4 Codifying the Risk Assessment–Risk Management Framework

Ten years after its creation, the EPA embraced risk twice, but separately and to different degrees.[1] By the early 1980s, the notion of risk encapsulated a first design, according to which the agency produces decisions that are adjusted to the level of risk, determined by toxicological and statistical analysis and concurring policy assumptions about the nature of these risks. This design was embodied by cancer risk assessment methods. It was advanced by a fringe of the agency's scientists and adopted by a couple of its programs. It materialized in guidelines and improved communication between scientists, who were calculating the risks and estimating the hazards, and the various other actors involved in writing rules and standards--economists, policy analysts, lawyers, or office chiefs. Another design, a commensurative one, aimed at comprehensively reviewing agency activities against risk, cost, and benefit indicators, with a view to taking control over the agenda of the agency's offices in order to produce a more controlled and integrated image of what the agency was addressing. One design responded to industry judicial challenges against the ban of its chemicals, using the uncertainty surrounding carcinogenesis; the other tried to limit controversies stemming from the application of various risk criteria by separate regulatory offices to similar chemical conditions.

At the end of the 1980s, the risk assessment guidelines developed by the EPA—as well as other agencies—sparked more controversy. They displaced the legitimacy problem of the agency. It was no longer an issue of whether the agency had the authority to ban chemicals, but whether its mode of reasoning and making decisions about chemicals was right. For the chemical industry, these guidelines embodied an overly conservative and stringent regulatory philosophy of risk elimination, producing many false positives, and the action on cancer and chemicals was misguided. The chemical

industry opposed these guidelines, and took on the agency's way to use science. It entered the game of design, suggesting that the proper administrative form of using science was an independent science panel, separate from regulatory agencies. This proposal was based on a different design than that of EPA's health scientists and economists: a more scientistic and predictive one, according to which science can eliminate uncertainties and establish future risks with precision in such a way that the space for autonomous judgment by a political official, between the walls of an agency, should be restricted as much as possible. Industrial action displaced the design process from the agency itself toward another influential site, the NRC, in which a panel of experts pursued the work of organizing disputes and came up with a new representation of necessary knowledge for bureaucratic acts. The NRC panel built the knowledge representation and technologies that were emerging in the agency—quantitative risk assessment, risk-ranking—in its resulting NRC report, *Risk Assessment in the Federal Government: Managing the Process*. It articulated a generic framework that combined these technologies and that instantly (and surprisingly) appeared legitimate to nearly everyone involved in the controversy.

Industry in the Game of Design

As part of its campaign against the EPA's conservative assessments of chemicals, the AIHC developed a full, positive institutional proposition that suppressed regulatory agencies' mission to assess risk, entrusting this scientific work to a new, separate science panel.

In late 1979 and early 1980, the AIHC stepped up its campaign to institute this science panel. In November 1979, the group published a first Recommended Framework for Identifying Carcinogens and Regulating Them in Manufacturing Situations (AIHC 1979). The framework highlighted several necessary reforms: a separation of scientific from social decision-making; giving an increased role to risk estimation in assigning priorities for regulatory action ("risk estimation includes both identifying potential carcinogenic hazards and determining the probability of adverse occurrences, essentially scientific functions"); the importance of risk estimation to select "approaches" (types of regulatory measures) for priority subjects; and the organization of a "sequential interplay" between regulatory agencies and an expert scientific panel (ibid., 6–9).

The AIHC devised a whole new controlled process for scientific advice that was based on a list of nine steps, involving the science panel or the agency in turn.[2] The boundaries between the panel and the regulatory agencies, and science and regulation, were drawn by two kinds of value judgments: scientific and social, respectively. The qualitative determination of existence of a hazard and the calculation of the most probable risk estimate (quantitative), "although judgmental, are basically scientific efforts requiring interdisciplinary, scientific expertise." But the determination of the degree of control "is a social-value judgment, which should be influenced by the scientific determinations but in the end is political" (ibid., 10). This determination should be left to agencies, and the rest left to a science panel. Here, the AIHC was enlisting powerful allies: William Lowrance's work, first (see chapter 1), but also the newly published report of the OSTP (Federal Register 1980).

On February 21, 1980, the AIHC circulated a supplementary proposal that outlined the organization of the science panel (AIHC 1980). It would be a new standing committee within the NAS. The rationale behind its creation was to recruit the most experienced scientists, to harmonize scientific advice, and to construct the scientific basis for a national cancer policy. The panel was seen as a real panacea: it would eliminate scientific inconsistencies in scientific evaluation by agencies, provide evaluations by the most objective professionals, reduce conflicts of interest, and speed up the regulatory process. Benefiting from the excellent reputation of the NAS and delivering high-quality scientific opinions (AIHC documents generally used the term *determinations* to refer to these opinions), it would also have the benefit of minimizing controversies around basic scientific issues. The AIHC insisted that the individuals in charge of regulation would benefit from assessments produced by competent, experienced, and objective professionals. It proposed that the NAS has complete latitude in nominating the committee members.

Much like Dan Beardsley in the agency's policy office, the AIHC drew on the argument that "risk analysis" could be a vector of greater objectivity in policymaking—one that could eliminate the "biases" of an agency that was structurally inclined to regulate. The AIHC promoted a sequential model of decision-making in which the analysis of benefits would work as a kind of embedded veto point in order to derail conservative assessments. During the public hearings on cancer guidelines, the physicist Richard Wilson

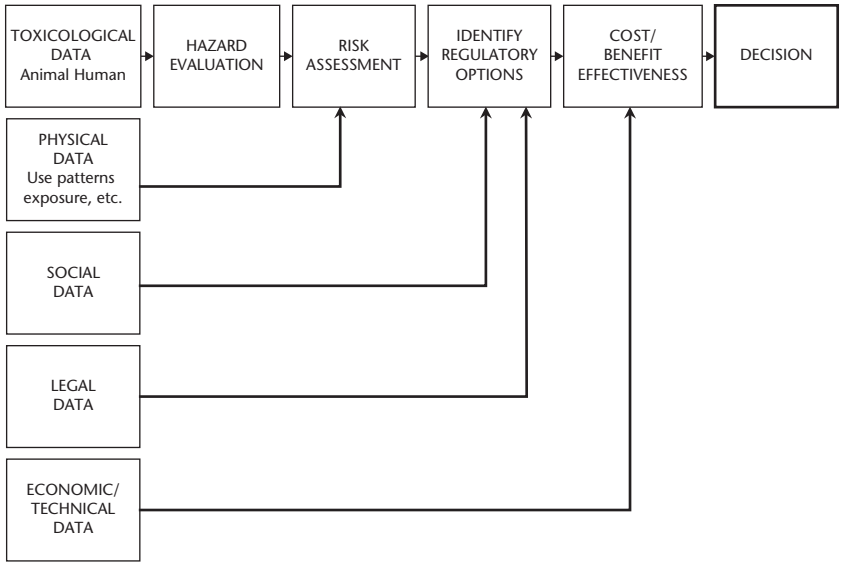

Figure 4.1
A linear risk analysis and decision-making scheme (adapted from Haight et al. 1980, 14).

maintained that the right approach to risk, as the former EPA administrator Russell Train said in his preamble to the 1976 guideline, consisted of first assessing the risk and then deciding what to do, taking into account not only the risk, but also the benefits associated with the substance: "It is important to start with a structure such as this because even though there are information gaps in the structure, without a structure illogical actions may be suggested" (EPA 1980c, 8).

This two-step design pleased Wilson, and more broadly the chemicals industry, as it afforded a procedural and systematic opportunity to overrule the estimates of the supposedly conservative scientists of the agency on the basis of benefits. The industry was also thinking in terms of this linear, step-by-step decision-making system, as in figure 4.1, where preliminary assessments of risk could subsequently be vetoed on the grounds of benefit or cost considerations before arriving at the final decision-maker. A report drawn up by the Chemical Manufacturers Association and the American Petroleum Institute for educating key industry representatives involved in the public debate on risk/benefit/cost analysis advocated this structure, with supplementary steps after the risk assessment to deflect the possible

decision to regulate (namely, an "identification of regulatory options") (Haight et al. 1980).

The AIHC's discourse on uncertainty—where risks come from a lack of knowledge that future, supposedly "sound" science will compensate for—was coherent with this proposed design: removing risk assessment activities from regulatory agencies and entrusting them instead to a dedicated science panel outside these agencies. The "science panel" proposal of the AIHC broke the step-by-step linear process of decision-making into two large modules at the stage of regulatory option identification. The first steps of the process (comprising health risk assessment) were to be removed from regulatory agencies and entrusted to a science panel, while the rest was left to the agencies. This would take away from regulatory agencies the possibility of articulating and legitimizing health-protective regulatory decisions through science. Instead, it would make science more amenable to other methodological, epistemological pressures, and focus regulatory agencies on the task of devising optimal decisions from the point of view of their costs incurred on businesses, and of their benefits. In this particular assemblage of knowledges and expertise, a boundary is drawn around cost-benefit analysis, left to regulatory agencies, probably because this expertise is the least likely to generate strong regulatory measures for industries.

In the chemical industry's action, the model of separating scientific knowledge from policy decision-making was thus associated with an institutional model, based on the view that science is a particular type of content that should have its own dedicated institutions and space, to remain as free as possible from any possible source of bias. The "science panel" concept echoed a parallel, quite animated debate and similar institutional proposal for dealing with scientific contestation: that of the "science court." This institutional, expert deliberation design had been proposed by Arthur Kantrowitz, a physicist in fluid mechanics and gas dynamics, but also a public proponent of the separation of science from ideology. He articulated a proposal to set up an institution for forming scientific judgments in the context of disagreements among experts (Kantrowitz 1967, 1975).

The idea pushed by Kantrowitz (though not by him alone)[3] was that an organized confrontation of scientific arguments would be an ideal setting for producing truth and objectivity. Despite constant references to democracy, the proposal was strongly rooted in an instrumental vision of science—a belief in its capacity to produce facts, separate from the realm of values—and

of overcoming excessively emotional debates. What Kantrowitz and other promoters of the scientization of public issues had in common was the belief that content-free procedures or settings would produce the right outcome in all cases. Following the right process of confrontation and deliberation among experts would produce objectification, regardless of the substance of the issue. Even though it proved to be illusory (Aakhus 1999), this institutional design appealed to those who defended a scientistic approach to the regulation of risks and technologies.

As a skilled and motivated promoter of his idea, Kantrowitz got President Gerald Ford to set up a task force under the Presidential Advisory Group on Anticipated Advances in Science and Technology, with the purpose of developing a workable scheme for such an institution. In those years (1975–1976), Kantrowitz published a paper in the journal *Science* that gave his proposal good publicity and sparked much debate on the nature of his proposal and its workability. A well-attended conference in 1977, sponsored by the NSF and the American Association for the Advancement of Science, concluded with an endorsement of the proposal by the leaders of the country's most prominent scientific societies—and of the AIHC.

There were notable differences among the designs pushed by Kantrowitz and the AIHC, however. Whereas Kantrowitz suggested bringing disagreements out into the open and forcing scientists to engage with opposing arguments, the AIHC embraced an altogether different method: it preestablished what the appropriate components of a consensual decision would be and defined a sequence of production, with standards applying at each step of the process. A strict corridor was defined that was presumed to lead to the articulation of consensual, fact-based decisions. In this process vision, which was quite fundamentally opposed to the forumlike idea of Kantrowitz's institution, the central expert panel was supposed to pour out authoritative formulations of facts—and hence it was not to be an arena for open disagreement. But the connection between the two enterprises certainly stemmed from the belief that there were institutional designs specifically suited to the production of scientific facts and truths.

The Committee on Risk and Decision-Making

The AIHC, Kantrowitz, and ongoing discussions inside the NAS showed that a particular phase of institutional imagination had opened. In the NRC, at about the same time as the AIHC was campaigning for a science panel, the

mathematician Howard Raiffa's Committee on Risk and Decision-Making (CORADM) was struggling with categories to represent and order the kinds of knowledge and activities implied by decisions on uncertain collective hazards. The final report of this committee contributed to the thinking around the respective roles of assessment, evaluation, and control of risks, as well as the organization of their interactions in concrete regulatory practice (NRC 1982). It reflected Raiffa's perspective as a decision analyst, valuing analysis as a tool for making legitimate decisions. Analysis was helpful in decomposing the components of a decision, thus laying the groundwork for negotiations among actors making or being subjected to the rule in development.[4] Therefore, analysis should be preserved. But decisions in controversial contexts were obviously limited by what the report called "conflicts of interest," and with these, professional analysis provided no solution.

An additional solution, therefore, was needed to decrease the level of contestation surrounding risk decisions. Raiffa saw that solution as bracketing out the most controversial part of these decisions: the value that people assigned to the actual object of the decision. In a typically analytical style of thought (breaking down predecisional sequences of thinking), the report promoted the notion of a discrete risk evaluation stage, lodged between the assessment of the risk (pertaining to science) and decision-making or policymaking. It is unclear, when reading the report, whose job it was to consider values and how values could be decided. On the one hand, risk analysis was said to encompass risk assessment and risk evaluation, seemingly indicating that values should be an integral concern of the scientists assessing risks. On the other hand, the report occasionally folded risk evaluation into policy analysis, arguing that risk evaluation was connected to the identification and choice of policy alternatives, and as such was policymakers' responsibility.[5]

Raiffa believed this knowledge representation in terms of risk assessment and risk evaluation was concordant with the practices and problems of agencies, although no concurring evidence seemed to exist at the level of the formalisms developed by the EPA or of its organizational chart. It invented a risk evaluation step that was empirically nonexistent and prescriptively useless for risk assessors who were, de facto, faced with these problems of values and alternatives within the confines of their scientific exercise. The conflict that set organizational sociologist and political scientist Charles Lindblom against the rest of the committee members revealed the limits of this category of "risk evaluation" as a way to salvage a professional,

objective analysis. Lindblom was intellectually and politically convinced that the knowledge underpinning decision-making and policymaking was not professional, specialized, formal knowledge. He argued that decisions were most often derived from and shaped by the articulation of ordinary and socially distributed knowledge. No knowledge stands outside or exists prior to decisions, independent of social perspectives and experiences. The whole demarcation of an intermediate step of risk evaluation to cloister the controversy-prone consideration of values, preserving science's "safe space" of facts, just did not make sense.

Lindblom fundamentally disagreed with the whole endeavor and thrust of the CORADM, which was to formalize procedures of analysis that would produce "superior policy alternatives" (NRC 1982, 30). Policies could not be rationalized on the basis of formal knowledge produced before they were made, precisely because they were not a sort of neutral enactment of predetermined data, but rather situations of active engagement with, and production of knowledge about, the problem. Lindblom maintained that the proper use of knowledge in action consisted of improving learning capacities through action, not of importing decisions from external knowledge, the objectivity and authority of which he considered to be mere myth (Cohen and Lindblom 1979).[6] On the page of the final report that listed the members of the CORADM, his name was followed by an asterisk with the following statement: "Charles Lindblom does not approve of this report." The limits of the science/evaluation/policy sequence as a representation, accentuated by the conflict between Lindblom and Raiffa, undermined Raiffa's entire effort. At the end of the day, the final report[7] did not put forward any concrete recommendations as to how to manage the interfaces among assessment, evaluation, and decision-making. No trace of this thinking can be found in the documents and practices of agencies today.

AIHC in Congress

Despite the failure of CORADM to institute a new design for science and making decisions, the AIHC considered it a good strategy to create its own proposal for a science panel endorsed by the various academies (of science, engineering, or medicine) in order to undermine agencies. The AIHC mobilized elite representatives of large chemical and petrochemical companies, who consistently made contacts and sent letters to various congresspersons

to advance the collective industry proposal on risk assessment, specifically on its dissociation from regulatory agencies.

Several bills proposed in Congress echoed the concerns of these companies during that period. In February 1980, Congressman William C. Wampler (a Republican from Virginia) had introduced a bill suggesting the creation of an eminent scientific panel inside the White House's OSTP. The panel would effectively be akin to a court; anyone would be allowed to refer issues to it to adjudicate agencies' decisions. Another proposal was pushed by Congressman Donald L. Ritter (a Republican from Pennsylvania), which concerned the activities of the five health and safety agencies and foresaw the coordination of risk research by the OSTP, as well as the development of prototypical risk analyses by the five regulatory agencies, to strictly frame their capacity to develop these risk assessments.[8] The bill reflected the AIHC's ideas of restricting the scientific capacity of regulatory agencies and giving more control over risk assessment to the federal government.

The AIHC made another proposition to Congress: to have the NAS discuss, and possibly endorse, the science panel idea. To that end, AIHC representatives engaged in simultaneous lobbying of the NAS, the House of Representatives, and the Senate. In March 1980, the industry group sent a letter to Senators Thomas Eagleton and Ted Kennedy (both Democrats; from Missouri and Massachusetts, respectively). In this document, they required the senators and corresponding committees to include in the appropriation bills that were under way a proposal for an amendment on the need for agencies to avail themselves of the best scientific advice, as well as to give $500,000 to the NAS for a study on how best to achieve this. The NAS was in the process of working on risk assessment methods and on designs for distinguishing science, policy, and the gray zone of risk evaluation (NRC 1981, 1982). Having it give its imprimatur to the science panel idea, and even agree to form the panel within its walls, would decisively advance the attack on regulatory agencies.

Congress's oversight of the EPA and ongoing disputes about chemical cancer assessment meant that it was receptive to institutional proposals to examine new possible designs for science and policy. In November 1980, the Senate, supported by the NAS, approved the AIHC's proposal to allocate $500,000 from the FDA budget for a study of risk assessment. The objectives were formulated in almost the same terms as those used by the AIHC in its documents: to assess the merits of institutional sharing of scientific

functions through the separation of the objective risk assessment process from the regulatory process per se; to consider the feasibility of unifying the various functions of risk analysis, and study the possibility of developing a coherent risk analysis methodology likely to be taken up by all regulatory agencies in the decision-making process; and to list the procedural and institutional questions that would arise from the interaction between the selected risk analysis methodology and the regulatory processes.[9] In short, the NRC was charged with investigating whether assigning risk assessment functions to a dedicated institution in the federal government, separate from specific regulatory agencies like the FDA, the EPA, and OSHA, would remedy the alleged distortion and politicization of science by regulatory agencies. Because this alleged distortion was embodied in the cancer guidelines, the question of guidelines was explicit in the charge. The committee had to examine the feasibility of setting uniform guidelines. The project was explicit: It aimed to reduce the autonomy of an agency that was perceived to overregulate, through a definition of the knowledge it could use and how.

The NRC's interest stemmed from the fact that risk was an increasingly hot topic, for which it was getting many report requests. A 1981 overview report on the activities of the NRC noted that 49 percent of the reports produced by NAS in the preceding years included some aspect of risk assessment (NRC 1981, 2). That review report, authored by a set of top academics in the nascent field of risk research and risk analysis (e.g., Robert Kates, Howard Raiffa, and Gilbert White), inaugurated a generic definition of risk assessment, encompassing a wide variety of analytic methods: "Risk assessment as its practice has evolved is a rubric covering a broad range of analytic activities including: the identification of hazard, the estimation of probabilities of occurrence of hazardous events of specific magnitude, the linkage of such events with various undesirable health, safety, environmental and other societal consequences, and the evaluation of risks by comparison with costs, with other risks, with benefits, with alternative ways of reducing risks, or with the risk of substitute activities. A complete risk assessment would involve most or all of these elements" (ibid., i). Reviewing a number of risk assessments done by the NRC itself, the authors learned that most of these exercises involved ambiguous definitions, paucity of data, or controversy around the main subject, and that the questions addressed in the reports were difficult to answer or intractable, with unclear modes of analysis. They reached the conclusion that in risk assessment, there should be a

concerted effort to distinguish among scientific findings and personal or value judgments if these findings are to be translated into policy.

The NRC thus had some experience in the field of risk assessment, and this time around, it had a clear, feasible charge to answer—and one that promised an impactful report. Expectations were high.[10] The committee had a precise, feasible task, and a mission: first and foremost, to assess the AIHC proposal for a science panel (that is, the separation of assessment and decision-making into distinct institutions). Its work was very straightforwardly connected to events and debates that were just unfolding, and had attracted more attention only since the ILRG's work on cancer guidelines. In that sense, the pressure of events and of the discussions that were ongoing at just about the same time, outside the walls of the NRC across Washington, was probably stronger than usual.

The Risk Assessment Committee

Frank Press, the president of the NAS and the NRC, moved away from the solution of relying on the conclusions of the CORADM, or mandating Raiffa for this new study, and instead created a new committee named Committee for the Institutional Means for Risk Assessment (Risk Assessment Committee, or RAC). The Board on Toxicology and Environmental Health Hazards (BOTEHH)[11] of the NRC worked on setting up the panel to do the study. People were selected to represent the following subfields of expertise: risk assessment policy, risk assessment, law, economics, decision analysis, political science/organization theory, psychology/perceived risk, epidemiology, biostatistics, oncology, public, industry, and basic science/other. More informally, and in line with NAS's practice, the board was looking for people that would represent the various viewpoints on the subject: those of the agencies, of scientists, of regulatory bureaucrats, and of environmental or health activists and industry.[12]

Frank Press suggested taking William Ruckelshaus as an expert on risk assessment policy, by virtue of his previous position as EPA administrator. Ruckelshaus had also been a member of the CORADM. Bob Tardiff, a toxicologist and influential member of the NRC Board of Toxicology,[13] made several important recommendations, namely Morton Corn (to cover risk assessment policy), Richard Merrill (law), Joseph Rodricks (risk assessment), and Reuel Stallones (nominated as an "alternative," without mention of

his particular expertise in cancer risk). Most of these people accepted the nomination, and they turned out to be key, influential drivers of the discussion. At this stage of the process, the NRC continued to be inspired by the experience of the CORADM, insofar as it aimed to attract first-rate scholars: Solow and Arrow were the nominee economists, and Charles Lindblom and Don Price the political scientists. None of these nominees were eventually selected, which left the committee without economic expertise. Political science was eventually represented by two political scientists who joined later in the process: Terry Davies and Ted Greenwood, both of whom would turn out to be essential to the committee's thinking, owing to their experience and primarily their understanding of the intricacies of knowledge and policy relations.[14]

As was often the case, the question of the committee chair proved to be a thorny one. In July 1981, NRC staff recommended that Press give the chair to Gil Omenn. It may be that the name of Gil Omenn was suggested to the NRC and to Press, who was personally involved in the selection of experts, by the AIHC. The AIHC had appreciated and defended the work of the OSTP and Omenn on carcinogen identification and evaluation. Omenn was also the deputy of Frank Press when the latter was the chief of OSTP.[15] Robbins, a member of the NRC staff, wrote to Press that "Gil is presently writing a monograph on air pollution and has been very interested in this question. I would consider him one of the best qualified people I can think of to do the job."[16] Omenn was given the chair just a few days later, but he occupied the position for a very short time. A full week after the first meeting of the committee in October 1981, Press asked him to step down. This change was motivated by the opinion of several members of the BOTEHH, that the position of Omenn and the OSTP for a "two-step" decision-making process--insulating science from regulatory control and leaving key choices to scientists in a central risk assessment program under the National Toxicology Program (Federal Register 1980)--seemed incompatible with examining all possible options. It seemed just too close to the chemical industry's preferred design of insulating a scientific stage and entrusting it to a science panel. Reuel Stallones, an epidemiologist and specialist of cancer and smoke from the University of Texas—and a consultant to the AIHC—was immediately appointed to replace Omenn.[17]

The Committee on the Institutional Means for Assessment of Risks to Public Health eventually comprised fourteen people. Besides Stallones, four

members provided academic expertise in environmental health and toxicity testing, particularly with respect to cancer risks. Morton Corn was an industrial hygienist from John Hopkins University and a specialist of workplace safety risks related to aerosol particles. He was also the former administrator of one of the agencies of interest in the study, OSHA (1975–1977). Vincent Dole was a professor of medicine, a member of the Institute of Medicine (IOM), another branch of the complex of Academies, and a researcher in biochemistry. He was already mostly known for his research on heroin addiction, understood as a metabolic process. Kenny Crump was a mathematician and biostatistician who had developed a reputation in the field of environmental health and regulation for his method of extrapolation from low dosage of chemicals to high dosage—a method used by the EPA at the time. Elizabeth Weisburger from the National Cancer Institute brought her knowledge of oncology and carcinogenic substance identification.

There were several experts of administration of health and environment, most notably Richard Merrill, a graduate of the University of Virginia School of Law and former chief counsel of the FDA between 1975 and 1977. He was also a member of the NRC's Board on Toxicology. Ted Greenwood was an assistant professor in political science at MIT. He was on secondment to the OSTP between 1977 and 1979, dealing with energy policy, and since then had returned to his research, dedicated to agencies' use of scientific knowledge. Terry Davies, a political scientist and early researcher on environmental policy, was a member of the group that President Richard Nixon consulted to create the EPA in 1970 (Davies 1970). He was based at the Resources for the Future think tank at the time of joining the committee.

Mediating between the two groups was a smaller subset of two men who had a mixed scientific and administrative profile. One was Rodricks, a biochemist and toxicologist by training (PhD, University of Maryland), who was at the FDA between 1969 and 1980, ending his career there as deputy associate commissioner for health affairs from 1977 to 1980. Before joining the RAC, he had left the FDA to establish a private risk assessment consultancy. He had chaired the IRLG risk assessment working group (see chapter 3). The other was Omenn.

The rest of the group was less vocal, though they contributed to the overall balance of the committee and the variety and novelty of the recommendations it would make. Two members of the committee were identified as specialists in the emerging science of risk assessment. Warner North

was a young up-and-coming decision scientist and an early developer of applications of this science to environmental and health issues. By his own admission, he was a protégé of Raiffa and other pioneers in decision science.[18] When the study began, he had already looked at such things as the process of making decisions about air pollution or chemical-related risks, both through his own research and also through his participation as consultant to NRC committees. He had founded his own consultancy, Decision Focus, after leaving the Stanford Research Institute.[19] The second risk research expert was Paul Slovic, a psychologist and pioneer in risk perception research, at the time a research consultant with his own company, Decision Research. Slovic and North knew each other since Slovic had worked with the behavioral psychologist and economist Amos Tversky, who interacted intensively with the Stanford Research Institute. Frank Mirer and William Utidjian had been selected to represent the public and the industry, respectively.[20] Mirer was a chemist and toxicologist who had spent time as a PhD candidate and postdoctoral researcher at the Harvard School of Public Health. He joined the RAC as the head of the health and safety department of the United Automobile Workers Union. He was mostly interested in occupational health chemical safety standards and the activity of OSHA. Utidjian was the corporate medical director of the chemical company Cyanamide.

Beyond the inherent diversity of backgrounds and differences in views on the science panel debate, the committee was unique in that a majority of members had some exposure to, or even experience in, administrative and regulatory affairs, either as political analysts or as consultants or staff members of these agencies or of the federal government. This probably gave the group a particular center of gravity. The director of the project for the NRC was Larry McCray, a political scientist by training, who had worked in NAS already in the 1970s, as well as at the EPA and in the White House. After Ronald Reagan's election, he returned to NAS to join the Commission on Life Science, under which the RAC had been formed. He played a decisive role in shaping the report. He recalls: "I think the thing I liked most was that we really knew what was going on in agencies. That's unlike other committees I have seen. I always say to my colleagues that we need practitioners.… This committee was different because people really knew about agencies. Rodricks, Merrill, Omenn … these are people who really respected government."[21]

The Charge, Formal and Informal

The RAC first convened in October 1981. The group set out rapidly to discuss the AIHC proposal. The committee's collective position on the science panel idea crystallized early on. The members rejected the idea on the grounds that it was too impractical for regulators and too disruptive of their functioning.[22] But the committee had to take into account another contextual element, which played out in favor of *more* separation of science from policy: the ongoing scandals about the intrusion of the EPA's political appointees in the work of health and environmental effect assessors.

As the committee was meeting, the EPA was rapidly falling into an institutional crisis. Ann Gorsuch succeeded Douglas Costle as Reagan's appointed administrator for the EPA in May 1981. A district assistant attorney, Gorsuch had virtually no experience in Washington policymaking or public administration. The main reason for nominating her for the job was that she was a Reagan enthusiast and a good soldier for the budget-cutting and regulation rollback campaign that the president was launching against social regulation. Most of her leadership of the EPA was inspired by the goals of curtailing the agency's capacity to make decisions and issue standards, drastically reducing staff and budgets overall, closing the enforcement office, encouraging regional offices to settle issues instead of going to court, and requiring more detailed review, by senior officials or by the SAB, of the standards prepared by the various offices (Layzer 2012).

A sense of crisis very quickly emerged after she took office. Hearings held at the House of Representatives in October and November 1981 give a sense that the EPA was in the largest crisis of its young existence was already spreading in Washington, D.C., well beyond the federal government and through the business and environmentalist communities. At the hearings, an emphatic Toby Moffett (a Democrat from Connecticut) opened the session by stressing the exceptional nature of what was going on at the EPA at the time and the willingness of Congress to question and take on the leaders of the agency directly.[23] Moffett's concerns were quite widely shared. But the worries of the chemical industry were no less substantial, as an article in the October 21 issue of *Chemical Week* signaled.

News had emerged, in particular, of wrongdoing around the use of scientific arguments to prevent regulatory developments in the agency. John W. Hernandez, the deputy administrator, had held closed, unannounced

meetings with industry representatives. These so-called science forums—which were called "science courts" by Hernandez in his letters of invitation to industry groups, betraying his proximity to the proposal floated by the AIHC (EPA 1981a, 1)—were held on six occasions in 1981 for high-profile chemicals considered under the TSCA—formaldehyde and DEHP—and served to cast doubt on the value of the scientific studies that established the risk and toxicity of the substances, including the EPA's own in-house estimates. Hernandez, who conducted the meetings alone, put the emphasis on the exercise of quantitative risk assessment, reminding everybody that "a thorough and independent scientific review of the evidence that relates exposure to pre-established dose-response effects must precede any regulatory decision" and that "scientific review, as a process, must not limit the policy-making authority of the administrator. Instead, good science, with ample peer review, must be the foundation for all appropriate Agency decisions." This authorized him to reject the "questionable assumptions" that underpinned the risk extrapolations of his own staff (EPA 1981b, 7).

Other direct interventions in health assessments included Hernandez sending a health assessment performed by agency staff to Dow Chemicals and deleting portions of the text arguing that Dow's manufacturing complex in Midland, Michigan, was the main source of dioxin pollution in the region. John Todhunter, the assistant administrator for toxic substances and pesticides, was no less bold: in the spring of 1981, his staff had come to the conclusion that, given a recent study by the Chemical Industry Institute of Toxicology showing a link between formaldehyde and nasal tumors in rats, the substance should be designated for priority review (Jasanoff 1987a). Todhunter reversed this decision in a memo to the EPA administrator from February 1982,[24] in which he single-handedly declared past exposure estimates to be "completely incorrect." Against the weight of evidence traditionally considered by the agency, Todhunter used the existence of one negative study to justify not regulating the chemical. He also overrode the existence of a positive carcinogen test in animals, arguing that the product was probably genotoxic, and thus exhibited a threshold. He lowered the EPA's typical acceptable risk threshold of one cancer in 1 million to one in 100,000 (US Congress 1982). Most of these interventions in science were judged illegitimate because they originated from political appointees, with a clear agenda of delaying or halting the regulation of major products. The interventions did not go unnoticed, precisely because these products and

environmental problems were in the news anyway. These cases were widely publicized through congressional oversight hearings and media inquiries.

These widely decried political interventions in the science of chemical risks constituted the public backdrop in which the RAC was due to arbitrate for or against the proposal of the AIHC to disempower regulatory agencies to perform risk assessments. In a sense, the problems caused by Hernandez and Todhunter lent support to the AIHC's proposed institutional scheme. Their behaviors were breaching a well-accepted norm of independence of science, and of mutual autonomy of science and decision-making, on which the AIHC was capitalizing to deploy its enterprise of limiting the powers of regulatory agencies.[25] But the RAC quickly took distance with the science panel idea, because it was a clear attack on and a potential disruption of an institutional system for which the RAC saw no need.

From a Linear Scheme to a Modular Framework

To develop its recommendations, the RAC first clarified the components of the design of science-based decision-making on risks. The group had quickly realized that it was missing definitions that were key to simply mapping out what regulatory agencies were doing when they were dealing with uncertain hazards, as well as where lines could be drawn between science, policy, and other aspects. According to McCray, the construction of the definitions that eventually composed the risk assessment–risk management framework, of which RAFG is so often given as the source, "was really an internal thing."[26] At no stage did the group seek to draw up the formal framework that RAFG is now credited with providing, and for which it is now famous. Furthermore, there was no intention (let alone a mandate) to standardize the practice of regulatory agencies based on that scheme. Ironically, what was later to constitute a renowned framework were the definitions that the group designed for itself, to give some order to the set of terms that had emerged in recent years to characterize risk knowledge—from *risk assessment* to *risk analysis*, through *risk evaluation* and *health assessment*. The definitional work required was a way to manage the various viewpoints inside the committee, where contradiction, or conflict, was evident. People with a background in biological sciences were not accustomed to considering that scientific practice, even for regulatory purposes, might be informed or underpinned by values, whether implicit or explicit.

Stallones, Corn, Crump, Dole, and Weisburger were designated by Davies as the "science camp": those people from biology, broadly speaking, who were most likely to defend the idea that risk assessment is science and that science is objective and not influenced by values (Davies 2003). The "social science group," or the "values side," were considered to include those who initially would be more inclined to defend the view that risk assessment is a mix of scientific and political values. But others in the group did think along those lines, and rather than sweeping the issue aside, they addressed it head on.

The particularity of that committee was that it acknowledged that there was a need to analyze risk analysis—that is to say: to unpack it, clarify what it was made of, schematize it, repackage it, and define what would be a proper institutional shell for it. Larry McCray did an essential part of this work in what he termed his "anatomy of risk assessment" (McCray 1983). The anatomy of risk assessment was really an X-ray of uncertainties and "assumptions"—not "values"—intruding on the process of health and effects assessments, which listed the thirty-six points at which choices are made in a risk assessment process. In that forensic study of the exercise of scientifically assessing risk, McCray showed that multiple choices were being made at all levels based on professional judgment, experience, and, possibly political preferences. Indeed, risk assessment is nothing but a series of "discrete decisions," a sort of scaffolding of judgments that allow one to produce the final estimate (ibid., 83).[27] The anatomy was essential to define the utility of guidelines: These were tools to explicate the numerous choices, many of which were extrascientific, that were made in the course of analyzing cancer data. It was decisive (Jasanoff 1987) to inspire the group's conclusions on the need to keep risk assessment and risk management in interaction, and to reject the science panel idea. These assumptions are the ground where scientists responsible for calculating hazards and bureaucrats defining the standard meet.

The group also benefited from the many hours of presentations by members of the EPA, FDA, and other early practitioners of risk assessment. Elizabeth Anderson, from the EPA's CAG, in many ways the precursor of risk assessment in the federal government, spent a great many hours with the committee outlining the meaning of the terms in use in the agency, or at least in certain parts of it. Therefore, the RAC did not start from scratch. The EPA was already in the process of self-codifying and schematizing its work,

defining for the purpose of its guidelines the meaning of *risk assessment, health assessment, dose-response assessment,* and the like. The RAC invested even further in this conceptual work, drawing from Lowrance's 1976 book *Of Acceptable Risk: Science and the Determination of Safety*, which Slovic distributed to the group to consider. The committee also surveyed how various agencies were organized to produce and use scientific data, identifying the pros and cons of each organizational model.[28] Those who worked on the survey were not the natural or medical scientists of the committee, but a lawyer and two political scientists: Merrill, Davies, and Greenwood. In parallel, the project director, McCray, a political scientist, surveyed the mechanisms for institutional separation and the current agency practices.[29]

Whatever the source of the inspiration, the RAC showed particular agility in assembling the set of terms to formulate a cohesive, integrated scheme that would describe the whole of the regulatory process. They assembled and simplified the representation of environmental scientific assessment and decision-making. Traces of this work are apparent in the draft frameworks shown in figures 4.2 and 4.3.

From this sequence of figures (the graph on page 21 of RAFG, reproduced in figure 0.1, being its final form), the following process can be inferred. The first move was the semantic *generification* of risk assessment, under which four clearly defined and distinct operations were progressively subsumed. The notions of risk assessment, risk assessment policy of the analytic process, and others already existed in the bureaucratic or scientific discourse.[30] But a diverse range of definitions and schemes coexisted (Lave 1982; OTA 1981). In documents of the EPA predating RAFG, risk assessment was used alongside other terms, but with considerable variations and confusion. For people in the OHEA, risk assessment covered the quantitative work of computing a dose-response curve. Combined with exposure assessment, it produced the synthetic estimate of the excess risk. By 1982, however, things were changing in other parts of the EPA, but the actual place of quantitative extrapolation and calculations in the procedure was not completely clear or free of contradictions. In the 1982 document of the Water Office (EPA 1982), the term *health assessment* defined the hazard that may potentially be derived from being exposed to a chemical, and included what the OHEA termed "risk assessment" ("the quantification of the carcinogenic risk, the threshold for acute and chronic toxicity, the impact on sensitive populations, the ADI …"). Exposure assessment reviewed not only the data on the

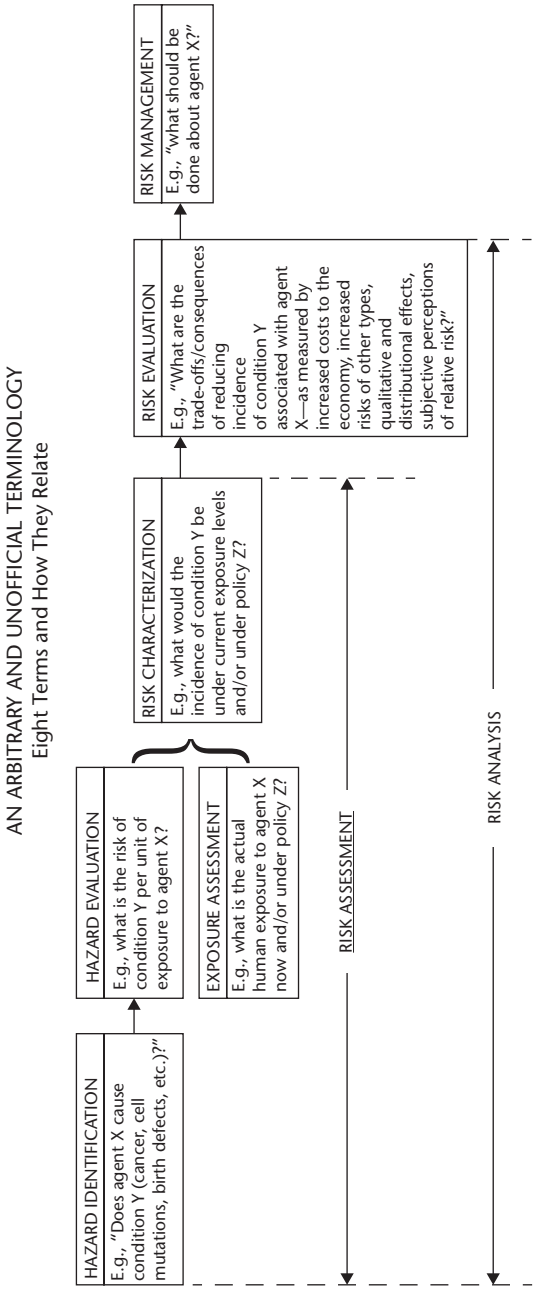

Figure 4.2
First draft of the institutional framework for risk decision-making composed by the NRC's RAC.

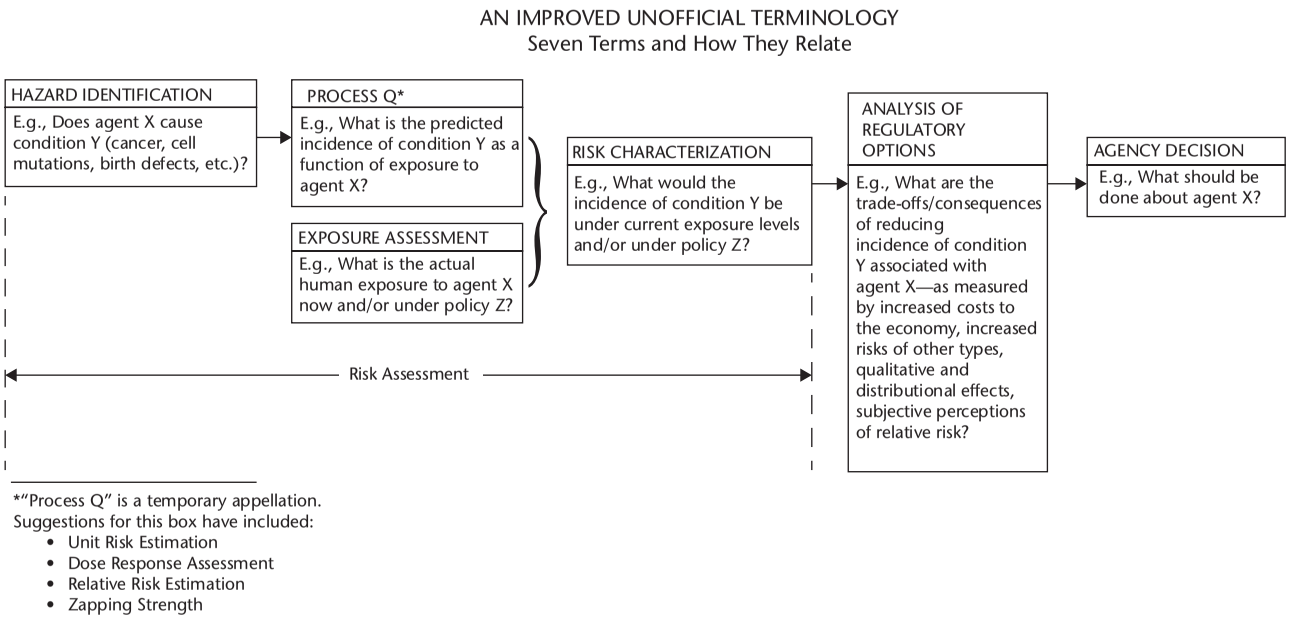

Figure 4.3

Second draft of the institutional framework for risk decision-making composed by the NRC's RAC.

size and nature of the population and species exposed, but also the technology for controlling this exposure. The risk assessment part combined the first two components through an estimate of the likelihood that the hazard would materialize in the indicated population. It also included references to regulatory and nonregulatory control options. Throughout the document, risk assessment was used in lieu of the generic health assessment notion.[31] In the report of the Raiffa committee (NRC 1982), assessment was always twinned with evaluation (as discussed previously). So risk assessment was not a generic category under which exposure and hazard assessments could be subsumed. Figures 4.2 and 4.3 show that the specific contribution of RAFG is to have promoted, or generified, the notion of risk assessment, not by inventing it from scratch, but rather by promoting it and dropping other parallel terms.

The stage 2 graph mentions "temporary appellations" and displays the options that were being considered. The committee was explicitly in the business of forging workable, collective, and one could even say conventional appellations, as opposed to exhaustively and objectively describing the practices of agencies. In fact, an appendix to the report ("Anatomy of Risk Assessment") was dedicated to this sort of description of the thirty-six steps of risk assessment. The report went further in the direction of modeling risk assessment through a set of parsimonious (and, by necessity, more generic) categories. Four clearly delineated operations, corresponding to well-identified disciplinary expertise, were defined specifically as the four steps to populate the rubric of risk assessment. Genericization also provided a way to hold together the necessary emphasis on quantification of risk and to preserve the narrative-based interpretation of risk in risk characterization—something for which Omenn pushed.

The second move (which was somewhat surprising for a committee that was meant to focus on risk assessment) was its invention of the generic notion of *risk management.* Until then, that term either referred to an engineering exercise involving the design of systems to render them less risky, or it was so broad that it was an ineffective technology to use to make a decision (e.g., NRC 1982). The committee focused the definition of risk management on the notion of policy alternatives, based on various analyses and evaluations (of benefits, costs, social values, and other elements). It became "the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment

with engineering data and with social, economic, and political concerns to reach a decision" (NRC 1983), much in the way the AIHC or members of the nascent risk analysis community were starting to use it. One of the members of the AIHC, Shell's Vice President for Health, Safety and Environment, Paul Deisler, had introduced the term *risk management* in just this fashion, through the linear scheme shown in figure 4.4.

As a consequence, risk management became a broader category than *risk control* or *decision and action,* and also a recognizable, autonomous activity. The notion of policy alternatives also precluded the impression of the definitiveness and authoritativeness of the concept of *decision,* and also of a mechanical move from science to decision. Risk management was a weighing of options as a relative, revisable judgment, with an inherent temporal dimension. It was very well suited to an agency that worked through controversial decisions for decades, without ever reaching closure, and that wanted to evolve toward more fine-tuned prioritization and comparison of risks, as in the Toxics Integration initiative.

The third move, which resulted from the first two, was the elimination of the controversial notion of *risk evaluation.* In previous NRC reports, as well as in public discourse, values had consistently been a bone of contention and the main problem in the concrete allocation of tasks and responsibilities for decision-making. Of scientists, economists, lawyers, or administrators, the question of who would be the evaluator designated in previous expert reports, such as that of the NRC Committee on Risk and Decision-Making, was fundamentally ambiguous. The work that the RAC did on risk terminology unlocked this problem by simply dropping the term *value.* In the proposed architecture of terms, structured by notions of risk assessment and risk management, it simply became unnecessary. It was replaced by a more straightforward language of choice among scientific assumptions.[32]

The political dimension of risk decision-making was covered by the symmetrical notions of risk assessment and risk management. Both activities were conceptualized as similar, insofar as they grappled with uncertainty. In previous reports and proposals, such as the one by the AIHC, uncertainty was supposed to have been dealt with and eliminated during a prior scientific stage. Now, risk assessment and risk management covered the political aspects of dealing with risk, which took away altogether the need (at least provisionally)[33] to speak of values. Risk evaluation was replaced by a much more positivistic notion of *risk assessment policy.* In a clear act of

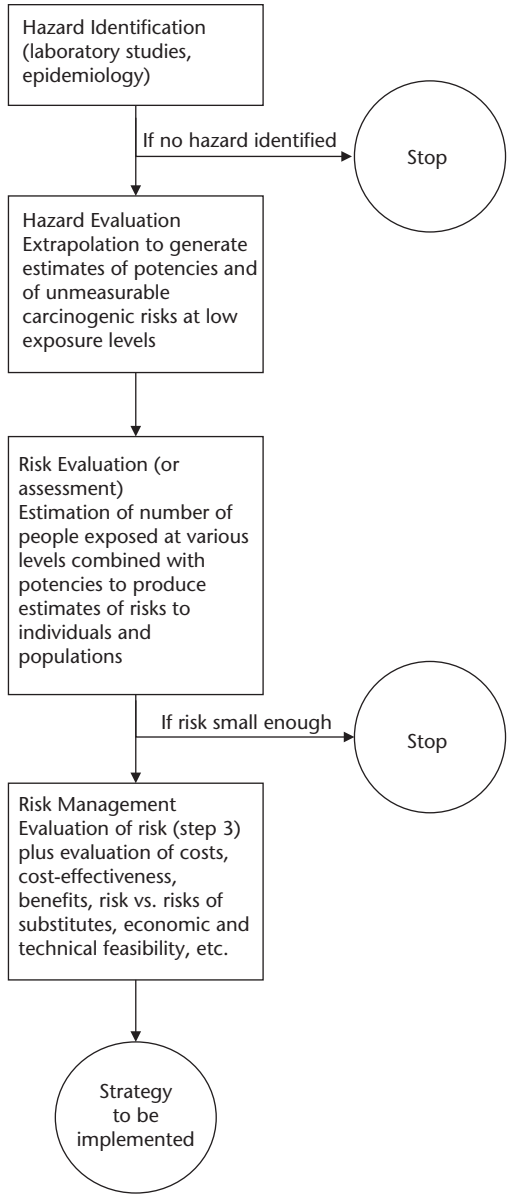

Figure 4.4
The graphical framework for risk decision-making of the Office of Technology Assessment (adapted from OTA 1981), based on Deisler's notion of risk management.

simplification and deconflictualization, that facilitates the packaging and commodification of this knowledge of decision-making (Suddaby and Greenwood 2001), a term was coined to embrace all the judgments made by assessors in the face of uncertainties and gaps in their knowledge, as listed in McCray's important annex. Interestingly, uncertainties, assumptions, and risk assessment policies were neither represented in the graph nor included in the set of highly cited definitions on page 3 of RAFG. As a result, the idea did not travel much with RAFG and was mostly traded for an even more positivistic idea of science policy (Jasanoff 1995); more on this topic is covered in chapter 5.

The combination of the two generic terms of *risk assessment* and *risk management*, which took the place of *science* and *decision* that had been used more frequently until then, made it easier to envision a variety of ways in which science and decision-making could be articulated in practice. The report made it clear that the distinction between risk assessment and risk management closely parallels the distinction that the OSTP report had made, three years earlier, between a first stage of identification and characterization of chemical substances and a second stage of evaluation of regulatory options. But in the work of the RAC, the linearity of the sequence was somewhat minimized: A regulatory decision was depicted as the product of two activities of risk assessment and risk management running in parallel, not the end sequence of a linear process starting with assessment. The RAC thus effectuated an important and innovative terminological construction in which regulatory decision-making in the face of risk ceased to be represented as a linear process of science informing policy. Instead, it was seen as the assemblage of two concurrent activities—namely, risk assessment and risk management—one of which was rooted in environmental and health sciences, and the other in economic and regulatory analysis.

The group effected a move from a representation of risk calculation as a "rigid formula"[34] to a depiction as "concomitant processes." These terms form what could be called an institutional thesaurus. In that lexicon, the terms had either an associative relationship (risk assessment/risk management) or a hierarchical one (*risk assessment* being the generic term for the four specific operations of hazard identification, dose-response assessment, exposure assessment, and risk characterization). The terms could be combined to shape the process of risk regulation. The thesaurus served to index, flexibly, different types of policy content, as well as to distinguish how

and when to employ them to shape a regulatory decision. This was a very effective scheme, not just for making decisions, but for making sense of risk politics, comparing different agencies' organizations, highlighting the importance of guidelines, and demarcating zones of ignorance and judgment from zones of knowledge and fact. The whole design, one could say, is generative rather than merely representational (Drucker 2014).

The subtly intertwined and abstract definitions of risk assessment and risk management were an alternative to the science panel. The committee refrained from imposing a single organizational template and becoming involved in the design of local applications of a general scheme. It adhered to a higher-level, somewhat codified (if not coded) discourse on the associative relationship between risk assessment and risk management. The concepts conveyed the idea that it was not advisable to remove risk assessment from regulatory agencies.

Reading *Risk Assessment in the Federal Government*

By September 1982, people in the NRC were convinced that the committee's work would have a greater impact than other NRC reports had had. First, it had aroused the interest of many in Washington, and expectations had increased. Moreover, the press had covered the work already, as the committee was progressing. On January 15, 1982, the *Environmental Health Letter* reported: "Regulators Urged to Separate Facts from Values in Risk Assessment." A month later, the newspaper *Food Chemicals News* published an article titled "NAS Committee Urged to Consider Guidelines for Risk Assessment," reporting on a public meeting held by the RAC on February 10.[35] When the report reached reviewers, it soon seemed that the new formalism would have palpable effects on the understanding of science and policy conundrums in regulatory agencies.

The introduction to the report pointed out that the context in which the charge emerged was one of controversy and conflict. Then it moved directly to the presentation of those now highly quoted and institutionalized definitions:

> Regulatory actions are based on two distinct elements, risk assessment, the subject of this study, and risk management. Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy

alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision.

Risk assessments contain some or all of the following four steps:

- Hazard identification: the determination of whether a particular chemical is or is not causally linked to particular health effects.
- Dose-response assessment: the determination of the relation between the magnitude of exposure and the probability of occurrence of the health effects in question.
- Exposure assessment: the determination of the extent of human exposure before or after application of regulatory controls.
- Risk characterization: the description of the nature and often the magnitude of human risk, including attendant uncertainty. (NRC 1983, 3)

This definition drew from the work of McCray, appended to the report as a working paper on the anatomy of risk assessment, which defined the concept as a combination of "a hazard identification or a dose-response assessment with an exposure assessment" (McCray 1983, 84). This meant that it compounded knowledge of how hazardous the risk object was in different conditions (meaning, for a chemical, at different levels of exposure or dosage), with knowledge of how many people lived in those conditions. The outcome turned out to be increased knowledge of when and where (or for whom) the harm was likely to materialize. In RAFG, these definitions were represented in a general diagram depicting key operations and mechanisms in shaping regulatory decisions (see figure 4.1, earlier in this chapter). The committee spent very little time on this diagram, but it was the form under which the report traveled by far the most.

The definitions were laid out in chapter I of the report, drafted by Warner North. Armed with these terms, the group then focused on what it called the "tricky issue" of how to handle the relationship between risk assessment and risk management, as well as between science and policy. The remainder of the report thus addressed the interplay between risk assessment and risk management, notably through the use of guidelines (chapter II, drafted by Rodricks) to clarify the respective ambit of politics and of science in the process, and the organizational arrangement of these interactions (chapter III, drafted by Merrill).[36] Chapter IV detailed all ten recommendations.

The report argued that the main political problem in risk decision-making was not whether and how science should inform policy (or vice

versa), but a practical issue of making sure that choices pertaining to the analysis of hazards and uncertainties on the one hand, and to regulatory strategies on the other, were made not only transparently and separately, but also in full awareness of one another. Risk assessment and risk management were both in dialogue, and yet transparently distinguished from one another. This rule was most important for what the report called "risk assessment policy"—that is, the models and assumptions that the various scientists performing the calculation of the risk chose to apply. In the words of recommendation A in the report: "[R]egulatory agencies [should] take steps to establish and maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic and technical considerations that influence the design and choice of regulatory strategies" (NRC 1983, 7).

In the rest of the report, and in the appendix in particular, risk assessment was clearly presented as a mix of science and policy. Originally, the report argued that there was politics in risk decision-making throughout the process, in both risk assessment and risk management. This was stated several times in the report, notably on page 7 (recommendation A), and was also noted in subsequent presentations of the report around Washington. In his 1983 testimony before the Committee on Agriculture of the House, Rodricks expressed it thus: "One central point [in the report] is that, while subjective judgments that have policy implications—particularly on the degree of conservatism that should be applied in areas of scientific uncertainty—may be an inherent part of risk assessment, certain other types of policy considerations, such as the economic importance of a substance, should not be permitted to influence risk assessments" (US Congress 1983c, 360). In short, there were politics or elements of policy throughout the regulatory decision-making process, but some were classified as ingredients to assess risks, and others as ingredients to manage them. Both, however, were equally political, which is why neither could claim to have the upper hand.

Admittedly, there was residual ambiguity in RAFG as far as uncertainty was concerned.[37] The definitions on page 3, in the summary of the report, seem to exclude uncertainty, defining risk assessment as the use of "the factual base" to define risks. Nowhere was it mentioned that it incorporated inferences or assumptions to compensate for missing data. Recommendation A

presented risk assessment as a compound of "scientific findings and policy judgments," but again emphasized very little the uncertainty of the whole exercise. "Risk characterization" was the only module in the whole exercise that seems to involve uncertainty. So the summary was expurgated of almost all uncertainty. These first pages were written by Stallones, the chair of the committee, whom Davies placed in the so-called science camp (Davies 2003). Those who defended the view that risk assessment was a mix of science and policy were rather unhappy when they discovered the content of those pages—but it was too late to make any amendments to it before publication.[38] Another ambiguity lay in the general design of the process: Was risk assessment a sequence of necessary and logical steps—as in the stylized decision tree depicted on the cover—or not? Page 3 spoke of "steps," but also mentioned that a risk assessment might contain "one or more" of the components of the framework. On page 21, the graph contained "elements of risk assessment," but described a converging flowchart, in which most elements seemed interdependent and necessary. That graph, which arguably circulated more than McCray's appendix (in which uncertainties and corresponding inferences were detailed), made no mention of uncertainty, or even of the crucial category of "risk assessment policy" that denoted the space where policy and science were hybridized.

The other two general recommendations essentially concerned the issue of guidelines. Recommendation B recommended that agencies develop what was termed "uniform inference guidelines"—namely, a document listing, as comprehensively and in as much detail as possible, the choices that risk assessors might make in the course of a risk assessment. Recommendation B derived from chapter III of the report, where a highly informative and clear history of the effort of creating guidelines in regulatory agencies was recounted. These lines of the report were also extremely helpful to make sense of what the guidelines actually were and why they were an important instrument. The report spoke of "guidelines," not to refer to any official legal pronouncements of procedure satisfying legal requirements, but rather "the principles by which risk assessments are to be performed." The report used this definition "because that is the term Congress used in the legislation that authorized this study" (NRC 1983, 52), and because the term had gained currency since its use by the EPA and the IRLG.

Recommendation C advised the federal government to create a central board for risk assessment methods, whose function would be, among other

things, to review the guidelines adopted by regulatory agencies, and to ensure that they were in keeping with the advancement of scientific knowledge in the area. That recommendation read like a balancing act: The report clearly accredited the need to change something to the current institutional organization of science-based decision-making and of regulatory agencies, but it also went against the AIHC proposal to take risk assessment away from agencies, which were perceived as too disruptive.

The reviewers of the report noted how the report furthered understanding of the processes and politics involved in regulating controversial substances. NAS generally organizes a very strict and demanding review process for each of its reports.[39] The review of RAFG was no exception. In fact, Al Lazen of the NRC made sure that the review would be even more stringent than usual. Six months later, the reviews arrived on the chair's desk, and they were excellent. One reviewer was of the opinion that the report was first rate and provided "an excellent analysis of the subject, stated with exceptional clarity. The clear separation of risk assessment and risk management is particularly helpful." Another stated simply that "the overall report is superb … well-written, very balanced, extremely timely, and offers lucid, realistic and intelligent conclusions and recommendations." Two others stressed that the "workable" and "reasonable" recommendations would definitely improve the situation. Stallones commented to his fellow committee members, a few weeks before the report's release: "The general comments of the NAS were so good that I have included them as an appendix to this memo. When your car won't start, your students won't study, your rats won't die, or your boss just won't, then you pull out these pages and read them again, and bask in the warmth of well-deserved praise."[40]

The analytical quality of the group goes a long way to explaining how and why this integrative, simplified outcome could be reached. The NRC staff had found that the job was of relatively high quality, despite an uncommon and complicated institutional mission. Lazen, the head of the Life Sciences division of the NRC, who oversaw the committee, wrote to Frank Press: "The committee is one of the most intellectually gifted I have had the pleasure to deal with. The chairman, after a slow start, is now a very strong and effective leader who will do very well in front of the press or a congressional hearing. The report's acceptance and impact will depend in large part on the credibility of its authors as individuals, and here we are on firm ground."[41] The members of the panel, in retrospect, readily

praised one another's intellectual quality and breadth of knowledge about risk assessment and agencies. McCray was described as a "superb analyst," Rodricks as someone who was able to grasp the science and yet understand the institutional and political big picture as well, and Merrill as a first-class mind and legal scholar.[42] The decision-theoretic perspective brought in by Warner North was also recognized as a crucial component in the committee's collective capacity to articulate an effective knowledge representation. The intellectual and political diversity of the group, combined with the effective direction given by the NRC staff and the chair, contributed to turning the committee into a place where things that were conflicting outside could be discussed inside.

Thus, there was a fine line between success and failure in the work of creating frameworks. In this particular case, the committee could very well have failed due to the inability of the members of the group simply to communicate with one another and to engage in the elaboration of a common view. There was actually a real possibility that this would happen. Lazen, ex post facto, wrote to the chair with the following words of gratitude: "How you got a consensus out of such a vocal and diverse group will always be something of a mystery to me—but I'm not knocking it!"[43] The immediate, instrumental action of the new EPA administrator, with the proposed design, soon showed that he was exactly right.

Conclusion

The episode of the writing of RAFG richly illustrates how and why, in their diversity, experts of science and of its use in decisions can foster the design of legitimate administrative forms. It demonstrates how this form of science can bring order to an area of governance otherwise steeped in public controversy, interest group conflicts, and interinstitutional disagreement. The moment that a report on the legitimacy of regulatory agencies to analyze and regulate risks was requested from the NRC is one of intense controversy around particular chemicals and the risks they cause, but also and more broadly, around the legitimacy of regulatory agencies to intervene to control these products. It is also a configuration in which scientists with an experience in administration, with growing social capital and reputation in Washington, D.C., as well as a common belief in the possibility to invent acceptable decisions thanks to science, were brought together. A

configuration, finally, that sparked multiple processes of abstraction, formalization, and standardization of new designs for decision-making, underpinned by different representations of what comprises legitimate bureaucratic knowledge and technology.

What is particular, in the case of the RAC, is that it concentrated a collective capacity to commodify knowledge, deriving in this case from the application of a decision-aiding perspective and an ability to think in terms of process; an ability to insert one's contribution into a longer history of codification and to build on elements of already genericized and tested bureaucratic knowledge; finally (and perhaps more important), the internal diversity of the group functioned as an initial trial for the framework, which made it resistant, presumably, to subsequent trials and controversies in the wider world. Frameworks, this case shows, result from the modeling of intraorganizational diversity, its components, and their assemblage. They successfully emerge where the diversity that is modeled in the framework is represented in the very site in which it is designed and in its content.

It is frequently argued that the RAC constructed a new framework, almost ex nihilo. This chapter illustrates the concrete work involved in creating an organizational and administrative order, by renaming and articulating the elements of decision-making that were already emerging from the practice of agencies, and their own, initial design work. The committee was less inventing new elements of a framework than working to articulate already-identified elements, renaming them so that they become part of a process that appeared to respond to the expectations about what people in an agency should or should not do. Its most original product is also the one that is less often cited: it is the formalization of a notion of risk management. The notion allowed rearticulating science and policy in a way that administrations such as the EPA—an agency that the experts knew of and in some sense defended—could recognize and appropriate. It asserted the decisionistic design emerging in the agency, combining the calculation of risks using medical, toxicological, and statistical expertise, and the use of criteria of cost, benefit, and policy opportunity, which help compel a decision and end a dispute. The framework uniquely recognizes the place that health scientists and economists were in the process of carving for themselves in the agency. The posterity of RAFG was in no manner written. But the configuration in which it emerged made it a potentially influential design effort. What happened, nearly as and when it came out, confirms this point.

The Science of Bureaucracy

Risk Decision-Making and the US Environmental Protection Agency

By: David Demortain

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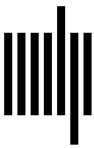

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