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Environmental Risk and Cost-Benefit Analysis: A Review of Proposed Legislative Mandates, 1993-1998

January 22, 1999

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ABSTRACT

Between 1993 and 1998 Congress considered many proposals that aimed to increase or improve the use of risk analysis by federal agencies, especially in developing environmental rules. This report describes differences and similarities among selected provisions of key proposals: Senate-passed Johnston amendments to S. 171 and S. 2019 in the 103rd Congress; S. 343, as reported by the Committee on the Judiciary, in the 104th Congress; House-passed H.R. 9 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. This report will not be updated. Issues related to EPA's use of risk analysis are analyzed in CRS Report 98-618, *Environmental Risk Analysis: A Review of Public Policy Issues*. For current information about legislation, see CRS Issue Brief 94036, *The Role of Risk Analysis and Risk Management in Environmental Protection*. For a broader look at regulatory reform initiatives targeting environmental regulations, see CRS Report 96-949, *Environmental Reauthorizations and Regulatory Reform: From the 104th Congress to the 106th*.

Environmental Risk and Cost-Benefit Analysis: A Review of Proposed Legislative Mandates, 1993-1998

Summary

Between 1993 and 1998 Congress considered many different proposals that aimed to increase or improve the use of risk analysis and cost-benefit analysis by federal agencies, especially in developing environmental rules. Key proposals include: the Senate-approved Johnston amendments to S. 171, a bill to confer cabinet-level status on the Environmental Protection Agency (EPA), and to S. 2019, a bill to reauthorize the Safe Drinking Water Act, 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.

From the 103rd to the 105th Congress, proposals broadened in scope to encompass more federal agencies and more kinds of agency activities. At the same time, recent proposals apply to a smaller fraction of promulgated rules that are “major,” rather than to all final rules. All highlighted proposals mandate risk analysis when environmental regulations are promulgated, and the specificity of proposed requirements grew in each Congress. Similarly, all the highlighted bills, with one exception, mandate analysis of the costs and benefits of some new rules, and these requirements have been elaborated in each consecutive Congress.

Most of the six highlighted bills would have established economic criteria for evaluating and choosing among regulatory options. Four of the six bills would have directed agencies to promulgate cost-effective rules. Four bills also would have advised or required that benefits of a rule should justify its cost. Other proposed criteria included: flexibility to regulated entities and governments, net benefits, incremental costs and benefits, and costs. However, only the bills of the 104th Congress explicitly would have prohibited promulgation of a rule unless economic criteria were met.

Three of the highlighted proposals would have directed the executive branch to coordinate and oversee regulatory analyses by agencies, but limited the time for review and required public disclosure of relevant communications with the regulatory agency and others outside of the federal government. Two of these bills also would have required peer review to ensure the quality of agencies’ analytic work. All highlighted Senate bills in the 104th and 105th Congresses would have suspended deadlines to facilitate agency compliance with analytic requirements for rules. Most of those bills would have required agencies to review existing major rules, as well as newly promulgated rules. Other provisions of bills in the 104th Congress that would have authorized citizen petitions and judicial review or required risk-based budgeting were eliminated or modified in bills of the 105th Congress.

Proposed mandates for risk analysis and cost-benefit analysis of environmental rules became more complex after the 103rd Congress, as they included more exceptions and caveats for analytic requirements and decision rules, as well as more mechanisms to ensure the quality of analyses.

Contents

Introduction	1
Key Legislative Proposals	2
103 rd Congress	2
104 th Congress	3
105 th Congress	3
Comparison of Selected Provisions	4
Applicability	4
Analytic Requirements	5
Regulatory Decision Criteria	6
Effect on Existing Law	7
Coordination and Quality Control	8
Executive Oversight	8
Peer Review	8
Other Provisions	8
Deadlines	9
Review of Rules	9
Citizen Petitions	9
Judicial Review	9
Risk-Based Priorities	9
Conclusion	10

List of Tables

Table 1. Decision Criteria Employed by Key Proposals in the 103 rd , 104 th , and 105 th Congresses	7
Table 2. Cost-Benefit Analysis in the 103 rd , 104 th , and 105 th Congresses	11

Environmental Risk and Cost-Benefit Analysis: A Review of Proposed Legislative Mandates, 1993-1998

Introduction

The 103rd, 104th, and 105th Congresses considered whether to require risk analysis¹ 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). But, so far 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 more recently evolved proposals lack most of the provisions that historically have been stumbling blocks to passage, and they see a gathering momentum for a legislative mandate. Others see waning congressional interest.

At some point, however, Congress is expected to debate again an overarching mandate for risk analysis of environmental regulations. Many believe that environmental programs could be more efficient and flexible, and less costly to the regulated community, if 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. The issues and legislative options surrounding the use of risk analysis at EPA are described and analyzed in CRS Report 98-618, *Environmental Risk Analysis: A Review of Public Policy Issues*.

Proposed mandates for risk analysis must be considered in the context of existing and perhaps past mandates, as well as agencies' practices. Executive orders, environmental statutes, and other provisions of law authorizing, mandating, or constraining EPA's use of risk analysis are discussed in CRS Report 98-619, *Risk Analysis: Background on Environmental Protection Agency Mandates*.

¹ "Environmental risk analysis" refers to any quantitative or qualitative scientific description of an environmental hazard, the potential adverse effects of exposure, the risks of these effects, events and conditions that may lead to or modify adverse effects, populations or environments that influence or experience adverse effects, and uncertainties with regard to any of these factors. For a more detailed definition, see the Appendix to CRS Report 98-618, *Environmental Risk Analysis: A Review of Public Policy Issues*.

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

- the Johnston amendments to S. 171, a bill to confer cabinet-level status on the Environmental Protection Agency (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 focuses on the general provisions of highlighted sections of bills that are large and complex; 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, P.L. 103-354, 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 Section 123 in S. 171, a bill to raise the U.S. Environmental Protection Agency (EPA) to department (cabinet) status. In the House, a proposal to similarly amend a bill to elevate EPA to the cabinet (H.R. 3425) was unsuccessful, however. 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 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, they were merged and introduced on the Senate floor by Senator Dole as a substitute amendment for S. 343, as reported by the Committee on the Judiciary. After two weeks of debate and three failed votes to invoke cloture, the Senate turned to other issues. The reported bill (also known as the Dole bill), rather than the substitute amendment, 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 that saw action in the 103rd Congress, including a slightly modified version of the original Johnston amendment, with coverage expanded beyond 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 through D. Each division 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 included in major legislation addressing drinking water (P.L. 104-182) and food safety (P.L. 104-170), as well as 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 enacting comprehensive regulatory reform legislation or other provisions that would have increased use of risk analysis by EPA. The most comprehensive bill, S. 981, as reported by the Senate Committee on Governmental Affairs, had 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, amended, on May 11, 1998, but the bill received no floor action. The Majority Leader introduced a risk-

only version of S. 981, 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

In general, bills mandating risk analysis have become more complex and detailed since 1993. Table 2 summarizes selected provisions of key bills in the 103rd, 104th, and 105th Congresses, beginning on page 11

Applicability

From the 103rd Congress to the 104th Congress, proposed mandates for risk analysis in the federal government have broadened in scope to encompass more agencies. The Johnston amendments would have mandated risk analysis only by EPA, while proposals in the 104th Congress would have targeted all federal agencies, including the independent boards and commissions which, unlike other federal agencies, have never been required by executive order to perform risk analysis or economic analysis for proposed or final rules.²

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 Congress. 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.³

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 not connected with rulemaking would have been affected as well as 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.⁴ S. 1728 would have required analyses when a significant substitution risk resulted from promulgation of a rule.

² President Reagan issued the first explicit mandate for regulatory risk analysis in January 1985. For more information about the requirements of executive orders, see CRS Report 98-619, *Risk Analysis: Background on Environmental Protection Agency Mandates*.

³ 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.

⁴ “Risk characterization” is the final step in a risk analysis, which summarizes scientific judgments about the existence and overall magnitude (that is, the incidence) of adverse effects, given specified levels of exposure to a hazard.

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 impact of a rule. Under the Johnston amendment to Senate-passed S. 2019, analysis would be required only for rules with an annual effect on the economy of \$100 million or more. In the 104th Congress, S. 343 and H.R. 9 Division C would have applied to rules with an estimated cost of \$50 million or more in a year, while H.R. 9 Division D would have affected rules likely to cost \$25 million or more. In the 105th Congress, both S. 981, as reported, and S. 1728, as introduced, would have applied to rules likely to have a gross annual cost of \$100 million or more.

Definitions of “major rules” and “significant risk assessments” also varied in the amount of discretion they would have provided to the Office of Management and Budget (OMB) to designate rules as major or non-major. Rules likely to result in major increases in costs or 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.⁵ The Senate bills during this period also would have authorized designation of a rule as major due to its effects on health, safety, or the environment. S. 981 would have given OMB the authority to require a risk analysis 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 provided for emergencies, while S. 343, H.R. 9 Division D, and S. 981 would have exempted from risk analysis requirements rules approving product labels (e.g., for pharmaceutical drugs). S. 171 and S. 2019 would have required 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 they are 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 required analyses of:

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

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

⁵ 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.

H.R. 9 and S. 343, as reported in the 104th Congress, would have included requirements to analyze uncertainties, assumptions, the distribution of risk in a population (that is, who is at risk), substitution risks (risks resulting from regulation), and 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 to which covered agency analyses and presentations of results would be required to conform. 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 the highlighted bills (except the bill introduced by Senator Lott late in the 105th Congress), but the bills differed in how they would have directed agencies to relate costs and benefits.⁶ Both versions of the Johnston amendments (103rd Congress) and S. 343 (104th Congress) would have required consideration of whether benefits would justify costs. S. 343 and S. 981 (105th Congress) 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.

Additional 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 comparison of 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 flexibility provided to local and state governments and the regulated community, and the quality of information. S. 981, like S. 343 before it, specified certain principles of economic analysis.

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 which are summarized in Table 1. Both Johnston amendments, S. 343, and S. 981 would have directed EPA to consider whether benefits would justify costs. The

⁶ The Unfunded Mandates Reform Act (P.L. 104-4) requires federal agencies to analyze costs and benefits of all proposed and final rules with an expected cost of \$100 million or more.

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 required a determination as to whether the rule was most cost-effective or 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.⁷

Table 1. Decision Criteria Employed by Key Proposals in the 103rd, 104th, and 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 EPA should weigh costs and risks in developing regulations. Neither would they have authorized EPA to employ risk-based or economic criteria when implementing other statutes, some argued. 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 still greater assurance that its requirements would apply only to the extent that they were not inconsistent with existing statutes. However, the neutrality of proposed requirements relative to existing statutory requirements never was stated absolutely clearly, according to some observers. 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

⁷ The Unfunded Mandates Reform Act (P.L. 104-4) enacted by the 104th Congress requires federal agencies, except for independent regulatory boards and commissions, to promulgate the alternative that is least costly, most cost-effective, or least burdensome, or to explain why such an alternative was not adopted.

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. 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, 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 highlighted in this report (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 OMB. Only economic analyses of regulations would have been reviewed under H.R. 9, but 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 OMB oversight for risk assessments and peer review, as well as economic analyses. H.R. 9 would have required OMB to evaluate federal agencies' rulemaking procedures, while S. 981 would have directed OMB to evaluate agencies' cost-benefit and risk analyses periodically.

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

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 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 or oversight by the executive branch of government.

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 7 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 nor the analyses themselves 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, including that there is “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 to judicial review agency decisions about which rules are major, and agency risk analyses in connection with review of a final agency action. Both bills in the 105th Congress would have required only that the rule not be arbitrary or 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, and (under S. 1728), that designation of a rule not be “clearly and convincingly” erroneous.

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 plans 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.⁸

Conclusion

A comparison of selected provisions of key legislative proposals mandating risk analysis and cost-benefit analysis of environmental regulations indicates that proposals broadened in scope to encompass more federal agencies and more kinds of agency activities. At the same time, the more recent proposals apply to a smaller fraction of promulgated rules that are “major,” 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 OMB and the regulatory agency or between OMB and anyone outside of government about rules under review would have had to be disclosed to the public.

⁸ However, S. 2019 Section 15 would require a report of the relative risk of various sources of pollution and of the costs and benefits of risk reduction strategies.

Table 2. Cost-Benefit Analysis in the 103rd, 104th, and 105th Congresses⁹

Provision	103rd Congress Johnston Amendments, as passed by the Senate	104th Congress S. 343, as reported by the Judiciary Committee	104th Congress H.R. 9, as passed by the House	105th Congress S. 981, as reported	105th Congress S. 1728, as introduced
Affected Agencies	U.S. Environmental Protection Agency (EPA)	All federal agencies	Rulemaking: All federal agencies Risk analysis: EPA, ACOE, CPSC, DOE, DOI, DOT, FDA, MSHA, NOAA, NRC, OSHA, USDA, and other agencies designated by OMB ¹⁰	All federal agencies	All federal agencies

⁹ Because the report omits specific provisions that modify general requirements of the highlighted sections, reference to the bills themselves is advisable.

¹⁰ The affected agencies are: Environmental Protection Agency (EPA), Army Corps of Engineers (ACOE), Consumer Product Safety Commission (CPSC), Department of Energy (DOE), Department of Interior (DOI), Department of Transportation (DOT), Food and Drug Administration (FDA), Mine Safety and Health Administration (MSHA), National Oceanographic and Atmospheric Administration (NOAA), Nuclear Regulatory Commission (NRC), Occupational Safety and Health Administration (OSHA), United States Department of Agriculture (USDA), and other agencies designated by the Office of Management and Budget (OMB).

Provision	103 rd Congress Johnston Amendments, as passed by the Senate	104 th Congress S. 343, as reported by the Judiciary Committee	104 th Congress H.R. 9, as passed by the House	105 th Congress S. 981, as reported	105 th Congress S. 1728, as introduced
Rules and Other Products or Activities Affected	<p>S. 171 — Final rules relating to human health and safety or the environment</p> <p>S. 2019 — Proposed and final major rules relating to human health or the environment</p>	<p>Varies section by section., but generally applies to all generally applicable rules, including substantive rules¹¹; interpretive rules or rules of agency organization, procedure, or practice that alter or create rights or obligations of persons outside the agency; and rules pertaining to agency acquisition, management, or disposal of property or services if not by GSA procedures; excepts rules pertaining to military or foreign affairs</p>	<p>Division C — Substantive rules, excluding rules issued in an emergency, under a deadline, or to implement tax laws or international sanctions</p> <p>Division D — Generally applicable rules, including substantive rules; excepts rules issued in an emergency, approving food, drug or other product labels, approving state programs, or relating to military readiness, health insurance, or medical services</p>	<p>Substantive rules, excluding rules required to be issued annually; authorizing introduction into commerce of food, drugs, or cosmetics; issued by the Federal Election Commission or in some cases by the Federal Communications Commission; or affecting tax, monetary policy, security brokers and dealers, or bank safety or soundness</p> <p>Economic analyses of new major rules</p>	<p>Substantive rules the primary purpose of which is to address health, safety, or environmental risks; excludes the same rules excluded by S. 981, except does not exclude rules authorizing introduction into commerce of food, drugs, or cosmetics</p> <p>Risk analyses for major rules relating to human health or the environment and for rules that result in a significant substitution risk</p>

¹¹ Substantive rules are those rules for which agencies are required to provide public notice of rulemaking and opportunity for public comment under the Administrative Procedure Act (5 U.S.C. 553). They exclude rules pertaining to military or foreign affairs, agency management or personnel or to public property, loans, grants, benefits, or contracts. Except when notice and comment is otherwise required by law, this category also excludes interpretative rules, general statements of policy, rules of agency organization, procedure, or practice, and rules for which the agency finds for good cause that notice and public comment procedures are impracticable, unnecessary, or contrary to the public interest.

Provision	103 rd Congress Johnston Amendments, as passed by the Senate	104 th Congress S. 343, as reported by the Judiciary Committee	104 th Congress H.R. 9, as passed by the House	105 th Congress S. 981, as reported	105 th Congress S. 1728, as introduced
Affected Activities (cont.)		<p>Policy statements that alter or create rights or obligations of persons outside the agency</p> <p>Economic analyses for new major rules, cleanup plans, and reviews of existing rules; excepts analyses in emergencies, for rules authorizing or recognizing a commercial product, for inspecting or permitting facilities, registering pesticides, reviewing toxicity information for commercial chemicals, setting limits for pesticide residues in food, screening analysis, or product labels</p> <p>Risk analyses and characterizations in connection with health, safety, or environmental risks, excluding those that support approval of new products or permitting actions, screening analyses, inspections or enforcement actions</p>	<p>Risk analyses and communications in support of “significant” risk documents</p>	<p>Risk analyses in connection with major rules addressing health, safety, or environmental risks, and other risk analyses designated by OMB;¹² excepts analyses for emergencies, inspecting or permitting facilities, screening analysis, or product labels</p> <p>Risk characterizations in risk assessment documents, regulatory proposals, or decisions by covered agencies</p>	

¹² This would be a new authority for OMB. Current practice and provisions proposed in all the above abstracted bills from the 104th and 105th Congresses provide OMB with the authority to designate rules to be treated as major, but no other bill confers such power with respect to risk analyses.

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Major Rules	<p>S. 171 — Not applicable</p> <p>S. 2019 — Rules that may have an effect on the economy of \$100 million or more in any one year</p>	<p>Covered rules with an estimated cost of \$50 million or more in a year, or with specified significant adverse effects on economic activity, innovation, health, safety, or the environment; excluding tax rules and rules approving or removing a product in commerce</p>	<p>Division C — Substantive rules likely to result in an annual effect on the economy of \$50 million or more, major increases in costs or prices, or significant adverse effects on economic activity or innovation</p> <p>Division D — Rules likely to result in an annual increase in costs of \$25 million or more; excepts rules approving products or substances</p>	<p>Substantive rules likely to have a gross annual cost of \$100 million or more, or to result in other specified significant adverse effects on economic activity, innovation, public health, safety, the environment, state, local, or tribal governments, or communities</p>	<p>Same as S. 981</p>

Provision	103 rd Congress Johnston Amendments, as passed by the Senate	104 th Congress S. 343, as reported by the Judiciary Committee	104 th Congress H.R. 9, as passed by the House	105 th Congress S. 981, as reported	105 th Congress S. 1728, as introduced
Mandates for Economic Analysis	<p>S. 171 — For final rules relating to health and safety or the environment; agencies must analyze costs, benefits, and whether benefits will justify costs</p> <p>S. 2019 — For all major proposed and final rules relating to human health and the environment, agencies must analyze costs and benefits to governments and the private sector; cost-effectiveness of the rule and alternatives; and whether benefits justify costs</p>	<p>For proposed and final major rules, major cleanup plans, and existing rules being reviewed, agencies must analyze costs, benefits, incremental costs and benefits, feasibility of specified alternatives, cumulative compliance burden, net effect on small businesses, whether benefits justify costs, and whether greater net benefits or lower net costs are achieved; also must describe persons who are likely to benefit and to bear the cost</p>	<p>Division C — For major proposed or final rules, agencies must analyze costs, benefits, and distribution of costs and benefits for the proposal and less-cost alternatives</p> <p>Division D — For each proposed or final major rule, agencies must analyze incremental costs and benefits of the rule and alternatives</p> <p>For each final major rule, agencies must analyze whether benefits are likely to exceed costs, and effects on small businesses, net employment, and cumulative financial compliance burden</p>	<p>For major new rules, agencies must analyze benefits; costs; benefits relative to costs; cost-effectiveness; net benefits; a reasonable number of reasonable alternatives; feasibility of using market-based mechanisms; flexibility provided to local and state governments and the regulated community; and quality of information</p>	No provision
Principles of Economic Analysis	No provision	Specifies principles of economic analysis	No provision	Specifies principles of economic analysis	No provision

Provision	103 rd Congress Johnston Amendments, as passed by the Senate	104 th Congress S. 343, as reported by the Judiciary Committee	104 th Congress H.R. 9, as passed by the House	105 th Congress S. 981, as reported	105 th Congress S. 1728, as introduced
Mandates for Risk Analyses	<p>S. 171 — Agencies must analyze a rule’s effect on health or the environment; estimate risk to individuals; and compare risks</p> <p>S. 2019 — Agencies must analyze risks to human health, including risks to significant subpopulations disproportionately exposed or particularly sensitive, and compare risks for at least 6 other hazards</p>	For new major rules, major environmental cleanup plans, and reviews of existing rules, agencies must analyze risks, data quality, and incremental risk reduction, and must compare risks	For all proposed or final major rules designed to protect health, safety, or the environment, agencies must assess incremental risk reduction, distribution of risks, known substitution risks, and comparable risks	For proposed and final major rules the primary purpose of which is to address health, safety, or environmental risk, agencies must analyze risk and distribution of risk to exposed populations, subpopulations, or natural resources, and must compare risks when data are available	For proposed and final major rules the primary purpose of which is to address health, safety, or environmental risk, agencies must analyze risk to exposed individuals, populations, or natural resources, including substitution risks

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Principles of Risk Assessment and Risk Characterization	No provision	<p>Specifies principles of risk assessment and risk characterizations</p> <p>Risk analyses for major rules must be plausible and realistic</p> <p>For human health risk analysis for a major rule, agencies must use: the most scientifically plausible model; best estimates; and probabilistic descriptions of uncertainty and variability; data must be developed in accord with - promulgated standards for toxic substances and pesticide tests</p>	<p>Specifies principles of risk assessment and risk characterizations</p> <p>Agencies must analyze uncertainties, conflicting data, and assumptions; be scientifically objective and unbiased; and rely on scientific findings and consider all relevant scientific data</p> <p>Agencies must express risk as a reasonable range of estimates, including a best estimate; distinguish scientific findings from other considerations and for human health risk assessments, discuss conflicting data</p>	<p>Specifies principles of risk assessment and risk characterizations</p> <p>Agencies must analyze uncertainties, variabilities, conflicting data, inferences, and assumptions; consider “all relevant, reliable, and reasonably available scientific information”; be objective and systematic, and carefully analyze the weight of the scientific evidence</p> <p>Agencies must revise assumptions to incorporate new relevant and reliable scientific information as it becomes reasonably available</p> <p>Agencies must express risk estimates as reasonable ranges</p>	<p>Specifies principles of risk assessment and characterizations</p> <p>Agencies must analyze uncertainties, variabilities, and assumptions; consider reliable and reasonably available scientific information and promote rational and informed risk management decisions and informed public participation; and provide for public input to the process</p> <p>Agencies must express risk estimates as reasonable ranges or probability distributions, including the most plausible risk estimates for the general population</p>

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Certification	<p>S. 171 — For each final rule EPA must certify that: the estimate and analysis are based upon “a scientific evaluation of the risk” and supported by the “best available scientific data”; the rule will substantially increase health or environmental protection; and the rule will produce benefits that will justify the costs</p> <p>S. 2019 — For each proposed and final major rule relating to human health or the environment, EPA must certify that: the analyses are based on the “best reasonably obtainable scientific information”; the rule is likely to significantly reduce</p>	No provision	<p>For each final rule, an agency must certify that: analyses are based on objective and unbiased scientific and economic evaluation of all information provided; incremental benefits are likely to justify and be reasonably related to the incremental costs; and alternatives are either less cost-effective or provide less flexibility to regulated entities or local or state governments</p>	<p>For each major rule, an agency must certify: its compliance with rulemaking procedures and the satisfaction of decision criteria, or an explanation of why certification cannot be made</p>	No provision

Provision	103 rd Congress Johnston Amendments, as passed by the Senate	104 th Congress S. 343, as reported by the Judiciary Committee	104 th Congress H.R. 9, as passed by the House	105 th Congress S. 981, as reported	105 th Congress S. 1728, as introduced
Decision Criteria for Rules	<p>S. 171 — Benefits will justify costs</p> <p>S. 2019 — Likely benefits will justify costs, and rule is most cost-effective alternative allowed by law</p>	<p>Potential benefits justify potential costs</p> <p>Rule is the most cost-effective or least-cost alternative</p> <p>Rule does not disapprove a product on the basis of safety if it presents a negligible human risk under intended conditions of use</p>	<p>Prohibits adoption of a final rule without certification that— incremental benefits are likely to justify and be reasonably related to the incremental costs, and rule is most cost-effective or provides more flexibility than alternatives</p> <p>Prohibits promulgation of a major rule unless agencies have complied with analytic and certification requirements and these are supported by substantial evidence of the rulemaking record</p> <p>Prohibits promulgation of a major rule without OMB approval or</p>	<p>Whether a rule is likely to be most cost-effective or to provide the greatest net benefits</p> <p>Whether likely benefits will justify costs</p>	<p>No provision</p>

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Effect on Implementatio n of Existing Laws	<p>S. 171 — Certification requirement does not amend, modify, or alter any statute</p> <p>S. 2019 — Does not affect any other provision of federal law or authorize EPA consideration of additional factors in its decisions</p>	<p>Prohibits promulgation of a rule unless decision criteria are met; decision criteria supplement existing statutory requirements</p> <p>Notice and comment procedures apply to rules under statutes not generally subject to 5 U.S.C. 553</p> <p>Requires analysis of an alternative to a cleanup plan only if it is consistent with the agency’s statutory authority</p> <p>Supersedes laws prohibiting or denying approval of a product on the basis of safety if it poses a negligible risk to human health under intended conditions of use</p>	<p>Requires agencies to consider analyses required by Division C only “to extent permitted by law”</p> <p>Rulemaking provisions of Division D supersede provisions of existing laws authorizing regulatory activities designed to protect health safety, or the environment</p>	<p>Requirements apply to the extent that they are not inconsistent with existing statutes</p>	<p>Adds new requirements to rulemaking under existing statutes and apparently would supersede them if requirements conflicted</p>

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Executive Coordination and Oversight of Agency Analyses	No provision	<p>Executive branch must develop uniform procedures for regulatory analysis and oversee agency implementation; limits time for review of proposed or final regulations to 30 days, which may be extended</p> <p>President must issue guidance for risk analysis, and OMB must issue guidance for cost-benefit analysis</p> <p>Agencies must maintain a rulemaking file containing copies of all material that pertains directly to the rulemaking that was available to the</p>	<p>OMB may review draft and final economic analyses and rules; limits time for review to 90 days; OMB must approve of, or comment on, final economic analyses for major rules</p> <p>Similar to S. 343</p> <p>Agencies must disclose changes made from the preliminary risk analysis in the final regulatory impact analysis</p>	<p>OMB must establish a process to review and coordinate agency regulatory actions; limits time for review to 90 days, but allows extension</p> <p>OMB, in consultation with the Council of Economic Advisors (CEA), the Director of the Office of Science and Technology Policy (OSTP), and relevant agency heads, must issue guidelines for cost-benefit analyses, risk assessments, and peer review</p> <p>Agencies must disclose changes to regulatory proposals that result from OMB review</p>	No provision

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Congressional Review of Agency Rulemaking	No provision	Agencies must submit final regulations to Congress, which may reject them by joint resolution of disapproval ¹³	No provision	No provision	No provision

¹³ This provision was enacted by the 104th Congress in Public Law 104-121.

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Peer Review	No provision	<p>Covered agencies must have uniform peer review procedures; peer review panels must include a balanced group of experts representing all interests and not exclude those with a potential interest in the outcome, if disclosed, unless a single entity is affected by a regulatory decision; excludes people associated with generation of the work being reviewed; requires reporting of minority views</p> <p>Federal Advisory Committee Act (FACA) applies to peer review panels</p>	<p>Agencies must have independent, external peer review programs; review panels must be balanced and not exclude those with a potential interest in the outcome, if disclosed, unless a single entity is affected by a regulatory decision</p> <p>Requires peer review of risk analyses and economic analyses for major rules with an impact of at least \$100 million, and of any analysis likely to have a significant impact on public policy decisions, if ordered by OMB</p> <p>A National Peer Review Panel must annually review agencies' cost assessment practices</p>	<p>Agencies must arrange for independent peer review by broadly representative expert groups; panels must adhere to agency standards and practices governing conflicts of interest</p> <p>Federal Advisory Committee Act does not apply to peer review</p> <p>Requires peer review of risk analyses and cost-benefit analyses of major rules likely to have an annual effect of \$100 million or more</p> <p>Agency must publish a statement by a federal official from outside the agency indicating that review participants were independent and expert and that the agency has</p>	No provision

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Peer Review (cont.)		Requires peer review of: risk analyses, cost-benefit analyses, and supporting data for major rules and reviews of rules; - data supporting risk analysis of cleanup plans; quantitative estimates of risk or hazard used in regulations; entries into EPA's risk database; guidelines for cost-benefit analysis; and regulations for the conduct of risk analysis and risk characterization			
Deadlines	S. 171 — No provision S. 2019 — Action required to meet a statutory or judicial deadline shall not be delayed	Suspends judicial and statutory deadlines for rulemaking until requirements for regulatory analysis are met	Agencies may promulgate a rule prior to completing economic analyses required by Division C if analysis conflicts with deadlines	During the first 2 years after enactment, suspends statutory and judicial deadlines for rulemaking for 6 months or until requirements for regulatory analysis are satisfied	Same as S. 981

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Review of Existing Rules	No provision	Agencies must review all existing major rules, rules that are inconsistent with this Act, and rules designated by the President; existing rules would terminate in 7 years, new rules in 5 years, unless reviewed	Division D — Agencies may set priorities and procedures for review, revision, and repeal of major rules promulgated prior to the effective date of the Act	Agencies must review existing major rules as necessary	No provision

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Citizen Petitions	No provision	<p>Citizens may petition for judicial review of agency analysis and certification of a rule's impact on small entities</p> <p>Citizens also may petition for: issuance, amendment, or repeal of any rule; amendment or repeal of any interpretive rule, guidance, or general policy statement; a variance or exemption from any major rule; cost- benefit analysis of a major rule; review of a risk assessment or cost-benefit analysis for a major rule or major cleanup plan; and review of any risk assessment or any entry on an agency- developed database</p>	Citizens may petition for judicial review of agency compliance with Division C analytic requirements	No provision	No provision

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<p>Actions Subject to Judicial Review</p>	<p>S. 171 — Certification is not subject to judicial review; no cause of action is granted to any person</p> <p>S. 2019 — Does not create any right or benefit, substantive or procedural; adequacy of certification or alleged failure to comply is not grounds for invalidating a major rule</p>	<p>Subjects to judicial review all agency decisions (and any failure to make such decisions) to issue, grant, or deny rules, orders, petitions, licenses, sanctions, or relief</p> <p>Subjects to judicial review agencies’ regulatory flexibility analysis and certification regarding impact of a rule on small entities</p>	<p>Division C — Subjects agency analyses regarding the effect of a rule on small entities to judicial review in connection with promulgation of a major rule</p> <p>Division D — Subjects agency compliance with analytic requirements to judicial review under the authorizing statute and the Administrative Procedure Act</p>	<p>Permits judicial review of agency compliance with requirements for regulatory analysis only in connection with review of a final agency action</p> <p>Subjects to judicial review agencies’ regulatory flexibility analysis and certification regarding impact of a rule on small entities</p>	<p>Subjects to judicial review agency (but not OMB) designations of rules as major or not major</p> <p>Subjects risk assessments to judicial review when final rules are reviewed</p>

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Standard of Judicial Review	No provision	Whether there is substantial support in the rulemaking file for the factual basis of agency actions, findings, or conclusions; whether agencies observed procedural requirements; whether statutory authority was exceeded; or whether the agency interpreted the rule in a narrow way when a broader interpretation would have allowed the agency to design a rule with benefits that justified costs and that would be more cost-effective or less costly	Division D — Whether agencies substantially complied with the principles for risk assessment and characterization	Whether the cost-benefit determination, risk assessment, or peer review was wholly omitted Whether the final rule is arbitrary, capricious, an abuse of discretion, or is unsupported by substantial evidence where that standard is otherwise provided by law	Whether the designation of a rule as major or non-major clearly and convincingly is shown to be erroneous Whether the final rule is arbitrary or capricious Whether an agency failed to perform a required risk assessment

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Risk-Based Priorities	No provision	Agencies must reflect risk-based priorities in annual budget requests	The President must identify relative risks and cost-effective risk reduction strategies and opportunities and obstacles to reflecting priorities within regulatory programs to protect health in a cost-effective and cost-reasonable manner	<p>OMB must contract with a scientific institution to compare risks to human health, safety, and the environment; to study methodologies for comparing dissimilar risks; and to recommend how to set priorities for reducing risks</p> <p>Agencies must use the results of the study to inform their annual budgets and strategic plans and performance plans</p>	No provision