect health, safety, or the environment with a potential annual cost to the economy of $100 million or more.

Comparison of Selected Provisions

Applicability

In general, bills mandating risk analysis have become more complex and detailed since 1993. From the 103rd to the 104th Congress, proposed mandates for federal risk analysis have broadened to encompass more agencies. The Johnston amendments would have required risk analysis only by the EPA, while proposals in the 104th Congress would have targeted all agencies, including independents that, unlike others, have never been required by executive order to perform risk analysis or economic analysis for proposed or final rules.[1]

[1] President Reagan issued the first explicit mandate for regulatory risk analysis in January 1985. For more information about the requirements of executive orders, see Linda-Jo Schierow, *Senator Johnston's Proposals for Regulatory Reform: New Cost-Benefit Risk Analysis Requirements for EPA,* 6 Risk 1 (1995).

It is not clear whether bills in the 105th Congress would have required more or fewer risk analyses and economic analyses by individual agencies than those in the 104th. The Johnston amendment to S. 171 would have applied only to final rules that related to human health and safety or the environment, while later legislation would have mandated analysis of proposed as well as final rules, and (with the exception of S. 1728 in the 105th Congress) would have covered rules for any regulatory purpose.[2]

Moreover, although the proposed bills generally would have affected all substantive rulemaking (that is, rule development for all rules covered by the notice and comment requirements of the Administrative Procedure Act), some proposals in the 104th and 105th Congresses would have affected additional activities. For example, under S. 343, risk analyses unconnected with rulemaking would have been affected and interpretive rules or rules of agency organization, procedure, or practice, if they had altered or created rights or obligations of persons. Similarly, S. 981 would have affected risk characterizations in risk assessment documents and agency decisions, as well as regulatory proposals. S. 1728 would have required analyses if a significant substitution risk resulted from promulgation of a rule.

Proposals in the 104th and 105th Congresses would have applied only to rules with a "major" or "significant" impact on the economy, health, the environment or public policy. In contrast, the Johnston amendment to S. 171 in the 103rd Congress applied regardless of the rule significance. Under the Johnston amendment to Senate-passed S. 2019, analysis would be required only for rules annually costing $100 million or more. In the 104th Congress, S. 343 and H.R. 9 Division C would have applied to rules with an estimated annual cost of $50 million or more, while H.R. 9 Division D would have affected rules with a probable cost of $25 million or more.[3] In the 105th Congress, both S. 981, as reported, and S. 1728, as introduced, would have effected rules annually costing $100 million or more.

2 S.1728, like the Johnston amendment to S.171 in the 103rd Congress, targets only rules for which the primary purpose is to address health, safety, or environmental risks.

3 The language used to define a "major rule" is precise and meaningful. Note that the number of rules with an "effect on the national economy" of a certain monetary value is likely to be much greater than the number of rules with a "cost" of equal value.

Definitions of "major rules" and "significant risk assessments" also varied in the amount of discretion they would have provided to the President's Office of Management and Budget (OMB) to designate rules as major or non-major. Rules likely to result in major increases in costs, prices or significant adverse effects on economic activity could have been designated as major under any of the legislative proposals in the 104th and 105th Congresses. The Senate bills during this period also would have authorized designation of a rule as major if it had effects on health, safety, or the environment. S. 981 would have given the OMB authority to require a risk analysis in order to comply with proposed requirements.

All of the proposed mandates, except the Johnston amendments, authorized exemptions for certain types of rules. For example, S. 343, H.R. 9 Divisions C and D, S. 981, and S. 1728 would have applied to emergencies, while S. 343, H.R. 9 Division D, and S. 981 would have exempted from risk analysis, requirement rules approving product labels (e.g., for pharmaceutical drugs). S. 171 and S. 2019 would have required the EPA to perform the analyses or to report the reasons for noncompliance in the Federal Register and to Congress.

Analytic Requirements

All of the proposals would have required agencies to analyze risks when developing rules; generally before the risk is addressed by the regulation, relative to other risks that could be addressed, and after a risk is managed under the rule to estimate the incremental amount of risk reduction that might be achieved. For example, the Johnston amendment to S. 171 would have demanded analyses of:

- risks to individuals addressed by the regulation;
- the health and environmental effects of the regulation; and
- addressed risks compared to other risks.

S. 2019 added a requirement to analyze risks of "significant subpopulations disproportionately exposed or particularly sensitive." It also explicitly required qualitative, as well as quantitative, analysis of risks.

H.R. 9 and S. 343, as reported in the 104th Congress, would have included requirements to analyze: (1) uncertainties; (2) assumptions; (3) substitution risks (risks resulting from regulation); (4) the distribution

of risk in a population (that is, who is at risk); and (5) the likelihood that exposure to risks would occur. All these analytic requirements were included in S. 981 (105th Congress).

Beginning in the 104th Congress, proposals specified certain principles of risk analysis that covered agency analyses and presentations of results requiring conformity. The bills proposed various means of estimating and then expressing risk: in the 104th Congress, agencies would have been directed to use "plausible" or "unbiased" models and to present a "best estimate"; S. 981 would have mandated a "weight of scientific evidence" approach, and expression of a central and high end risk estimate; and S. 1728 would have required public input and statement of the "most plausible" risk estimates.

Analysis of costs and benefits would have been mandated by all highlighted bills (except that introduced by Senator Lott late in the 105th Congress), but the bills differed on how agencies would relate costs and benefits.[4] Both versions of the Johnston amendments (103rd) and S. 343 (104th) would have required consideration of whether the benefits would justify the costs. S. 343 and S. 981 (105th) would have mandated analysis of net benefits explicitly. S. 2019 and S. 981 in the 105th Congress also would have required a cost-effectiveness analysis.

More elements of economic analysis were added to bills in the 104th Congress. Both S. 343 and H.R. 9 would have required analysis of the distribution of costs and benefits, incremental costs and benefits, effects on small businesses and the cumulative cost to the regulated community — and comparing all these measures for all specified alternatives to the proposed or final rule. S. 343, but not H.R. 9, would have directed EPA to assess net benefits, net costs and net effects on small businesses. H.R. 9 would have mandated analysis of whether benefits would exceed costs.

S. 981, in the 105th Congress, would have added requirements to analyze the feasibility of using market-based mechanisms, the quality of information, and the flexibility provided to local and state governments and the regulated community. S. 981, like S. 343 before it, specified certain principles of economic analysis.

4 The Unfunded Mandates Reform Act (P.L. 104-4), enacted by the 104th Congress, requires federal agencies to analyze costs and benefits of all proposed and final rules with an expected cost of $100 million or more.

Regulatory Decision Criteria

Except for S. 1728 (105th Congress), all of the highlighted bills would have established criteria for evaluating and choosing among regulatory options, based on analytic results. Excluding S. 1728, the bills would have established economic criteria that are summarized in the table below. Both Johnston amendments, S. 343, and S. 981 stated that benefits should justify costs. The Johnston amendment to S. 2019 also would have required a rule to be most cost-effective. S. 343 would have required a rule to be most cost-effective or least-cost. S. 981 would have promoted selection of the rule that was most cost-effective or that provided the greatest net benefits. Finally, H.R. 9 would have mandated rules that were most cost-effective or provided more flexibility, and that had incremental benefits likely to justify and be reasonably related to the incremental costs.[5]

Table 1
Decision Criteria Employed by Key Proposals in the 103rd – 105th Congresses

Decision Criteria	S. 171	S. 2019	S. 343	H.R. 9	S. 981	S. 1728
Benefits justify costs	X	X	X		X	
Most cost-effective		X	X	X	X	
Least cost			X			
Greatest net benefits					X	
Flexible				X		
Incremental costs — incremental benefits				X		

Effect on Existing Law

Arguably, the highlighted bills of the 103rd and 105th Congresses would not have superseded other provisions of federal law, such as the Clean Air Act or the Safe Drinking Water Act, with regard to how the EPA should weigh costs and risks in developing regulations. Some argued that the Congresses would not have authorized the EPA to employ risk-based or economic criteria when implementing other statutes either Nevertheless, this apparent neutrality with respect to existing law was made more explicit, as time passed; the amendment to S. 2019 was more explicit than that to S. 171, and in the 105th Congress, S. 981 provided greater assurance that its requirements

5 The Unfunded Mandates Reform Act, *supra,* requires federal agencies to promulgate the alternative that is least costly, most effective, or least burdensome, or to explain why such an alternative was not adopted.

would apply only to the extent that they were not inconsistent with existing statutes. According to some observers, however, the neutrality of proposed requirements relative to existing statutory requirements never was stated clearly. S. 1728 would not have established decision criteria, so its analytic requirements apparently would not have conflicted with existing legal requirements.

In contrast, S. 343 explicitly would have prohibited promulgation of a rule unless decision criteria were met (that is, benefits justified costs, and the rule was the most cost-effective or least-cost alternative). Similarly, H.R. 9 Division D would have superseded provisions of existing laws and prohibited promulgation of a major rule, unless incremental benefits were likely to justify and be reasonably related to the incremental costs, and alternatives were either less cost-effective or provided less flexibility to regulated entities or local or state governments.

Coordination and Quality Control

Executive Oversight. The OMB has been overseeing cost-benefit analyses of regulations under the authority of executive orders since President Reagan issued Executive Order 12291 in 1981. In contrast, the OMB has no clear authority to oversee risk analyses, except to the extent that they underlie benefit analyses for regulations under review.

Three of the bills (S. 343, H.R. 9, and S. 981) would have authorized executive branch oversight of agencies' regulatory analyses and mandated issuance of guidance for the conduct of economic and risk analyses. Two (H.R. 9 and S. 981) would have assigned these tasks to the OMB. Only economic analyses of regulations would have been reviewed under H.R. 9, but the OMB would have been required to approve or comment on a final cost-benefit analysis prior to promulgation of a major rule. S. 981 would have authorized the OMB to oversee risk assessments and peer review, as well as economic analyses. H.R. 9 would have required the OMB to evaluate federal agencies' rulemaking procedures, while S. 981 would have directed the OMB to evaluate agencies' cost-benefit and risk analyses periodically.

As a check on the new statutory authority of the OMB to supervise regulatory proposals, S. 981 and H.R. 9 would have limited the time for the OMB review to 90 days, while S. 343 permitted only 30 days.

However, all three bills would have allowed the period to be extended. In addition, S. 981 would have required public disclosure of any changes to regulatory proposals that resulted from the review, and a written record of relevant contacts the OMB had with the regulatory agency and persons outside the executive branch. H.R. 9 also required a written record of relevant contacts made with persons outside the agency. Neither the Johnston amendments in the 103rd Congress nor S. 1728 in the 105th had any provision regarding oversight by the executive branch of government.

Peer Review. Peer review was another mechanism proposed to ensure the quality of agencies' analytic work and the scientific soundness of decisions. S. 343 in the 104th Congress, relied most heavily on peer review, as it would have required peer review of agencies' analyses for major new rules, reviews of analyses for existing rules, risk estimates supporting database entries, and clean-up plans for hazardous waste sites. Also in the 104th Congress, H.R. 9 would have required peer review of analyses for major rules worth at least $100 million and of other analyses designated by the OMB. In the 105th Congress, S. 981 would have required peer review only for major rules. Neither the Johnston amendments in the 103rd Congress nor S. 1728 in the 105th had any provision regarding peer review.

Other Provisions

Deadlines. Statutory and judicial deadlines for promulgation of rules were treated in various ways by the bills of interest. The original Johnston amendment was silent on the subject of deadlines. Risk analysis requirements imposed by the Johnston amendment to S. 2019 and H.R. 9 would have been waived or deferred when there was a conflicting statutory or judicial deadline. In contrast, S. 343, S. 981, and S. 1728 would have suspended deadlines to allow compliance with requirements for regulatory analysis.

Review of Rules. Only S. 343, H.R. 9, and S. 981 would have required agencies to review existing major rules. Under S. 343, all existing rules would have terminated in seven years unless they were reviewed by the administering agency.

Citizen Petitions. Bills in the 104th Congress would have authorized citizen petitions for judicial review of agency compliance with analytic requirements. In addition, S. 343 would have provided broad authority for citizen petitions to force agencies to examine and redesign rules so that they conformed to decision criteria. Bills in the 103rd and 105th Congresses did not provide for citizen petitions.

Judicial Review. Proposals differed widely in their treatment of judicial review. The Johnston amendments in the 103rd Congress would not have subjected either the compliance of agencies with analytic requirements or its analyses to judicial review.

In the 104th Congress, S. 343, as reported, would have subjected all agency decisions regarding rules, orders, petitions, licenses, sanctions, or relief to judicial review, and it would have established a new set of standards for judicial review, which includes a "substantial support in the rulemaking file for the factual basis of agency actions." H.R. 9 Division D would have directed courts to consider agency actions unlawful solely on the basis of a significant risk characterization or risk analysis in the rulemaking record that did not substantially comply with the proposed requirements.

In the 105th Congress, S. 981, as reported, would have permitted review of agency compliance with analytic requirements only in connection with review of a final agency action. S. 1728 also would have subjected agency decisions about which rules are major, and agency risk analyses in connection with review of a final agency action to judicial review. Both bills in the 105th Congress would have only required that the rule not be arbitrary, capricious or an abuse of discretion (or unsupported by substantial evidence where that standard otherwise was provided by law), that the agency performed requisite analyses where the designation of a rule not be "clearly and convincingly" erroneous(under S. 1728).

Risk-Based Priorities. Several of the highlighted bills would have promoted use of analytic results to prioritize regulatory efforts within agencies: S. 343 would have required agencies to reflect risk-based priorities in annual budget requests; H.R. 9 would have required that relative risks and cost-effective risk reduction strategies be identified within regulatory programs; and S. 981 would have required agencies to inform annual budgets, and strategic and performance plans with the

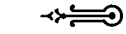
results of a study by a scientific institution of relative risks and strategies for reducing them. S. 1728 in the 105th Congress had no comparable provision and the Johnston amendments in the 103rd Congress did not mention the setting of priorities.[6]

Conclusion

A comparison of selected provisions of key legislative proposals indicates that they broadened to encompass more federal agencies and more kinds of agency activities. At the same time, more recent proposals apply to a smaller fraction of "major" rules — often defined as a rule with an annual cost of at least $100 million.

Most of the highlighted bills would have required economic analysis, as well as risk analysis, and would have established economic criteria for choosing among regulatory options. The preferred option typically was the most cost-effective alternative and one that would have produced benefits justifying costs. Such requirements became more specific and increased in number between 1993 and 1998.

Proposals also became more complex as legislators tried to ensure that unintended adverse consequences of an overarching mandate (e.g., delayed rulemaking in emergencies) would be avoided. Thus, each Congress considered more exceptions, and caveats for analytic requirements and decision rules. At the same time, perhaps to compensate, proposals included more mechanisms to ensure the quality of analyses. Compared to key proposals in the 104th Congress, the more comprehensive proposal in the 105th Congress, S. 981, as reported, would have reduced reliance on judicial review, while leaning more heavily on peer review and executive oversight of analyses. Executive branch reviews of agencies' rules generally would have been limited to 90 days, and the substance of communications between the OMB and the regulatory agency or between the OMB and anyone outside of government about rules under review would have required disclosure to the public.



6 However, S.2019 § 15 would have required a report of the relative risk of various sources of pollution, and of the costs and benefits of risk reduction strategies.