Regulatory Reform Proposals and the Public Health

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The U.S. Congress is considering legislation that would change policy for environmental health in important ways. Current approaches have been criticized for addressing the wrong set of priorities and consuming too many resources. The legislation requires additional analyses and sets new decision criteria to be applied to federal agency actions taken to protect the environment and public health. Close review of the legislation suggests that, though it is intended to address identified problems, it is unlikely to lead to an improved basis for public policy and is likely to paralyze the regulatory process. Reform proposals that reduce rather than increase fragmentation of decision-making and that address problems comprehensively rather than selectively are needed. Key words: environmental policy, federal regulation, legislation, U.S. Congress. Environ Health Perspect 104:356-361 (1996)

The U.S. Congress is debating changes in environmental and public health regulation. Although bills on this subject previously have been introduced, the passage of HR 9 in the House of Representatives and consideration of similar legislation in the Senate have given renewed visibility to issues of risk assessment and priority setting that have been discussed in Environmental Health Perspectives (1-4).

The focus of current legislation is on regulatory programs intended to protect the environment and the health and safety of the public. Debate has centered on whether regulations adopted to achieve these purposes are too costly, whether they are too inflexible, whether they reflect the correct set of priorities, and whether they incorporate scientific findings in appropriate ways. Neither the health of the public nor the environment is receiving much attention in this debate.

Environmental and health regulations have been criticized as not always adopting the most cost-effective methods to achieve specific goals, as having costs that outweigh the benefits, and as requiring resources that could be used for other purposes (5,6). Economists argue that market-based methods and economic incentives may be more effective and less expensive than centralized regulatory approaches (7-9).

Priority setting is a second area of concern. Many have argued that the mix of approaches adopted over the years to address environmental and health issues no longer reflects the most useful set of priorities. Some problems receive too much attention; others receive too little (10,11). Some in the scientific community have expressed the view that the scientific basis for some regulatory decisions has been insufficient or that current findings have not been accurately reflected. The stated goals of legislation are to improve priority setting and the scientific basis of regulation and to ensure that benefits achieved are worth the costs incurred (12).

The academic and research communities have supported improvements in risk assessment and risk characterization. A committee of the National Research Council (NRC) of the National Academy of Sciences (NAS) recently issued an extensive report recommending improvements in assessment and characterization of risk (13). The Carnegie Commission on Science, Technology and Government has recommended a stronger role for the Office of Science and Technology Policy in overseeing improvements (14). Many participants in the policy debate have advocated consideration of cost to inform decision-making, while recognizing the limitations of cost-benefit analysis (15).

The federal government has taken action on such recommendations. For example, the Environmental Protection Agency has embarked upon a review of its cancer risk assessment guidelines (16) and is developing guidelines for assessing neurotoxicity. Since the 1970s, presidents have prescribed analyses to be conducted as part of the regulatory process. Executive Order 12866 was adopted in September 1993 and requires analysis of major regulations to ensure that benefits are in proportion to costs, as well as assessment of risks (17).

The criticisms of current regulatory approaches are important, and real change is needed. Few would argue against the need to streamline regulation and focus on important problems. We need to assess whether the proposals are likely to result in improvements to the current situation. True reform will reflect the underlying purpose of the regulations (i.e., protection of the health of the public and the environment).

The Proposals and Their Four Major Components

In the House of Representatives, the Job Creation and Wage Enhancement Act of 1995, HR 9, was introduced as one of the bills in the "Contract with America" package developed by the Republican leadership. The portions most relevant to environmental health were Title III, risk assessment and cost-benefit analysis for new regulations; Title IV, establishment of federal regulatory budget cost control; Title VI, strengthening regulatory flexibility; Title VII, regulatory impact analysis; and Title IX, private property rights protection and compensation. The bill was divided into pieces that were referred to different committees for hearing and revision. Title III was referred to the House Committees on Science; Commerce; and Government Reform and Oversight. The Title III provisions were reported back as HR 1022, the Risk Assessment and Cost-Benefit Act of 1995, which was passed by the House and rolled back into a new version of HR 9 as part D. HR 9 passed the House by a vote of 277-141 on 3 March 1995 (18).

The Senate has also developed legislation on risk assessment and cost-benefit analysis. S 343, the Comprehensive Regulatory Reform Act of 1995, introduced by Senator Bob Dole (R-KA), was reported from the Senate Judiciary Committee in May (19). The Senate leadership attempted to bring this bill to a vote in July, but adequate votes to bring debate to a close were lacking (20,21). Section 4 of S 343 is considered in this paper. Other sections of the bill address administrative procedures and regulatory impact analyses, among other topics.

Although they differ in many ways, HR 9 and S 343 include four provisions in major areas that will impact public health: 1) new or revised procedures for analysis include prescriptions for how to conduct risk assessments and cost-benefit analyses and how to characterize risks; 2) new criteria for making decisions specify that the results of the new approaches to risk assessment and...
Characterization are to be incorporated into regulatory proposals. Proposals are to pass a cost-benefit test before they may be adopted: 3) new processes or rights for appeal or review of current or new decisions or analyses allow individuals to petition to reopen existing environmental or health standards based on new criteria and substantively challenge in court elements of risk assessments and risk characterizations required as the basis for new agency actions; and 4) new approaches to priority setting specify that executive agencies are to perform comparative risk analyses on subject areas under their jurisdiction.

New Mandates and Methods for Risk Assessment and Economic Analysis

Both HR 9 and S 343 include provisions for risk assessment and economic analysis for agency actions projected to have impacts above a defined threshold. This threshold is $25 million in HR 9 (22) and $50 million in S 343 (23). In the House bill, requirements for risk assessment and risk characterization apply to 10 federal agencies and 6 types of actions, including (29): risk assessment documents or risk characterization documents prepared by or on behalf of a Federal agency in the implementation of a regulatory program designed to protect human health, safety or the environment and used as the basis for . . .

- any proposed or final rule . . .
- any proposed or final cleanup plan . . .
- any proposed or final permit condition . . .
- any report to Congress
- any regulatory action to place a substance on any official list of carcinogens or toxic or hazardous substances including the Integrated Risk Information System (IRIS) database
- any guidance . . .

The Senate bill addresses "all risk assessments and characterizations prepared by, or . . . adopted by any agency in connection with health, safety, and environmental risks" (25). Both provide exceptions in certain cases including emergencies, screening analyses, and some permitting actions.

The agency actions to be affected are authorized by many different federal statutes. However, there is no more specific identification of the actions to be affected, or how they would be affected in the record of hearings and committee reports for the bills (13,26). The bills would overlay a variety of new requirements on a variety of established standards, without analyzing the effects of the changes.

Risk assessment. The bills prescribe what is to be included in health risk assessments. The House bill requires that assessments include "relevant laboratory and relevant epidemiological data of sufficient quality which finds, or fails to find, a correlation between health risks and a potential toxin or activity." In cases where conflicts between data "appear to exist" or "where animal data is used as a basis to assess human health," the bill would require that the assessment "include discussion of possible reconciliation of conflicting information, and as relevant, differences in study design, comparative physiology, routes of exposure, bioavailability, pharmacokinetics, and any other relevant factor, including the sufficiency of basic data for review" (27). In cases where assumptions or models are used, the documents are to "present a representative list and explanations of plausible and alternative inferences or models; explain the basis for any choices; and [identify any policy or value judgments . . . " (28).

These provisions raise several questions, none easily answered at this point. One is whether the extensive information to be compiled will be informative for all the agency actions for which it will be required. The information required is most pertinent to assessments of single agents for carcinogenic effects. However, the actions that will be covered will include assessments of many kinds of health and environmental issues, at varying scales. Some will require consideration of multiple agents and multiple effects, which, while based in part on animal data, may not lend themselves to this type and level of analysis. In other cases, altogether different approaches may be more useful. For example, in testimony before the House of Representatives, Tara O'Toole, Assistant Secretary of the Department of Energy, described significant actions for which the required data will be of little value. One example was an assessment of health, safety, and management issues associated with spent nuclear fuels including plutonium, for which methods previously developed were more appropriate (29).

Second, the applicability of the requirements for risk assessment to noncancer health effects needs to be examined. The regulatory approach to contaminants that may pose noncancer health effects is different from that for carcinogens. For contaminants that cause noncancer health effects, animal testing is used to identify a dose for which no adverse effects are reported, called a no-observed-adverse-effect level (NOAEL). The NOAEL is adjusted for humans by use of uncertainty and safety factors, resulting in an estimate of a dose assumed to be safe, often called a reference dose. This approach is based on an assumption that there is a threshold for exposure to contaminants causing noncancer effects. While the House bill's provisions apply to all cases where animal data are used, it does not appear to have contemplated this practice.

A third issue is the effect of the legislation on use of default values or models in cases of uncertainty. The bill would appear to prohibit use of agreed-upon default values and require that issues of model selection, as well as use of other default values, be decided de novo in every action. If so, it would impose a vastly increased analytic burden and inhibit action in cases where uncertainty does not allow a definitive resolution of conflicting approaches. This appears to be contrary to a recent NAS recommendation, which endorsed use of default options as a workable approach in cases of uncertainty. The NAS recommended that (15):

EPA should continue to regard the use of default options as a reasonable way to deal with uncertainty about underlying mechanisms in selecting methods and models for use in risk assessment.

The NAS noted that the basis for each default option should be defined and criteria for adequate scientific evidence to depart from a default option should be adopted (13).

A central question is whether it makes sense to adopt into statute specific provisions for conducting risk assessments, as methods are evolving and still highly controversial. New methods for risk assessment will continue to be developed. Some questions may be resolved. For example, EPA is reportedly considering revising guidelines to provide for the consideration of mechanisms of action in risk assessment (30). Freezing the process is unlikely to be the best approach.

Characterization of risk. The legislation prescribes how risks are to be characterized after they are assessed. The House bill says that numeric risk characterizations shall provide "the best estimate or estimates for the specific populations or natural resources which are the subject of the characterization . . . and a statement of the reasonable range of scientific uncertainties" (31). The "best estimate" is defined in HR 9 as (32):

a scientifically appropriate estimate which is based, to the extent feasible, on one of the following:
- (A) Central estimates of the risk using the most plausible assumptions.
- (B) An approach which combines multiple
Economic analysis. The economic provisions of the legislation are not considered in detail here, but should be noted. Both the House and Senate bills require that alternative means of achieving an objective be considered, including market-based methods such as tradable permit systems. These alternatives are to be evaluated for their cost-effectiveness (35,36). Cost-benefit analysis is to be performed for major rules. What may be considered in a cost-benefit analysis and how nonmone- tary costs and benefits may be considered vary between the bills.

New Decision Criteria

The bills would change how agencies make decisions. The bills require use of new decision criteria for agency actions under existing statutes, such as the Clean Water Act or the Occupational Safety and Health Act. The criteria are different from those of the existing statutes. How such conflicts would be resolved is unclear. HR 9 says that its criteria "supersede the decision criteria for rulemaking otherwise applicable under the statute to which the rule is promulgated" (21). However, HR 9 also says that "... nothing in this title shall be construed to modify any statutory standard or statutory requirement designed to protect health, safety, or the environment" (37). Whether the new criteria would override or merely supplement existing statutes is a matter of significant debate (38). This is a critical, unresolved issue with the legislation.

With regard to risk assessment, the decision criteria appear to give a special status to the risk analysis and characterization required in the bill. In HR 9, before taking an action, an agency must certify that all of the required analyses have been completed, including the required comparison of costs and benefits. The analyses must be "based on objective and unbiased scientific and economic evaluations of all significant and relevant information . . . " (39). This suggests that the risk characterization required in the bill be used as the basis of the proposal for the cost-benefit analysis that must be completed and thereby serve as the basis for agency action. Because a central tendency estimate will underpredict actual risk 50% of the time, this would appear to make it difficult to use values that are protective of a population, given population variability.

For economic issues, decision criteria included in the bills generally do three things: 1) require that the most cost-effective of the alternatives analyzed be selected; 2) create a preference for "market-oriented" approaches over centralized regulations and performance standards over prescriptive standards; 3) require that the proposals pass a cost-benefit test. The House bill requires that "the incremental risk reduction or other benefits of any strategy chosen will be likely to justify, and be reasonably related to, the incremental costs" (40). The Senate bill says that a final rule may not be promulgated unless (41)

(1) the potential benefits from the rule justify the potential costs of the rule; and
(2) the rule will produce the most cost-effective result of any of the reasonable alternatives that the agency has the discretion to adopt . . .

The values and limitations of cost-benefit analysis have been discussed and debated in the policy literature (42). It is fair to say that most proponents of the method do not advocate its use as a litmus test for whether to proceed with an intervention, but rather as a technique that contributes valuable information to the decision-making processes. As economist Paul Portney testified during Senate hearings (43):

[Re]form legislation should avoid the perils of excessive quantification. It is useful—nay, essential—to make our regulators think hard and analytically about the good their programs will do and the burdens they will impose. Where these benefits and costs can reasonably be identified and expressed in dollar terms, they should be accompanied by sensitivity analysis to reflect uncertainties. But it makes no sense to me to pretend that we can, at this point in time, at least, make predictions of ecosystem damage analogous to the estimates we can make of expected reductions in cancer cases that might accompany reduced ambient concentrations of a carcinogenic air pollutant. While we should push regulators to be quantitative and precise where they can, they need also to be able to say, "This program will have other good (or bad) effects. While I cannot estimate their likelihood or magnitude at this time, they played a role in the decision I made.

The necessity of quantifying costs and benefits in comparable terms means that they must be converted to monetary values. The relative difficulty of quantifying health benefits as compared to quantifying risk reduction costs is a concern when a cost-benefit test is mandatory. Methods for quantifying the value of a human life are more controversial than methods for quantifying costs, such as compliance costs, that are inherently expressed in dollars. The quantification of noncancer chronic health effects is another important issue. As noted above, current methods for assessing non-

estimates based on different scenarios and weighs the probability of each scenario.
(C) Any other methodology designed to provide the most unbiased representation of the most plausible level of risk, given the current scientific information available to the Federal agency concerned.

The Senate language is similar (33). Other estimates may also be provided. The best estimate as defined above is emphasized. A purpose of this language appears to be to require a departure from existing practice of using default methods to estimate unit risk for carcinogens. Currently, when animal data are used, high doses given to animals must be extrapolated to a lower dose range typical of environmental exposures. A linear nonthreshold model may be used to estimate the potency of the carcinogen. The upper confidence interval is often used, for several reasons. One is that it yields a more stable estimate, less subject to perturbation from small changes in experimental results, than a maximum likelihood estimate. A second reason is that it is linear at the low-dose range (34).

The language applies to other elements of a risk assessment process and would seem to preclude use of conservative estimates at any point. This would be important because the actual risk (or parameter value) should not exceed an upper-bound estimate of risk (or a parameter) more than 5% of the time. If a central tendency estimate is used, the actual value would be expected to exceed the estimate 50% of the time. This distinction is important because, while the bill also allows reporting of upper-bound and lower-bound estimates, the "best" estimate is given a particular significance as the preferred way to characterize risk. Given inherent biological variability, as well as uncertainty, mandating this approach in all cases is troubling.

The legislation would also allow best estimates to be based on modeling of probability distributions of input parameters. Such methods could be valuable where adequate data for input parameters are available. However, they are demanding of computing resources and data and often not feasible to use.

Issues for risk assessment are complex. There is no agreed-upon definition of what a best estimate will be in every case, even if this were an appropriate approach. If the legislation requires revisiting every issue for every assessment, more resources will go into risk assessment and fewer resources will go into public health. Under such an approach, lack of data will preclude action to an even greater extent than it does now.
cancer health effects do not lead to a risk estimate but are expressed qualitatively, making it more difficult for them to be incorporated into a cost–benefit assessment. Cost–benefit analysis also fails to address distribution of either costs or benefits, an important consideration for public health. It is also interesting to note that the bill includes no provision for reporting uncertainty in estimates of costs and benefits.

**Judicial and Administrative Review**

The bills allow for judicial review and for both existing regulations and new proposals for agency action. In the House bill, all of the required analyses are available for judicial review when appealed by an affected party. Specifically, “the court shall consider the agency action unlawful if the criteria are not met” (44). The court may decide whether the standards for risk assessment, risk characterization, and cost–benefit analysis, as well as the decision criteria, have been met. This could mean that even a risk assessment or cost–benefit analysis, including aspects that necessarily require the exercise of judgment in the face of uncertainty, would be resolved by the courts. Issues that are quite appropriate for debate in a collegial setting would be subject to review and decision by the courts. The Senate bill differs from the House in that it does not allow review of analyses except as part of the record for the decisions the analyses support (45).

S 343 would establish rights for review of all existing regulations upon petition of a concerned party (46). All existing regulations would be retroactively available for appeal, based on new standards defined in the statute. The potential for paralysis of federal health and environmental agencies is considerable. Even management tools such as EPA’s Integrated Risk Information System, used to adopt toxicity values, would be subject to reevaluation.

**Priority Setting**

The bills have provisions for a larger priority–setting process, in addition to the extensive review of individual agency proposals for action. HR 9 directs the president to “identify opportunities to reflect priorities within existing Federal regulatory programs” (47). The Senate bill directs the Office of Management and Budget (OMB) and the Office of Science and Technology Policy (OSTP) to commission a study of methods for comparative risk assessment and completion of a comparative risk assessment, for all programs of the federal government. The study is to be completed within 3 years, is to be subject to peer review, and is to report results “in a manner that distinguishes between the scientific conclusions and any policy or value judgments embodied in the comparisons” (48). Moreover, individual agencies are directed to prioritize use of resources.

Methods to identify the relative significance of different environmental problems through comparative risk assessment have been developing for several years (11). Comparative risk assessment was begun as an attempt by EPA in the 1980s to make sense of multiple, conflicting priorities set through various statutes and court decisions (10). EPA produced an assessment of the relative risks posed by a list of environmental problems and noted that the results of its review differed from results obtained by polling the public for environmental protection priorities (49). EPA subsequently asked its Science Advisory Board (SAB) to comment on how comparative risk assessment should be done. The SAB produced a series of recommendations on how the process could be improved and better informed by available scientific data (50). Since then, EPA has sponsored and cooperated in comparative risk projects at the state and local level throughout the country to review the available data and identify priorities for action. Typically these projects have considered risks to health, ecological systems, and social welfare. The state and local projects have typically produced priorities and action plans based on a combination of technical inputs, including assessments of risk, and other considerations such as public comment and judgments on the part of those ultimately responsible for the projects (51).

Distinctions between scientific findings and other policy inputs have not been an important result. Based on this experience, comparative risk assessment is viewed by its sponsors and major practitioners as necessarily combining elements derived from quantitative risk assessment methods and thoughtful judgments by individuals reflecting a variety of perspectives informed by contributions of the public. This experience suggests that societal values are also important and should be considered in environmental decision-making.

The value of ranking risks is often cited, but it is important to acknowledge the differences that arise in doing this at different scales and to acknowledge the difficulty of performing credible assessments on a large scale. The debate over risk assessment has focused attention on the limits of our ability to accurately assess risk of even relatively well-described exposures to single substances. The issues associated with ranking risk at a national scale are orders of magnitude more difficult. Such exercises are far from being as well described as quantitative risk assessment and necessarily involve common-sense approaches to grouping and comparing problems.

Priority-setting is more than a technical process; it is a policy process as well, and in some sense belongs in the risk management side of the risk assessment–risk management continuum. As the Carnegie Commission on Science and Technology wrote in its recommendations (14):

> Agencies should place problems in broad risk categories and develop strategies to address risks of high priority. To do this, each regulatory agency addressing environmental and risk-related issues should develop a broad-based risk inventory. The agencies should use the inventories’ output to help develop multidimensional risk rankings. The agencies should experiment with methods to integrate societal values into relative risk analyses where statutes do not supply all the value judgments necessary to rank risks.

The limited ability of more risk assessment to resolve uncertainty is a major concern. The case of the dioxin reassessment is instructive in this regard. This topic has been covered previously in EHP (52). The health risks of dioxin have been exhaustively examined by EPA in a process costing upwards of $2 million, resulting in a document of more than 2000 pages, recently reviewed by the SAB. Despite this level of effort, the debate over level of risk has not been fully resolved. Continued analysis has the effect of postponing any action. In the meantime, dioxins, which are persistent compounds, continue to be released into the environment.

Lash identified four factors to be considered in setting priorities: risk, feasibility of an effective response, cost, and public preferences (53). This is a useful formulation. If we are to pursue reform that promotes public health and the environment, the primary goal is not to assess and characterize risks, but to reduce risks. Ultimately, efforts should focus on finding opportunities for the greatest risk reduction. This requires not only an accurate assessment of risk but also an assessment of the feasibility of risk reduction. Focusing all attention on the “worst” problems does not make sense in cases where the worst problems are intractable while others are more easily or economically resolved, perhaps to the same net benefit. This is a fundamental limitation of using risk alone as a way of identifying problems for resolution. The process should assess opportunities for effective intervention.

To develop an approach, the deficiencies of current policy should be assessed
and addressed comprehensively, not selectively. The reform debate focuses on how to change assessment as if the list of potential hazards being addressed is complete and the only problem is conservatism. Yet this is not the case. The relatively short list of known carcinogens is regulated only in some environmental media, in some programs (34). Very few of the 65,000 chemicals in EPA's inventory have been tested for cancer effects, and far fewer have been tested for other effects. Approaches are available to speed the assessment of chemicals (54). A credible reform approach needs to address these issues.

Such an approach requires a broad rather than a narrow view. Rather than overlaying new requirements for analyses over an already complex, and flawed, system, a focus on priority-setting requires a process that considers all of the potential problems and forecasts the future to the extent possible. The needs and goals of scientists and health professionals as well as the public and the regulated industries should be included in such a process. The public health community needs to face up to the importance of working with the community and incorporating public values into its priority-setting. To fail to do this will substantially limit our effectiveness. We need to free both management agencies and our thinking from narrow media- and problem-specific constraints and create incentives for pollution prevention and toxic use reduction. This will require new structure, new roles, and visionary leadership.

Conclusion
Risk assessment is a valuable but limited tool. We should not expect that increasing use of improved risk assessment methods will resolve uncertainties and preclude the need for the exercise of judgment. A solution to this dilemma will require a different approach.

We need to recognize what science and risk assessment can contribute to regulatory policy. We must also recognize what they cannot contribute. We need to use credible scientific data and conclusions, but we also need to recognize that uncertainty will persist. Epidemiological studies, properly recognized in the legislative proposals as providing the best basis for risk characterization, have limits, especially in cases of low-level environmental exposures (55). Both scientific judgment and policy judgment are needed to address the important issues of the day. In science, judgment is needed to weigh evidence and achieve an understanding of what can be gleaned from often incomplete, contradictory, and conflicting data.

In scientific work, our highest goal is to reach valid conclusions about the truth. We want to avoid reaching incorrect conclusions, and we employ our scientific methods accordingly. But there is a tension between avoiding incorrect conclusions about the presence of an effect and the absence of an effect. From an environmental and public health perspective, the failure to identify a significant health risk is of considerable importance. Both overprotection and underprotection have consequences, though the consequences differ for different groups. When we take too strong an action (false positives), parties incur inappropriate and excessive costs with no real benefit. When we take a weak action or no action (false negatives) the public pays the costs of increased health risks (56). Both are to be avoided. Absence of evidence is neither evidence of the lack of an effect nor grounds for presuming that a hazard exists.

In public policy, and especially public health, our highest goal is to make reasonable decisions to protect the health of the public from unacceptable risks. We must also recognize the limits of science and the differences between sound science and sound policy. This process will be greatly enhanced by comparative risk methods that integrate societal values into relative risk estimates. Unfortunately, while intended to address overreaction to environmental threats, this legislation does little to advance the public interest but could, in fact, tip the scales away from the public health.

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