Advancing Environmental Protection Through Risk Assessment

Christopher J. Daggett
Robert E. Hazen
Judith Auer Shaw*

INTRODUCTION

In early 1988, EPA Deputy Administrator Jim Barnes appointed Region II as the lead region for risk assessment for EPA. As such, Region II was asked to help shape the agency's continuing efforts to improve knowledge of the risk assessment process and develop the training and communication strategies needed to integrate risk assessment into the overall management of the Agency. This was an opportunity to examine both the utility of risk assessment and the problems posed in its increasingly dominant role in environmental policymaking.

The Spanish philosopher George Santayana once wrote, "Science is nothing but developed perception, interpreted intent, and common sense, rounded out and minutely articulated."[1] Since 1970, the year of the first Earth Day and the creation of EPA, EPA has tried to articulate common sense in the protection of the environment. At the same time, evolutionary changes were taking place in environmentalism, both in this country and in much of the industrialized world.

The obvious need to remedy the neglect of the past resulted in the passage of environmental laws that still form the base of EPA protection programs: the Clean Air Act, the Toxic Substance

* Christopher Daggett, Ed.D., Univ. of Massachusetts, is Commissioner of New Jersey Department of Environmental Protection. At the time of this presentation, Daggett was the Regional Administrator of Region II of the U.S. E.P.A. Robert Hazen, Ph.D. in Biology and Environmental Sciences, N.Y.U., manages the Risk Assessment Unit in the Division of Science and Research in the New Jersey Department of Environmental Protection. Judith Auer Shaw, M.S., Community Development, Univ. of Michigan, manages the Risk Communication Research Unit in the DSR of DEP. An earlier version of this article was presented by Commissioner Daggett at a symposium on risk assessment presented by the Environmental Law Committee of the Association of the Bar of the City of New York on February 4, 1988.

1. G. Santayana, *The Life of Reason: Reason in Science*, in EVANS, DICTIONARY OF QUOTATIONS 609 (1968).

Control Act, the Safe Drinking Water Act, and the Federal Insecticide, Fungicide and Rodenticide Act.[2] In each of these laws, Congress specified actions that would control and reduce environmental contamination.

A number of indices show that a reduction in ambient pollutant levels has indeed occurred. From 1975 to 1982, the air pollutants sulfur dioxide, carbon monoxide and lead have decreased by thirty-three, thirty-one and sixty-four percent, respectively. Toxic residues of DDT have decreased from 1970 to 1979: in fish by sixty-three percent, in humans by sixty-one percent and in starlings by fifty-two percent. Residues of PCBs show similar declines in fish and birds between the years 1972 and 1979. However, over this same period, PCB residues in humans increased by about ten percent.[3]

Tackling those historic problems was imposing, but the task was a great deal simpler than it is today. In the 1970's the steps necessary to begin the environmental cleanup were clear. Funding questions were readily resolved. There was a spirit of consensus and purpose, and much progress was made.

Once the most visible abuses were addressed, the true scientific, social and economic complexity of the problems became apparent. Concern about the environment itself was refocused on the effect of pollution on human health. Legislation in the late 1970's, such as Superfund,[4] dealt with hazardous waste issues. Past disposal practices had left thousands of sites where pollutants were leaking into the groundwater and many of these pollutants were known carcinogens. In some cases, the presence of these chemicals could not be detected without sophisticated equipment. Investigative activity shifted from visible environmental degradation to the invisible threat of toxic chemicals.

This focus called for a new way to apply science to practical questions of public health protection and environmental regulation. It also raised the issue of government's role in the management of chronic health risks potentially associated with

2. Clean Air Act, 42 U.S.C. § 7401 (1982); Toxic Substances Control Act, 15 U.S.C. § 2601 (1982); Safe Drinking Water Act, 42 U.S.C. § 300f (1982); Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 (1982).

3. COUNCIL ON ENVIRONMENTAL QUALITY, Environmental Quality 1983: 14th Annual Report of the Council on Environmental Quality (1984).

4. Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. § 9601 (1982).

environmental contamination. In response to these concerns, quantitative risk assessment and risk management have proved to be the most effective means available to address the complex policy dilemmas created by the wide range of pollutants, and the uncertainty of their effects.

I. The Role of Risk Assessment

Broadly defined, risk assessment is a scientific enterprise in which facts and assumptions are used to estimate the potential for adverse effects on human health or the environment resulting from exposures to specific pollutants.[5] Within EPA, risk assessments are factored into economic decisionmaking as well, but its primary function lies in the determination of health effects.

EPA uses risk assessments in two complementary branches of the Agency. The Risk Assessment Council, based at EPA headquarters, focuses on science policy issues that require coordination across EPA programs and may involve other regulatory agencies as well. The Risk Assessment Forum, which reviews specific scientific and technical issues, works closely with the Council and refers broad science policy questions for the Council's consideration.

EPA adopted the National Academy of Sciences' definition of Risk Assessment as including the following four steps:

- Hazard Assessment, a qualitative judgment about the toxicity of a substance based on the existing evidence;
- Dose-Response Assessment, evaluation of animal experiments and human epidemiological studies to infer a quantitative relationship between the dose level of a toxicant and the likely human response;
- Exposure Assessment, an estimate of the likely degree of human exposure to a specific chemical; and,
- Risk Characterization, a description of the nature and often the magnitude of human risk, including the assumptions and uncertainties that were part of the process.[6]

Basing environmental health decisions on risk assessment has raised considerable discussion about its utility. One common complaint is that EPA overestimates risk and creates unnecessary public concern. To these critics, the science policy judgments

5. Committee on the Institutional Means for Assessment of Risks to Public Health, Risk Assessment in the Federal Government Managing the Process 18-20 (1983).

6. *Id.* at 3.

built into the assessment procedures are too conservative; that is, they have an excessive bias towards health protection, assume worst case scenarios and thereby lead to overly stringent controls. Those who question the use of risk assessment altogether often argue for the continued use of pure technology-based standards or for strict zero pollutant discharges.

The opposite criticism is also common: that EPA risk-based decisions are called insufficiently protective. The argument here is that risk assessment tools are too uncertain to account for all the potential health effects of pollutants or to measure the synergistic and antagonistic effects of combined pollutants.

II. RISK ASSESSMENT WITHIN THE EPA RISK MANAGEMENT FRAMEWORK

Risk management integrates the data and conclusions from assessment into an overall process that also considers public concerns, economic costs and benefits, statutory requirements, technological feasibility and long term reduction potential.

The individual statutes that require EPA to protect public health are often guided by factors other than risk assessment. In such cases, risk assessment can be used to ensure compatibility of standards across environmental media and to set priorities for EPA's focus within each environmental medium. Risk assessment also helps determine if each increment of a control program is cost-effective, given the resources available, or whether those same resources would be better spent on more pressing environmental issues.

In the early days of environmental regulation, priorities and standards were set by each individual program focusing on a particular environmental problem; priorities in the air or water pollution program would be aimed at attacking major industrial discharges. The Resource Conservation and Recovery Act (RCRA) standards for these sources, for example, were based first upon control technologies and then upon more stringent ambient standards.[7] The ambient standards were based more upon the ability of a medium to absorb and dilute the emission than upon the effects of the residual contaminants.

This method for setting priorities may work when small numbers of pollutants, restricted to one medium, are involved. A

7. Resource Conservation and Recovery Act, 42 U.S.C. § 6901 (1982).

problem occurs when the pollutants are transferred from one medium to another; for example, the pollutants removed from waste water produce sludge. Whether that sludge is disposed of on land, incinerated, or dumped in the ocean, some measure of those pollutants are transferred to another medium. With limited exceptions, the relative risks were not being considered.

III. Public Perception, Risk Assessment and Democracy: The Effective Use of Risk Information

The concern over the proper role of risk assessment in risk management is not merely the use of risk assessment, but rather the difficulties inherent in the use of risk information generally. The effective use of risk information in risk management needs to address three issues: the public's perception of risk, the uncertainty and developing nature of risk assessment and the difficulty of making tough policy choices in open, democratic societies.

The public's perception of risk is seldom derived from a scientific perspective. The role of the media, the effect of catastrophic events, and a general sense of lack of control all affect how the public perceives risk.[8] EPA's own regulatory priorities reflect this same tendency to draw conclusions from seemingly unrelated events.

In 1986, EPA undertook an internal review of current priorities to compare the risks posed by thirty-one major environmental problems and rank them according to the risk they presented. This assessment was not a scientific study, but rather the best professional judgment of environmental protection experts. These experts composed a task force that surveyed EPA staff about these problems and ranked them each in four separate areas: cancer risk, non-cancer health risks, ecological effects and welfare effects. Within EPA, the problem areas were ranked by risk, then ranked according to the current program priorities of the agency. In a third analysis, these collective rankings were compared with available public polling data. The findings indicated that the public's perception had a higher correlation with the actual EPA priorities than with the findings of the task force. For example, the task force found that hazardous waste posed a low-to-medium risk.

8. N. Weinstein, Public Perceptions of Environmental Hazards: Study 1 Final Report (1986) (Research Contract C29510, Office of Science and Research, NJ Department of Environmental Protection).

However, according to EPA program priorities, and the public studies cited, hazardous waste was a high priority. Issues such as radon or pesticides, which ranked high for the EPA task force, were given a low risk value by the public, and correspondingly lower priority by EPA's own regulatory programs.[9]

Risk alone does not drive public perception of hazards. The public's perception of risk includes an array of considerations: does the information come from a trustworthy source, are the risks naturally occurring, are the risks familiar and how much control do individuals have over the risk.[10] If risk assessment is to be integrated into the process of prioritizing risk, public education and efforts to build consensus will be necessary. Agency policymakers need to know where gaps exist between agency priorities and public perceptions. Frequent surveys can provide a base of information on public perception that can be integrated into the decisionmaking process as well.[11]

The second issue to address in effective use of risk assessment is the inherent uncertainty and constant evolution of the body of scientific information. New toxicological studies that characterize the health risk of specific chemicals may require a reevaluation of the regulatory status of the chemical. The basis for the judgment that a chemical does or does not cause harm, however, may rest on endpoints that are hard to observe and are scientifically debatable.

Unfortunately, regulatory decisions must be made regardless of gaps or uncertainty in the scientific data. In order to be protective of public health, the risk models used and the science policy judgments made allow for a margin of scientific error and are therefore possibly more stringent than they would need to be if additional scientific information were available. For example, when a particular chemical or the potential health threat from a Superfund site is evaluated, a cancer rate of one excess cancer death per million people is the criterion for agency action. This compares with a background incidence of cancer of approximately one in four. The low threshold for action is due to the fact

9. U.S. Environmental Protection Agency, Unfinished Business: A Comparative Assessment of Environmental Problems (1988) (Overview Report).

10. B. Hance, C. Chess & P. Sandman, Improving Dialogue with Communities : A Risk Communication Manual for Government (New Jersey Department of Environmental Protection, January 1988).

11. N. WEINSTEIN, *supra* note 8.

that there is very little information about the true effects of low doses of carcinogens.

Risk assessment as applied to chemical contaminants at Superfund sites often involves the determination of a theoretical increase in cancer which might result if people were exposed, through a variety of physical pathways, to site contaminants. These pathways might include the ingestion of contaminated drinking water or the inhalation of contaminated air. The techniques for specifying a numerical increase in risk over background, such as one in a million, rest on the fundamental principal of toxicology that a positive relationship exists between the amount of the dose and the degree of harm or response.[12]

In the case of cancer risk assessment, epidemiologic studies and animal studies define the dose-response relationship for a given chemical. The dose for carcinogens is defined in terms of the amount of chemical received every day for a lifetime per kilogram body weight.[13] Of course, there can be no contamination related cancer risk without exposure, and often the most uncertain part of a Superfund risk assessment is not whether or not a chemical is a carcinogen or how carcinogenic it is, but rather how much of the chemical an individual might be exposed to.

Exposure determinations involve either chemical measurements of actual contaminants or the use of environmental fate modeling equations to estimate movement of contaminants into areas where people might be exposed to them. Exposure estimates determine dose estimates which determine risk. For example, if drinking water is contaminated with benzene to a concentration of ten parts per billion (ppb), and the average person drinks two liters per day, the upper bound excess lifetime cancer risk would be fourteen in a million. At low doses such as this, the dose-response curve is assumed to be linear. Therefore, at twice the dose, 20 ppb, the risk is also doubled to twenty-eight excess cancers per million people.

Research is being conducted to improve risk assessment in the areas of exposure assessment and internal dose estimation. Measurements of chemical concentrations in the environment are often used to infer likely doses to exposed persons. Using these

12. Doull & Bruce, *Origin and Scope of Toxicology*, in CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 3 (1986).

13. Anderson & The Carcinogen Assessment Group, *Quantitative Approaches in Use to Assess Cancer Risk*, 3 RISK ANALYSIS 277 (1983).

environmental data, the fraction of time the population may be in contact with the contaminated area must be estimated in order to determine human exposure. The process is prone to error. Time estimations may be too high or low or, the frequency of environmental measurements may not accurately reflect the true average concentrations. Studies of total human exposure to environmental pollutants are gradually reducing uncertainties in exposure assessment assumptions concerning human activity patterns.[14] In addition, these measures only estimate what an individual is exposed to and not how much of the chemical is actually absorbed. One method to improve the accuracy of the human exposure evaluation is to use biological monitoring techniques which can directly quantify the internal dose of the chemical or its metabolite in the person's body fluids (e.g. blood, urine or saliva) or in exhaled breath. For example, as part of the risk assessment process under the Federal Insecticide Fungicide and Rodenticide Act, EPA now recommends that pesticide registrants use biological monitoring in their exposure assessment studies.[15]

Because risk assessments often involve the use of animal studies, it is important to know if a chemical behaves the same way in animals and people. It is possible, for example, that due to differences in chemical metabolism, animals will have a greater or lesser percentage of a toxic metabolite reach a target site in the body. Understanding this difference would enable more accurate dose-response comparisons to be made between species.

Presently, biomonitoring research is also being used to provide a more rational basis for risk extrapolation between laboratory animals and humans. Regulators today often face the predicament of having only carcinogenicity data from animal experimentation available. Using biological dosimetry information such as studies which measure markers of biologically effective doses of carcinogens in an exposed population (i.e. DNA adducts chromosomal aberrations or other measurements of genotoxic damage), human populations can be compared to animal systems in order to determine risk.[16]

14. Ott, *Total Human Exposure*, 19 ENVTL. SCI. & TECH. 880 (1985).

15. Reinert, *The United States Environmental Protection Agency's Guidelines for Applicator Exposure Monitoring*, 33 TOXICOL. LETTERS 183 (1986).

16. Perera, *Identification and Regulation of Occupational Carcinogens: The Role of Biological Monitoring*, 2 SEM. IN OCCUPATIONAL MED. 325 (1987).

Research is therefore likely to change regulatory thresholds for action for both carcinogens and non-carcinogens. Current regulations are beginning to reflect scientific reassessment of health risk. For example, an evaluation of the toxic effect of lead revealed that it posed a greater risk of nerve and kidney disorders than had been previously thought. As a result, EPA called for stricter limits on the amount of lead in the environment. When the data on dioxin was reassessed, however, less stringent limits were proposed.[17]

New scientific information can also reinforce existing policy, as with the case of the recent National Academy of Sciences' report on radon. For over two years, EPA has maintained that radon is responsible for close to ten percent of the total lung cancer deaths reported in the United States each year. The results of the NAS report confirm those statistics. Although critics claimed that the EPA stand on radon was overstating the risk and unduly alarming the public, the NAS report confirms EPA policy. The Academy's report notes that cancer risk increases with the amount of radon present, the length of exposure and the age of those breathing it. The report further states that radon was found to be a particular risk for cigarette smokers, whose risk of lung cancer in the presence of radon and cigarette smoke is greater than the sum of the individual risks.[18]

In this case, despite the knowledge of the dangers of radon, public response to the threat has been minimal. Agency efforts to alert people to the potential danger have been extensive, yet only a few of the millions of homeowners living in high-risk areas have tested their homes for radon. It is an invisible danger: tasteless, odorless, colorless and easy to ignore.

The lack of public response to scientifically substantiated risk underscores the third concern regarding the effective use of risk information: that of resolving environmental and health risk management issues in the context of an open, democratic process. Debate is a primary characteristic of policy formation in a democratic society. The use of quantitative risk assessment is an attempt to initially contain that debate within a scientific framework. The difficulty is that scientific, social and economic issues are not dis-

17. Draft Updated Assessments for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (2,3,7,8-TCDD), 53 Fed. Reg. 24,141 (1988).

18. BEIR IV, HEALTH RISKS OF RADON AND OTHER INTERNALLY DEPOSITED ALPHA-EMITTERS (1988).

crete spheres; value judgments can intrude on scientific investigations simply by the decision of whether or not a problem is to be investigated at all. Compounding this dilemma is the fact that, given the inherent uncertainties of risk assessment science, the same data can be rationally interpreted in different ways,[19] and can lead to the adoption of one of several different policies. This fuels debate and can be used to justify various and conflicting notions of the appropriate balance between environmental protection and economic costs.

When the democratic process is used for decisionmaking on public health issues, many complicating social factors come into play. A risk-based approach to environmental policymaking requires striking a delicate balance between competing objectives. The importance of social networks, economic costs and benefits, degree of local control and the history of the agency within a community, need to be recognized and integrated into risk-based decisionmaking.[20] Without that balance, policy decisions cannot easily be implemented, and a state of environmental gridlock exists.

The quandary is evident in Superfund cleanup standards, drinking water quality standards and how to best balance environmental protection and economic growth in our valuable wetlands across the country. Arguments over solutions often land in court, and decisions are made on legal grounds, not on scientific bases. Given the technical and social complexities of these issues, this is not the best way to make these decisions.

IV. LOOSENING THE GRIDLOCK

Environmental gridlock is not an inevitable phenomenon, and can be dissolved by addressing the very issues that drive effective use of risk assessment and risk information generally. Understanding how the public sees risk is a critical first step. Public perceptions of risk affect the viability of scientific data and will determine whether the public supports or resists a recommended direction for management.[21] Loosening the gridlock also means

19. Ruckelshaus, *Risk in a Free Society*, 3 RISK ANALYSIS 157 (1984); Ashford & Gregory, *Ethical Problems in Using Science in the Regulatory Process*, 2 NAT. RESOURCES & ENV'T. 13, 55 (1986).

20. Johnson, *Accounting for the Social Context of Risk Communication*, 5 SCI. TECH. STUD. 103-11 (1987).

21. N. Weinstein, *supra* note 8.

broadening the scope of the science that stands behind our risk assessments. Certainty may not be possible, but information on what we *do* know and *do not* know must be collected and given to the public. Scientists must focus on providing the information necessary to restore public confidence in technology. Government agencies must demonstrate their ability to identify, prevent, and correct environmental and human health problems. Evaluation of the efforts in both science and government to address these gaps in knowledge and confidence must be conducted through issue-specific assessments of public perception.

EPA's Risk Assessment Forum is working to strengthen the consistency and technical quality of agency risk assessment guidelines. Five guidelines were published in 1986 on mutagenicity, carcinogenicity, suspect development toxicants, chemical mixtures and estimating exposures. A sixth guideline, systemic toxicants, is in development.[22]

Mutagenicity, carcinogenicity, developmental toxicology and systematic toxicology are all potential adverse outcomes of exposure to toxic chemicals. A single chemical can have effects which fall into multiple categories. Carcinogen risk assessments receive a great deal of attention because they often result in the lowest dose serving as a threshold for regulatory action.

The Guideline for Chemical Mixtures provides an overall framework for considering the combined toxic effect of multiple chemicals. The Exposure Assessment Guideline provides decision trees and checklists for determining which environmental pathways are significant routes of exposure, and how large a population is potentially impacted. The EPA Risk Assessment Council is also taking action to develop research that will reduce uncertainties in risk assessment. Ten million dollars has been earmarked by Congress for this research to improve risk assessments involving biotechnology, and to examine the ecological, neurological and other non-cancer health effects of substances.

Finally, a democratic form of decisionmaking must be adopted to bring the public into the policymaking process itself. All of the available risk data must be shared with the communities from the beginning of the process, with time and resources allocated to dealing with their concerns. Agency apprehensions that opening

22. U.S. ENVIRONMENTAL PROTECTION AGENCY, THE RISK ASSESSMENT GUIDELINES OF 1986 1-1 (August 1988).

up the management process to the public will render the agency incapable of making any decisions must be acknowledged. Bringing the public into the decisionmaking process may slow the process down, but the decisions that emerge from an integrated process will be ones that both the public and agency can accept. Internal communication of successful experiences, with public participation and meaningful dialogues with affected communities, can build support and foster agency perceptions of the value of the process. Reaching consensus on a process for environmental management will free both agency staff and the public to address the issues.[23] Once the issue of process is resolved, the focus can then shift to the scientific information, and mutually acceptable solutions become possible. Discussions with the public can identify concerns and how the public wants to be involved in overall risk management. Public participation can help both science and government agencies to become accountable. To break the gridlock and move ahead, we must operate in a fishbowl.

V. CONCLUSION

The future will be dominated by technologies we can barely imagine now. Each of these will bring new and unfamiliar risks. The risk assessment process, in addition to being a vital tool to sort these risks out, will also be used to focus on ecological risks, and will enable us to make policy choices accordingly.

EPA is moving to institutionalize the use of risk assessment. Through the Risk Management and Risk Assessment Councils and the Risk Assessment Forum, regional offices are providing training for all the staff in building communications with the public. Attention now needs to be focused on regaining public confidence. This focus must encompass both the social and scientific contexts of risk; it is necessary to address public concerns about process before the public will be open to educational outreach efforts. Once assured of government's willingness to open up the process to public scrutiny, agencies will have the opportunity to demonstrate their ability to establish, maintain and explain the environmental standards and criteria that will be protective of human health and the environment. Industry, too, must open up to the same scrutiny in order to regain public confidence in its

23. Shaw & Herb, *Risk Communication: An Avenue for Public Involvement*, 80 AM. WATER WORKS A. J. 42 (1988).

ability to meet environmental protection standards and to initiate open assessments of the potential effects of new products and potential pollutants. Finally, the legal system must effect changes that demonstrate an ability to resolve issues and minimize delays in the system. The key to effective risk management lies in a cooperative effort, arrived at through consensus between all parties; for only with solid public support can solutions to environmental risks be realized.