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Comparison of Environmental Risk Provisions in the 103d Congress*

Linda-Jo Schierow**

Introduction

In response to growing concerns about such things as unfunded federal mandates to state and local governments, industry's growing cost of compliance with environmental regulations, the federal budget deficit, and the efficiency and effectiveness of Environmental Protection Agency (EPA) programs, Congress is showing interest in risk analysis.

More than a dozen bills and amendments on risk analysis were introduced in the 103d Congress. House and Senate Committees of jurisdiction reported several proposals, and a few were approved by one chamber. This summary draws upon work done for the House Committee on Science, Space and Technology, and following pages provide a tabular, side-by-side comparison of provisions related to environmental risk analysis in bills at least ordered to be reported.

Provisions in nine bills¹ are compared to those in the most

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

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¹ House-passed, Environmental Research, Development, and Demonstration Authorization Act of 1993 (ERDDAA, H.R. 1994); Department of Environmental Protection Act, as reported by the House Committee on Government Operations, (DEPA, H.R. 3425); Department of Agriculture Reorganization Act, as reported by the House Committee on Agriculture (USDA Reorganization Act, H.R. 3171); House-passed Environmental Technologies Act of 1994 (ETA, H.R. 3870); Risk Assessment Improvement Act of 1994 (H.R. 4306), as ordered to be reported by the House Committee on Science, Space, and Technology; Superfund Reform Act of 1994, as reported by the House Committees on Energy and Commerce, Public Works and Transportation, and Ways and Means (H.R. 3800) and incorporated into the newly introduced H.R. 4916; House-passed Radon Awareness and Disclosure Act of 1993 (H.R. 2448); Senate-passed Department of the Environment Act of 1993 (S.

comprehensive, stand-alone, risk proposal, the Risk Assessment Improvement Act of 1994 (RAIA, H.R. 4306). Only provisions that would, if enacted, affect the development and practice of risk assessment or risk characterization are considered;² substantive provisions establishing a level of safety or tolerated risk associated with environmental media are not compared.

Since the data were tabulated, H.R. 4306 was reported October 7, 1994. However, the House, Senate and White House failed to reach agreement on it or any other risk legislation that would have affected the EPA, and no such legislation was adopted.

Consensus was achieved on risk provisions to apply to the Department of Agriculture (USDA). The Conference Committee reported a new measure, H.R. 4217, that combined the USDA Reorganization Act, H.R. 3171, with the Federal Crop Insurance Reform Act of 1994. The House and Senate approved the Conference Report, and the President is expected to sign it.

The bill as amended creates an USDA Office of Risk Assessment and Cost-Benefit Analysis and requires its Director, e.g., to develop a strategy for ensuring consistent risk/benefit analyses of regulations with an economic impact over \$100M. It also dropped the certification requirement mentioned below in favor of requiring the Director to state, e.g., that a regulation has been evaluated with regard to advancing protection against the risk addressed and that it will produce cost-effective benefits.

171); Superfund Reform Act of 1994, as reported by the Senate Committee on Environment and Public Works (S. 1834); and Senate-passed Safe Drinking Water Act Amendments of 1994 (S. 2019).

² The term "risk assessment" is not used in S. 2019, but the requirement to assess risk is implied in the phrases "sound scientific practices for the implementation of the authority with respect to the contaminant [that is regulated on the basis of health effects other than carcinogenic effects]" and "practices that would be necessary to support the implementation of clause (i)(II)" which authorizes EPA to promulgate a standard based on health effects other than cancer that will "ensure a reasonable certainty of no harm."

Comparison of Risk Provisions in House and Senate Bills (103d Congress)

Provision	Risk Assessment Improvement Act of 1994, as ordered to be reported (RAIA, H.R. 4306)	Other House Proposals House-passed: H.R. 1994, 2448 & 3870 Reported: H.R. 3171, 3425 & 4916	Senate Proposals Senate-passed: S. 171 & 2019 Reported: S. 1834
Risk Assessment Program	§ 4(a)-(e) - Establishes a Risk Assessment Program in EPA, headed by a Director	H.R. 3425 § 113 - Establishes Office of Environmental Risk in EPA, headed by a Director H.R. 3171 § 804 - Establishes Office of Environmental Risk Assessment (OERA), headed by a Director, in Department of Agriculture (USDA)	No comparable provision
Scientific Peer Review, Response to Comments, and Report to Congress	§ 4(c) - Requires Director to provide for independent scientific peer review of EPA's risk assessment guidelines, to respond in writing to reviewers' comments, and to report to Congress on the Director's plan for peer review	H.R. 3425 § 114(a) - Requires EPA to develop, publish, and implement meaningful peer review guidelines for selected "science-based" and "technical products" H.R. 1994 § 3(d) - Requires EPA's Science Advisory Board to review EPA research activities	S. 2019 § 4(d) - Requires a National Academy of Sciences (NAS) study and recommendations to ensure EPA decisions about contaminants regulated on the basis of health effects other than cancer are based on appropriate, peer-reviewed, scientific information and sound scientific practices; requires publication of EPA guidelines establishing sound scientific practices for risk assessments
Advice to the Administrator	§ 4(d) - Requires Director to advise the Administrator on the conduct of risk assessment, research needs, and guideline development	H.R. 3425 § 113(a) - Requires Director to advise EPA offices about environmental relative risk matters H.R. 3171 § 804 - Requires Director to advise USDA offices and agencies about risks addressed by regulations and associated costs	No comparable provision

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Consultation Authority of Risk Assessmt. Program Dir.	§ 4(c) - Authorizes mechanisms for the Director to consult with risk assessment experts	No comparable provision	No comparable provision
Development of Risk Assessment Guidelines	§ 4(f)(1) - Requires regular and systematic development, publication, and review of risk assessment guidelines to provide consistency and technical quality and to ensure that: EPA's risk assessments are scientifically objective and unbiased; significant uncertainties are clearly disclosed; and guidelines ensure use of the best information and most plausible and unbiased assumptions.	H.R. 3171 § 804 - Requires OERA Director to develop a strategy for consistent risk/benefit analyses of regulations using state-of-the-art scientific methods H.R. 3870 § 601 - Requires specified procedures in risk assessments to develop research priorities for environmental technologies H.R. 4916 § 501 - Requires EPA to develop a national risk protocol for assessments related to Superfund sites to promote realistic estimates that neither minimize nor exaggerate risks or potential risks; requires establishment of guidelines for such risk assessments	S. 1834 § 501 - Requires EPA to develop a national risk protocol within 18 months of enactment for conducting risk assessments related to Superfund sites; requires establishment of guidelines for all such risk assessments
Interim Guidance	§ 4(f)(1) - Requires the Director to provide interim guidance when significant scientific progress or need warrants updating of a guideline	No comparable provision	No comparable provision

<p>Risk Assessment Guidelines Development Process</p>	<p>§ 4(f)(2) - Requires public notice of intent to publish guidelines; opportunity for public comment, and written EPA response to public comments</p>	<p>H.R. 4916 § 501 - Requires promulgation of a national risk protocol in accord with 5 U.S.C. 561-570, as appropriate</p>	<p>No comparable provision</p>
<p>Applicability of Risk Assessment Guidelines</p>	<p>§ 4(f)(3) - Requires EPA to conduct all risk assessments according to guidelines; allows reference to existing documents to satisfy some requirements; exempts internal planning, screening, and emergency risk assessments</p>	<p>H.R. 4916 § 501 - Requires use of national risk protocol and guidelines for assessments underlying remedial action decisions, establishing protective concentration levels, and evaluating remedial alternatives</p>	<p>S. 1834 § 501 - Identical to provisions in H.R. 4916</p>
<p>Contents of Guidelines</p>	<p>§ 4(f)(4) - Requires guidelines to include: explanation of their scope and applicability; criteria for accepting and evaluating data; descriptions of models and assumptions, default options, and conservatism; criteria for iterative approaches and uncertainty analysis; guidance for risk characterization; methods for clearly reporting risk assessments; and criteria for identifying and using the most plausible and unbiased methods and assumptions</p>	<p>H.R. 3870 § 601 - Contains the same requirements for risk assessments (with a few exceptions) as guidelines required under H.R. 4306, § 4(f)(4) and § 4(h) Floor amendment to H.R. 3870 - Directs the White House Office of Science and Technology Policy (OSTP) to establish criteria for accepting and assessing data for setting environmental technology research priorities H.R. 4916 § 501 - Requires national risk protocol, to extent appropriate and practicable: to include, e.g. standardized exposure scenarios and methods for evaluating exposure and developing protective concentration levels; to define use of probabilistic modeling and to identify selection criteria for models; to define use of high end and central tendency exposure cases, and assumptions</p>	<p>S. 2019 § 4(d) - Requires EPA publication of guidelines establishing sound scientific risk assessment procedures for contaminants regulated on the basis of health effects other than cancer; requires publication after a National Academy of Sciences (NAS) study recommends how to ensure decisions are based on appropriate, peer-reviewed, scientific information and sound scientific practices S. 1834 § 501 - Identical to provisions in H.R. 4916</p>

Comparison of Risk Provisions in House and Senate Bills (103d Congress)

Provision	Risk Assessment Improvement Act of 1994, as ordered to be reported (RAIA, H.R. 4306)	Other House Proposals House-passed: H.R. 1994, 2448 & 3870 Reported: H.R. 3171, 3425 & 4916	Senate Proposals Senate-passed: S. 171 & 2019 Reported: S. 1834
Report to Congress on Guidelines	§ 4(i)(5) - Requires report to Congress on the status of risk assessment guidelines relative to the requirements of this Act and annual updates of EPA's plan for achieving full compliance	No comparable provision	No comparable provision
Use of Risk Assessment Guidelines	§ 4(g) - Requires the Director to ensure that EPA risk assessments are conducted in accord with the guidelines, to the extent permitted by law; prohibits departures from guidelines unless permitted by interim guidance or the Director's written approval after scientific peer review	No comparable provision	No comparable provision
Development of Risk Characterization Guidelines and Report	§ 4(h) - Requires regular and systematic development and updates of risk characterization guidance to ensure EPA risk characterizations distinguish between data and policy assumptions and facilitate accurate interpretation and appropriate use; requires EPA's risk characterizations to distinguish human health risks from other risks; directs EPA to consider and incorporate recommendations of the NAS; and requires EPA to report on implementation	No comparable provision	No comparable provision

<p>Contents of Risk Characterization</p>	<p>§ 4(h) - Requires risk characterizations to include information on: data and methods; limitations, assumptions, and default options and extent of scientific consensus with respect to them; major uncertainties and their influence; "range and distribution of exposures ... and their ... likelihood;" quantitative and qualitative descriptors of the range of risks to populations, individuals, species, and ecological communities; statistical expressions of the range and variability of the risk estimate, including the population, central estimates, appropriate upper-bound and lower-bound estimates, and the reasonable range of uncertainties; and comparisons (together with relevant distinctions and limitations of comparisons) with other familiar, routinely encountered health risks and substitution risks</p>	<p>H.R. 2448 § 12 - Requires information on health risks associated with radon exposure to be unbiased and informative; requires public descriptions of the degree of risk to characterize the population and to state the expected risk and reasonable range of uncertainty H.R. 4916 § 101 - Contains provisions similar to those of H.R. 2448 § 12; also requires EPA to state upperbound and lower-bound estimates and to provide comparisons of the level of risk at Superfund facilities to "comparable levels of risk from hazardous substances ordinarily encountered by the general public"; § 102 - Requires Citizen Information and Access Office to disseminate risk characterizations for the facility, including different views when people disagree</p>	<p>S. 1834 § 101 - Contains provisions identical to § 101 of H.R. 4916</p>
<p>Risk Communication</p>	<p>§ 4(i) - Directs EPA to promote open dialogue among scientists, decision makers, and the public to improve communication</p>	<p>H.R. 4916 § 101 - Establishes mechanisms to increase communication about risk and hazards, emphasizing citizen input</p>	<p>S. 1834 § 101 - Contains provisions similar to § 101 of H.R. 4916</p>
<p>Report on Research & Training Needs</p>	<p>§ 4(j) - Requires Director to regularly evaluate and report to Congress on EPA research and training needs in risk assessment and communication; also required to develop a strategy and schedule and to delegate responsibility for research and training activities</p>	<p>H.R. 1994 § 5(b) - Requires EPA studies to identify personnel needs and recommendations for attracting and retaining qualified research personnel</p>	<p>No comparable provision</p>

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Review of EPA Risk Characterizations	<p>§ 4(k) - Requires Director to provide 3 annual reviews and a review every 3 years thereafter by independent technical experts of all EPA risk characterizations to determine compliance with guidelines; requires independent experts to report to Congress annually on EPA compliance; requires EPA to revise risk characterizations that experts identify as failing to conform with guidance</p>	<p>No comparable provision</p>	<p>No comparable provision</p>
Risk Ranking	<p>§ 5 - Establishes 2-year pilot project to develop and test methods for ranking dissimilar environmental risks and comparing strategies to reduce or prevent risks; requires participation of technical and nontechnical persons broadly representing the public and private sectors; requires peer-reviewed report of results; requires federal agencies to contract with the NAS NRC to provide technical guidance on approaches to using comparative risk analysis and other considerations in setting environmental priorities</p>	<p>No comparable provision</p>	<p>S. 2019 § 15 - Requires EPA to identify and, to the extent practicable, rank sources of pollution with respect to the relative degree of risk of adverse effects on human health, the environment, and public welfare, taking into consideration the extent and duration of risk and broad societal values</p>

<p>Interagency Coordination</p>	<p>§ 6 - Requires OSTP to survey agency risk assessment practices; to advise the President and Congress of results; to establish mechanisms for interagency coordination and use of state-of-the-art risk assessment practices; to disseminate the results of the risk ranking study required by § 5; and periodically to meet with states and others to assess effectiveness of cooperation in developing and applying risk assessment</p>	<p>No comparable provision</p>	<p>No comparable provision</p>
<p>Savings</p>	<p>§ 7 - Does not require risk assessment or risk characterization that is not required by law and does not modify any other legal requirement for risk assessment or to protect health, safety, or the environment</p>	<p>H.R. 3870 § 602 - Same requirements as H.R. 4306 H.R. 3425 § 3 - States that § 113, establishing the EPA Office of Environmental Risk and an Advisory Committee on Relative Risk and requiring a strategy for risk reduction, does not amend specified statutes relating to health and safety or environment or affect implementation H.R. 3171 §804 -Neither the section nor required certification amends other laws, is subject to judicial review or grants cause of action</p>	<p>No comparable provision</p>
<p>Research Priorities</p>	<p>§ 8 - Requires EPA to identify, prioritize and describe at least 10 research areas that could significantly reduce scientific uncertainties regarding highest risk environmental hazards; requires research to reduce scientific uncertainties and reference in budget requests for 5 years</p>	<p>H.R. 1994 § 13 - Same requirements as H.R. 4306. Also requires research to improve methodologies to assess the economic impact of technologies developed under the research program</p>	<p>No comparable provision</p>

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Definitions	§ 9 - Defines "comparative risk analysis," "default option," "environmental hazard," "risk assessment," "risk assessment guideline," "risk characterization," "scientific peer review," "uncertainty analysis," "central estimates," and "substitution risk"	H.R. 3870 § 603 - Defines "comparisons of risk," "default option," "risk assessment," "uncertainty analysis," "central estimates," and "substitution risk"	S. 2019 § 15 - Defines "risk," "source of pollution"
Risk Assessment Research Program	No comparable provision	H.R. 1994 § 11 - Establishes a separately identified risk assessment research program to develop and improve methodologies for identifying, assessing, and comparing risks	No comparable provision
Cost-Benefit-Risk Analysis of Regulations	No comparable provision	H.R. 3171 § 804 - Requires Director to publish a risk estimate, cost estimate, and comparative risk analysis for each USDA-proposed major regulation relating to public health, public safety or environment; "major regulation" undefined; requires Director to certify that the cost estimate and comparative risk analysis are based on the best available scientific data, will substantially protect public health or the environment and that benefits will justify costs; requires report when certification cannot be made	S. 171 § 123 - Similar to H.R. 3171 § 804 but directed to EPA; requires analysis of all final, not proposed, rules S. 2019 § 18 - Also similar to § 804 but defines "major regulation" as affecting the economy \$100 M or more per year; requires risk analysis but not numerical risk estimate; requires certification that "there is no regulatory alternative ... that would achieve an equivalent reduction in risk in a more cost-effective manner"; and permits use of analyses for proposed rules to satisfy requirement for final rules

<p>Risk Reduction Strategy</p>	<p>No comparable provision</p>	<p>H.R. 3425 § 113(b) - Requires Director to develop and implement a strategy to attain reductions in risk to human health and the environment that are practicable with available resources; § 108(c) - Requires report to Congress on EPA's progress in implementing its risk reduction strategy</p>	<p>S. 2019 § 15 - Requires identification of reasonable opportunities to achieve significant risk reduction associated with sources of pollution and federal regulations</p>
<p>Advisory Committee on Relative Risk</p>	<p>No comparable provision</p>	<p>H.R. 3425 § 113(c) - Creates an Advisory Committee on Relative Risk to advise EPA on its strategic direction, policies, and programs related to risk reduction</p>	<p>No comparable provision</p>
<p>Evaluation of Environmental Management Decisions</p>	<p>No comparable provision</p>	<p>No comparable provision</p>	<p>S. 2019 § 15 - Requires EPA to evaluate, to the extent practicable, and report to Congress on risk management decisions under federal environmental laws that present inherent and unavoidable choices between competing risks; requires report review by EPA's Science Advisory Board</p>

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Methods for Determining Costs & Benefits of Environmental Regulations	No comparable provision	No comparable provision	S. 2019 § 15 - Requires EPA to establish by rule methods for determining costs and benefits of environmental regulations and other federal actions
Analysis of Costs & Benefits of Risk Reduction Opportunities	No comparable provision	No comparable provision	S. 2019 § 15 - Requires EPA to estimate the costs associated with each source of pollution and the costs and benefits of complying with regulations designed to protect against risks associated with those sources; requires EPA to estimate costs and benefits associated with selected major federal actions that have the most significant impact on human health or the environment; directs EPA to identify major uncertainties and determine research needed to reduce them and its cost; requires consideration of, and, to the extent practicable, estimation of the monetary value of, specified benefits of risk reduction; requires report to Congress and public