

## 8 The Rise and Fall of Comparative Risk Assessment

The leaders of the EPA may draw on a variety of possible designs to represent what the agency knows and what it does effectively. There are different ways of formalizing its generic object, the kinds of knowledge it uses to make its decisions, and how it manages to forge decisions on highly disputed issues. These designs vary according to the political configuration in which the agency is caught—the networks of supporters or adversaries that form around environmental issues and its action on these uncertain issues, and the inevitable controversies that ensue. The ambition to systematically measure the risks, costs, and benefits associated with decision projects lasted for most of the 1980s, despite some doubts as to the importance that William Ruckelshaus's successor, Lee Thomas, would grant to this technology, particularly after the departure of Alvin Alm, the deputy administrator who championed cost-benefit analysis and instilled the motivation in the agency to use that kind of information.

At the end of the 1980s, in a new configuration marked by renewed controversies over the EPA's priorities—stemming from its treatment of the discovery of supposed widespread risks from exposure to the gas radon and the pesticide alar, pressures on its budget in an aggressive Republican administration, and a changing national environmental agenda—the commensurative design assumed greater importance. During the term of Thomas (1985–1989), and even more so during the stint of Bill Reilly (1989–1993), efforts were made to create new knowledge representations and technologies to link risk assessors of various program or regional offices, so as to extinguish the uncertainty caused by these offices' nebulous and variegated ways of deciding which risk matters, and closing subsequent controversies concerning the EPA's inability to focus on the right subject. This mainly

took the form of comparative risk assessment, a design that was concretely, albeit fugaciously, instituted in the agency between 1990 and 1992 thanks to Administrator Bill Reilly and his policy chief, Terry Davies, a member of the team that had designed the agency in the early 1970s and a long-time critic of its structure in regulatory silos. The mandate of Carol Browner, the first EPA administrator to be appointed by a Democratic president, in January 1993 marked a major shift, with a clear renegotiation of the role of risk assessment and cost-benefit analysis in EPA policies.

### Bringing in Comparative Risk Assessment

In his job as assistant administrator for solid waste and Superfund between 1983 and 1985, Lee Thomas had frequently been in conflict with OPPE about his proposed decisions. When he succeeded Ruckelshaus in March 1985,<sup>1</sup> he felt that assistant administrators should regain some autonomy and be able to prepare and finalize rules without systematically referring them to the deputy administrator or to the administrator, as under Alm's cross-agency decision-making system (see chapter 6). Milton Russell and other managers of the OPPE, therefore, feared that under the new administrator, they would lose the transversal, policy development role that Ruckelshaus and Alm had instituted.

Russell devoted a good part of his energy in 1985 to convincing Thomas that the OPPE could play a very beneficial, supportive role in program offices. He particularly insisted that giving too much weight to program offices again could create problems: "In general, centrifugal forces in this Agency are powerful and engrained in its structure. Checks and balances are resisted. It will require constant attention to keep on track."<sup>2</sup> Russell maintained that the OPPE was there to make sure that all regulatory options were considered when the offices proposed a rule, and that cross-media problems were taken into consideration, even though program offices developed their decisions independently. In his view, the OPPE really should be considered a consultant to the administrator, helping to improve and evaluate the quality of decision options, and warning of potential future issues.

As the administrator, Thomas carried on using the same risk assessment–risk management language as the public reflection of the EPA's mode of action and goals as Ruckelshaus. In an address to the petrochemical industry, for instance, he reiterated that the EPA aimed to ensure continuous

protection of the environment in the context of preserving economic growth, and that it did so “by carefully assessing the risks we face as an industrial society, and managing those risks effectively.”<sup>3</sup> He took care to define the two processes of assessment and management, as though the creed needed to be further inculcated: “To assess the risk at hand, we gather as many facts as possible about the problem. This is a scientific process in which experts thoroughly review the extent of our knowledge and carefully design and conduct experiments to expand that knowledge. This scientific process gives us a basis for understanding the risk we face. It tells us what the risk is, what we know about it, and who is exposed. Then comes the hard part—risk management—deciding what to do about a problem once we are sure there is one.... The options before us include such things as new regulations, additional reporting requirements, new outreach programs or some combination of these and other approaches.” Thomas soon endorsed the OPPE in its role, both as participant in the development of regulation by program offices and as monitor of the quality of these regulations. But he also pushed Russell to abandon an overly confrontational posture and to work as a consultant to offices for the development of their risk, regulatory, or cost-benefit analyses. In short, the idea was that the OPPE should be there to “push risk assessment/risk management,”<sup>4</sup> but not to do it instead of program offices, or to counter what program offices did.

The OPPE soon found a specific role for itself, which had not been attempted under Ruckelshaus: that of ranking and prioritizing issues for regulatory attention for the whole agency. Ranking risks, first, had the advantage of corresponding to Thomas’s intention to rebalance the agency’s agenda overall. A concern emerged in the mid-1980s already, that the EPA was dedicating too much attention, at least at the administrator level, to issues of health. At the time of writing of the flagship EPA report *Risk Assessment and Management: A Framework for Decision-Making*, several assistant administrators were concerned that the agency’s leadership was placing far too much emphasis on health issues, when many program or regional offices were in fact struggling daily with pollution and environmental quality issues. Thomas, then assistant administrator for waste, was among them. Now the administrator, he was less inclined than Douglas Costle or Ruckelshaus to put emphasis on health protection as the global agenda for the agency. Between 1983 and 1985, he had managed the solid waste and Superfund programs, where health issues were not as predominant as in the

Air, Water, or Toxic Substances offices. Moreover, in the second half of the 1980s, the public's concerns seemed to be shifting back toward ecological threats as much as the health effects of chemicals—whether carcinogenic or other. Acid rain, protection of the ozone layer, or more localized cases of vast beach pollution were as frequently in the news as were chemicals. At the senior conference of May 1985, before his assistant and regional administrators, Thomas put forward four priorities, among which was the preservation of a strong scientific and technical capability, particularly from a cross-media perspective.

Second, there were a lot of ideas and competences in the OPPE for performing risk comparisons. This was not a new concept. Comparative risk assessment was already well established in the field of risk analysis (see chapter 2), and Dan Beardsley had developed a scheme to this end in 1977, in the context of toxics integration work. His Environmental Integrated Assessment Division was, overall, the comparative risk assessment shop in the agency. Beardsley had already advised Russell in 1984 to capitalize on the comparison among office priorities in order to prove the value of the OPPE's participation in interoffice deliberations. He argued that risk analysis, as a method for comprehensively reviewing issues and putting them on the same plane to orient broad decisions, was more valuable for the agency and the rationality of its policies than individual, in-depth risk assessment of substances. Rational and justifiable priorities for the agency would emerge from synoptic consideration of all issues, not from concentration and investigation of one after the other. Consistency mattered more than accuracy. Or, in Beardsley's words: "It is the continuing, consistent use of risk analysis that we believe is desirable."<sup>5</sup> The implication for the OPPE, which did not have the same level of access to the scientific data that program offices had, was to avail of its own data on environmental issues and to quantify and rank them. What the OPPE had was information about budgets for each office and program. Beardsley suggested to Russell that he compare the broad levels of risk for each environmental program across the agency, with the budget levels and priorities established by statute.

The OPPE inaugurated formal comparisons of risk in 1986. That year, Robert Wolcott, an economist in the office of policy analysis, undertook a comparison of the risks, costs, and benefits of a set of agricultural chemicals. The motivation was political: Thomas wanted to initiate more special reviews of pesticides than had been the case in the past.<sup>6</sup> In October 1986,

Thomas imposed an emergency ban on the pesticide dinoseb, and a definitive ban was concluded with the concerned companies in the middle of 1988. At the time, alar, and the hazards of its breakdown products to children and young people through consumption of apples, was prominent in the national news. The work of Wolcott would help in selecting products for special review and give managers resources to detect potentially concerning pesticides before they made it into the press and started to rock the agency's work program and priorities. The *New York Times* reported on the results of the comparative risk assessment of 1986 with an article headlined "Pesticides Finally Top the Problem List at E.P.A.," putting forward the words of the new head of the pesticides division, Steven Schatzow, that "[t]he pesticide problem is worse than ever" and that "virtually everyone" was exposed to that risk (Shabecoff 1986, B12). The EPA had rarely, if ever, singled out a class of risk in such a way in its young history.

In 1986, also at the request of the administrator, the director of the Office of Policy Analysis, Richard Morgenstern, began outlining a study to compare the risks addressed by the agency's major program elements and activities. The expansion of risk assessment techniques, along with increasing standardization due to guidelines, offered a chance to compare the issues that the various offices were dealing with. But the exercise was innovative: It was an attempt to introduce risk analysis in ways that were useful for planning, budgeting, and strategy, rather than only for individual programs and for quantification of health effects.

The methodology that was crafted was ecumenical. First, there was no exclusive emphasis on quantifying all risks on a common scale. The study would not be one of these "hard version" comparisons of risk (Hornstein 1992), like the one attempted by Chauncey Starr in 1969, based on a quantitative scale of benefits, measured in dollars, and risks, measured in terms of mortality. It involved a mix of quantitative assessment and qualitative judgment, by officials of the various program offices, of the agency's level of investment in each risk. Second, the exercise went beyond health and cancer.<sup>7</sup> Risks were defined as falling into four large types: cancer, non-cancer, environment, and welfare. A workgroup was formed for each. The OPPE's balanced method for the comparative exercise reflected the rebalancing of the agency's overall agenda and a new strategy on ecological risks.<sup>8</sup>

The report came out in 1987 as *Unfinished Business—A Comparative Assessment of Environmental Priorities* (EPA 1987). In several ways, it was a

surprise. First, the external reactions to the report were generally favorable. It was immediately picked up in congressional hearings, where the possibility to compare risks and modify priorities was seen by many as a very interesting methodological breakthrough. The document was, and still is, considered to be a landmark, groundbreaking study (e.g., Hammitt 1997). Second, the ranking of risks revealed by the report did not “correspond very well with EPA’s current program priorities” (Morgenstern and Sessions 1988, 36). EPA’s priorities were aligned on public perceptions. The authors indicated that indoor radon, indoor air pollution, ozone depletion, global warming, pesticide residues, and worker exposure, among other issues, were areas of relatively high risk and low EPA effort. The report gave force to observations that had emerged both in various parts of the agency and outside it, concerning its focus and action. It argued that the EPA’s action was characterized by fragmentation, whereas the state of the environment should be approached in a holistic, integrated fashion. The cost of attacking risks one by one was much too high, and the effectiveness of individual risk strategies severely limited. That piecemeal strategy, moreover, would not be effective at addressing the problems that were topping the national agenda at the time, such as global warming or ozone layer depletion. The EPA could not continue to let its action be directed by public scares and the “chemical of the month” syndrome.

Thomas soon publicly endorsed the report and decided to make it publicly available. In all respects, it supported both his choice to continue using “Risk management” as the homogenizing motto of the agency, and his ambition to steer the agency’s priorities back toward ecological and pollution problems. The actual consequences on the agency’s operations were limited. Some attempts were made to redirect the budget toward the new priorities, such as global warming and depletion of the ozone layer. However, as the mobility of EPA funds was strictly limited by negotiations with the OMB and Congress, as well as the various tasks programmed by the legislation passed by Congress, these budgetary changes remained marginal. The report motivated Thomas to give greater support and resources to the Integrated Environment Management Division, inaugurated in the first years of the Toxics Integration initiative (see chapter 3). The Unfinished Business experiment also triggered a series of comparable comparative risk analyses at State level, by regional offices (EPA 1989).

### Picking the Wrong Fight?

The EPA was not done with controversies surrounding its use of science and its manipulation of data to fit preferred decisions. In two cases at least in those years, the agency was accused of being not only conservative, but also alarmist, and of having pushed highly precautionary policies before clarifying the science. Those judgments on the EPA were also legacies of recent affairs that escalated and blew up in the space of just a few months, creating a public experiment for real-time observation of the peculiar modes of agenda-setting at the EPA.

Alar was the first case in point. The risks associated with this pesticide were the subject of an intense, short-lived national drama in 1989. On February 26, 1989, CBS aired a report on alar in a newsmagazine, including an advance look at the results of an analysis of twenty-three pesticides, including alar, by the Natural Resources Defense Council (given in a report entitled *Intolerable Risk*). The next day, the council released its report through press conferences in twelve cities, targeting the hazard of pesticide residues in apples and setting off a real panic among consumers of apples and apple juice. The action of the environmental group took the EPA aback. It found itself under a deluge of pressing questions from members of the public and the media, all in need of immediate, precise confirmation of the risks involved. The EPA had been considering the risks of that substance for more than ten years, but the deregistration of the chemical, once contemplated for its carcinogenicity, had been abandoned in confusing exchanges between the CAG, the Office of Pesticides, and the Science Advisory Panel, characterized by disagreement on the product's carcinogenicity.<sup>9</sup> The comparative risk studies of 1986 and 1987 had shown, however, that pesticide risk should top the agency's list of priority issues. Once the crisis had begun, the EPA did its utmost to reframe the controversy.

John Moore, former assistant administrator for OPTS and then acting administrator of the agency, issued a press release arguing that the Natural Resources Defense Council was misleading the public, but that the hazard, in case of long-term exposure, was real. The crisis continued unabated, spurred by a public campaign orchestrated by a public relations company under contract with the council. The actress Meryl Streep, leading a movement of "Mothers and Others," famously testified before Congress and on television shows about alar's dangers. The consumption of apples

plummeted for months. The end of the story came with the deliberate withdrawal of alar by its manufacturer in June 1989. The EPA ended up being hard hit in its reputation and credibility for having admitted under pressure from the Natural Resources Defense Council that alar posed a risk and that farmers should stop using it (even though it had hesitated for years to actually make such a definitive pronouncement on the basis of animal cancer studies in its possession).

At the other extreme was the radon affair. Until 1984, the potentially high background level of this colorless, odorless, cancer-causing gas fell in the interstices of the EPA regulatory programs. The Superfund program could have legitimately tackled the problem of radon, which had been known since at least 1975 with the discovery of high levels of radiation in Pennsylvania. In 1981, the director of the program proposed a radon plan, but it was blocked by the OMB. Then, in December 1984, Stanley Watras, an engineer working on the construction of a nuclear plant, discovered extremely high doses of radon in his home due to infiltrations from a mine below.

This propelled the issue onto the EPA agenda and heavily damaged the agency's credibility. How could the agency overlook a substance potentially linked to 20,000 lung cancers per year—far more than any of the other substances that the agency considered to be high-profile and high-visibility issues—and affected up to 8 million homes? Even after the Watras discovery and recognition of the gravity of the issue, it remained very difficult to get a national radon policy off the ground. The EPA launched research to curb levels of exposure to radon, but was blocked by conflicts with the US Department of Energy and the OMB over the threshold under which the homes at risk of infiltration should be brought: 4 picocuries per liter, or more? Even inside the EPA, the director of the Office of Radiation, Richard Guimond, found it difficult to find support for the proposed policies. In 1988, at a key point in the radon controversy, EPA managers even suggested that Congress authorize an ORD budget with fewer monies for radon.

Eventually, in 1987's *Unfinished Business* report, radon was listed as one of the top carcinogens that the EPA should be concerned about. A radon action program was set up, involving surveys in schools, homes, and workplaces around the country, as well as investigation of high-radon-potential natural sites. A risk communication program was also established, with large public information campaigns. The EPA furthermore engaged in the testing and distribution of technologies to monitor radon levels.



Even though it remained obvious that radon was a hazard, this episode left a majority of the public with the impression that the EPA had overblown the issue, as no big cancer epidemic materialized (Edelstein and Makofske 1998). It harmed the agency's scientific credibility and spread the need, in the public, for an environmental policy rooted in "good science" (Abelson 1990; Brody 1991). Further complications emerged when the EPA proposed to regulate the levels of radon in drinking water, ensuring that they were in line with the levels that it had declared safe as part of its other action to reduce radon in indoor air. Congress imposed a moratorium on the regulation of radon under the Safe Drinking Water Act and requested a multimedia assessment of the gas in an attempt to put an end to the inconsistencies.

The public risk controversies of alar and radon had in common the fact that they called into question the reliance on animal studies in human health risk assessment research. These affairs showed that epidemiological studies and monitoring data were of utmost importance to characterizing the risks and, even more so, to defining appropriate, targeted measures. They were also of value to escape the unending interpretive controversies surrounding animal tests and the linear extrapolation methods.

The alar controversy played a particular role in the emergence of the problem of epidemiology, monitoring and data, because it caused Bruce Ames, a prominent biochemist and molecular biologist, to intervene publicly and minimize the risks of the chemical. Ames was renowned for his invention of a rapid test to identify carcinogenic chemicals (Ames 1979), which is now standard. While he was praised by the environmental movement for his decisive contribution to the detection of chemical risks, he gradually changed his mind concerning protection against chemicals, to the point of becoming an outspoken critic of environmental regulation (Proctor 1995). Starting in the 1980s, he developed a large database of chemicals, both natural and synthetic, and their cancer potency, showing that many synthetic chemicals were in fact safer than those that occurred naturally in food. He published an article in *Science* based on the results of his research, arguing that animal tests were not appropriate to calculate cancer risks (Ames et al. 1987) and taking on public regulators of chemicals for their science and choices.

Ames appeared in the second CBS program on alar, in May 1989, arguing that conventional extrapolation from high to low doses had enormously exaggerated the possible hazards compared to the risks linked to natural

carcinogens generated by plants in defense against pest attacks. In a letter to the editor of *Science*, with the heading “Pesticides, Risk, and Applesauce” (Ames and Gold 1989), he ridiculed the focus on alar and reiterated his arguments about the unreliability of animal tests and EPA’s misplaced focus on synthetic pesticides. The intervention by Ames mattered because his arguments motivated the manufacturers of a number of high-profile chemicals regulated as air pollutants (including EDB and PCE), to sue the EPA: Dow Chemical, Shell Oil, Accidental Chemical Corporation, together with the Chemical Manufacturers Association and others, launched their action in March 1991, drawing on Ames to demonstrate, like tobacco companies later on passive smoking (see chapter 9), that the EPA was acting in an arbitrary and capricious manner. The court did not heed their challenge.

The series of controversies were the sign of a particular climate surrounding the EPA, with various arguments compounding to downgrade the credibility of its research base. The agency was now appearing to choose the wrong targets and chasing ridiculous risks. It became common to hear in those days, including in Congress, that the EPA was wasting “vast amounts of resources chasing down infinitesimally small amounts of high-profile, media-sensitive, low-risk substances, resources that might have been more effectively used to boost jobs and American competitiveness or applied to other environmental problems or opportunities,” as declared by the Republican senator Don Ritter (US Congress 1995, 155). In *Fortune*, a journalist ran a popular story called “The Big Clean-up Gets It Wrong” (Main 1991). After all, ten years after the major scandal, were people not relocating in Love Canal, that territory contaminated by Monsanto’s polychlorinated biphenyl (PCB), and the case behind the adoption of the major Superfund decontamination program? In those days, journalists filled bookcases with such titles as *Toxic Terror* (Whelan 1993) and *The Asbestos Racket* (Bennett 1991), spreading the word that animal testing to spot cancer risks came down to a “mouse terrorism” (Whelan 1994b).

### Reilly and “Relative Risk”

Bill Reilly became the new EPA administrator in January 1988, just before the alar controversy but after the publication of *Unfinished Business*. Reilly was one of the few Republican environmental leaders, and he had been chosen by President George H. W. Bush to show that he would deliver on

the pro-environmental commitments made during his electoral campaign. Reilly's environmental credentials came from his membership in the Council for Environmental Quality in the 1970s and his presidency of the Conservation Foundation (Landy et al. 1994, 279). After being appointed, Reilly worked with Terry Davies, who was also at the Conservation Foundation, and Dan Beardsley to develop strategic priorities for his administration.<sup>10</sup> Both of these men had a strong inclination toward risk analysis, understood as the comparative analysis of policy priorities and decisions with regard to environmental hazards. Davies had been among the people who had pushed the EPA's design along functional lines, with a central role in opening an analytics office under President Richard Nixon. He was a member of the RAC, which proposed this reading of the administration of risk as structured by two processes of risk assessment and risk management, the latter including regulatory analysis. Beardsley was a policy analyst with the OPPE at the EPA until 1987. He was the leader of the Toxics Integration initiative under Costle and a key part of the enterprise of developing risk assessment and risk analysis during Ruckelshaus's second term as EPA administrator (see chapters 3 and 6).

This small group of three confirmed the strategic priority given to new global ecological issues such as global warming and ozone layer depletion, as well as a moderation of the toxics and health agenda. The group also forged Reilly's positive appreciation of *Unfinished Business*, and the virtues of comparative risk analysis as a tool for setting priorities in the area of environmental action, or as a way to take control of its priorities, over its principals in Congress or in the White House. Beardsley held the view that the main risk manager in the country was Congress, in that the laws it voted on and budgets it appropriated were de facto defining the priorities to which the agency was according resources and attention (Beardsley 1987). By engaging in comparative risk assessment, the EPA would gain a resource to demonstrate to Congress where, rationally rather than politically, the resource may be allocated.

*Unfinished Business* was still only an internal EPA report, even though it had been widely publicized and positively reviewed in the press. Reilly reasoned that having it peer-reviewed, like other kinds of scientific productions of the agency, would give it further authority and political clout. He and his top aides decided to use the SAB for this. It had already ventured into the area of relative risk in 1988. Its chairman had taken the initiative to form a research strategy committee to advise the EPA on how to orient

its research efforts. The SAB defined “risk reduction” as the main overarching goal of the agency, above and beyond the goals defined by statutory programs, and noted that “EPA’s basic mission is to reduce the level of risk to health and to the environment posed by wastes, residues and contaminants” (EPA 1988, 4).

In this report, the lessons of the difficulty of actually regulating the risks posed by widely diffused chemicals (carcinogenic or otherwise) were transparent. It argued, first, that instead of trying to regulate risks *ex post facto* by removing chemicals, the EPA should embrace a preventive strategy: act so that chemicals and pollutions are not generated in the first place. Second, the EPA should focus on those risks that it has the greatest chance of actually being able to reduce (“relative risk reduction”). Reilly asked the SAB to pursue this effort on relative risk through a review of *Unfinished Business* that would help him draw conclusions from this report for the strategic management of the agency’s orientations.

In response to Reilly’s request, the SAB formed a special committee, the Relative Risk Reduction Strategies Committee. The conclusions of this committee, laid out in a report called *Reducing Risk*, were that the EPA should rebalance its priorities, giving greater importance to ecological issues. It called for attention to be given to neglected high-risk issues, such as indoor air pollution and radon. *Reducing Risk* did not quantify all costs and benefits any more than did *Unfinished Business*. It was, to a large extent, based on expert evaluation of the potential for risk reduction and the gravity of environmental impacts of various sources. Interestingly, neither of these reports was criticized for being based on expert judgment or for overlooking massive uncertainties that necessarily moderate the reliability of a large comparative risk assessment exercise.

Reilly did not stop there—he asked a panel of high-level scientists to review the state of science in the agency in the context of limited resources for research, risk comparison, and priority-setting. In March 1992, the panel handed in its report, *Safeguarding Science: Credible Science, Credible Decisions*, to Administrator Reilly, concluding that the scientific basis of decisions was not sufficiently well organized. The report led to the creation of a council of scientific advisors, individually located in each programmatic and regional office. A new position of science advisor was established, under direct supervision of Reilly. For the time that was left before the end of Reilly’s term, the science advisor experiment worked well. Guidelines for

research quality started to be established and applied, and communication between the ORD and program offices was rapidly restored.

The *Risk Reduction* report supported the development of the Pollution Prevention Strategy and the launch of a program collecting ecological data (the Environmental Monitoring Assessment Program). It motivated Reilly to decide on an increase of around \$7 million in the budget for the so-called geographic priorities, or holistic problems concerning such areas as the Great Lakes, Chesapeake Bay, and the Gulf of Mexico. Senator Daniel Patrick Moynihan, a Democrat from New York, tabled an Environmental Risk Reduction bill in 1992 and 1995, but it failed to pass each time. Only the bill H.R. 2910 became law,<sup>11</sup> applying the concept of risk reduction to specific issues such as mercury pollution (Susskind et al. 2001, 46). In the agency, the OPPE managed to institutionalize a procedure for program offices to report on the overall benefits of their programs. There was strong resistance there, especially by offices that ran expensive programs, such as Superfund. The OPPE forced offices to document the benefits of their programs only when they asked for supplementary funds (known as “budget add-ons”) during the year.

Between 1990 and 1992, at the top of the agency, the image of risk assessment changed from a tool to inform risk-specific management measures to a tool to enable planning and prioritization; a tool for the administrator to steer the agency, as opposed to a tool for regulatory offices; a tool that manipulates information about safety, probabilities of health, and ecological effects, but also about the magnitude of a problem in terms of the costs of mitigating it, as well as the ease with which it could be brought down to acceptable levels. At the ORD conference on “Risk Assessment after Ten Years,” Don Barnes, the staff director for the SAB, noted that the approach of RAFG provided no solution to rank risks and choose which one to tackle in priority (Barnes 1993).

Comparative risk assessment, or risk analysis, was the solution for the former and current leaders of an agency that had too often fallen victim to the unpredictable dynamics of public controversies about cancer-causing chemicals. Alm, who sat on the SAB committee that wrote *Reducing Risk*, perceived the EPA’s environmental action as a “treadmill,” with more offices, more personnel, more priorities piling up, and no ability “to get to all the problems” (US Congress 1994b, 197). The need for a mechanism to impose agency-level priorities was clear. Reilly was explicit about the need to move

away from ungovernable controversies about chemicals, the inability to pin down levels of risk, and constant legal challenges against the agency.

This new take on risk analysis—as an agencywide planning tool rather than a problem-focused quantifying exercise—was a way to decide on greater numbers of environmental priorities, as opposed to being driven by episodic alarms such as Love Canal and oil spills, and constrained by laws passed by Congress. It was well noted in Washington and signaled a new kind of bureaucratic discipline. Terry Davies coordinated a project at the think tank Resources for the Future, on request from the OSTP, to assess how to generalize the kind of “programmatic Comparative Risk Assessment” that the EPA had pioneered. He proposed a similar framework for the administration of risk than the EPA was moving toward: “*When describing the risk-based disciplines, risk analysis is the most general term, which encompasses comparative risk analysis, risk analysis, risk assessment, risk management, and risk communication*” (Davies 1996, 5).

Another important event, attracting top EPAers, was a conference organized by Adam Finkel on the ranking of national environmental priorities (Finkel and Golding 1994). *Reducing Risk* was widely cited in congressional debates and hearings as an element in favor of the move toward greater expert-driven selection of environmental issues—in the terms that were then used, *prioritization* and *planning*, to be applied both to the agency’s research programs and to the definition of its budgets. It concurred with what others were saying at the time. The White House’s proposed budget for 1992 had mentioned “risk-based budgeting,”<sup>12</sup> soon followed by a prestigious Carnegie Commission on Science, Technology, and Government—including Alvin Alm, Justice Stephen Breyer, former FDA general counsel and RAC member Richard Merrill, as well as Gil Omenn—through its report *Risk and the Environment: Improving Regulatory Decision-Making* (Carnegie Corporation 1993).

### **Risk Analysis in a Democratic Administration**

President Clinton’s EPA was different—it placed less importance on proper risk and policy analysis, and in the calculation of the benefits of its policies, than before. Clinton’s election put an end to three consecutive Republican administrations. He brought in Carol Browner, a former legislative director for Senator, now Vice President Al Gore, and formerly the head of

the Department of the Environment of the state of Florida. Environmental policy changed more dramatically than during any of the last transitions, between Ruckelshaus and Thomas, or Thomas and Reilly. Browner's priorities, as she took the office, were pollution prevention, environmental justice, and innovation in control technologies (Fiorino 1995). The focus on risk clearly receded during this transition, with Browner's intention to shape a different EPA. Risk assessment and cost-benefit analysis stopped being presented in agency documents as generic policy tools, as they had been in the 1980s.

The OPPE in fact lost its prominent role of the 1983–1993 years—its “glory days,” as one of the policy analysts of that period called them.<sup>13</sup> It no longer occupied the privileged advisory role to the administrator that it had acquired in 1983, and it was no longer managed by a political appointee: a signal of its decline in the internal hierarchy of offices. Because the Clinton administration was overall less adverse to environmental regulation, the agency got less pushback from the White House and the OMB during most of the 1990s, and the OPPE's most critical utility for the administrator was precisely in making proposed rules more robust with aspects of costs and benefits.<sup>14</sup>

The forays in comparative risk assessment of the early 1990s were not replicated. What remained of the comparative risk assessment drive of those years was a subcommittee within the SAB dedicated to residual risk, as well as other program-specific initiatives. One consisted of formalizing a system of technological evaluation inside the Office of Pollution Prevention and Toxics (OPPT), formerly the OPTS, which restored the importance of that approach by using the risk-ranking notion as a springboard. Effectively, engineers in various offices where pollution-reducing technologies were being discussed had always thought that risk assessment distracted from the achievement of actual reductions in pollution levels in industry processes. The Office of Pesticides as an office in precisely this situation, realized that the valuation perspective implicit in risk-ranking took advantage of the new agenda to try to push forward a new scheme for technology assessment. It legitimized the initiative by incorporating it into the framework of risk assessment, risk management, and risk reduction through the formal ranking and weighing of priorities (EPA 1994a). But no new rule or guideline emerged to make those processes more systematic in the agency. Besides local initiatives, the heads of the agency stopped supporting risk analysis

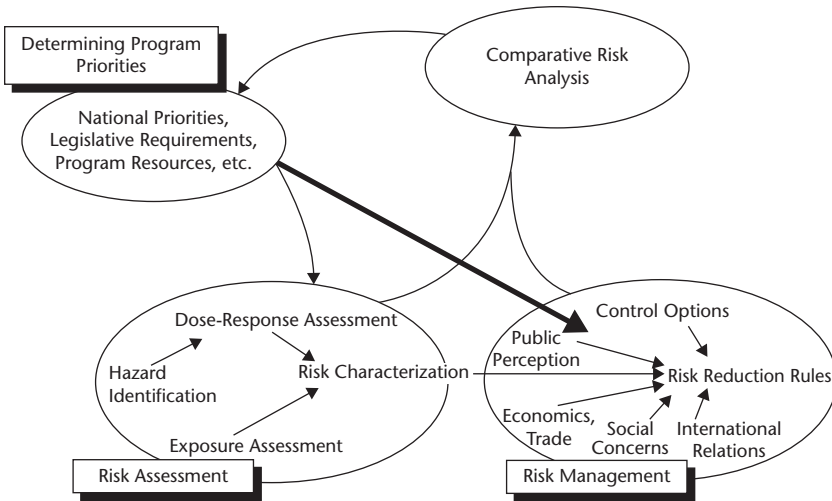
across the agency, or did so only to ensure continuity of what had become essential processes in the agency, such as guideline development and coordination of risk assessment science through the Risk Assessment Forum.

More than a new internal rule, comparative risk assessment became a strategic bureaucratic screen against the various audiences demanding changes in the agency. Thus, comparative risk assessment continued to feature prominently in public expositions of the agency's way of making decisions and of its priorities. Risk analysis remained an important theme for representing the agency, materializing its rationality for audiences, and constructing the credibility of its choices. Such was the case during congressional hearings on the ORD. In the early 1990s, the financial situation of the ORD seemed sufficiently bad for a group of industry leaders and environmental activists to write to Congress, asking legislators to appropriate more money for the ORD than pledged by the White House (US Congress 1992).

The ORD budget had never really recovered from the cuts of the Ronald Reagan era. In constant dollar terms, it was even in decline, and it seemed to have an aging workforce as well. At the same time, the strength of its research in human health risk assessment was in question, as was its way of deciding on risks to investigate in short- and long-term research efforts. Several attempts at reforming the EPA's science and the ORD emerged from Congress and within the EPA. Congress requested a report from its Office of Technology Assessment. It then took various legislative initiatives, introducing a Risk Assessment Improvement Act, in terms of which the EPA administrator was to report to Congress on ten environmental issues correlated to the highest environmental risks, "with respect to which uncertainties could be significantly reduced through research."<sup>15</sup> The head of the ORD had to establish a strategic plan for his office and procedures for ensuring the quality of research.<sup>16</sup>

At another hearing to discuss two proposed bills about environmental quality and environmental justice, Lynn Goldman, assistant administrator for the OPPT brought in by Browner maintained that the paradigm of risk assessment and risk management "established" by the National Academy of Sciences and "adopted" by the US EPA, had now been enlarged to include new undertakings: it was now "helpful to distinguish between risk assessment, risk management, comparative risk analysis, and risk communication" (US Congress 1994a, 16). The statement that she put on the record of Congress included the graph shown in figure 8.1, enlarging the RAFG-based





**Figure 8.1**

An integrated risk decision-making design incorporating comparative risk analysis (adapted from US Congress 1994a, 33).

scheme to incorporate a “comparative risk analysis” process for the agency. The bottom circles represent the standard modules of risk regulation that RAFG conceptualized and that were institutionalized in the agency in the 1980s. The processes are run in accordance with an a priori, upstream determination of national priorities. Risk assessment and risk management generate information that feed a new module of comparative risk assessment, which in turn is used to inform this broad agenda.

Comparative risk assessment was even more important as a design in the relation to the White House, which was working on the topic for itself, using comparative risk assessment and risk ranking as a political solution to demonstrate the balance existing in its environmental and economic policies. In October 1993, President Clinton issued Executive Order 12866, which superseded the Executive Order of 12291 issued in 1981. The EPA was still directed by this new Order to conduct benefit-cost analyses for significant regulatory actions and to select options which “maximize net benefits” to the extent permissible by law. But “net benefits” were now parenthetically qualified to include “potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity” (Federal Register 1993, 51735).

Clinton's executive order provided more flexibility in environmental policy because it explicitly recognized a role for nonmonetary considerations in policymaking (Goodstein 1995). The executive order materialized in the setting-up of a working group, led by the OMB's OIRA, alongside the OSTP, with the participation of a large set of federal regulatory agencies. The group came out with risk analysis principles that essentially perpetuated the rationality of policy analysis and options development—and was thus not to be confused with the more routine practice of health or environmental risk assessment: “Risk assessment’ is the term that is used for the process of describing or characterizing the nature or magnitude of a particular risk. Risk assessment is the foundation of risk analysis. The terms are sometimes used interchangeably, but assessment is a gathering, the assembling, and the arraying of information on the risk. Risk analysis includes not only risk assessment but also risk management, how you are going to respond to this risk, risk communication ... Risk analysis, taken as a whole, provides a means for organizing scientific, technical, social, and economic information” (Sally Katzen, quoted in US Congress 1994d, 10).

## Conclusion

From the creation of the EPA until the beginning of the 1990s, the comparison of costs and benefits of various environmental policies has constantly gained importance in the agency. With administrator after administrator, and through the succession of deputy administrators and leaders of its policy office, this expertise has slowly institutionalized, to embody a part of what the agency does and how, for its audiences. There is a strong, symbolic aspect to this—especially when the rationale of analyzing and comparing risk emerges in the public discourses of the leaders of the agency (e.g., before Congress)—but also a material one. Guidelines for risk comparison and risk-ranking were developed; policy analysts received a formal, official function of performing agencywide, synoptic analyses of the risks that the agency was to tackle; risk analysis was concretely articulated with the work of scientific risk assessors; and even the agency's prominent SAB was consulted, and it contributed to manufacturing and applying these methodologies.

The notion of risk analysis that was formalized at the beginning of the 1990s to generalize risk comparison, risk-ranking, and environmental

valuation may not appear to be that different from scientific risk assessment. Indeed, the risk assessment–risk management framework explicitly combined them. But behind seemingly arcane debates and subtle choices among equally generic terms lay a fundamental difference in the design that various leaders and experts of the agency pursued: a reductionist one, aiming for accuracy in the description and explanation of a risk taken individually, against one of comprehensive attention to sets of problems emerging in the environment as a whole and analyzed synoptically. The latter design emerged in the agency for different reasons and at a different moment than quantitative risk assessment. It appeared when the agency's mission and policy started to be questioned by a Republican Party that was itself becoming less environmentalist. The controversies that led the agency to design itself in this way typically concerned the priorities of the agency, its way of choosing among the environmental issues to pursue, the fact that it was seen to be “asking the wrong questions” (Landy et al. 1994).

Risk analysis was, then, the bureaucratic technology of the day—the tool to limit contestation, to reframe public debates about environmental issues, and to make the outputs of the agency more acceptable and effective. But this technology was also more short-lived: Its importance declined as soon as the political atmosphere evolved and as the agency got less contested in its choices—at least provisionally, when Clinton accessed power, and before the Republican political landslide that allowed the party to take total control of Congress in 1994. Risk analysis, as a technology for producing rational administrative decision, closely reflects the cycles of political support and contestation that the agency goes through. And the early 1990s mark the beginning of a cycle of politicization of the EPA's science and ways of making decisions. Risk analysis—its rise and fall—reflects it, but so will risk assessment, and soon. A period of intense and contentious definition and formalization of the science of the agency had indeed begun.



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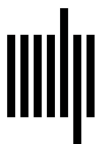
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