RISK: Health, Safety & Environment (1990-2002)

Volume 1
Number 4 *RISK: Issues in Health & Safety*

Article 4

September 1990

The Role of Scientists in Risk Assessment

Halina Szejwald Brown

Robert L. Goble

The Role of Scientists in Risk Assessment*

Halina Szejnwald Brown and Robert L. Goble**

Introduction

An increasing number of scientists who would have once introduced themselves as biologists, chemists, physicists, or toxicologists now call themselves risk assessors. The term describes a professional activity, a job or a social function. It also represents an ideology; a belief that a society should make use of objective scientific analysis in setting its agenda and in managing its hazards. What is it that risk assessors actually do?

To answer this question, it might be helpful to define risk assessment. Volumes have been written during the last decade, most of them emphasizing one of the two "main lines" of risk assessment: risks of chemicals or risks of large engineered systems, especially nuclear power plants. We have been associated with an approach which embeds the term in a more general frame of hazard analysis and hazard management.[1] Perhaps the best known effort to define risk

* We are grateful to our colleagues at CENTED, especially to C. Hohenemser, J. Kasperson, R. Kasperson, I. Palmlund, and O. Renn, and to several anonymous reviewers for their very helpful criticisms of earlier versions of this paper.

** Dr. Brown has a B.A. from Washington University and a Ph. D. in chemistry from N.Y.U. She is Associate Professor of Environment, Technology and Society and a member of the Center for Technology, Environment and Development at Clark University. Dr. Goble has a B.A. from Swarthmore and a Ph.D. in physics from the University of Wisconsin. He is a Research Associate Professor of ETS and also a member of CENTED.

1 Hohenemser, Kasperson & Kates, *Causal Structure*; Kasperson, Kates & Hohenemser, *Hazard Management*; and Hohenemser, Kates & Slovic, *A Causal*

assessment has been made by the National Research Council (NRC) Committee on the Institutional Means for Assessment of Risks to Public Health.[2] The conceptual model of risk assessment and risk management proposed by the committee, while emphasizing the scientific uncertainty in risk assessment and the role of science policy in addressing that uncertainty explicitly, presents risk assessment as an objective scientific activity, distinct from risk management in its exclusion of social, political and institutional values. The NRC model, though posed only for risks from chemicals, is widely accepted in both the public and private sector in the U.S. and it is the basis for structuring much of the regulatory activity at the Environmental Protection Agency (EPA).[3]

The 1983 report had several impacts:[4] (1) It helped address industry concerns that more coherence and consistency were needed in regulatory programs. (2) It helped restore public confidence in, and bolster the internal morale of the EPA, which was deeply shaken by the initial years of the Reagan administration. (3) It defined the tasks involved in performing risk assessment, thus shaping its overall identity. (4) It stressed the overt separation of scientific assessment from the formulation of public policy, thus reinforcing the image of risk

---

Taxonomy, all in PERILOUS PROGRESS: MANAGING THE HAZARDS OF TECHNOLOGY 25–90 (R. W. Kates, C. Hohenemser & J. X. Kasperson eds. 1985) [hereinafter PERILOUS PROGRESS].

2 NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983). Ruckelshaus, *Risk, Science and Democracy*, 1 ISSUES IN SCI. AND TECH. 19 (1985).

3 Russell & Gruber, *Risk Assessment in Environmental Policy-Making*, 236 SCIENCE 286 (1987).Yosie, *EPA's Risk Assessment Culture*, 21 ENVTL. SCI. AND TECH. 526 (1987).

4 P. F. Deisler, Jr., *Interface of Risk Assessment and Risk Management*, in RISK ANALYSIS IN THE CHEMICAL INDUSTRY, CHEMICAL MANUFACTURERS ASSOCIATION SYMPOSIUM PROCEEDINGS 14 (1985). Deisler, Jr., *The Risk Management-Risk Assessment Interface*, 22 ENVTL. SCI. AND TECH. 15 (1988) [hereinafter *Risk Management*].

assessment as objective. (5) It recognized the social need for resolving the scientific uncertainties about hazards, thus giving the scientists specific social functions.

From the beginning, however, the risk assessment community felt uneasy about the model. Critics argued that the view of risk assessment and management as totally separate and occurring in an orderly sequence (with management always following assessment), while superficially appealing, is far from what happens in "real life". It may, in fact, be a wrong model for approaching complex problems that involve social, political and scientific considerations: it has been argued that it would make the field too sterile and routine and stifle the creative impulses of its practitioners,[5] that it would result in addressing the wrong societal problems and thus be irrelevant,[6] and that it would be inappropriate on technical grounds.[7] The implicit assumption that risk assessors can be value-free is also far from ordinary experience.[8] Indeed, many of us got into risk assessment because of our values, a desire to be useful to society (however we may happen to define "usefulness"). Finally, external pressures on scientists to produce "hard facts", to defend their positions publicly, and to actively advise decision makers often distort the results of scientific analysis (the process called by Rip "fabrication

5 Hattis & Kennedy, *Assessing Risks for Health Hazards: An Imperfect Science*, 3 TECH. REV. 60 (1986).

6 Von Winterfelt, *Four Theses on the Application of Risk Assessment in Relation to Environmental Mutagens and Carcinogens*, in RISK AND REASON: RISK ASSESSMENT IN RELATION TO ENVIRONMENTAL MUTAGENS AND CARCINOGENS (P. Oftedal & A. Brogger, eds. 1986).

7 Wilson & Clark, *Risk Assessment and Risk Management; Separation does not Mean a Divorce*, in PROCEEDINGS OF THE 1988 ANNUAL MEETING OF THE SOCIETY FOR RISK ANALYSIS (in press).

8 Ruckelshaus, *supra* note 2, at 19–38. Lynn, *The Interplay of Science and Values in Assessing and Regulating Environmental Risks*, SCI., TECH. AND HUMAN VALUES II 40–50 (1986). Lynn, *OSHA's Carcinogens Standard: Round One in Risk Models and Assumptions*, in THE SOCIAL AND CULTURAL CONSTRUCTION OF RISKS 345 (B. B. Johnson & V. T. Covello eds. 1987).

of facts"[9]), or introduce a political element into the analysis, thus making the separation not possible.[10] Defenders of the model, including the authors of the NRC model assert that the critics are attacking a straw man: no one claims that assessment and management can or should really be totally separated. The idea of the separation, they argue, is essential if risk assessment is to function as an objective scientific discipline.[11] More recently, Graham and co-workers have proposed that these arguments are misplaced and that the real problem lies in false expectations that scientific research automatically leads to more knowledge and that, in turn, to less controversy.[12] Both of those assumptions, they argued, are just as likely to be true as false.

The criticisms raise three issues: (1) Is the model general enough to reflect the realities of hazard management? (2) Is the idea of separating assessment from management so inherently flawed that it should be abandoned or redefined? (3) Regardless of what model is adopted, what roles should scientists play in assessment and management?

While the model needs generalization,[13] we consider only the second and third questions in this paper. As supporters of the model we believe that it is both possible and very useful to maintain a conceptual separation between assessment and management activities. The main argument of this paper is that the general dissatisfaction with the separation in the NRC model stems from confusing two distinctly different ways of talking about risk assessment — the conceptual

---

9 Rip & Groenewegen, *Les faits scientifiques à l'epreuve de la politique* in LA SCIENCE ET SES RESEAUX 149 (Michel Callon ed. 1989); English version, *The Fabrication of Facts for Public Arenas* available from the authors.

10 Rip, *Experts in Public Arena*, in REGULATING INDUSTRIAL RISKS 94 (H. Otway & M. Peltu eds. 1986).

11 Deisler, *supra* note 4.

12 J. GRAHAM, L. GREEN and M. ROBERTS, IN SEARCH OF SAFETY (1988).

13 *See, e.g.*, Hohenemser, *Hazard Management*, in PERILOUS PROGRESS, *supra* note 1.

description of steps in risk assessment and the activities actually performed by the risk assessor. While some steps can and should be relatively objective, value free, and characterized by scientific methodology, other steps inextricably mix scientific and nonscientific activity. Risk assessors have an essential role in performing the latter steps; however, they are not acting as scientists when they do so. Participation in such boundary activities produces role conflicts for scientific risk assessors and often earns them criticism.

Three Case Studies

To support these arguments we briefly analyze three very familiar case histories, ethylene dibromide (EDB) in food and water, nuclear probabilistic risk analysis and emergency planning, and the release of genetically engineered Ice Minus bacteria. The cases are chosen because of their familiarity and the controversies associated with them; they serve as benchmarks in the development of risk assessment.

I. The EDB Hazard and EPA

The agricultural uses of EDB, most importantly fumigation of soils, stored grains, stored fruits and vegetables, and grain milling machinery, are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[14] Under the statute, each use of a pesticide requires registration which can be denied or cancelled if a pesticide presents unreasonable risks to the environment (i.e. the risks outweigh the benefits). The decision to cancel must be based on a thorough risk and benefit analysis, open to the public, a process triggered by announcement of a Notice of Rebuttable Presumption Against Registration (RPAR).

The EDB story we have chosen had its formal beginning in December 1977 when EPA, prompted by the alarming report from its

14 7 U.S.C. § 136 (1988).

Cancer Assessment Group[15] published an initial risk assessment for EDB, Position Document 1 [PD 1].[16] A notable aspect of that story is the gradual change over time in the scopes of several consecutive risk assessments for EDB. As summarized in Table 1, both the number of pathways considered and the depth of quantitative estimation of cancer risks underwent expansion.

The primary focus of PD 1 was on identifying major agricultural uses of EDB and its key adverse health effects. Very little exposure analysis or quantification of risk was attempted. In contrast, the risk analysis published three years later in Position Document 2/3 [PD 2/3] was far more detailed on both counts.[17] Three exposure pathways were considered in PD 2/3 — consumption of contaminated fruits, vegetables and grains, inhalation of contaminated air during application, and dermal contact with milling machinery — and the magnitude of cancer risks from these exposures was estimated for affected populations. The difference in scope can be directly traced to the two sets of regulatory needs of EPA that triggered the two assessments. In 1977, as the agency considered issuing a RPAR Notice, the principal question, as dictated by the legal requirements of the enabling legislation FIFRA, was: "Is the potential hazard of EDB sufficient to require further risk assessment?" A sufficient basis for an an affirmative answer was provided when EPA documented strong carcinogenic, mutagenic and reproductive effects of the agent and potentially extensive population exposure. No further quantitative analysis was needed at that

---

15 U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF RESEARCH AND DEVELOPMENT, CARCINOGEN ASSESSMENT GROUP, INTERNAL DOCUMENT, PRELIMINARY CARCINOGENIC RISK ASSESSMENT FOR ETHYLENE DIBROMIDE (December 2, 1977).

16 Notice of Rebuttable Presumption Against Registration, Position Document 1, 42 Fed. Reg. 63,134 (1977).

17 U.S. ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF PESTICIDE PROGRAMS, ETHYLENE DIBROMIDE: POSITION DOCUMENT 2/3 (1980).

stage and very little was performed; the notice of RPAR was issued simultaneously with PD 1.

Once the RPAR process was triggered, however, the EPA management problem changed. Now, the agency faced one major question: "To ban or not to ban?"There are also two follow-up questions: "If so, what uses, and how soon?" These questions required a comprehensive analysis of the costs of a ban and the consequences of no ban; hence the detailed analysis in PD 2/3.

Despite its broadened scope and greater depth, the risk assessment in PD 2/3 did not include one of the most important pathways of exposure to EDB — that of groundwater. That omission later proved to be a serious flaw which subsequently contributed to a public crisis in 1983 and cost the agency in credibility. Although we can only guess at the causes of that misjudgment, they appear to have included the lack of groundwater monitoring data, the original narrow scope of PD 1, which had little mention of that pathway, and probably the disciplinary biases of the risk assessors. It is also likely that the lack of management options at the time contributed to the omission. (Soil fumigation, the source of groundwater contamination, was the largest agricultural use of EDB and its abrupt discontinuation would have been a serious problem). That the agency still had concerns that soil fumigation might endanger groundwater is clear from its continued requirement of water testing by applicators.

Based on the results of risk analysis in PD 2/3, its authors recommended cancellation of three major uses of EDB: fumigation of milling machinery and stored grains (immediately), and stored fruits and vegetables (delayed). The fourth use, soil fumigation, was to continue, albeit with some restrictions. EPA did little to implement these recommendations until the summer of 1983 when alarmingly high concentrations of EDB were found in groundwater in Georgia, Florida,

California and Hawaii. These findings dramatically altered the management problem of the agency. EPA was no longer moving through a procedurally predictable, if slow, regulatory process. While confronting a new and poorly understood dimension of the EDB hazard, the agency now also faced a major credibility problem and an increasingly alarmed public. The agency's management needs were two-fold — to assess the risks from groundwater contamination relative to the fairly well understood risks from other pathways of exposure and to act promptly. By September 1983, the agency issued an updated risk/benefit analysis [PD 4][18] which, in addition to revising and updating PD 2/3, contained a risk assessment of groundwater as an route of exposure. Based on this analysis, EPA issued an emergency suspension of soil fumigation,[19] followed by cancellation, by February, of all major uses of EDB.[20] These steps are summarized below in Table 1.

---

18 U.S. ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF PESTICIDE PROGRAMS, ETHYLENE DIBROMIDE: POSITION DOCUMENT 4 (1983).

19 Ethylene Dibromide: Decision and Emergency Order Suspending Registrations of Pesticide Products Containing Ethylene Dibromide for Use as a Soil Fumigant, 48 Fed. Reg. 46,322 (1983).

20 Ethylene Dibromide: Intent to Cancel Registrations of Pesticide Products Containing Ethylene Dibromide; Determination Concluding the Rebuttable Presumption Against, 48 Fed. Reg. 46,234 (1983). Decision and Emergency Order Suspending Registrations of Pesticide Products Containing Ethylene Dibromide, 49 Fed. Reg. 4452 (1984).

Table 1

Risk Assessments for EDB: Interpretation and Recommended Actions

Date & Reference	Management Questions	Management Options	Risk Assessment				Recommended Action
			Pathways	Scope		Answers	
				Consequence	Language		
12/1977 PD 1	Is risk potentially unreasonable	• RPAR • No RPAR	• Grain • Fruit/Veg. • Work air • Machinery	C, M, R/D*	Qualitative	• Yes	• RPAR
12/1980 PD 2/3	Is risk from any pathway unreasonable	• Cancel/ suspend some uses • No change	• Grain • Fruit/Veg. • Work air • Machinery	C, M, R/D*	Qualitative and Quantitative	• Yes • Yes • Yes • Yes	• Cancel • Delayed cancel • Protection • Cancel
9/1983 PD 4	Is risk from any pathway unreasonable	• Cancel/ suspend some uses • No change	• Grain • Fruit/Veg. • Work air • Machinery • Soil/ Groundwater	C, M, R/D*	Qualitative and Quantitative	• Yes • Yes • Yes • Yes • Yes	Suspend and cancel all uses
2/1984 PD 4	What to do with tainted food	• Set tolerance level • Destroy food • No change	<-------No new risk assessment------->			Keep some Discard others	Set tolerance levels for grains, fruits and vegetables

* C, carcinogenicity; M, Mutagenicity; R/D, reproductive and developmental

Until February 1984, the principal issue for EPA was that of continuing use of EDB in agriculture. Now, having eliminated all major uses that contributed to its presence in foods and drinking water, the agency faced a new question: What should it do with the huge stocks of contaminated grains already on the market? Pressed by public anxiety about carcinogens in the diet and by a food industry concerned about financial losses, as well as being required by FIFRA to weigh the risks and benefits of its actions, the agency chose to address this question in February and March by setting tolerance levels for EDB in foods.[21]

21 Ethylene Dibromide: Proposed Revocation of Exemption From the Requirement

The previously completed risk assessment, [PD 4], was sufficiently detailed to serve as the basis for deriving the tolerance levels, and no new risk assessment was therefore performed.

The EDB case history shows that the scope of EDB risk assessment was developed over time in response to several discrete forces. These included: statutory requirements, pressing management questions of the agency (many generated by social pressures), availability and methods of analysis, and, quite likely, the management options available and the disciplinary biases of the assessors. The breadth and complexity of each of the risk assessments mirrored the management questions facing EPA at the time. To that extent, the risk assessments (though at times criticized on technical grounds) served the agency's needs well; they provided a scientific justification, a database, and impetus to support several key policy decisions. The major management difficulties of EPA were caused by omissions of important pathways in the risk assessments and from delays in implementing the recommendations of the assessors, not from essentially flawed analysis or from misuse of its results. Our next case, in contrast, shows what happens when the management questions are poorly defined and when the appropriate risk assessment methodology is not used.

II. Emergency Planning for Nuclear Reactor Accidents

Present day emergency plans for nuclear power plants are tied closely to the Reactor Safety Study (RSS).[22] This study (also known as the Rasmussen Report or WASH 1400) was produced in the context of Congressional debate over the renewal of Price Anderson limitations on nuclear accident liability. At that time, it was by far the most

of a Tolerance, 49 Fed. Reg. 6696 (1984). Pesticides; Ethylene Dibromide; Proposed Revocation of Tolerances, 49 Fed. Reg. 8406 (1984).

22 N. C. RASMUSSEN et al., REACTOR SAFETY STUDY: AN ASSESSMENT OF ACCIDENT RISKS IN U.S. COMMERCIAL NUCLEAR POWER PLANTS (U.S. Nuclear Regulatory Commission, WASH-1400, NUREG-75/014, 1975).

comprehensive assessment of sequences of events leading to reactor accidents, their probabilities, and the magnitude of potential consequences. Despite a number of well-founded criticisms, RSS remains a landmark in probabilistic risk assessment.[23] The general methodology has served as a model for many further studies of nuclear and nonnuclear technology and has led to numerous successful applications, most notably in developing safety modifications to nuclear power plants and in modifying operating procedures. Nevertheless, despite its general impact, the RSS risk assessment methodology was not incorporated in emergency planning in the U.S. The history of this failure, which was accompanied by a failure to adequately define the management problem for emergency response, is summarized below.

RSS served as a focus for anxieties about large nuclear power plant accidents.[24] It was not the first official discussion of such accidents,[25] but it was the first to describe realistic mechanisms and to gain widespread public attention.[26] At that time, the regulations

23 H. W. LEWIS et al., RISK ASSESSMENT REVIEW GROUP REPORT TO THE U.S. NUCLEAR REGULATORY COMMISSION, NUREG/CR-0400, (1978). R. Wilson et al., *Report to the APS of the study group on radionuclide release from severe accidents at nuclear power plants*, 57 REV. OF MOD. PHYSICS, S1-S154 (1985). S. Sholly & G. Thompson, The Source Term Debate: A Report by the Union of Concerned Scientists (1986) (available from the Union of Concerned Scientists).

24 Hohenemser, Kasperson & Kates, *The Distrust of Nuclear Power*, 196 SCIENCE 25 (1977). Hohenemser, Kasperson & Kates, *Nuclear Power* in PERILOUS PROGRESS, *supra* note 1 [hereinafter *Nuclear Power*]

25 An earlier document, WASH-740, in 1957 considered the consequences of a major accident at one of the small experimental reactors then planned; this study was updated in 1965 to commercial sized reactors, but was unpublished for eight years to "avoid great difficulties in obtaining public acceptance of nuclear energy." U.S. ATOMIC ENERGY COMMISSION, THEORETICAL POSSIBILITIES AND CONSEQUENCES OF MAJOR ACCIDENTS IN LARGE NUCLEAR POWER PLANTS, WASH-740 (1957). Mulvihill, Arnold, Bloomquist & Epstein, ANALYSIS OF UNITED STATES POWER REACTOR ACCIDENT PROBABILITY (Planning Research Corporation, Los Angeles, PRC R-695, 1965).

26 *Nuclear Power, supra* note 24, at 228–233. D. F. FORD, THE HISTORY OF FEDERAL NUCLEAR SAFETY ASSESSMENT: FROM WASH 740 THROUGH THE REACTOR

governing siting of nuclear reactors only considered smaller, so-called design basis accidents, and there were no requirements for emergency planning outside the low population zone immediately around reactors. [Yet, the Nuclear Regulatory Commision (NRC) and the Federal Emergency Management Authority did provide assistance to some communities which wanted to plan on a voluntary basis.]

Public concerns about whether states and local communities were prepared, should one of the core-melt accidents described in the RSS occur, led to the formation of a joint NRC/EPA Task Force on emergency planning. The charge of the Task Force was taken from a request by a 1976 conference of State Radiation Control Program Directors to define the most severe accidents for which emergency plans should be developed by offsite agencies.[27] The Task Force further refined that charge by targeting two specific management needs — a specification of the range of accident conditions which should be considered and a definition of emergency planning zones. Conspicuously missing from the problem definition was any attempt to specify precise objectives for emergency plans or to specific criteria for evaluating emergency plans as they were developed. The methodology chosen by the Task Force was to "base the rationale ... on a spectrum of consequences, tempered by probability considerations." Surprisingly, despite the prominent role of the RSS and the suitability of its risk assessment methods for at least some aspects of emergency response planning, the Task Force specifically rejected the use of risk considerations for its analysis.

The principal recommendations of the Task Force, published late in

---

SAFETY STUDY (Union of Concerned Scientists, 1977).

27 *Nuclear Power, supra* note 24, at 228–233. U.S. NUCLEAR REGULATORY COMMISSION & U.S. ENVIRONMENTAL PROTECTION AGENCY, PLANNING BASIS FOR THE DEVELOPMENT OF STATE AND LOCAL GOVERNMENT RADIOLOGICAL EMERGENCY RESPONSE PLANS IN SUPPORT OF LIGHT WATER NUCLEAR POWER PLANTS, NUREG-0396, (1978) [hereinafter PLANNING BASIS].

1978, were to establish: (1) two emergency planning zones, a plume exposure planning zone with a radius of 10 miles to provide protection against exposure to airborne and ground-deposited radioactivity *and* an ingestion pathway planning zone of 50 mile radius to protect from exposure through the food chain; and (2) a definition of the potential timing, magnitudes, and composition of anticipated releases.[28]

A few months later, in April 1979, the Three Mile Island reactor, Unit 2, became the first large commercial nuclear power plant to suffer severe core damage. Although the accident proved to have only minimal off-site threats to health, it forcefully demonstrated that the nuclear industry, public officials, and the public were all woefully unprepared for a nuclear emergency.[29] Responding to Congressional demands, the NRC produced emergency planning regulations within a year,[30] using the Task Force report for a basis. These cover a wide range of planning activities not discussed by the Task Force, including such matters as notification and communications systems, mobilization for traffic handling, preparations for decontamination and medical treatment, specific plans for evacuating special decontamination and medical treatment, specific plans for evacuating special institutions, provisions for school buses, etc. The regulations were largely drawn from previous NRC planning documents developed for the smaller, design basis.[31] However, they explicitly use the Task Force report to determine where

28 PLANNING BASIS, *supra.*

29 J. KEMENY, REPORT OF THE PRESIDENT'S COMMISSION ON THE ACCIDENT AT THREE MILE ISLAND (1979).

30 U.S. NUCLEAR REGULATORY COMMISSION & FEDERAL MANAGEMENT AGENCY, CRITERIA FOR PREPARATION AND EVALUATION OF RADIOLOGICAL EMERGENCY RESPONSE PLANS AND PREPAREDNESS IN SUPPORT OF NUCLEAR POWER PLANTS, NUREG-0654, Rev. 1 (1980).

31 U.S. NUCLEAR REGULATORY COMMISSION, GUIDE AND CHECKLIST FOR DEVELOPMENT AND EVALUATION OF STATE AND LOCAL GOVERNMENT RADIOLOGICAL EMERGENCY RESPONSE PLANS IN SUPPORT OF FIXED NUCLEAR FACILITIES, NUREG-75/111 (1975).

and on what time scale these activities must be planned for.

The contribution of the RSS to the NRC emergency planning regulations was thus primarily to set spatial and temporal scales for planning. From a risk assessment perspective there are serious omissions. Emergency response strategies are not compared for effectiveness. The choices of size of zone and timing of response are not justified in terms of risk reduction. Like the Task Force report, the regulations do not provide clear objectives or standards for emergency plans: What risks, with what priorities are to be addressed? The regulations do not provide either an absolute performance standard for emergency plans — a specific level of protection — or a relative performance standard. The absence of precise objectives and of risk-based criteria for comparing the effectiveness of alternative measures has meant that much of the detailed guidance has been converted to plans which read like checklists rather than coherent organizations of activity.[32] Two important and relatively noncontroversial deficiencies in the planning regulations would have been corrected using risk-based criteria[33] — precautionary evacuation is not identified as a protective action requiring systematic appraisal and development,[34] and the size of the ingestion pathway planning zone is much too small, as was glaringly brought home by the accident at Chernobyl.[35]

Why did the Task Force restrict itself to a narrow use of the RSS,

---

32 Golding & Kasperson, *Emergency Planning and Nuclear Power: Looking at the Next Accident*, 5 LAND USE POL'Y. 19 (1988).

33 Goble & Thompson, *The Use of Probablistic Risk Assessment in Emergency Response Planning for Nuclear Power Accidents*, in Proceedings of the 1988 Annual Meeting of the Society for Risk Analysis (in press).

34 *Id.*

35 Hohenemser, *The Accident at Chernobyl: Health and Environmental Consequences and the Implications for Risk Management*, in 12 ANN. REV. ENERGY (J. Hollander ed. 1987). DEPARTMENT OF ENERGY, HEALTH AND ENVIRONMENTAL CONSEQUENCES OF THE CHERNOBYL NUCLEAR POWER PLANT ACCIDENT DOE/ER-0332 (1987).

and why, especially, did it choose not to take a risk assessment approach to emergency planning? It is worth remembering that the Task Force worked at an early period in the development and use of risk assessment methods. In the 1970's, issues were posed in the form: "Is a particular risk 'acceptable'?" — and the answer was often sought by examining comparable risks that were accepted. The Task Force therefore assumed that using risk estimates would have obliged it to compare nuclear emergencies with nonnuclear emergencies in order to identify absolute needs and standards. The Task Force did not feel comfortable with such an approach and therefore rejected the method altogether:[36]

> ...a risk related rationale might imply the determination of an acceptable level of risk which is outside the scope of the Task Force effort. Choosing a risk comparable to non-nuclear events, therefore, was not directly used as the rationale for an emergency planning basis.

The alternative approach of using risk estimates for relative evaluations of safety measures (including emergency response measures) would be commonplace today but was not considered then. For one thing, the power of risk methodology to organize safety management according to effectiveness in meeting management objectives was not then widely appreciated. Moreover the Task Force did not see a need to go beyond its immediate charge. Finally, risk assessment did not then have sufficient stature as an objective discipline to command attention for such an application.

Why have these regulatory deficiencies not been corrected? Much research and new information has appeared in the last decade concerning accident risks and characteristics and concerning effectiveness of emergency planning efforts. This work has found its way into federal training guidance[37] and into a small number of state planning

36 PLANNING BASIS, *supra* note 27, at 1 and 2.

programs. However, the expert community largely lost control over the processes of interpretation and review of regulations; these processes occur almost exclusively in the realm of litigation. The only substantive change in regulations has been the elimination of a requirement that state and local authorities produce and administer plans, and the Task Force report and original regulations are now encrusted with a series of court interpretations. Litigation almost always dealt with new plants, following the 1980 requirement that plants must have approved emergency plans to receive an operating license. Litigation was, thus, the last opportunity for opponents of a power plant to stop it. The major concern of both sides in the proceedings was whether or not an argument can be used to block the issuance of an operating license, not whether safety can be improved. The expert community has not objected very strongly to these developments: As a community, they overwhelmingly support the further use and development of nuclear power, and they have been persuaded (perhaps erroneously) that legal challenges to reactor licensing need to be countered primarily within the legal arena.

Our third case study shows how divergent the scopes of risk asssessment can become when a much less closely knit community gets involved in defining the management questions and what problems appear when analysis and interpretation are not separated conceptually. Also, the third case allows us to probe further the role of individual scientists in all stages of risk assessment.

III. Ice Minus Field Testing: Response by Three Agencies

Late in 1984, Advanced Genetic Systems of California (AGS), informed the EPA of their intention to conduct outdoor experiments using the ice nucleating inactive bacteria, Ice Minus. The full

37 T. J. MCKENNA et al., PILOT PROGRAM: NRC SEVERE REACTOR ACCIDENT INCIDENT RESPONSE TRAINING MANUAL (U.S. Nuclear Regulatory Commission, NUREG-1201, 1987).

chronology of the ensuing controversy, has been described by Naimon[38] and by Krimsky and Plough.[39] Our analysis, based on these sources, covers the period between 1984 and 1986 and focuses on the risk assessments performed by three government agencies: the EPA, the California Department of Food and Agriculture (DFA), and the Monterey County Health Department.

Table 2

Consequences Included in Risk Assessment by Three Agencies for the Ice Minus Hazard

Agency	*Orientation of the Agency*	*Consequences Addressed*
EPA	Effect on environment and population, broadly defined	Pathogenicity to plants Pathogencicity to humans Ecological disruption Weather changes
California DFA	Effect on agricultural industry	Pathogenicity of humans Pathogenicity to plants
Monterey County	Effect on health and welfare of the local population	Pathogenicity to humans Pathogenicity to plants Ecological disruptions

The risk assessment for release of Ice Minus bacteria was performed independently by each agency. Each structured the scope of its risk assessment by choosing the consequences it considered important. As

38 J. Naimon, A Case Study of the First Proposed Field Test of an Environmental Application of Biotechnology in the United States (1987) (Master of Science Thesis, available from Department of Environmental Sciences and Engineering, University of North Carolina).

39 S. KRIMSKY & A. PLOUGH, ENVIRONMENTAL HAZARDS, COMMUNICATING RISKS AS A SOCIAL PROCESS (1988).

shown in Table 2, the agencies were quite selective in their choice of consequences and differed from each other significantly. Their choices appear to match the overall missions of the agencies and the nature of the hazards traditionally addressed by these agencies.

The EPA, whose mission is to protect the environment from adverse effects of human activities, adopted the broadest definition of environmental threats. Because of the agency's determination that the proposed test would be regulated under FIFRA, the AGS proposal was channelled to the Hazards Evaluation Unit within the EPA Office of Pesticide Programs. The scientists in that unit initially defined the problem by identifying four types of consequences of concern: (1) changes in the atmospheric precipitation pattern in the area by depression of the rate of formation of water droplets in the clouds; (2) pathogenic infection of commercial plant relatives of strawberries, the intended target of the modified bacteria; (3) pathogenic infection of humans; and (4) ecological disruption. The initial risk assessment that followed was primarily performed by these scientists with an informal input from various experts and from the EPA Science Advisory Panel. It resulted in a decision, issued on February 1, 1985, that the company would be required to obtain an Experimental Use Permit (EUP) for the proposed test. The decision document also specified the questions to be addressed in the permit application and the data needed by the agency to review the application.

The EUP requirement was equivalent to requiring a comprehensive risk assessment. That assessment was performed first by the company in the application and then by the scientists in the Hazards Evaluation Unit, who reviewed the application. These scientists also made a preliminary decision to approve the proposed test. In the course of their analysis the Hazard Evaluation Unit narrowed the focus by emphasizing pathogenic effects rather than ecological effects of the Ice Minus

bacteria. This emphasis was consistent with the mission of the Office of Pesticides, which traditionally has been concerned with adverse health effects of chemical pesticides. After a lengthy review process, EPA granted permission in December of 1985 to the AGS to pursue the field test.

The mission of the DFA, which was selected in 1984 by the state legislature to regulate the agricultural applications of biotechnology (in preference to the Department of Environmental Quality which is the state-equivalent of the EPA), is different from that of the EPA pesticide program. With strong interests in promoting and protecting the state agricultural industry, the DFA was primarily concerned with workers' health and with pathogenicity to agricultural plants. Not surprisingly, effects on weather and on the ecological balance were given little consideration in the risk assessment.

The scope of the risk assessment performed by the Monterey County Health Department was the narrowest of the three. Its principle focus was on human health, a choice consistent with the primary mission of a local health department. The choice also reflected the highly personalized nature of the problem once it reached the local level. Abstract questions about weather were no longer the issue but rather the immediate effects on neighboring communities.

The three agencies' institutional arrangements for performing the risk assessments were also different. Although both the federal and state agencies sought the counsel of outside experts, the EPA external review process was far more extensive than the California process. At EPA the results of the analysis and the preliminary decision were subjected to a review process that included the general public as well as scientists from the EPA Science Advisory Panel, other EPA offices, and other agencies. A wide range of disciplines including meteorology were represented in that review. The agency also gave more weight to the outside expert opinions by encouraging free debate among the panel

members and by seeking a consensus.

In California, the scientific analysis was delegated to a working group of experts from four state agencies. Unlike the external review process adopted by the EPA, the members of the California working group had little interaction with each other. Instead of seeking group consensus, the agency's analyst in charge of risk assessment collected the opinions of the individual members and, based on his own interpretation of the data, made a recommendation to grant a permit. In short, the state agency did not seek to resolve the scientific uncertainties either through public debate or through a consensus seeking group of experts. Again, the differences between the federal and the state processes are reflective of the routine modes of operation of each agency; all major EPA programs are legislatively mandated to use advisory groups and input from the public, whereas the state agency practices a more centralized decision making process.

The orderly process conducted by the state and federal agencies provided well defined roles for the participating scientists. These roles extended well beyond the strict scientific analysis of data. In each case, the staff scientists defined the problem, with input from the outside experts, by listing the pathways and consequences of the hazardous agent and by formulating specific questions for analysis. After performing the analysis, the scientists interpreted its results by making recommendations to the heads of their respective agencies to grant the permits. In both cases, these recommendations were adopted, thus strengthening the advisory role of the scientists in the process.

The procedure chosen by the county for its risk assessment was much less orderly. The risk assessment and management functions were consolidated in the hands of one person, the County Health Director, who defined the scope of risk assessment, searched for data, interpreted scientific information, solicited expert opinions, evaluated the economic

value of the product and searched for management options. Because the scientific debate was incorporated into highly adversarial public hearings, the risk assessment took the form of contradictory opinions of a group of experts who had strong individual preferences for the outcome. Neither was this risk assessment a major factor in the decision in February 1986 to impose a moratorium on all testing (first for 45 days and later for a year). That decision was based primarily on the social, political, and economic significance of this case to the county and had little input from the scientists. The minor role of risk assessment at the county level stands in contrast to the EPA and DFA processes where scientific analysis formed the basis for policy decisions.

Why was the county process so different from that of EPA and DFA? Both politics and institutional circumstances played a part. First, the county was indignant when the state and federal agencies issued permits without giving county officials a voice in the process; this provoked an adversarial position of the county. Second, the county health department was quite unprepared to handle this unusual case in terms of administrative arrangements or scientific expertise. The authorities therefore improvised the process as they went along — while being subjected to floodlights of publicity and a highly politicized atmosphere. Not surprisingly, the risk assessment served primarily to express the strong opposition of the county to the proposed test.

Characteristics of Risk Assessments and the Role of Scientists

Even in the sketchy form in which we presented them, the cases suggest three general observations about risk assessments in the public arena. For presenting them, it is helpful to view risk assessments as consisting of three conceptual phases: (1) definition of scope, (2) analysis, and (3) interpretation of the results of the analysis.[40]

I. The scopes of assessments are usually narrow

The omission of the EDB groundwater pathway, the choice to present an emergency planning basis but no emergency planning guidance, and the differences between the EPA and California characterizations of the potential hazards of Ice Minus are illustrations of a general tendency. Narrowness in scope comes from four influences:

- *Scientific/technical.* Scientists may see certain problems as intractable and exclude them. They may limit consideration of problems when there are data limitations or other major uncertainties. Also, the particular disciplinary background of scientists may affect their characterization of problems as in the Ice Minus assessments.
- *Political/legal/social.* Regulatory authority often defines the scope of an assessment, as in the early stages of the EDB analysis. The traditional missions and constituencies of an agency will strongly influence its approach, as was also clear in the case of Ice Minus. And other institutional and political considerations are often barely below the surface, as, for instance, the conflict between federal and state and local authority in nuclear planning.
- *Managerial.* Many risk assessments begin as the evaluation of a particular management option — to site a facility or operation, or to use or ban a technology, as in the EDB and Ice Minus cases. Problem definition will be limited unless there are opportunities for considering further options.
- *Logistical.* Assessments are made in fixed periods of time with particular allotments of people and other resources, and usually with only limited opportunities to augment the existing data base.

A narrow scope is not altogether harmful. Such a scope may actually strengthen a risk assessment by giving it clarity, reducing uncertainty, concentrating resources, and by focusing subsequent analysis of

40 Similar schematic language could be used to describe scientific work as well. However, in contrast to scientific work, it is intrinsic to risk assessment that both problem definition and interpretation are necessarily nonscientific. Only the analysis proper can be performed as a scientific objective assessment, uncolored by issues of management prerogatives and social values.

management options. For example, the problems with the emergency planning basis could also be viewed as stemming from too broad and vague an interpretation of the problem objective. However, when such narrowing is performed for political reasons, with no regard for the scientific evidence, or too early in the process — as was the case with EDB in groundwater — or if it is not reevaluated later, it may lead to bad decisions.

II. Scientists who perform assessments do much more than analyze scientific data

The cases show that scientists who perform the scientific analysis also perform other key functions: they structure problems, articulate specific questions for analysis, arrange the external review process (and give charges to expert panels), interpret the results of the scientific analyses, and make recommendations on ways to manage a hazard. These scientists have their own individual connections with the larger institutional and societal context in which they operate, and they use that context in organizing the analysis and interpreting the results. This was particularly apparent in the Ice Minus case where the different technical staffs were clearly sensitive to the missions of their respective agencies.

While many risk assessments can appropriately be performed in a routine manner,[41] our case studies show that creative technical analysis by the scientists involved can be the major contribution (or potential contribution) provided by the assessment. Thus, the analysis of potential effects on weather patterns and the ecological balance in the Ice Minus case broke new ground for risk assessments. Risk assessment could have been used to improve the effectiveness of emergency planning for large nuclear accidents had the Task Force chosen to pursue it.

---

41 U.S. ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF SOLID WASTE AND EMERGENCY RESPONSE, DRAFT SUPERFUND PUBLIC HEALTH EVALUATION MANUAL (1985).

III. Scientists are often not involved in following up their analysis — resulting in uncorrected errors and inadequacies

While scientists played a substantial role in defining the scope of each of the assessments, responsibilities for interpretation and use of the assessments were less consistent and often limited. Nuclear emergency planning is the most egregious of our examples: Failure to assess the effectiveness of alternative measures are still uncorrected, and most technical issues have been converted to legal issues. The EDB case was mixed: The risk assessors produced a set of policy recommendations in PD 2/3 on how to manage the EDB hazard; three years later when the EPA had done nothing about EDB, and new management at EPA faced a set of public crises, the recommendations were criticized as insufficient. In the Ice Minus case, the EPA and California scientists had a significant effect on their agencies' policies, when field tests were approved. In this case, however, it is too early to say what further follow up will be needed.

Risk Assessment as Part of a Dynamic Process

The picture of a useful risk assessment that emerges from our analysis is an extension of the static, self-contained idealization of the NRC Committee. Their ideal risk assessment is insulated from and is followed in an orderly manner by the messy societal process of risk management. It starts with hazard identification, which focuses on consequences, and draws only on science. Their model is shown in schematic form in Figure 1, below.

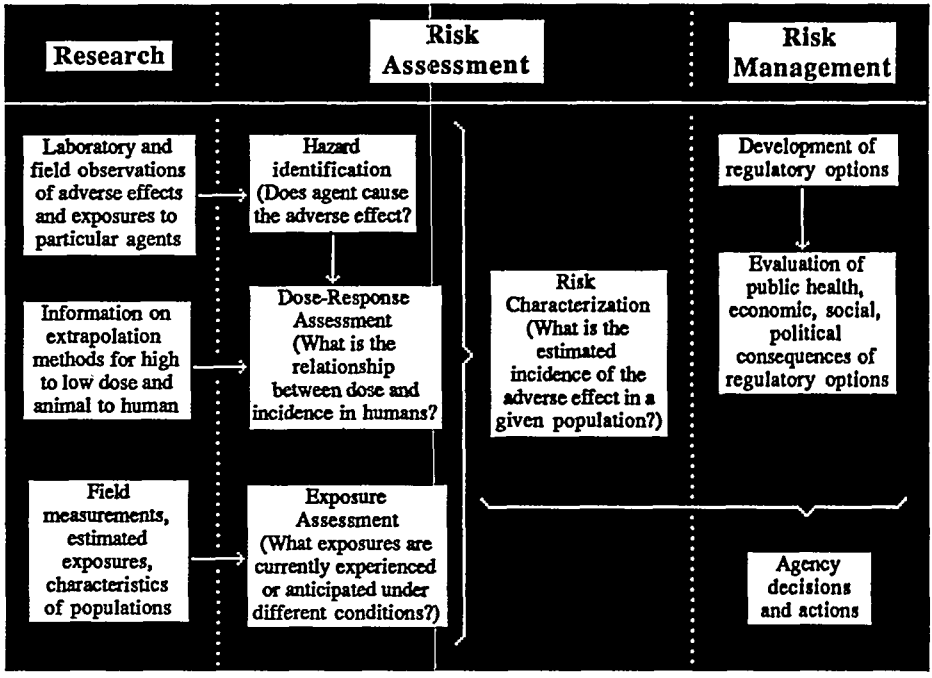
Problem definition in our picture (Figure 2) goes considerably beyond hazard identification and includes consequences, pathways, and other considerations including management opportunities. As shown there, we regard problem definition as a merger of the interplay of three

general areas: science, social/legal considerations and management options. For the process to be useful, risk assessors must be able to step out of their role as the interpreters of scientific data and, together with risk managers, provide a bridge between science and society at the boundaries where the two interact.[42] In the problem-definition stage, a risk assessor needs to advise the risk manager on the scientific tools available for risk analysis, the availability of data, the extent of the theoretical understanding of the scientific phenomenon at hand, and on the relative feasibility of providing reasonably certain answers to the management questions likely to arise. Risk assessors need, in turn, to be advised on the management options available, on the potential impacts of their decisions on the society, and on the legal and social constraints placed on the scope of risk assessment. A similar mutual interaction is needed in interpreting the results of technical analysis.

Although our picture of risk assessment modifies that proposed by the NRC Committee (see Figure1, below), we preserve its key elements: the central role of objective scientific analysis and the distinction between assessment and management activities. Distinctions are essential for maintaining the integrity in the process and for keeping the science sufficiently isolated from value judgments and political manipulation.

42 *Risk Management, supra* note 4, at 15.

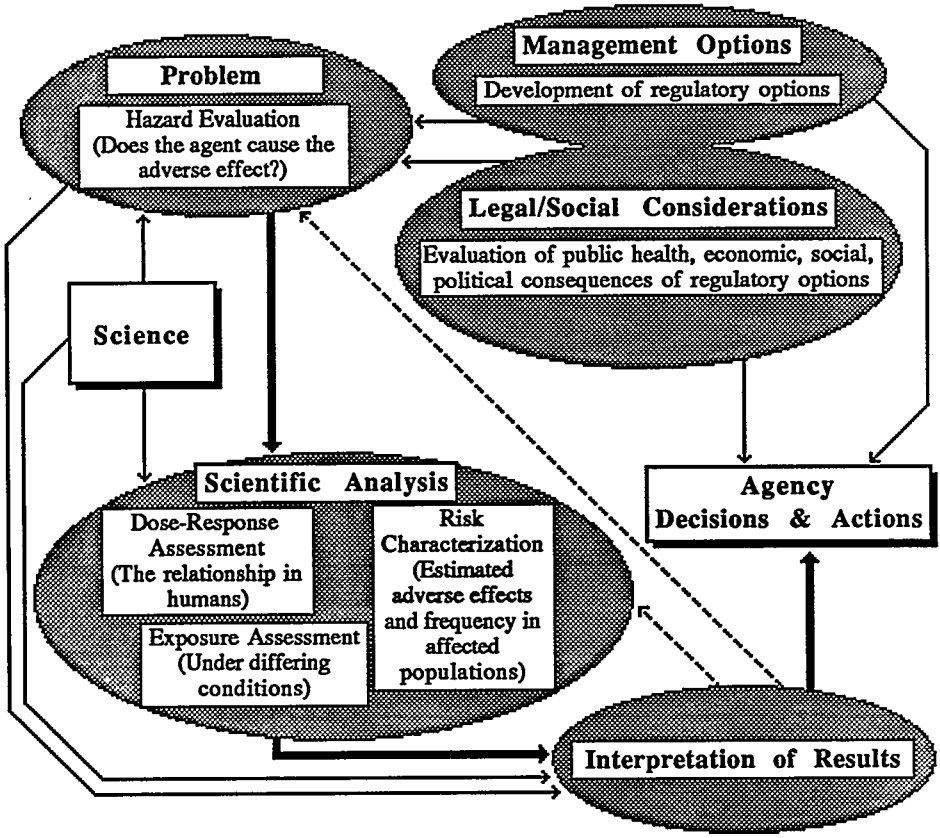
Figure 1[43]



Nevertheless, we argue that dividing the process of risk assessment into conceptual steps should not be used directly to assign functions to involved individuals. Whereas particular types of activities represented by separate boxes in Figure 2 are placed in conceptually and organizationally distinct compartments represented by shaded areas, the individuals who perform these activities cannot and should not be locked into specific narrowly defined functions. Risk analysis, to be relevant, needs a connection with the larger context, and therefore the people must be also a part of that context. Who is better equipped than a well-informed scientist to interpret the results of analysis, with the attendant uncertainty, and to convert it into advice?

43 *Supra*, note 2.

Figure 2[44]



Final Observations

For a risk assessor, a dual role clearly means a conflict between the demands of a scientist's code of conduct — unwillingness to draw conclusions from inadequate evidence, avoidance of subjective judgments — and the need for her or his active involvement in solving a specific societal problem. However, since the role conflict is

44 In our model, thin, solid lines represent the flow of information; dotted lines represent the occasional flow of information; and bold, solid lines represent the flow of activities.

unavoidable, the best approach is to recognize it openly. As observed almost a decade ago by Philip Handler, then President of the National Academy of Sciences, grave problems arise when individuals confuse these dual roles, problems of lost integrity and diminished public confidence in science.[45] The individual risk assessor has several responsibilities: (1) to keep track of the distinction between those activities she or he does which are objective and analytic and those which incorporate individual and social values and intuitions, (2) to make clear the distinction to the public and to others in the field who may agree or disagree on policies, and (3) in both roles, to perform the work with sufficient clarity, openness, and honesty that an objective characterization of any risk assessment will be feasible.

Risk assessors and other experts who form the risk community have further obligations to that community and to the field:

• Critical review is often needed of how and by whom and on what basis the scope and content of risk assessment is defined. In current practice, external reviews are usually concentrated on the credibility of the scientific methods and data base. While important, this type of review needs to be expanded to include the questions related to problem definition.

• More flexibility is needed in the interpretation and use of risk assessment results. Very often a risk assessment provides a perspective on a problem, rather than a definitive answer to a policy question: results of that sort should be used as positive contributions to policy formulation, not considered to be defective analyses.

• The institutions which sponsor risk assessments must pay attention to societal context. There is a tendency to assemble panels of experts to consider a particular scientific question, an answer to which may be crucial in a specific policy decision, without giving that panel much

45 Handler, *Public Doubts About Science*, 208 SCIENCE 1093 (1980).

information about the nature of the decision problem. Such isolation, intended to keep values out of science, may not always be the most effective way of using such panels; cases where that is and is not appropriate must be carefully identified.

• Risk assessors and other experts involved in risk assessment must make a particularly strong personal commitment to the integrity and development of the field: Support is needed for the development and strengthening of the analytic base for assessment; the community needs professional standards for what is and what is not objective analysis. As noted in a recent editorial by Jasanoff, "honesty, rationality and full disclosure are of paramount importance to science as well as public policy."[46]

Most importantly, the community must become more willing to take a critical look at its past activities and draw the needed lessons for improvement.

46 Jasanoff, *Norms for Evaluating Regulatory Science*, 9 RISK ANALYSIS 271 (1989).