The Use of Technical Information in Environmental, Health, and Safety Regulation: A Brief Guide to the Issues

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Controversies over the development, legality, or implementation of environmental, health, and safety regulation often focus on the nature and quality of the relevant technical information, as well as on access to that information, and on how it is used. One of the more serious questions that regulators face is uncertainty in both the available data and methods for analyzing the data. A review of how and where such information comes into play can provide guidance to understanding the essentials of the regulatory process itself. The following discussion is presented as a quick primer for those who may be less familiar with this area of public policy analysis.

Information Uses

Research That Precedes or Justifies Regulatory Decisions

Virtually all substantive regulatory decisions concerning health, safety, and the environment require the input of data and the application of analytic methods for their interpretation. Such data may include toxicological or epidemiological information about the effects of a chemical present in food or the environment, physiological information about the consequences of a certain kind of injury, technological information about the effectiveness of a pollution control device, or any of a wide array of data on specific scientific or technical topics.

Sometimes the information needed pertains only to a narrow question or dispute, such as the effects of human exposure to one specific chemical. However, although the regulatory agencies do conduct some research, it is generally beyond their resources to develop all their own information, and so they must rely on outside sources, usually academic or private research organizations or the nonregulatory, science-based federal agencies. Additional data may be drawn from studies sponsored or conducted by private industry.

Some information cannot be generated in advance of the instigation of a regulatory action because the data are privately held, cannot be located, or do not exist. The agencies therefore may need to support or encourage innovative research that justifies an immediate regulatory response, even if data are incomplete. For example, current attention to the risk of carcinogenic effects of exposure to formaldehyde resulted from a Chemical Industry Institute of Toxicology study of cancer in animals. In this case, regulatory action has been delayed because of disagreement on how (or whether) to extrapolate the animal data to humans, and because human data are not available at present. Long-term innovative research will help in constructing and validating models that address the general problem of interspecies comparisons. Meanwhile, the regulatory decisions about formaldehyde must be made.

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Science, Technology, & Human Values, Volume 9, Issue 1, pp. 130–133 (Winter 1984) CCC 0162-2439/84/010130-04$04.00

Dispute Resolution

Regulatory decisions often require the resolution of scientific or technical questions. For example, it may be necessary to determine which of several studies should be given the most credence or whether an investigator's methodology was sound. Before an agency can begin to examine regulatory policy toward a specific hazard, it must evaluate the information that exists, determine what information is lacking, and, as necessary, seek additional scientific or technical input.

Argument and persuasion on technical grounds can, of course, resolve some disputes. There may be a strong consensus of scientific opinion which, while not verifiable beyond all doubt, is nevertheless considered scientifically or technically reliable. General acceptance of the proposition that vinyl chloride causes human cancer provides a good example of such consensus. Some technical disputes *are* resolvable; here, agreement may be reached without resort to policy considerations. The issues to be resolved in such a technical dispute resolution are usually both specific determinations of scientific or technological import, and, in certain cases, priority-setting for agency action in risk assessment and hazard control. A number of vehicles—including advisory committees, blue-ribbon panels, improved agency coordination, and adversarial hearings—assist the regulatory agencies in dispute resolution. But parties (including the government) that control a disproportionate share of scientific, legal, and other resources may also have an undue influence on the outcome of regulatory disputes. Even when purely factual matters are at issue, resolution can depend on the availability of information and the ability to present it effectively: Some parties can simply produce and disseminate data and arguments better than others. Mechanisms to ensure effective public participation in the decisionmaking process are therefore essential.

Uncertainty

Regulatory agencies also constantly face situations in which good technical information fails to resolve fully or satisfactorily the fundamental policy questions. Even when the health or safety payoffs of a number of strategies are known, the policy decision of how much protection to require and at what cost will remain a problem—but not a scientific/technical problem. With uncertain or equivocal information, how far to go becomes a policy decision that must account for uncertainty in the data. And so the management of uncertain risk has and continues to be a major problem. Using existing data, agencies must make judgments that involve legal, political, and value-laden considerations. This situation, in turn, gives rise to many questions about how the science is factored into such judgments.

The Role of the Courts

The judicial system is an important actor in the regulatory process. The courts, particularly at the appellate level, play a crucial role in the outcome of regulatory activities. In the United States, for example, regulations and standards are subject to judicial review, and can be overturned, modified, or remanded. Many agency decisions that are preliminary to the issuance of a final agency action are taken with a view to their possible effect on subsequent litigation.

In overseeing agency rulemaking activities, courts have differed widely in their approaches. Some give the government great discretion and decline to meddle in technical and value judgments, confining their scrutiny to procedural matters; others have evaluated more actively all aspects of regulatory outcomes, acting almost as partners in the process. The wide range of action (and opinion of that action) perhaps understandably provokes inquiries about the courts' competence to decide different types of issues and about the appropriate level of their involvement in the decisionmaking process as a whole.

Current Values Issues in Regulatory Policymaking

Analyses of government environmental, health, or safety regulatory policy exhibit a number of common themes, many of which are addressed in the essays published in this special issue of *Science, Technology, & Human Values.* For example:

- the value-laden nature of the stages and processes involved in regulatory decisionmaking,

including the funding of research, the use of scientific data, decisionmaking under unresolvable uncertainty, and the monitoring of programs;
- the role of political and economic power and influence in determining the outcome of scientific as well as value disputes;
- the importance of determining priorities in research and policymaking, and the need to target resources;
- the interrelation among all aspects of the regulatory process, the difficulty of separating scientific and policy judgments, and the need to coordinate the different aspects; and
- the importance of ensuring broad public representation and participation at all stages of regulatory decisionmaking.

Sources of Funding

When a concerned participant in the regulatory process—such as a regulatory agency, industry, or public-interest organization—funds the research, the results may be biased or unreliable. Moreover, the recent debates over industry funding of university-based research call into question the independence of even the traditionally neutral academic researcher. The agencies themselves are also sometimes accused of ignoring negative findings. One crucial issue is thus the need for the institution or reform of appropriate mechanisms to promote objective review of research. If government support of research by interested or nonneutral participants is questionable, how can reliable data be produced?

Choice of Projects

A related concern is the choice of subjects and methods and the setting of priorities. What will be studied? How, and at what rate, will it be investigated? Is research being diverted into areas in which significant hazards are unlikely to be found, thereby leaving more serious questions unexamined? Or are resources concentrated on readily apparent problems to the exclusion of more subtle ones? Many observers believe that, for example, the problems of reproductive hazards are addressed inadequately in current research programs. How should regulatory priorities research be determined? And by whom?

Choice of Researchers

The individual investigator can have a major impact on a research study; personal values and ideologies influence the choice of problem, the ways they are examined, and how the results are reported. If certain types of researchers are systematically included in or excluded from participating in research related to regulatory policy, for example, how will that affect the kinds of results produced?

Reporting of Results

The way in which research results are reported can also affect how they are perceived. Should agencies be required, for example, to report their findings in such a way that the general public can understand their significance to the agency's decision? Many commentators have argued the need for a comprehensive legal reporting requirement pertaining to research or data relevant to public welfare, such as now required for health and safety data in Section 8(e) of the Toxic Substances Control Act. Should results always be presented in a form that maximizes public understanding and acceptability, or in a form convenient and useful to the decisionmakers?

Access to Results and Confidentiality

Agency access to information does not insure access by the affected public. When reporting requirements are absent, the public's access to data may be hampered further by, for example, exemptions from disclosure under the Freedom of Information Act. What if an agency's collection, reporting, or use of scientific data impinges on trade secrets? Information sought for regulation may also go far beyond "neutral" scientific or technical data. Economic data and use profiles, for example, raise questions of proprietary information. When should proprietary interest override societal need for information?

Separating Technical and Regulatory Decisions

Should decisions on scientific issues be separated from regulatory policy determinations? This goal was one rationale for the creation of science courts.

Such separation is not possible, of course, where the technical data are uncertain. The calculation of causal inferences from inconclusive studies or the prediction of technological response to regulation, for example, are themselves value-laden and, hence, policy-relevant determinations. Similarly, decisions regarding research priorities cannot be divorced from policy.

How much discretion should be permitted an agency? To the extent permitted by law, an agency must exercise discretion in setting priorities where uncertainty of the payoffs exists. Policies made under these conditions will necessarily reflect general attitudes toward risks and risk postures in light of incomplete data. Some attention to improving decisionmaking under uncertainty by devising new analytic approaches has already been suggested, but wherever an agency has broad discretion for making decisions based on uncertain data, someone will always be critical of the policy adopted and many will disguise this criticism as displeasure with the resolution of the factual issues.

Reform Initiatives

A number of specific proposals have been made for changing the regulatory process. In addition to considerations of efficiency and procedure, such proposals reflect various political and ideological perspectives on the role of government regulation. Common types of reform proposals include:

- improvements in scientific and technical information for agencies, Congress, the courts, and the private sector;
- using science courts to resolve technical disputes;
- requiring the use of formal or quantitative risk assessment for regulatory action;
- requiring the use of cost–benefit analysis as a predicate to regulatory action;
- a regulatory "budget" that limits the extent to which an agency may impose an economic burden through regulation;
- using the legislative veto as a check on agency regulatory decisions;
- shifting responsibility for hazard control to the states or the private sector;
- imposing financial liability on the government when government regulations fail;
- enacting job and technology redesign as a national policy;
- developing economic incentives to supplement or substitute for government regulation;
- encouraging collective bargaining between labor and management as a supplement or substitute for occupational health and safety regulation;
- increasing citizen involvement in the regulatory process; and
- encouraging private lawsuits for regulatory law enforcement and for injunctive relief/damages.

Each of these mechanisms has the potential to provide advantages for different participants in the regulatory process. Each engenders substantive, occasionally even harsh criticism. And, as this quick review of the processes and key issues has shown, each proposal also carries along its own value considerations, a dimension that must not be lost in the technical debates over procedures or politics.

Conclusion

The functioning of a regulatory process that relies on scientific and technical information requires considerable attention to (1) minimizing uncertainty in scientific/technical information and analytic methods, (2) providing democratic and competent mechanisms for scientific/trans-scientific dispute resolution, and (3) enforcement and monitoring (evaluating) the performance of agency programs in order to provide feedback and opportunities for redirection. The success of the regulatory system thus depends on both the nature and quality of the utilized technical information and on effective and democratic decisionmaking processes.