Notes

Introduction

1. The NRC is part of the complex of US national scientific academies, which include the NAS (the oldest academy, founded in 1863), the Institute of Medicine (IOM; recently renamed the "National Academy of Medicine"), the National Academy of Engineering, and the NRC. The NRC is the operational arm of the Academy complex and most frequently delivers the reports that customer organizations (often governmental) request and fund.

2. I am using the acronym *RAFG*, and not "the Red Book," in order to remind the reader of the content of this report—originally a report about the organization of risk assessment in the federal government, with nuances and ambiguity even as concerns this very issue (Jasanoff 1992). Using the nickname "Red Book" tends to simplify the representation of what is inside the report, and let people believe that it offers a ready-made administrative model for the use of science in decision-making. As this book shows, it is an oversimplification of the historical process by which risk analysis *became* a model.

3. It is also sometimes called *the NRC paradigm, the NAS paradigm,* or *the risk assessment–risk management framework*. It is difficult to overestimate the number of reports, articles, or books that call this a paradigm, with *Risk Assessment in the Federal Government* as its sole origin (Newman 1994, 2014; Cothern 1995; Brownson and Petitti 1998; Holgate et al. 1999; Gardner et al. 2000; Jayjock et al. 2000; Aron and Patz 2001; IOM 2001; Thornton 2001; Vallero 2003; Kassim and Williamson 2005; WHO 2005; Calow 2009; McQueen 2010; Sigel 2011; Driver et al. 2012; Friis 2012; Linders 2012; Gulis et al. 2013; Simon 2014; Doern et al. 2016; Fabiansson and Fabiansson 2016; Frantzen 2016). The Scopus/Elsevier database indicates that the report had been cited more than 1,700 times (as of November 30, 2018).

4. The list of administrators of the EPA since its foundation is as follows:

William Ruckelshaus: 1970–1973 (under Richard Nixon)
Russell Train: 1973–1975 (under Gerald Ford)

Douglas Costle: 1975–1981 (under Jimmy Carter)
Ann Gorsuch: 1981–1983 (under Ronald Reagan)
William Ruckelshaus: 1983–1985 (under Ronald Reagan)
Lee Thomas: 1985–1989 (under Ronald Reagan)
Bill Reilly: 1989–1993 (under George H. W. Bush)
Carol Browner: 1993–2001 (under Bill Clinton)
Christine Todd Whitman: 2001–2003 (under George W. Bush)
Michael O. Leavitt: 2003–2005 (under George W. Bush)
Stephen L. Johnson: 2005–2009 (under George W. Bush)
Lisa P. Jackson: 2009–2013 (under Barack Obama)
Gina McCarthy: 2013–2017 (under Barack Obama)
Scott Pruitt: 2017–2018 (under Donald Trump)
Douglas Wheeler: 2018–present (under Donald Trump)

5. Ellen Silbergeld, interview with the author.

6. The Society for Risk Analysis (SRA) never succeeded in agreeing on a common glossary of terms, including a definition of *risk* (Gratt 1987).

7. Labeling literatures and perspectives always involves a simplification of the often-vast set of studies published, as well as their nuances. The opposition between a strategic and cultural view of rationalization, however, helps set the terms of the debate and stimulate the search for alternative explanations of the process of organizational rationalization through the incorporation of analytical knowledge. For a similar opposition between strategic and cultural (or new institutionalist) views, see Brunsson (1985), Oliver (1991), Dobbin (1994), Suchman (1995).

8. Historians of science, for their part, have shown that even the best-known incarnations of rationality and rational tools, such as game theory, have diversity (Erickson et al. 2013). Berg's work on the tools of rational decision-making in medicine is also illustrative of the internal diversity and dynamics of rationalization (Berg 1997).

9. On the notion that design is a dialectical process between the shaping of an object outside use settings and inside situations of use, see Storni (2012) and Bjogvinsson et al. (2012).

Chapter 1

1. Hoos (1983, 294) later wrote that technology assessment was the umbrella term for the administrative use of many of these techniques.

2. For Cooke (1991, 41), "Policy analysis is really a catchall for everything that does not fit into the areas discussed [scenario analysis, systems analysis, probabilistic risk analysis]. It will be understood to include macroeconomic modeling, economic

forecasting, energy planning, project management, environmental impact studies, etc." William Thomas, a historian of operations research, more recently identified "sciences of policy" (Thomas 2015).

3. "Operations research is a scientific method for providing executive departments with a quantitative basis for decisions" (Kittel 1947, 150). Its generic process "begins by carefully observing and formulating the problem and then constructing a scientific (typically mathematical) model that attempts to abstract the essence of the real problem" (Hillier and Lieberman 1980).

4. That redefinition of systems analysis provided a platform for statisticians and mathematicians to start dealing with public programs in various areas, connecting to the ongoing but separate development of a policy science by Lasswell (Lasswell 1951; Farr et al. 2006). The two editors of the book *Pitfalls of Analysis,* both of whom had formerly worked for RAND, approached systems and policy analysis as equivalents: "In this volume, systems analysis and policy analysis are used as essentially synonymous terms for the same activity: research that attempts to bring modern science and technology to bear on society's problems, seeking ameliorative solutions" (Majone and Quade 1980, 6). Like systems analysis, Laswell's policy science was a science that optimized the efficiency of military and governmental organizations' decisions, strategies, and programs. But his platform for the development of policy sciences had other facets as well. One of these was training the practitioners of "the science of democracy," (Lasswell 1942) for the purpose of explicating and clarifying the goals of policies, their relation to democratic values, and their capacity to solve collective problems. This noninstrumental public policy analysis later developed through A. Wildawsky, H. Heclo, and C. Lindblom (see Hoppe 2005; Spenlehauer 2013).

5. The preference for viewing the war in numbers, including during field visits by Washington-based strategists and by McNamara himself, prevented many from contemplating the possibility of a defeat in the Vietnam War (Halberstam 1988).

6. See the title of her obituary in the *New York Times*: "Ida R. Hoos Is Dead at 94; a Critic of Systems Analysis."

7. Technology assessment took shape in 1972 with the US Congress Office of Technology Assessment, headed by Emilio Daddario. In a bill that he tabled in the House of Representatives in 1967, technology assessment announced risk assessment: It was a way of "identifying the potentials of applied research and technology and promoting ways and means to accomplish their transfer into practical use, and identifying the undesirable by-products and side-effects of such applied research and technology in advance of their crystallization, and informing the public of their potential danger in order that appropriate steps may be taken to eliminate or minimize them" (cited in Wynne 1975, 117).

8. The Windscale Inquiry was a public hearing series under the Town and Country Planning Act of 1971 in the United Kingdom, over the application by British Nuclear Fuels Limited to establish a plant for processing irradiated fuels.

9. This paper was republished in his book *Normal Accidents* (Perrow 1984).

10. Lester Lave is called a "self-styled right-wing economist" and a "liberal academic" found to appear "to be to the right of Sierra Club interveners" (Perrow 1982, 299)

11. Wildavsky followed a different path. In *Searching for Safety*, he shows that the calculation of risks pertains to a generic strategy of anticipation and avoidance of potential harm. Anticipation is a much less effective strategy than its generic opposite—accepting that risk will materialize anyhow, and preparing to counter it—which he calls "resilience." Learning from experience is objectively better than calculating subtle variations in probabilities through experiments and models that cannot anticipate or even imagine "major surprise, a change in kind, a change like acquired immune deficiency syndrome that central decision makers could not imagine might occur" (Wildavsky 1988, 8).

12. This does not apply as strictly to the work of a philosopher such as Kristin Shrader-Frechette, who forensically deconstructs the scientific methodologies and values of risk assessors as observed in particular cases (see Shrader-Frechette 1985, 1991).

13. One of the explanations for why Beck omits the term and makes no reference to the SRA is that at the time that he wrote this, risk analysis was only slowly emerging as a discipline, and mainly in the United States. By 1985, for instance, the SRA membership had just reached 1,000 people. Although there were many Europeans in the SRA, it was predominantly US-based. Another reason for the absence of the term is that it was not a relevant phenomenon in the framework of Beck's sociological program. His work was on social change, individuation, and new modes of social stratification (as well as new forms of politics), so the emergence of probabilistic sciences and instruments was of far more interest to the other facet of social science research on risk, which applied a Foucaldian governmentality perspective, in which "risk is analysed as a component of assemblages of practices, techniques, and rationalities concerned with how we govern" (Dean 1999, 132).

14. There were repeated efforts in the 1970s to structure the field and to identify the common concepts and methodologies that specialists of variegated sources of hazards (plants, chemicals, natural disasters, etc.) could claim to have in common (Boudia 2014). In the late 1970s, the National Science Foundation (NSF) founded the Technology Assessment and Risk Analysis (TARA) group to manage the impetus and funding for research on these new perspectives on probabilistic and quantitative risk assessment, the calculation of the benefit-risk ratio and the perception of risks. The NSF's arrival on the scene resulted in an expansion of research devoted to the issue and contributed to structuring a professional community dedicated to risk analysis and management (Golding 1992). This was the context in which the SRA took shape.

It was created in 1981 in Washington, D.C., and the journal *Risk Analysis* published its first issue that same year. The aim was to create a common home for geographers, toxicologists, and engineers who were motivated to turn safety and risk into a sui generis specialty rather than a peripheral object for their initial discipline (Rip 1986).

15. Starr was an engineer and physicist. He was a member of the Manhattan Project, working on the delivery of uranium-235 material to Los Alamos for the production of the atomic bomb. After the war, he worked at Oak Ridge National Laboratory in Tennessee on the development of nuclear propulsion for rockets and ramjets, miniaturized nuclear reactors for space, and the design of atomic-power electricity plants. In the report and in a paper published in *Science*, risks were quantified in terms of the number of deaths attributable to the use of this technology, while its benefits were measured using the proxy of dollar amounts of consumption of the technology. The paper introduced multiple risk-benefit comparisons and inspired the subsequent development of so-called comparative risk assessment. Starr also introduced the quantification and monetary valuation of risks and benefits, paving the way for the application of cost-benefit and risk-benefit analysis to environmental issues. The third opening concerned the measure of social opinions on hazards. Starr borrowed from economists the method of revealed preferences to measure this perception of the risk. He saw this dual quantification (of real and perceived risks) and the reconstruction of relative risk levels as means to show that citizens overestimate numerous risks, particularly those that are involuntary. The paper is often cited by people both within and outside the field as the origin of the field of risk analysis (Short 1984; Hacking 2003; Burgess 2006).

16. Starr was an outspoken supporter of the development of nuclear energy. He founded the Electric Power Research Institute in 1973 as an industrywide cooperative program for electricity and environmental research. In the 1990s, Starr joined the ranks of climate-change deniers, signing onto the 1998 Global Warming Petition Project opposing the Kyoto Protocol.

17. Two American political scientists launched a survey of "risk professionals" (Dietz and Rycroft 1988); that is, those "who spend most of their time dealing with environmental risk concerns" (ibid., 8) and who self-identify with this label. The survey itself showed that the population of risk specialists was increasing at the time and becoming increasingly visible and active. Its results showed that the field, though diverse, was becoming increasingly well structured. Risk professionals, the two authors found, were generally highly educated in specific disciplines, ranging from physical sciences, engineering, mathematics, and statistics (about a third of them), to biological sciences (13%), including medicine and public health (6%). Risk professionals worked within a wide variety of organizations, but federal organizations hosted nearly 30% of them (including 15% at the EPA alone). Risk professionals shared an ideology that combined scientism and environmentalism. These professionals typically adhered to the views that the environment needed to

be protected and that the diffusion of scientific information was necessary and sufficient to clarify concerns and find solutions. This was combined with a strong belief in the virtue of policy, decision or risk analysis for improving or optimizing governmental intervention, and with a preference for working with and helping decision-making by large administrative organizations in government, or corporations.

18. This claim of relevance to public decisions is repeated in the first issues of *Risk Analysis*, by the founders of the SRA: "Decision-making is an essential feature of human society and anything which impedes it must be regarded as non-adaptive. Thus, mechanisms must be developed to allow the decision-making process to go on in the face of risk and uncertainty. Such mechanisms can be collectively called 'risk management' … The risk analyst should look at the particular risk problem in its context and finally consider the decisions that must be made, the options involved, and not only the risks" (Cumming 1981, 97–99). Weinberg (1981, 7) called for risk analysts to deal with decision and administrative action: "I hope those who work on the scientific side of risk analysis will interest themselves in the formulation of policy that flows from their scientific findings."

Chapter 2

1. Assistant administrators manage the various offices of the EPA, from the ORD to the Office of Policy, among others, and the various "program offices" (Office of Air and Radiation, Office of Water, etc.). Assistant administrators are political appointees, not career staff. They are chosen by the incoming EPA administrator, after approval by the White House, and must be approved by the Senate.

2. The committee and report were the latest moves in a battle of opposing factions of medical scientists on the issue of carcinogens. The Saffioti report was a reaction to a report (NRC 1969) that suggested that one could compute "safe" levels of carcinogens in food, in an attempt to scientifically justify moving beyond the precautionary, zero-tolerance Delaney amendment (McGarity 1983). Public Citizen Health's Research Group accused the NRC panel of being biased toward the views of the chemical and food industries (Vogel 2013), which then were actively at war against the Delaney amendment.

3. This office has changed names several times during the period covered by this book. It was first called the Office of Planning and Management (1970–1975), then the Office of Policy and Resources Management (OPRM) (1976–1981). It then became the Office of Policy, Planning, and Evaluation (OPPE). What this text really discusses is the activity of the latter, in the 1980s and 1990s. Currently, the office is called the Office of Policy. Its activity is described in the following way on the EPA website (accessed in February 2017): "the Office of Policy (OP) is the primary policy arm of EPA. We work with our EPA colleagues to support Agency priorities and enhance decision-making. We provide multi-disciplinary analytic

skills, management support, and special expertise in five areas: regulatory policy and management, environmental economics, strategic environmental management, sustainable communities, and climate adaptation" (https://www.epa.gov/aboutepa/about-office-policy-op).

4. Source: Economist, Office of Policy Analysis, interview with the author.

5. See, for instance, Anderson's testimony before Congress in 1983: "In assessing the possible risk of carcinogens posed by individual chemical substances, EPA follows a two-step approach. Risk assessment attempts to answer two questions: 1) how likely is the event to occur? 2) on the assumption that the event does occur, what is the magnitude of the public health impact? Since only rarely do we know for sure that an agent is indeed a human carcinogen, the first step involves an evaluation of all the biomedical data to determine the weight-of-evidence that an agent might be a human carcinogen. The second step involves the quantification of risk, that is public health impacts, in terms of rough estimates for current exposures as well as estimated exposures for various regulatory options" (US Congress 1983a, 372). See also Anderson (1983).

6. *Ethyl Corp. v. EPA,* United States Court of Appeals for the District of Columbia Circuit 541 F.2d 1 (1976).

7. The first quantitative risk assessment performed in the EPA was the "Quantitative Risk Assessment for Community Exposure to Vinyl Chloride," completed in 1975 in the Air Office (Kuzmack and McGaughy, 1975).

8. The linear model, as its name indicates, is a mathematical model that forces the computation of dose effects that, plotted on a line, will produce a no-threshold, nearly straight line. Probit is a model that produces a supralinear or sublinear curve (half of a bell shape). Other models available at the time include K-hit, Armitage-Doll, and Weibull.

9. In February 1983, in a testimony before the House Committee on Agriculture, Albert argued that the only thing that could realistically be done to counter cancer was to regulate the excess cases of cancer in the population across all modes of exposure, instead of taking on substances individually, at the risk of losing each of these judicial battles. An overall target of reducing cancer, following the principle of protection against ionizing radiation, ALARA, was the only way forward. This became the policy of the agency: "Risk assessment of human exposure to radioactivity offered the conceptual framework for the assessment of risk from exposure to chemicals" (EPA 1985c, 2).

10. Landy et al. (1994) cite Anton Keller, an OSHA official, describing the 1976 EPA guideline as a "Sistine Chapel" approach: that is, experts go into the chapel and emerge with divinely expert judgment.

11. Scientific coordination among offices was feasible where there were programmable analytical tasks. The Air and Water offices, for instance, duly used the forces of OHEA to produce the series of "criteria documents" that had to be established for legally defined, definite lists of chemicals. As mentioned earlier in this chapter, the Air Office was the first to endorse ORD's risk assessment guideline of 1976 for application to the assessment of the six criteria chemicals designated under the Clean Air Act. The Air Office was the first "client" of the OHEA (around 1980, 45 percent of OHEA was dedicated to providing scientific advice to this program office). OHEA routinely did cancer and noncancer assessments for this office, limiting the risks of inconsistent opinions. In 1980, the Water Office announced the availability of water quality criteria documents for sixty-four contaminants. It published, along with the criteria, the guidelines that were used to calculate these numerical concentration limits, below which human health and aquatic life are believed to be safe, in terms of cancer risk, noncancer risks and organoleptic effects (Stephan et al. 1983). These guidelines are dubbed "the first EPA document describing quantitative procedures used in risk assessment" by the EPA staff paper on risk assessment principles and practices of 2004 (EPA 2004, 4).

12. When the EPA was created in 1970, the ORD was totaling 2,000 staff, out of the 6,000 employees of the agency. Ten years later, the ORD had 2,400 staff, out of 13,000 agency employees (the administrator's office counted around 1,100; Office of Water, 800; Solid Waste, 300; Air: 1,100; Pesticides: 1,360; ORD: 2,400; and the ten regional offices has more than 5,000 staff).

13. Partly as a consequence of the 1977 NRC report, Congress reestablished the Scientific Advisory Board in its 1978 Science Advisory Act (it had been created in 1974 to reunite various advisory committees inherited from the departments that preexisted EPA). After 1978, the SAB counted 100 external scientists and 300 consultants. Its mission was to provide extramural information and advice to the administrator and other officials of the EPA (Jasanoff 1990).

14. The Environmental Biology Research Laboratory; the Environmental Chemistry and Transport Research Laboratory; the Environmental Engineering Research Laboratory; the Environmental Measurements Research Laboratory; the Health Effects Research Laboratory; the Health and Environmental Assessment Center (tentatively renamed, but it would keep the name of OHEA eventually, until the reform of ORD in 1995).

15. Eight areas of potential cooperation had been identified in this agreement, including risk assessment, toxicity testing, joint research planning, information exchange, coordination of inspection efforts, uniform responses to problems of concern for more than two agencies, communication and education, and policy for the review of epidemiological data.

16. Omenn graduated from Princeton. He received the Freshman First Honor prize at Princeton University in the winter of 1961. He then obtained his medical

degree and PhD from Harvard. In September 1973, then an assistant professor at the University of Washington, Seattle, he took a year's sabbatical to serve as a White House fellow. He worked as special assistant to the Chairman of the Atomic Energy Commission. Omenn recounts this episode, as well as many others, to discuss his involvement in high-level policy issues throughout his career, as well as his position within both policy and medical elites (Omenn 2011).

17. A first step had been made in 1978: The Department of Health, Education, and Welfare moved in this direction when it centralized its research and evaluation work on carcinogens in a National Toxicology Program, partnering in this with the FDA, the National Cancer Institute, the National Institute for Environmental Health Sciences, and the National Institute for Occupational Safety and Health.

18. In 1982, the OHEA proposed additional guidance for cancer assessment. In this document, it opened up to considering mechanistic knowledge—understanding of the modes of action of chemicals in the body, to get to more nuanced judgment about their carcinogenicity. The guidance distinguished between mutagenic and nonmutagenic carcinogens and recommended the application of a conventional toxicological method to these (using the NOAEL and applying a safety factor, to determine a safe level of exposure). Roy Albert received dozens of letters of comments, with those from industry pleading for even more flexibility in the guidelines. Gehring, then-director for health and environmental sciences at Dow, explained that "sound scientific principles" demanded an "even more scientifically flexible guideline than currently proposed," away from the "inflexible predesignated 1000x safety factor," and the "assumed linearity at low doses" (Gehring, P. J., Letter to Dr Roy Albert, dated June 28, 1982, with enclosure). The scientists whom Dow recruited to comment on the guidance made it clear that the statistical model borrowed from Kenny Crump by the EPA to found the multistage model originally did not include any assumption of linearity. Dow's scientific consultants pointed out that the EPA had made a policy—not scientific—decision to incorporate this assumption in the model, and that it should assume the responsibility of this policy decision and agree to put it up for debate rather than presenting it as fact. David Hoel, from the US Department of Health and Human Services, argued against what he saw as a cookbook approach, while Ronald Hart, director of the National Centre for Toxicological Research, found fault with the logic of applying safety factors even in cases where human data were available, thereby suggesting that the guidance should make space for a case-by-case application of the safety factor and linear extrapolation methods (EPA 1980c, 55).

19. The IRLG document was published in the Federal Register, without endorsement by OSHA, which objected to this quasi-official status. Costle insisted on having the document endorsed by the White House Regulatory Council, which he chaired. This was done (at least somewhat) when the council published a statement on carcinogens, citing the IRLG guidelines in an appendix. But the document, as acceptable as it may have been to all those who participated in drafting it, was never reviewed

internally by the agencies or approved by them. After President Ronald Reagan's election in 1980, the IRLG group was disbanded. (For details, see Landy et al. 1994, 194–200.)

20. Justice Stevens stipulated, "The burden was on the Agency to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to 10 ppm of benzene presents a significant risk of material health impairment … In this case OSHA did not even attempt to carry its burden of proof." The closest that it came to making a finding that benzene presented a significant risk of harm in the workplace was its statement that the benefits to be derived from lowering the permissible exposure level from 10 to 1 ppm were likely to be appreciable. In truth, the agency did not draw a dose-response curve to extrapolate the effects of the substance at 10 ppm from the observed effects at higher concentrations. It stuck to a generic, qualitative consideration that no thresholds exist for carcinogenic substances, categorizing chromosomal effects as an adverse biological event of serious concern, which may pose or reflect a potential health risk. The Court recognized that imposing a proof of certainty before issuing a regulation to the agency would equate with paralyzing it, and that the Act requires no such proof. It also acknowledged that the rules for judging carcinogenicity, in the absence of the possibility of scientific certainty, were a matter of policy. In the words of Justice Stevens, "the requirement that a 'significant' risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considers to be a 'significant' risk."

21. A subsequent court ruling in another case upheld this principle: *American Textile Mfrs. Inst., Inc. v. Donovan,* 452 U.S. 490 (1981).

22. *Gulf South Insulation v. United States Consumer Product Safety Commission,* 701 F.2d 1137 (5th Circuit 1983). The CPSC had used a quantitative risk assessment, evaluating the excess cancer risk in the range of 0–51 per million, based on a single study.

23. *Ethyl Corp. v. EPA*.

24. One illustration of that is the fact that major judicial setbacks inflicted on certain agency programs, such as the "*Corrosion-Proof Fittings v. EPA*" ruling of 1991 concerning asbestos did not result in alterations of the preferred frameworks. Fisher et al. (2015) demonstrate this with regard to the NAAQS program: EPA analytical benchmarks are used by courts and generally upheld.

Chapter 3

1. A legal battle ensued to determine whether the Act superseded the decree, and whether the program launched by the EPA to establish criteria should be pursued—with the industry lobbying for its interruption and Gorsuch likewise leaning in this direction.

2. Clean Air Act, 42 U.S.C. § 7412(a)(1) (1982). The Act stipulates that there is a safety threshold, perhaps to compensate for the difficulty (or impossibility) of attaining zero risk. But as Powell (1999) explains, this assumption is incorrect in the case of air pollution because biological effects were found in conditions of exposure to ambient air pollution.

3. These were the major Acts for which the agency had full responsibility. Table 3.1 does not mention Acts of which the EPA implemented only a particular section. Some of the Acts indicated here contained more than one regulatory program. The Clean Air Act included a program that applied to criteria air pollutants, and another to hazardous air pollutants. The agency would generally create separate offices for each type of pollutant.

4. After Nixon's reelection, Costle spent some time at the congressional office of Budget. When Jimmy Carter appointed him, he strategically chose to espouse the presidential agenda in an attempt to foster the relationship with the White House and continue to amass support from the president (Landy et al. 1994).

5. On the one hand, Train won from the White House an ascendance over environmental decisions, notably through the written confirmation that the EPA, rather than the OMB, had the last word over the substance of its standards and regulations. On the other hand, Congress gained confidence to create new environmental laws and oversee environmental policy.

6. The EPA designated six criteria air pollutants: particulates, sulfur dioxide, nitrogen dioxide, carbon monoxide, ozone, and hydrocarbons (with the latter soon delisted and replaced by lead).

7. For instance, four people (one in OHEA, one in the Air Office, and two in separate parts of the Water Office) were working on formaldehyde. No fewer than six groups were dealing with benzene for technical assistance, regulation of environmental effects, the revision of the regulation of environmental effects, and the establishment of water quality criteria under the CWA; for regulation of its environmental effects under FIFRA; and for its preregulatory assessment of its health effects under the SDWA.

8. The EPA gained its independence from constant White House oversight only when its administrator, William Ruckelshaus, threatened to quit unless his authority was acknowledged (Eads and Fix 1984). Train, who had chaired the Council on Environmental Quality, had to do the same after he took the reins of the agency in 1973.

9. In his capacity as head of the Regulatory Council, Costle wrote to other heads of regulatory agencies and lawyers in charge of the development of regulations in these administrations in July 1980. He asked his counterparts and regulation writers in each agency to duly consider all regulatory options and alternatives as part of rule-making. His letter was founded on the work of Michael Levin, the chief of the

regulatory reform staff, a group created inside the Office of Planning and Evaluation to work toward the implementation of Executive Order 12044 for efficient and effective regulatory strategies. Levin had developed a checklist of all possible ways of regulating technologies and products and industries, ranging from direct regulatory mechanisms (technology-based standards, performance-based standards, prohibitions, and limitations) to innovation incentives, through information mechanisms. Toxics integration was fully in line with the process, given its recommendations to include cost considerations to help decide whether to regulate a substance.

10. Daniel J. Fiorino, Chief Regulation Management Staff, Memorandum to C. Ronald Smith, Director of the Office of Standards and Regulations, "Survey of agency practices regarding OMB review," Office of Policy and Resource Management, November 30, 1982, Milton Russell Special Collection.

11. Beyond cost-benefit analysis, the order also aimed to increase agency accountability for regulatory actions, minimize duplication and conflict of regulations, and ensure presidential oversight of the regulatory process. Therefore, while the OMB had neither the authority nor the competence to review the EPA's risk assessments, potentially it could still severely restrict the agency's authority and legitimacy for major decisions affecting highly toxic and widely used chemicals, as it did by regulating dioxin, benzene, lead, arsenic, or formaldehyde. Under that order, the OMB gained the right to review every single individual cancer regulation drafted by those agencies to examine the way that EPA staff considered the costs and benefits of the rules. It set up a dedicated task force to do so.

12. The passback was the OMB's communication (written or oral, in any case generally confidential) to the agency of its budget for the coming year, following decisions by the head of the OMB and the president.

13. Morgenstern had become director of the Office of Planning in mid-1982, on special assignment from the Urban Institute under the Intergovernmental Personnel Act. He was director of the Urban Institute's Energy Program from 1980 to 1982, senior legislative assistant to Senator J. Bennett Johnston from 1979 to 1980, and deputy assistant director for energy, natural resources, and the environment at the Congressional Budget Office from 1976 to 1979. From 1971 to 1976, Morgenstern was a tenured associate professor of economics at Queens College of the City University of New York. Prior to that, he taught for a year at the American University in Washington, D.C., and obtained a PhD from the University of Michigan in 1970.

14. Member of the Integrated Environmental Management Division staff, interview with the author.

15. Just as in 1977, these options differed widely, notably in terms of authority granted to functional offices, whose role has been difficult to define ever since the beginnings of the agency. The first option was to give a priority-setting task to the Office of Toxics Integration in the OPRM. The Office of Toxic Substances would

list substances for multimedia risk assessment and then coordinate the work by program offices. The second was to assign to a new office in the OPRM the task of coordinating and reviewing assessments done in separate offices, and of preparing guidelines for application by program offices. The third option was to combine all hazard, exposure, and risk assessments with economic analysis in a single organizational unit in OPRM. From option 1 to option 3, the degree of centralization obviously increased to the point of becoming politically unrealistic. Program offices were unlikely to give up their resources and mandates in risk assessment. Furthermore, options 2 and 3 outlined a system in which the OPRM effectively mediated among program offices and the top level of the agency, the deputy administrator and administrators, who signed regulatory decisions. In the eyes of its staff, the OPRM was to prepare the file for final decision-making and arbitration at higher levels. Nowhere in the regulatory regimes that the agency operated was it indicated that the OPRM would fulfill this role. Beardsley thus outlined several options and let the administrator decide.

16. The "conservative" (i.e., protective) policies were rooted in statements of individual risk, of the following kind: One (theoretical) person has 1 in a million chance of developing cancer from being exposed to substance *x*. The chemical industry was accustomed to criticizing this criterion, saying that, in the aggregate, the kind of individual risks that the EPA calculated amounted to no more than a dozen deaths per year for the whole US population—a very small number compared to casualties of automobile accidents, for instance. The OHEA always had difficulty countering these arguments. In 1981, in the era of systematic cost-benefit analysis, OMB supervision, and environmental skeptics at the top of the agency, cancer risk assessors conceded that indications of total risk should be provided alongside individual risk levels.

17. Arnold M. Kuzmack, Director, Office of Program Development & Evaluation, and Elizabeth L. Anderson, Director, Office of Health and Environmental Assessment, Memorandum to TSPC, "Request for Review of Draft Cancer Policy Statement," Office of Water, US EPA, July 22, 1981.

Chapter 4

1. Parts of this chapter have appeared in Demortain (2016). I thank the publisher for authorizing me to use parts of this chapter here.

2. For example, step 5, to be performed by the expert panel, concerned the preliminary estimation of carcinogenic hazards to determine the relative potency or severity of effects and to permit a reasoned and consistent setting of priorities. Step 6, a task of the regulatory agency, consisted of establishing preliminary priorities for regulation, if warranted by the outcome of scientific determination in step 5, and assembling data on actual or potential exposure. Then the regulatory agency would

continue to step 7, determining the need for and priority of regulation. The whole process ended with step 11, risk evaluation, including the identification of social valuation of the risk as derived through a risk-benefit evaluation, à la Chauncey Starr; and step 12, providing the most cost-effective method of achieving or maintaining a level of control.

3. See the comparable propositions put forward by the political scientist Allan Mazur (1973, 1977), who ultimately collaborated with Kantrowitz.

4. Raiffa is the author of a best-seller on negotiation games (Raiffa 1982).

5. "The policy maker has to consider, formally or informally, the alternative actions he or she might pursue, the institutional and political constraints, value and ideological judgments, and so on. This is risk evaluation. It can be viewed as a subset of what some people call policy evaluation or policy analysis" (NRC 1982, 33).

6. In a book that was published during CORADM's mandate, based on this committee's experience (Cohen and Lindblom 1980), Lindblom explained that the power of professional analysis to decide and set rational courses of action was a myth. The knowledge that was used in decisions was not professional, formal, or analytical knowledge.

7. A longer, 700-page report was written by Raiffa, but never actually published. The official report from the committee was a shorter, 82-page document entitled *Risk and Decision Making: Perspectives and Research* (NRC 1982).

8. Risk Analysis Research and Demonstration Act of 1981, H.R.3441—97th Congress (1981–1982), 11.

9. Projects Proposed: Risk Assessment and Federal Regulation Policies, Report No. 96–1030, Agriculture, Rural Development and Related Agencies Appropriation Bill 1981, Archives NAS-NRC Executive Offices Organization.

10. On November 18, 1981, the *Journal of Commerce* published a paper entitled "Gov't Reviewing Cancer Policy." The article quoted the executive director of the synthetic organic chemical manufacturers association as saying that a "pending study from the NAS [is expected] to fuel congressional investigations," especially on whether and how science could be separated from politics. See also *New York Times*, October 11, 1982, "The Calendar": "Risk assessment: How effectively are regulatory agencies working with scientists in assessing health and technology risks? That will be the focus of a three-day conference sponsored by the American Chemical Society and the National Bureau of Standards beginning today at the bureau's headquarters in Gaithersburg, Md. Wednesday."

11. The three academies (of science, engineering, and medicine) have standing committees of scientists, who are in charge of establishing the program of studies and events of the academies in a particular domain of competence. These boards

oversee the completion of studies, the establishment of the panels that will conduct the study. Board members may themselves sit on these panels.

12. NAS does not strictly require experts to be independent, but it selects people whose biases and attachments cancel each other out. Authority and neutrality are less properties of individuals than outcomes to be achieved through collective deliberation. The committee as a whole must appear as credible, authoritative, and speak with one voice. This subtle functioning gives committee chairs a key role. And while there are recipes for a successful committee, it is hard to predict whether a committee will succeed in producing a report consensually.

13. At the same time, Tardiff was playing an instrumental role in prefiguring the Society for Risk Analysis.

14. Ted Greenwood was then an assistant professor at MIT, working precisely on the question of regulatory agencies' use of science. His developing work proved useful to the committee to appreciate what he termed the interplay of "knowledge and discretion." He published a book called *Knowledge and Discretion in Government Regulation*, soon after the committee disbanded (Greenwood 1984).

15. Frank Press, before becoming president of the NAS in 1981, was President Jimmy Carter's science advisor and the administrator of the OSTP.

16. Fred Robbins, Memorandum to Frank Press, "Committee on Institutional Means for Assessment of Risk to Public Health," July 23, 1981, NAS-NRC Archives, RAC 1981–1983 files.

17. With both Omenn, the initial choice for the chair, and Stallones being in some way related to the AIHC or to the positions it advocated, the inference can be made quite safely that the AIHC was involved in suggesting names of experts to the NRC.

18. Interview with the author.

19. The Stanford Research Institute was Stanford University's contract research branch.

20. "Public" and "Industry" are the categories used in NRC documents.

21. Interview with the author.

22. It was clear, moreover, that the leaders of NAS did not want to create this panel within its walls. The panel would have given a quasi-regulatory role to NAS, irreconcilable with the institutional and intellectual independence that was the source of its great reputation and continued success in attracting study requests from the government or elsewhere. In September 1982, six months before the report was released, Stallones and Omenn briefed Lazen about some of the recommendations that were being sketched in the report, notably that of creating a "board for risk assessment methodology" within NAS/NRC, to get Frank Press's feelings about it. They felt that

this recommendation could embarrass the academies. First, it was not within the committee's ambit to develop such a line of recommendations. Second, a board for risk assessment methodologies would certainly represent a shift in the traditional activities of the NAS and the NRC, toward a more active regulatory role. It would necessarily involve some institutional and legal clarifications before being set up.

23. Moffett stated, "I must say in all candor that my reading last evening of the testimony that will be presented here this morning left me more than a little disturbed and disappointed, if not angry, about the performance of EPA during the past several months. There is apparently an awesome litany of retreat from serious environmental problems. […] Oh, yes, we are all in favor of regulatory reform. We all subscribe to the need for regulatory reform. There is a broad coalition indeed for getting rid of unnecessary and unproductive regulations, but what appears to be taking place is something more than that; something more than reform; something more than revision. This seems to be a radical departure. Yes, indeed, a radical or extreme departure from what the American people want and what their elected representatives have expressed legislatively. Perhaps the most important question that we need to explore today is what kind of regulatory mentality now exists at the lead environmental agency?" (US Congress 1982, 1–2).

24. John Todhunter, Memorandum to Administrator Gorsuch through Dr. Hernandez, "Review of Data Available to the Administrator Concerning Formaldehyde and Di(2-ethyl-hexyl)phthalate (DEHP)," US EPA, February 10, 1982 (US Congress 1983b, 248–249).

25. This separation played an important role in decision-aiding science from the outset. The prescription that problems should be clearly formulated before any procedure can be found in most handbooks of policy or systems analysis. According to Fortun and Schweber (1993), the physicists who founded operational research (the first to become involved in military affairs in the United Kingdom, and then in the United States) drew on a discourse of objectivity and neutrality, articulated with a practical reluctance to take the place of decision-makers.

26. Interview with the author.

27. McCray uses the language of "discretion" much more than the report will eventually do, in resonance with the work of Ted Greenwood (1984).

28. The group outlined a set of performance considerations and selected for case analysis: the relationship between the National Institute of Occupational Health and the OSHA, EPA's Scientific Advisory Panel (pesticides), the NRC, the CAG, EPA's Clean Air Scientific Advisory Committee (CASAC), OSHA's division of health standards, and the FDA's public board of inquiry.

29. The review showed that there were considerable variations across regulatory agencies, both in the kind of science they used and in the way they used it. Some

used in-house scientific departments' expertise, while others drew on that of external national research institutes. No one organization seemed better than the others in terms of producing more credible regulatory decisions, and there seemed to be no single best organizational solution for the use of science in regulatory decision-making processes.

30. The contract between the FDA and the NRC, dated September 18, 1981, No. 282-81-8251, stipulates that the committee should delineate the process of risk assessment "in terms of its individual components, identifying and distinguishing those that are scientific in nature from those that are value judgments or policy. In addition, an effort will be made to identify and describe those components that are neither strictly science or policy but a hybrid consisting of elements of both." It should be noted that the NRC was already thinking in terms of a hybrid category of "risk assessment policy" because this was used as a category of expertise to be populated by a nominee, back in June, as the council started to contact potential members. In short, the committee did not invent the hybrid notion of risk assessment policy. It was already available at the start of the process.

31. The document, for instance, stated that the purpose of the recommendation was to ensure consistency in risk assessments within the Office of Water. It also spoke of "risk assessment documents" (not "health effects documents" or "health assessment documents"), as comprising a health assessment, an exposure assessment, and … a risk assessment.

32. The word *value* appeared only three times in this 191-page report. RAFG went for a different, arguably less prescriptive term: *assumption(s)* (22 occurrences). For Shrader-Frechette, the report could very well have used a more normatively explicit term, like *methodological value judgment* (Shrader-Frechette 1995).

33. Subsequent discussions in the field of risk assessment and risk management revolved around the need to attend to the political aspect of risk decisions through more explicit communication with audiences and the public, or incorporation of the public in the process of making decisions, through deliberative arrangements (NRC 1989, NRC 1996, Stern 2009).

34. Warner North, interview with the author.

35. The article covered the positions of a number of attendees, such as Warren Muir of John Hopkins University, former director of the Office of Toxic Substances at the EPA (guidelines are beneficial; toxicologists want to exert professional judgments, but use unspoken assumptions); Nathan J. Karch, former staff member of the council on environmental quality (explicit criteria of risk will ensure consistency and lead to a more rational process of decision-making); Sherwin Garder of the Grocery Manufacturers of America (generic guidelines are possible for risk assessment; key is peer review); and Thomas Grumbly, former staff director of the House Science

Investigations and Oversight Committee (too many differences between agencies; focus away from a central board for risk assessment and toward a "let 100 flowers bloom" attitude in regulatory science; avoid separation). Karch and Swanson, of the American Petroleum Institute, concurred, demonstrating that the AIHC proposal was not so widely shared and that there were many people around Washington with a positive view of how agencies were doing their job.

36. Anonymous, "Schedule: Risk Assessment Study," 1982, NAS-NRC Archives, RAC 1981–1983 files.

37. Jasanoff (1992) also shows that the report was ambiguous as to its practical recommendations for handling the relation between risk assessment and risk management.

38. Terry Davies, interview with the author.

39. Academic panel members have often described this review process as the most rigorous that they have ever experienced.

40. Reuel Stallones, "Letter to Fellow Committeepersons," February 1, 1983, NAS-NRC Archives, RAC 1981–1983 files.

41. Al Lazen, "Letter to Frank Press," September 9, 1982, NAS-NRC Archives, RAC 1981–1983 files.

42. Various committee members, interviews with the author.

43. David Lazen, "Letter to Reuel Stallones," April 18, 1983, NAS-NRC Archives, RAC 1981–1983 files.

Chapter 5

1. See footnote 2 of the Introduction.

2. Larry McCray, Memorandum to Members of the Committee on the Institutional Means for Assessment of Risk to Public Health, "Recent events," April 18, 1983, NAS-NRC Archives, Risk Assessment Committee 1981–1983 files.

3. Joe E. Penick, letter to Philip Smith, executive officer of the National Research Council, March 31, 1983, NAS-NRC Archives, Risk Assessment Committee 1981–1983 files.

4. See also Ted Greenwood, letter to Larry McCray, April 1983, NAS-NRC Archives, Risk Assessment Committee 1981–1983 files.

5. After leaving the EPA in the spring of 1973, as the Watergate scandal was mounting, Ruckelshaus was called by Nixon to become acting director of the Federal Bureau of Investigation (FBI). He then moved to the second-highest position in the

US Department of Justice, but he was soon forced to resign after he refused to fire special prosecutor Archibald Cox. While Gorsuch was head of the EPA, between 1981 and 1983, Ruckelshaus worked at the timber company Weyerhaeuser as Senior Vice President of Legal Affairs.

6. William Ruckelshaus, interview with the author. Linda Nash mentions that Ruckelshaus's law firm had the AIHC as a client at the end of the 1970s (Nash 2017).

7. Bernard Goldstein, interview with the author. As mentioned by a member of EPA staff who worked closely with him in the early 1980s, Ruckelshaus "was a very very skillful, a very very influential thinker, and he would have been familiar with some of these conversations and debates already, both because of his work in public service but also in the private sector" (Terry Yosie, interview with the author). Ruckelshaus confirmed that he "had done some thinking about that problem for some time, because early on at the EPA, we did that kind of rigorous analysis" (William Ruckelshaus, interview with the author).

8. William Ruckelshaus, interview with the author.

9. In December 1983, the *National Journal* mentioned the June speech and the "Ruckelshaus approach" (Mosher 1983): "Specifically, Ruckelshaus wants EPA and other regulatory agencies to beef up the science of their risk assessment procedures. But he has also pressed for legislation that would give the regulatory agencies 'a common statutory formula' for clarifying how risks are to be managed.... The EPA chief signaled his intention to press for such changes in a speech to some 150 members of the National Academy of Sciences on June 22."

10. The speech was republished in several journals over time, including in *Science* (Ruckelshaus 1983). This version has been cited 200 times to date.

11. See also this excerpt of another speech delivered to the chemical industry: "We have shifted our attention and concern from problems that are relatively easy to see and solve, to those that are subtle and vexing, from smoke and sewage to the attempt to eliminate toxic substances from the human environment. I can tell you that this shift has caused substantial problems for EPA ... controlling toxics is an entirely different sort of business. Where we once dealt with a dozen or so pollutants, we now must consider hundreds. Before, we concentrated on removing familiar substances by the ton; now, we often must cope with the exotic and worry about micrograms because we are confronted with materials that may be able to cause serious human health damage in vanishingly small concentrations," William Ruckelshaus, "Our Challenge," Remarks at the Semi-annual Meeting of the Chemical Manufacturers Association in New York City, November 8, 1983. See also Anonymous (1984a).

12. Anonymous ORD risk assessment scientist, interview with the author.

13. There is evidence that Ruckelshaus was modifying his messages to suit his specific audiences, drawing on the variations that the risk assessment–risk management framework allowed. Elsewhere, he had stressed that ignorance, rather than science, characterized the conditions in which the EPA had to make decisions: "We may ask, why is rational argument less than convincing in discussions about toxic chemicals? Why aren't the judgments more in line with our calculations? I believe it is because public concern is centered on those dreaded diseases that are plausibly connected with low concentrations of toxic substances; that is, cancer and the genetic and reproductive disorders, and because, at the heart of our risk assessment, there is, undeniably, a hollow place. I think people sense that we really don't know how and under what circumstances chemicals cause cancer; they're right, we don't." He went on to liken his action on cancer to British water hygiene policies in the nineteenth century, citing them as two cases of "action in the face of ignorance." This was certainly a daring comparison to make before proponents of risk assessment, which generally decry any sort of action that goes beyond the science (or what is now known under the rubric of precaution). "I think people sense that we really don't know how and under what circumstances chemicals cause cancer; they're right, we don't" (Ruckelshaus 1984; see also Anonymous [1984a]).

14. In the same speech, he declared the following: "At EPA we have tried to disentangle risk assessment, as a process, from the policy considerations that go into making a final decision about regulating a substance, which we call risk management. I realize there is not an obvious bright line between the two; still, I believe that good public policy obliges us to make it as bright as we can." So, from the point of view of the due administrative process of dealing with risks, the subtle definitions crafted in RAFG were "somewhat of a nuance" (William Ruckelshaus, interview with the author). From a public standpoint, in the aftermath of the Gorsuch crisis, it was simply "important to let people know that there was a scientific part of trying to determine what the nature of the risk was, that it should in no way be subject to political interference, or there should be no pressure put on scientists" (ibid.).

15. Lee Thomas, memo to Milton Russell, draft final report on risk assessment/risk management. Office of Solid Waste and Emergency Responses, July 31, 1984.

16. The EPA webpage summarizing the history of the reduction of air pollution from transportation, and the EPA's actions in the area, state that "EPA vehicle emissions standards directly sparked the development and implementation of a range of technologies. The automotive catalytic converter, in particular is considered to be one of the great environmental inventions of all time." See epa.gov/air-pollution-transportation/accomplishments-and-success-air-pollution-transportation (accessed on June 10, 2016).

17. In August 1983, Ruckelshaus was interviewed by the *National Journal*. The published interview was preceded by an introduction stating that "his [Ruckelshaus's] most cherished goal is to streamline the assessment and management of

environmental risks throughout government, and that will probably include introducing considerations of cost in setting air quality standards." Ruckelshaus reiterated that "the difference between assessing the risk and managing must be carefully made," applying that principle right away to issues such as dioxin and risks from fine particles in the air, and then on the agenda of the EPA, the press, and others. On dioxin, he stated: "There are two issues. The first is to define the risk; what are the health effects of dioxins? This is a separate scientific process and should have nothing to do with determining what to do about it. If we find dioxins in the soil in some remote site, that may suggest one solution. If you find it in the middle of a city where many people are exposed to it, and there are ways of disposing of it that are safe and relatively cheap, that suggests another strategy. We simply have to have a more flexible management strategy than just saying a certain level is unacceptable under every condition." Clearly, here, risk management implied that policy decisions were informed by a judgment of what an acceptable risk actually was, not by an absolute level of risk protection. Moreover, solutions and strategies could vary depending on the conditions. The problems were to be managed according to the way they emerged in a given context, much more than being sorted out in absolute terms.

18. Milton Russell, Memorandum to the Administrator, "Interagency Liaison," EPA Office of Policy, Planning, and Evaluation, September 2, 1983, Milton Russell Special Collection.

19. William Ruckelshaus, letter to other heads of agencies, "Proposal for an Interagency Coordination on Risk Management," September 21, 1983, Milton Russell Special Collection.

20. It took less than a year for the White House to kill the initiative once more, by launching a competing Cabinet Council Working Group on Risk Assessment under the aegis of the Council on Environmental Quality. Ruckelshaus was offered the chair of this council as well. See the hearing of 1984 (US Congress 1984) for positive comments from various agencies on the Interagency Risk Management Council project.

21. Monte C. Throdahl, chairman of AIHC's science policy task force, wrote to Ruckelshaus in November 1983 to ask the EPA to lend support to the bill.

22. H.R.4192—"A bill to establish coordinated interagency research and demonstration projects for improving knowledge and use of risk assessment by those Federal agencies concerned with regulatory decisions related to the protection of human life, health, and the environment, and to provide for the establishment of a Central Board of Scientific Risk Analysis as a means of improving the scientific review and evaluation of risk analyses made by Federal agencies, with particular emphasis upon risk analyses involving issues of chronic health hazards." 98th Congress (1983–1984), https://www.congress.gov/bill/98th-congress/house-bill/4192.

23. Ted Greenwood, letter to Larry McCray, April 1983, NAS-NRC Archives, Risk Assessment Committee 1981–1983 files.

24. Following her assessment of the initial Ritter Bill, dated June 3, 1982, and in her testimony on June 23, 1981, at the House's Subcommittee on Operations, Research and Foreign Agriculture, she defended views that were highly concordant with those of the RAC. She criticized the definitions laid out in this bill, which distinguished between risk assessment and risk evaluation, and was not in line with emerging definitions of RAFG (even though it was not yet published, which meant she followed developments of the committee's work). She was happy with the general support that the bill gave to the development of risk assessment. But her comments consisted of putting the bill back into the context of what the EPA did and current developments of risk assessment in the federal government at large, which the bill seemed to ignore. The bill suggests that the OSTP should coordinate a program for improving and facilitating the use of risk analysis—a system that Anderson deemed unclear and burdensome for agencies and the OSTP. Elizabeth Anderson, memorandum to Bernie Goldstein, assistant administrator for the ORD, "Comments on the Ritter Bill," March 6, 1982.

25. Arnold M. Kuzmack, director, Office of Program Development and Evaluation, Office of Drinking Water, memorandum to Peyton Davis, Policy and Strategic Analysis staff, Office of Water, "Draft Bill to Create an Independent Science Panel within the NAS," EPA, November 4, 1983, Milton Russell Special Collection.

26. Richard Hill, Science Advisor to the assistant administrator for OPTS, "Amendment to HR3840 offered by Mr Martin," October 26, 1983, Milton Russell Special Collection; Milton Russell, special assistant to the administrator, memorandum to Josephine Cooper, assistant administrator for external affairs, "Martin Amendment to Ritter Bill (HR3840) on Central Board for Scientific Risk Analysis," Office of Policy, Planning and Evaluation, US EPA, October 20, 1983, Milton Russel Special Collection.

27. Don Ritter and David Martin eventually withdrew Title II of their bill, the most controversial part of it, instituting a board for scientific risk analysis. The White House also opposed the bill and lent support to interagency coordination initiatives.

28. Milton Russell, memorandum to Alvin Alm, deputy administrator, "First Thought Piece on What EPA Could or Should Do on Risk Communication," January 17, 1984, Milton Russell Special Collection.

29. Milton Russell, "Communicating with the Public on Issues of Environmental Risk: Issues and Options," Draft paper prepared for Deputy Administrator Alvin Alm, January 17, 1984, Milton Russell Special Collection.

30. Roger Gale, special assistant to the administrator, memorandum to EPA Administrator William Ruckeslshaus, through Milton Russell, "Recommendations of the Risk Working Group," Office of the Administrator, EPA, March 27, 1984, Milton Russell Special Collection.

31. Arsenic was one of these high-visibility chemicals that posed recurrent problems to the EPA. The regulation of this substance was forced on the agency by the result of a suit opened by the Environmental Defense Fund, which wanted the EPA to list

arsenic as a hazardous air pollutant under the Clean Air Act. In June 1980, the Air Office followed suit, making arsenic the seventh substance on that list. By January 1983, however, the agency was ordered by the Federal District Court of Manhattan to set a standard for arsenic within six months (the agency had failed, purposely or not, to meet several past deadlines). When he joined the agency in May 1983, Ruckelshaus found that dossier on his desk and quickly decided to make a decision on this issue that was so symbolic of the governing difficulties generated by these disputed chemicals.

32. Handling the meeting proved extraordinarily costly and difficult for an EPA staff that had little training in direct deliberation with the public. Experience was limited to formal hearings, with prepared testimonies and limited on-the-spot responses. The hearings also proved very resource intensive for the regional branch in charge. Exchanging with the public appeared difficult and did not unroll as Ruckelshaus had imagined. Eager to apply a risk assessment/risk management distinction, where the public would mostly discuss risk management and possible future solutions to apply, he did not allow a full discussion of the EPA's scientific assessment of the risk levels or of the accuracy of the estimates derived from dispersion models used by engineers. At the same time, risk management was not much of an issue either. The public represented there was concerned about deindustrialization, the anticipated closure of industries, and the need to attract jobs. The discussion soon turned to local industrial policy and the need to gain more jobs from less-polluting industries in the area—issues for which the EPA was hardly competent (Reich 1985; Gutmann and Thompson 1998; Heifetz 2009). After Tacoma, Ruckelshaus's special assistant on risk, Roger Gale, tried to moderate the use of risk-related categories in public circumstances. Claims about risk inherently derived from considerations about the value of life, which he felt was slippery ground for the EPA. Moreover, the agency would not be able to handle such a generic issue alone, given its statutes and the role of other agencies. Finally, risk issues are fundamentally complicated and unappealing to the public and the business community. This notion of risk, he felt, overintellectualized problems, leading to near blackmail of the public, as in Tacoma. Roger W. Gale, special assistant to the EPA administrator, "Risk Assessment and Risk Management," December 6, 1983, Milton Russell Special Collection.

33. Roger Gale, special assistant to the administrator, memorandum to EPA Administrator William Ruckelshaus, through Milton Russell, "Recommendations of the Risk Working Group," Office of the Administrator, EPA, March 27, 1984, Milton Russell Special Collection.

34. Roger W. Gale, special assistant to the EPA administrator, memorandum to the members of the Risk Working Group, "Review of Revised Draft of Risk Working Group Memo," March 14, 1984, Milton Russell Special Collection.

35. Derry Allen and Richard Morgenstern, Office of Policy Analysis, to Milton Russell, assistant administrator for the Office of Policy Planning and Evaluation,

"Briefing Memo for This Afternoon's Meeting with the Administrator on Risk Communication Activities," April 1, 1984, Milton Russell Special Collection.

36. Paul Slovic, Memorandum to Milton Russell, "Putting Risks in Perspective," Decision Research—A Branch of Perceptronics, March 1984.

37. The report *Improving Risk Communication* did not itself present such a graph, but an amended framework was soon to appear with the "risk communication" module incorporated, a first occurrence of which can be found in subsequent publications of the World Health Organization (WHO).

Chapter 6

1. Richard Morgenstern, memorandum to Alvin Alm, deputy administrator, and to Milton Russell, special assistant to the EPA administrator, "Agenda of the First Meeting of the Toxics Integration Task Force," June 2, 1983, Milton Russell Special Collection.

2. Ibid.

3. Ruckelshaus also brought back with him a number of advisors and colleagues that he knew he could work with efficiently, such as Jim Barnes, Howard Messner, Jack Raven, and Phil Angel.

4. John Todhunter, memorandum to Richard Hill, "Adoption of NAS Recommendations with Regard to Risk Assessment," March 11, 1983, NAS-NRC Archives.

5. Interview with the author.

6. Richard Hill, Office of Toxic Substances, memorandum to John Moore, assistant administrator for the OPTS, "A Regulatory Decision-Making Nosology," US EPA, January 12, 1984, Milton Russell Special Collection.

7. By his own admission, Goldstein did not handle the interview at the White House ideally, failing to demonstrate the Republican credentials that he did not have anyway (interview with the author).

8. In May 1984, he spoke once again with Gil Omenn at a conference, discussing in depth the various recommendations of the report as it concerned guidelines and a methodological risk assessment board.

9. Quite emphatically, the same staff member considered that Ruckelshaus and Alm were "very charismatic, thoughtful, brilliant leaders," the kind of people who "surround themselves with very capable people of independent stature, and when you put that caliber of independence and stature together, what you get is the ability to think through decisions, not just in terms of the next decision, but also more strategically, over longer periods of time, and I think that's what Ruckelshaus and his team did" (interview with the author).

10. In April 1983, Larry McCray had briefed senior people of the ORD and the Office of Resources and Policy Management of the agency. Later, on June 10, 1984, Corn, North, and McCray briefed the Environmental Health Committee of the EPA's SAB. In July 1983, the representatives of the AIHC and Terry Davies met Ruckelshaus, the EPA administrator, to describe a legislative proposal for application of scientific peer review to agency risk assessment.

11. After leaving the EPA in 1985, Alm served in top positions in a number of management consultancies. The *New York Times* obituary for Alm mentioned that he "operated just under the bureaucratic rank where public service translates into renown"—another way of saying that his reputation did not quite match the successes that were attributed to him and his actions in the various organizations he served (Cushman 2000, A19).

12. Alvin Alm, memorandum to the general counsel, assistant administrators, and regional administrators, "My Preferred Approach to Management at EPA," EPA, August 18, 1983, Milton Russell Special Collection.

13. Ibid.

14. He became assistant administrator after clearance from the White House, and after testifying before Congress in October 1983, like the other people picked by Ruckelshaus and Alm, such as Bernard Goldstein and Jack Moore.

15. Milton Russell, interview with the author.

16. Ibid.

17. Ibid.

18. Ibid.

19. A similar process had been instituted at the White House during the Ford administration, with the participation of Alm. The then called "options paper process" was managed by the White House chief of staff, Dick Cheney, known at the time as "Mr. Straight" (Milton Russell, interview with the author).

20. Interview with the author.

21. Goldstein stayed as head of ORD until 1986, and Russell remained at the OPPE until 1988. Moore stayed at the EPA until 1989. He also acted as deputy administrator that year.

22. John Moore, assistant administrator for pesticides and toxic substances, memorandum to Alvin Alm, deputy administrator, "Candidates for Options Selection Process," November 10, 1984, Milton Russell Special Collection.

23. Milton Russell and Roger Gale, memorandum to William Ruckelshaus and Al Alm, "Report of the Risk Working Group," March 28, 1984, Milton Russell Special Collection.

24. Both phrases were articulated by Alm. Milton Russell, memorandum to Alvin Alm, "Options Review Process," March 28, 1984.

25. Richard Morgenstern, "Toxics Integration Task Force: Final Report Outline," Office of Policy Analysis, EPA, April 1984, Milton Russell Special Collection.

26. Alvin Alm, memorandum to Milton Russell, "Draft Memorandum on Criteria and Guidelines for Review of Agency Actions," September 16, 1983, Milton Russell Special Collection.

27. The guideline continued the substance of what had emerged during the Carter administration through the Regulatory Quality Council (for more information, see chapter 3, on Costle's regulation development memo).

28. The contents of the format were organized by the following rubrics: Name and type of regulation/action; statutory decision/criteria; target of control action; primary object protected (human health, aquatic organism, etc.); economic impact; major uncertainties; and other important considerations governing decisions. Three annexes with data are cost-effectiveness estimates, hazard assessment, and exposure assessment. The cost-effectiveness key includes control options, data on maximum individual risk, data on aggregate population risk, and benefits other than risk reduction.

29. Milton Russell, assistant administrator, OPPE, memorandum to Alvin Alm, deputy administrator, "Procedures Regarding OMB Contacts," January 9, 1984, Milton Russell Special Collection.

30. For instance, the OPPE sided with the OPTS to defend the "New Chemicals" program against recurrent OMB accusations of excessive conservatism and bias with regard to new chemicals.

31. Interview with the author.

32. In this case, much like the formaldehyde case, Todhunter had asked an EPA statistician to alter her estimates for EDB using a theory that she had never seen before—namely, the fact that risk levels decline exponentially with decreasing exposure time.

33. Milton Russell, memorandum to Alvin Alm, "Regulatory Development," October 1, 1984, Milton Russell Special Collection.

34. Ibid.

35. Don R. Clay, acting assistant administrator for pesticides and toxic substances, memorandum to Dan Beardsley, director, Integrated Environmental Management Program, "Interagency Chemical Strategies," November 14, 1983, Milton Russell Special Collection.

36. Dan Beardsley, director, Integrated Environmental Management Program, memorandum to Don Clay, director of the Office of Toxic Substances, "Your Memo

on Interagency Chemical Strategies," November 30, 1983, Milton Russell Special Collection.

37. Milton Russell, memorandum to William Ruckelshaus, through Alvin Alm, *Report on Risk Assessment and Risk Management,* August 13, 1984, Milton Russell Special Collection.

38. Milton Russell, memorandum to all assistant administrators, *Report on Risk Assessment and Risk Management,* July 6, 1984, Milton Russell Special Collection.

39. John Moore, assistant administrator for pesticides and toxic substances, memorandum to Milton Russell, assistant administrator for policy, planning and evaluation, "Comments on the Draft Final Report on Risk Assessment/Risk Management," July 26, 1984, Milton Russell Special Collection.

40. Milton Russell, interview with the author.

41. Ibid.

42. John A. Little, deputy regional administrator for region IV, and Peter Preuss, director, Office of Regulatory Support, ORD, "Risk Assessment Review," December 12, 1985, National Archives and Records Administration, Records of the Environmental Protection Agency (Record Group 412).

43. Ibid.

Chapter 7

1. Ernest F. Cloyna, memorandum to the administrator, William Ruckelshaus, "Report of the Laboratory Organization Review Group," Science Advisory Board, July 28, 1983, National Archives and Records Administration, Records of the Environmental Protection Agency.

2. Bernard Goldstein, memorandum to ORD laboratory and center directors, "Research and the Regulatory Agenda," April 6, 1984, National Archives and Records Administration, Records of the Environmental Protection Agency.

3. Ibid.

4. The SAB is comprised of external scientists, but the agency also has a staff director who is in charge of coordinating the work of the board with the agency's priorities.

5. "Historically, ORD program managers and the OMB have viewed the short-term and long-term components of EPA research as pursuing incompatible or unrelated objectives. In reality, both can serve to support EPA's fundamental mission: to identify, assess and abate the risk of pollution to public health and the environment. Viewed in this context, the strategic mission of ORD's research program, in both the current fiscal year and over a longer time frame, is to advance and develop

the scientific and technical basis for risk assessment and risk management." Ernest Cloyna, *Report of the Laboratory Organization Review Group to the Administrator,* July 28, 1983.

6. Terry F. Yosie, memorandum to the administrator, William D. Ruckelshaus, "Making Effective Use of the Science Advisory Board," November 2, 1983, National Archives and Records Administration, Records of the Environmental Protection Agency.

7. Ibid.

8. "The Agency's referral of studies and assessments to the SAB for peer review preceded, but is consistent with, the recommendations of the National Academy of Sciences in its report on risk assessment in the Federal government. A major recommendation of this report was for regulatory agencies to create independent peer review panels to review scientific studies that form the basis for major agency regulatory decisions" (Yosie 1987, 6).

9. Alvin Alm, memorandum to assistant administrators, general counsel, inspector general, regional administrators, "Risk Assessment," May 21, 1984, Milton Russell Special Collection.

10. Interview with the author.

11. Milton Russell, assistant administrator, Office of Policy, Planning, and Evaluation, memorandum to Alvin Alm, deputy administrator, "Problems in Risk Assessment, Risk Management, and Risk Communication," October 5, 1983, Milton Russell Special Collection.

12. Anonymous ORD risk assessment scientist, interview with the author.

13. Alvin Alm, deputy administrator, memorandum to assistant administrators, general counsel, inspector general, and regional administrators, "Risk Assessment," May 21, 1984, Milton Russell Special Collection.

14. Rodrick's business is now a large, multinational risk assessment consultancy called Environ.

15. Alvin Alm, deputy administrator, memorandum to assistant administrators, general counsel, inspector general, and regional administrators, "Risk Assessment," May 21, 1984, Milton Russell Special Collection.

16. In the internal newsletter called the *Risk Assessment Review*, Peter Preuss of the OHEA (one of the main risk assessment shops of the agency) wrote a short article about this new Risk Management Council, noting, "Recently the Administrator has established a number of 'Risky' structures at EPA whose profusion can bring confusion to the eyes of even the most battle-hardened bureaucrat." For Lee Thomas, the main objective of the Risk Management Council was to have a place in which to

discuss and institute a cross-media perspective in the normal regulatory operations of the agency. The council was to identify such cross-media, multioffice issues and promote common management strategies.

17. Alan Ehrlich, 1988. "Advances in Risk Assessment Guidelines." Presentation at the 34th Anniversary Technical Conference Mid-Atlantic States Section Air Pollution Control Association, Milton Russell Special Collection.

18. An ADI is a computation made for regulatory purposes, consisting of dividing by a safety factor of 10 or more, the lowest possible dose at which a chemical substance shows no adverse activity in the body of an experimental animal. The computed dose is deemed acceptable as it is presumed that a human person can be exposed to it on a daily basis during his or her lifetime without developing any serious adverse effects.

19. Donn J. Viviani, Chief Regulations Analysis Branch, memorandum to Al Jennings, director, Chemical and Statistical Policy Division, "Haven't We Met Before?," August 20, 1985, Milton Russell Special Collection.

20. Anonymous ORD risk assessment scientist, interview with the author.

21. IRIS is an information technology database containing agreed-upon risk values for a wide range of chemicals, accessible by all regulatory offices, initially by internal email, aiming at improving the consistency of risk assessments across the agency. It has become one of the international databases of risk estimations of reference worldwide.

22. Guidelines provide an explicit point of reference, against which discrepancies between regulatory offices can be measured and explained too, though not necessarily reduced: "[P]reparation of the guidelines was an instrument for addressing both an internal administrative problem and an external political problem. Within the agency, they could serve as an instrument to control how various offices used scientific data and how they recommend policy choices to the administrator. Externally, they represented one of Washington's most venerable principles: be sure that your potential adversaries (be they industrial firms, environmentalists, Congress or the Office of Management and Budget) debate your ideas, and your agenda" (Yosie 1989, 3).

23. Dorothy Patton, interview with the author,

24. Milton Russell, special assistant to the administrator, memorandum to Alvin Alm, deputy administrator, "Expected Reactions to Proposed Memorandum on Criteria and Guidelines for Agency Review," September 16, 1983, Milton Russell Special Collection.

25. Paul Ehrlich, memorandum to Bernard Goldstein, assistant administrator for the Office of Research and Development, and Elizabeth Anderson, director of OHEA, "Progress report on guidelines," June 21, 1984, Milton Russell Special Collection.

26. Richard Nill, memorandum to Jack Moore, assistant administrator, Office of Pesticides and Toxic Substances, "A Regulatory Decision-Making Nosology," January 12, 1984, Milton Russell Special Collection.

27. Ibid.

28. Ibid.

29. Milton Russell, memorandum to the administrator, "Equity and the Choice of Risk Measures," Office of Policy Planning and Evaluation, EPA, June 7, 1984, Milton Russell Special Collection.

30. Milton Russell, memorandum to all assistant administrators, "Requirements for Exposure-Related Analysis," May 8, 1984, Milton Russell Special Collection.

31. Alvin Alm, memorandum to all assistant administrators, regional administrators, and general counsel, "Accuracy in Risk Assessment," January 1, 1984, Milton Russell Special Collection.

32. Anonymous ORD risk assessment scientist, interview with the author.

33. This means that the experiments in animals did not show cancer in all species tested, or only at certain doses, and tumors were difficult to analyze as malignant or benign.

34. Milton Russell, memorandum to Alvin Alm, deputy administrator, "Carcinogenicity, Strength of Evidence and the Need for Agency-wide Consistency," Office of Policy, Planning, and Evaluation, March 16, 1984.

35. Ibid.

36. Paul Milvy, Office of Drinking Water, memorandum to Al Jennings, Office of Policy, Planning and Evaluation, "The Three Conclusions Reached by CAG on the Carcinogenicity of Perchlorethyelene (PCE) and the 3/8 Memorandum Entitled 'Strength of Evidence of Carcinogenicity—a Need for a Consistent, Agency-Wide Policy,'" March 9, 1984, Milton Russell Special Collection.

37. Russell to Alm, March 16, 1984, attachment I.

38. Ibid.

39. Elizabeth Anderson, director of OHEA, memorandum to Richard Morgenster, director of Office of Policy Analysis, "Weight of Evidence in Decision-making," US EPA, March 28, 1984, Milton Russell Special Collection.

40. Russell to Alm, March 16, 1984, attachment I.

41. Bernie Goldstein, memorandum to the administrator, William Ruckelshaus, and deputy administrator, Alvin Alm, "The Presence or Absence of Thresholds in

Chemical Carcinogenesis: Scientific Issues," October 11, 1983, Milton Russell Special Collection.

42. Terry Yosie, interview with the author.

43. Elizabeth Anderson, director of Office of Health and Environmental Assessment, memorandum to Alvin Alm, deputy administrator, "Characterizing Cancer Risk Quantitatively," June 8, 1984, Milton Russell Special Collection.

44. William Ruckelshaus, administrator, "Letter to EPA Program Managers," November 23, 1984, Milton Russell Special Collection.

45. The guidelines, as agreed between Anderson and the SAB, would be reviewed later by the board, but they were to be applied right away by each office.

46. During the press conference for the launch of the guidelines, Bernard Goldstein said, "The overall theme is to improve accuracy" (Anonymous 1984b).

Chapter 8

1. Ruckelshaus joined a company in an industry that the EPA regulated. In 1987, he joined the waste disposal company Browning-Ferris as director, soon after the EPA announced that it would sue the company for violations at a Louisiana landfill. This led to a settlement between Browning-Ferris and the EPA, which was considered controversial by some commentators. After the settlement, Ruckelshaus was named president and CEO. Phil Angell, who had been his close adviser during both of his mandates at the EPA, was Browning-Ferris's spokesman.

2. Milton Russell, memorandum to the administrator, Lee Thomas, and to the deputy administrator, James Barnes, "OPPE Role in Decision Process," October 21, 1985, Milton Russell Special Collection.

3. Lee Thomas, "Assessing and Managing Risks in the Real World," address before the National Petroleum Refiners Association, San Antonio, TX, March 25, 1985.

4. Russell to Thomas, October 1985, Milton Russell Special Collection.

5. Daniel Beardsley, memorandum to Milton Russell, "Application of Risk Concepts," September 10, 1984, Milton Russell Special Collection.

6. A special review is initiated by the Office of Pesticides when it suspects that an already-registered product has "unreasonable adverse effects on people or the environment" (https://www.epa.gov/pesticide-reevaluation/reregistration-and-other-review-programs-predating-pesticide-registration, last accessed December 11, 2018). The review involves evaluating existing data, acquiring new information and/or studies, assessing the identified risk, and determining appropriate risk reduction measures; it may result in the cancellation of the registration.

7. A pilot effort had been attempted at the end of 1984, described as a "quick and dirty analysis" of all efforts related to risk reduction across programs. But this was done by the OPPE alone, without cooperation with program offices, and the office focused on cancer risks only (see EPA 1984a).

8. Milton Russell, interview with the author.

9. Alar is a pesticide that some studies had proved carcinogenic at the maximum tolerated dose, and that the EPA had informally placed under special review at the end of the 1970s. In 1980, after negotiations with the manufacturer, the idea of a formal special review was abandoned, and the manufacturer was asked instead to reregister the product. In 1984, however, the CAG produced a "Health and Environmental Effects Profile" for 1,1 Dimethylhydrazine (EPA/600X-84/134), with a quantitative potency estimate, confirming its carcinogenic nature. The Office of Pesticides reinitiated the special review and the cancellation procedure in 1985. It produced a draft position document, reasserting that alar was a probable human carcinogen (EPA 1985a). The SAP, which reviews all rules prepared by the pesticides office, criticized the draft position document. The panel delayed the action by arguing that there was insufficient experimental data available to perform a quantitative risk assessment or potency estimate as CAG did, and that more cancer studies should be performed. (The SAP opinion was critically regarded a couple of years later, when it surfaced that many of the members of the group had worked with the pesticide industry as consultants.) In 1986, the EPA followed the opinion of the SAP, announcing that Uniroyal could continue marketing the product, but the company would have to collect and frequently report monitoring data and chronic toxicity test results. For more on this, see the early and detailed account presented in Jasanoff (1987).

10. Terry Davies, interview with the author.

11. H.R. 2910, Mercury Environmental Risk and Comprehensive Utilization Reduction Initiative, 105th Congress (1997–1998).

12. The White House memo of January 20, 1992, on "Reducing the Burden of Government Regulation," with its ambition "to weed out unnecessary and burdensome government regulations" and issue a 90-day moratorium on all regulatory proposals, testifies to this stance (White House 1992). When Clinton came to office, he asked that those regulations that were on hold (there were several dozen of them, apparently) be returned to agencies to be reviewed by a Clinton appointee, to effectively end the de facto embargo that the OIRA/OMB created on all new pieces of regulation.

13. Anonymous policy analyst, Office of Policy Analysis, interview with the author.

14. Anonymous economist, Office of Policy Analysis, interview with the author.

15. H.R.4306, the Risk Assessment Improvement Act of 1994, 103rd Congress (1993–1994).

16. This was part of H.R.1814, the Environmental Research, Development, and Demonstration Authorization Act of 1995.

Chapter 9

1. The new estimate was that exposure to one-tenth of a pictogram per kilogram of body weight of dioxin every day over seventy years created a one in a million cancer risk. The previous estimate was that such a risk materialized at a much lower dose (in cases of exposure to one six-thousandth of pictogram per kilogram of body weight) (Powell 1999).

2. The debate revolved around the qualification as adverse or harmful of the (not contested) respiratory effects in conditions of low concentration/durable exposure, as opposed to high-concentration/short-term exposure.

3. Interview with the author.

4. PBPK is a method that helps specify the doses at which a given substance may be found in particular organs of the body. It is a modeling method by which the various organs and flux (e.g., blood, air) comprising the human physiological system are described in a set of equations. It helps to make a more precise determination concerning the doses at which a given chemical is found in the body of a human, based on experiments in animals, without applying protective uncertainty or safety factors that the standard methodology of risk assessment uses to err on the safe side.

5. Yosie, the former EPA staff director for the SAB, left the agency in 1988 to join the American Petroleum Institute.

6. The reauthorization of the Clean Air Act had been on the agenda of Congress since the beginning of the 1980s, but it failed on several occasions between 1981 and 1988. However, under the influence of a renewed public concern about environmental protection and the commitment of George H. W. Bush during the presidential election campaign in 1988 to strengthen air pollution control, Republican opposition in Congress to a revision of the Clean Air Act diminished (Oren 1991; Vogel 2012). The adoption of the Clean Air Act amendments in 1990 benefited from these circumstances.

7. These terms evoke those of economist Lester Lave, a key scholar in the professional field of risk analysis in the United States, during a hearing on environmental issues before the Subcommittee on Transportation and Hazardous Materials of the Committee on Energy and Commerce, House of Representatives, in November 1993 (US Congress 1994a, 45).

8. This was a popular comparison in books and articles of that time about the EPA and failed risk-risk trade-offs. See, for instance, Nichols and Zeckhauser (1986). Justice Stephen Breyer drew from these cases and from the OMB report in his 1993 book (Breyer 1993).

9. Throughout the 1980s and 1990s, Abelson published dozens of editorial papers attacking risk assessment as performed, or as appearing to be performed, by the EPA.

10. That is, other than those that qualify as "criteria pollutants" under title I.

11. S.1630—Clean Air Act Amendments of 1990, 101st Congress (1989–1990), 83.

12. Ibid., 83. For more on this point, see Graham 1985, 122, fn148.

13. See chapter 3 on Wilson's participation in an EPA conference on behalf of the industry in order to criticize the linear approach.

14. Thornton also writes: "I might have called this model [the NRC paradigm] the acceptable discharge paradigm, or the pollution control paradigm, or the technocratic paradigm; all of these names refer to essential elements of today's regulatory system" (Thornton 2001).

15. For environmental critics, the adoption of quantitative risk assessment, coupled with cost-benefit analysis, was deregulation in scientific disguise. In their eyes, Ruckelshaus was essentially pursuing the same Reaganite agenda: "EPA needed to find a way to continue the substance of the Gorsuch-Hernandez deregulation efforts but with the appearance of scientific 'objectivity.' William Ruckelshaus, then in his second turn as EPA administrator, took the risk assessment efforts developed by EPA, FDA, and NRC over the previous 15 years, added cost-benefit analysis (under the rubric of risk management), and proclaimed his agency's commitment to protecting public health and the environment in a 'cost-effective way.' The result was an 'objective' methodology, supported by the National Academy of Sciences, that enabled the EPA to set permit levels and clean-up levels for toxic substances. QRA theoretically gives them a method of determining what levels of pollution or pollutants are 'acceptably safe' without having to evaluate available technology, alternative processes, alternative substances, or community concerns" (Ginsburg 1997, 230).

16. In a subsequent paper, Goldstein more explicitly stated that the separation was a myth: "A myth about the early development of risk assessment was that it was believed to be fully independent of risk management. The simple dichotomy between risk assessment as science and risk management as policy has never really existed." He argued that the separation was barred first by the existence of guidelines, and then by practices of risk characterization and risk communication, by which all of the choices, assumptions, and uncertainties pertaining to the assessment of risk were shared by risk managers (Goldstein 2005, 141).

17. In its 1993 report *Researching Health Risk*, the Office of Technology Assessment (OTA) had reached the conclusion that "risk managers should be in contact with risk assessment researchers, the developers of methods and new approaches. The report sees the managers, who must apply the results of risk assessment, as becoming aware of where research might reduce reliance on assumptions, highlight qualitative uncertainties, improve the process, and improve public confidence" (Gough,

cited in US Congress 1994c, 10). The OTA suggested that risk assessment should be more integrated with research from the outset.

18. However, as the reaction of Warner North to Ruckelshaus's June 1983 speech shows (see North 2003, and chapter 5), the authors of RAFG clearly did not see their report as unilaterally advocating such a separation. What one could say is that their categories and overall framework of thinking were so effective that they influenced the way that people in the agency thought and behaved. Hence, those who saw themselves as doing risk assessment started to insulate themselves from others, just by virtue of embracing this identity. Organizational decisions in the agency did the rest.

19. Barnes wrote: "The vigorous developments in risk assessment that took place in the late 1970s and early 1980s shimmered and sparkled but, like so much Jello, lacked a unifying, undergirding structure. It was the NAS paradigm that finally succeeded in nailing much—but not all—of this Jello® to the wall. For example (to borrow from the comparison of the sacred and the secular), the paradigm provides a common, somewhat demystified language which both anointed practitioners (risk assessors) and laypeople (the rest of us) can use when communicating about risk. Both groups can appreciate that all scriptures (risk assessments) should have a common underlying structure (i.e., the four elements in the paradigm). Further, the paradigm lays out the moral equivalent of the Prime Directive (i.e. the separation of church [risk assessment] and state [risk management])" (Barnes 1993, 10).

20. The expression, for instance, is found in the NRC report *Issues in Risk Assessment* and in volume 19 of the *EPA Journal*, both published in 1993. During the 1970s and 1980s, the phrase "Red Book" referred to the FDA manual describing the data and methods applicable to the safety evaluation of food additives (Tardiff and Rodricks 1988).

21. A review of the use of risk management reporting formats across offices also showed that overall, they were accurate and useful. Where the formats were incomplete and insufficient, this was generally at the level of more contentious and sophisticated parts of the risk assessment, such as exposure assessment and quantitative estimation of cancer potency. Most of the time, or so it appeared, the delays were caused not of the review of regulatory aspects and the costs and benefits of anticipated decisions, but of the risk assessment. See Daniel Fiorino, Chief Regulation and Information Management Division Memorandum to Richard Morgenstern, Ron Smith, and Milton Russell, OPPE, "Use of the Risk Management Information Reporting Format," October 24, 1984, Milton Russell Special Collection.

22. The summary of a later workshop sponsored by AIHC et al. (1992, 5) similarly stated that risk analyses had to be "relevant, timely and comprehensible," and had to "provide a variety of risk measures (e.g., both societal and individual risk estimates), as well as a clear statement of uncertainties."

23. In the EPA's 1986 guidelines, the standard of proof of causal association between exposure and cancer was threefold: No bias could explain the association, the possibility of a hidden ("confounding") factor has been ruled out, and, most important, "the association is unlikely to be due to chance." This last item alone constituted the "statistical significance" criterion. In practice, it was expressed by the application of a 95 percent confidence level on all epidemiological studies—a standard of proof that environmental health scientists and environmental groups frequently decried because it excluded critical studies from consideration.

24. Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, No. 6:93CV00370, 1995 U.S. Dist. LEXIS 7521 (M.D.N.C. May 23, 1995).

25. Flue-Cured Tobacco Co-Op Stabil. vs. U.S. EPA, 4 F. Supp. 2d 435 (M.D.N.C. 1998), 466.

26. Anonymous former administrator chief of staff, interview with the author.

27. Ibid.

28. Anonymous ORD risk assessment scientists, interview with the author.

29. The 1980 CAG document on the calculation of the unit risk estimate for air pollutants, for instance, ends with a section noting that the unit risk estimate is a "rough indication" of the relative potency of the agent compared to other carcinogens. The document states that confidence levels for the estimate are generally not calculated "due to the difficulty of accounting for the uncertainty in the data" (EPA 1980b). The Water Office guidance of 1982 mentions the uncertainty surrounding the mechanisms of carcinogenic action, as well as the evidence of mutagenicity of a substance, to justify employing a conventional toxicity evaluation method (safety factor applied to NOAEL) in parallel with a linear extrapolation model, and presents the results side by side, with some elements to judge the relative weight of each of them (EPA 1982). The 1984 guidelines for deriving numerical national water quality criteria warn only that criteria should be established only if the data are of a good-enough quality, but they do not describe methods to analyze uncertainties in the resulting estimates (Stephan et al. 1983). The 1984 document on probabilistic analysis for water quality treats uncertainty via the application of the classical margins of safety and pleads for caution in altering this margin of safety, which provides a "cushion" for scientific uncertainty (EPA 1984c). The approach crafted by the Office of Pesticides' Hazard Evaluation Division for Ecological Risk Assessment is no more precise about the estimation of uncertainties. Although it mentions quantitative uncertainty analysis in the evaluation of ecological risk scenarios, the document remains close to the conventional elaboration of toxicity estimates, understood as "rough" indications of the potential risks of pesticides to nontarget organisms. At that time, it seemed simply impossible, given the data available, to engage in any sort of quantitative estimation of model uncertainty (Urban and Cook 1986).

30. Gil Omenn, interview with the author.

31. Bernard Goldstein, assistant administrator, ORD, memorandum to Alvin Alm, deputy administrator, and to Milton Russell, assistant administrator, OPPE, "Conservatism," October 28, 1983, Milton Russell Special Collection.

32. In 1991, two reports came out, both drafted under the aegis of the Board of Environmental Studies and Toxicology (BEST) at the NRC, and both were requested by the recently created Agency for Toxic Substances and Disease Registry (ATDSR) to push the development of exposure assessment and epidemiology in risk assessment: *Human Exposure Assessment for Airborne Pollutants: Advances and Opportunities* and *Environmental Epidemiology, Volume 1: Public Health and Hazardous Wastes*. These documents reemphasized the difficulties involved in performing exposure assessment, the lack of data about where substances were found in the environment and at what doses, and the pathways through which people were exposed to these substances, over what period of time, and at what doses. Despite the acknowledged need to construct larger databases for exposure, these assessments continued to rely on typically nonvalidated models.

33. Anonymous senior scientist of the Office of Pesticides, interview with the author.

34. The NRC report was also the source of a compromise in Congress that allowed the endless debate on the application of the Delaney clause finally to be closed.

35. Anonymous former administrator chief of staff, interview with the author.

36. Boland, J. E. Executive Order. August 5, 1992. Philip Morris Incorporated. Bates No. 2022852158–2160 at 2158. Minneapolis: Minnesota Tobacco Document Depository.

37. The staff of the Superfund program argued that they were already distinguishing between risk assessment and risk management, making it clear that baseline risk assessments were just one element for consideration by risk managers. Uncertainty analysis was already covered because the office applied a 95 percent confidence level on the arithmetic mean of site sampling data and used IRIS estimates. The program was slightly more challenged by the requirement to propose measures of high-end exposure and to take into account sensitive populations explicitly. However, the office argued, this was in progress. A new concept of "reasonable maximum exposure" was being articulated (Longest and Diamond 1992).

38. The year 1993 saw a succession of no fewer than three congressional hearings, on environmental issues, on risk assessment and the regulatory process, and on risk assessment research. Those followed hearings on the role of science at EPA in 1992 and on the strengths and limitation of the utilization of risk assessment for policy decisions in 1991 (US Congress 1991, 1992, 1994a, 1994b, 1994c).

39. Anonymous, 1986, "Board on Toxicology and Environmental Health Hazards," 53, NAS-NRC Archives.

40. This is now called BEST. See note 11 in chapter 4.

41. The 1993 CRAM report had three parts. The two other parts concerned ecological risk assessment and the use of the maximum tolerated dose in animal experiments. The workshop and resulting report addressed the questions of whether that dose created imbalances in the organism of the animal under testing, so that the cancer effects that may eventually be observed would not just be linked to the substance itself, but to these imbalances; and what other dose may be used that would reveal carcinogenic effects, without artificially inducing them? The group did not resolve this issue, but concluded that "use of the MTD itself does not predict whether a material will elicit a carcinogenic response in a standard animal bioassay. The basis of the relationship is not clear" (NRC 1993b, 62). It argued that the rationale for the selection of a dose in an animal experiment should always be made clear when reporting results of the study.

42. Anonymous member of the NRC panel, interview with the author.

43. Brauman, Finkel, North, and McClellan had the opportunity to warm up for the discussion in one of the many conferences on risk regulation in the Washington, D.C., area in those days—notably the 1992 conference organized by Resources for the Future (where Finkel was based at the time) on comparative risk assessment and risk ranking.

44. Interview with the author.

45. According to the two authors, this could best be implemented as part of a tiered approach to risk assessment (which also was suggested in the body of the report and defended by the committee as a whole), by which chemicals would be placed in three separate categories. The first covered chemicals "with the least amount of data," for which qualitative characterization was most appropriate. The second included "chemicals with more extensive data," for which generic default options would remain applicable. The third category was that of chemicals for which available data sets were "extensive." For those chemicals, "multiple risk calculations corresponding to alternative models and data sets corresponding to individuals and populations" may be provided (NRC 1994, 635). The two authors considered that the choice to depart from the default was the prerogative of risk managers, even though this claim was inconsistent with the principle that defaults should be overridden when better science was available, for who other than risk assessors could and should take care of appreciating the availability of better scientific knowledge? The two authors themselves wrote that "weighing the plausibility of alternatives is a highly judgmental evaluation that must be carried out by scientists" (ibid., 633).

46. In a footnote, he also took support from a previous NRC report on *Human Exposure Assessment for Airborne Pollutants* which asserted that public health policy

requires that decisions be made despite incomplete evidence, with the aim of protecting public health in the future.

47. Interview with the author.

48. Anonymous employee of the NRC, interview with the author.

49. Anonymous former administrator chief of staff, interview with the author.

50. Clinton, in his presidential campaign, was explicit about the need to be cost-effective in environmental policymaking and to resolve the paralysis and inconsistencies in scientific environmental assessments: "One of our biggest problems is the problem represented by the Superfund and some other areas, where you've got to fix something bad that's already happened, where we spend too much money on lawyers, too much money on consultants, the endless decisions. It's almost impossible to get anybody at the local level to agree what the best solution is.... I am just appalled by the paralysis and the political divisions and the fact that the money is being blown." he declared at the Economic Summit in Little Rock, Arkansas, on December 15, 1992. When she took office, Browner was queried on what she would do to improve the awful situation of those who are "governed by EPA," an agency that takes "two contradictory positions at the same time and puts the heat on that state and the private sector," or "takes one position, then another, and then another" (*EPA Journal* 1993). This was one of the reasons for her initial distancing from making risk assessment the systematic basis of all agency decisions, as Republicans required.

51. This office was formally named the Office of Science, Planning, and Regulatory Evaluation.

52. Other than that, it took time for Browner to deliver on her promise of placing science at the heart of the EPA's work. Recruiting the half-dozen top scientists, as suggested in *Safeguarding Science,* proved difficult, given the budget constraints. Browner could only pledge to recruit more researchers for ORD, thanks to the money saved on external contractors (Stone 1994a).

53. H.R.4306, the Risk Assessment Improvement Act passed by the 103rd Congress (1993–1994), directed the EPA administrator to issue risk assessment guidelines regularly.

54. In a memo from Philip Morris reporting on the policies initiated by Browner, it is indicated that she was releasing her own risk characterization policy because "most EPA risk assessors and risk managers simply placed the 1992 risk characterization policy in the bottom drawer of their desks and did not use it." Boland, J. E. Executive Order. August 5, 1992. Philip Morris Incorporated. Bates No. 2022852158–2160 at 2158. Minneapolis: Minnesota Tobacco Document Depository.

55. Edward Ohanian, interview with the author.

56. Ibid.

57. Various officials of the ORD and of the Office of Policy, interview with the author.

58. Al Meyerhoff, an attorney with the Natural Resources Defense Council, was among those who explained in the media that the increased flexibility would dramatically slow the whole process of regulating hazardous chemicals (Hanson 1996).

59. The EPA was now speaking of the effective dose—namely, the dose associated with a 10 percent biological response. Rather than an objective threshold that would be manifested in biological reactions, an effective dose is a regulatory artifact. The EPA later got in the habit of calling this a point of departure that was deliberately constructed to provide a floor from which the extrapolation to other doses could then be made. If the mode of action led to an expected linear low-dose tumor incidence relationship, then a straight line was drawn from the ED10 to the origin (linear). The molecular approach to cancer risk was presented by the EPA and accepted as a major change. Indeed, it came down to abandoning the default application of the LMS model, in favor of a quasi-avowal that there was a threshold.

60. The new criteria were (1) temporal relationship, (2) consistency, (3) magnitude of the association, (4) biological gradient, (5) specificity of the association, (6) biological plausibility, (7) information completeness, (8) coherence (EPA 1986a).

61. Interview with the author.

Chapter 10

1. The main project affected was the ongoing reflection on the methodology of minimal data values for chemicals under consideration in IRIS: a principle by which no safe dose would be set for chemicals for which studies and data were missing, and uncertainty appeared too large (Inside EPA 2010).

2. Speaking at the 40th anniversary of the EPA, he was quoted as saying, "I was assistant administrator of ORD soon after the Red Book appeared. My standard speech about the then new risk assessment paradigm contained the assertion that it would take ten years before we would know whether risk assessment was of value to the agency. I suspect that a similar time will be needed for sustainability" (Goldstein 2011, 308).

3. A separate initiative in the Air Office echoes the same sort of move toward enlarging the scientific base for decision-making from risk assessment to a broader set of techniques and methods. That initiative consists of producing science integration documents instead of risk assessments in order to set up standards for levels of chemicals in ambient air. Science integration was originally a proposal from the American Petroleum Institute, approved by the EPA administrator in 2006 (Cole 2007).

4. Interview with the author.

5. Ibid.

6. In subsequent discussions in the SAB and in the Science Policy Council on "science integration" (which partly followed from *Science and Decisions*), the language concerns "managers" only.

7. Specifically, this refers to the reports *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (NRC 2008) and *Toxicity Testing in the 21st Century: A Vision and A Strategy* (NRC 2007). Both offered generic advice on how to perform risk assessment in the EPA. To plan the conference, telephone interviews were conducted with participants, who were questioned about their knowledge and views of the NRC reports, their program's risk assessment activities, their needs for new and/or updated guidance, and their vision for risk assessment and the steps that the agency can take to achieve that vision" (Human Health Risk Assessment Colloquium Summary Report, April 25, 2012).

8. The framework "draws on agency experience" and "takes into account the recommendations" of the Silver Book and "a considerable body of additional expert advice," starting with the Red Book, the 1994 NRC report *Science and Judgment,* and the internal EPA report of 1984, *Risk Assessment and Management: Framework for Decision-Making* (EPA 1984b). It also cites eight other agencywide risk frameworks, from the Risk Assessment Guidance for Superfund Part, to the Framework for Ecological Risk Assessment, to the Guidance on Cumulative Risk Assessment.

9. During the campaign, the contest between Bush and Vice President Al Gore, an environmental champion, forced the former to green his discourse. He pledged to regulate carbon dioxide emissions and greenhouse gases. But as soon as he was in office, he reversed these pledges, overturning an eleventh-hour decision by Clinton to set a standard of 10 ppb for arsenic in water.

10. She later revealed that her departure was triggered by the White House's weakening of EPA regulations on air pollution from aging power plants. According to Whitman, Vice President Dick Cheney pushed hard for a rule that "didn't hamper industry," and the final rule was written "at the direction of the White House," over the objections of Whitman and EPA staff (Becker and Gellman 2007).

11. In the terms of the notice: "The appropriate level of precaution in risk assessment and management is complicated by the need to balance efforts to mitigate these potential risks with countervailing risks that may arise from other sources" (OMB 2003b, 5498).

12. Interview with the author.

13. Several important policy principles are summarized in the document—notably, the definition of what it is to be "conservative" and protective of the environment and of public health when one aims to root decisions in the best possible science.

Since *Science and Judgment* and the protracted debate that took place within the confines of the committee between "plausible conservatism" and "using all the science available" (as discussed in chapter 9), the agency made an effort to clarify its own position. The staff paper recalls this position: namely, uncertainty cannot justify inaction. The agency "seeks to adequately protect public and environmental health by ensuring that risk is not likely to be underestimated" (EPA 2004, 11). The staff paper also recalls the progress and changes made across the agency in the consideration of uncertainties and variabilities.

14. Under the pressure of the OMB and requests for enhanced analysis of uncertainties in risk assessments, the number of substances listed in IRIS declined dramatically in those years (GAO 2008).

15. This substance, a rocket fuel engine, was a bone of contention between the EPA and the US Department of Defense. It had been known to cause cancer since at least the 1950s. In 1999, the agency requested the department to send a list of sites contaminated with perchlorate. By 2003, the latter had still not complied, but the agency went forward anyway, defining benchmark levels for the cleanup of polluted sites under the cross fire of senators Barbara Boxer (D-CA) and James Inhofe (R-OK), acting for and against the establishment of a protective standard, respectively.

16. Graham also detailed OIRA's Nancy Beck to Gray's Office of Science Advisor at the EPA, where she was put in charge of the formulation of the agency's response to the OMB. In the end, the EPA did not really have to respond, as the bulletin initiative was essentially killed by the NRC's response.

17. Gil Omenn and Paul Slovic, also members of the earlier RAC, reviewed the report. Omenn concurred with the NRC's overall severe assessment (Omenn 2006).

18. Under Bush's EPA, the positions of assistant administrator for ORD and science advisor were occupied by the same person.

19. This last review was pushed by a Republican senator, David Vitter of Louisiana. Vitter threatened the EPA that he would oppose the nomination of the proposed new chief for ORD, Paul Anastas, until he came to a compromise with Lisa Jackson, the new administrator appointed by President Obama. Companies with stakes in the production of formaldehyde appear to have funded Vitter (Sapien 2010).

20. In 2012, Congress adopted a provision by which the EPA was directed to apply the recommendations of the NAS on formaldehyde, to report to the House and Senate how it did so, and to contract with the NAS for a set of three more reviews of IRIS assessments.

21. A ruling of the Supreme Court on greenhouse gases in Massachusetts [*Massachusetts v. Environmental Protection Agency,* 549 U.S. 497 (2007)] also took some of the heat out of the debate when it pushed the agency to regulate these gases, saying it should provide a scientific basis to justify not doing so (Greenhouse 2007).

22. Interview with the author.

23. Ibid.

24. Ibid.

25. Ibid.

26. Ibid.

27. He published a separate paper in an academic journal to outline the concept, as well as several other papers to test the concept in case studies (Finkel 2011).

28. Dourson was one of the fathers of the RfD/RfC concepts. He was a longtime staff member of the OHEA (from the early 1980s until 1995). In 2017, he was nominated for the job of director of the OPTS. But his past work as a consultant for the industry, combined with the revelation that he systematically defended less protective standards than the EPA for each of the chemicals on which he was consulted, made him appear too close to the regulated industry, which gradually compromised his candidacy, which he withdrew.

29. That included the Office of Modeling, Monitoring Systems, and Quality Assurance; Office of Environmental Engineering and Technology Demonstration; Office of Environmental Processes and Effects Research; Office of Health Research; and OHEA.

30. The downside of the reorganization, however, was that it made the ORD *more* autonomous from program offices and limited their interaction with the risk management side (Powell 1999). For instance, Huggett launched an exercise in prioritizing subjects for ORD research, ranking the thirty-one risks that the report *Unfinished Business* listed back in 1987. But the managers of program offices were not invited to participate in the exercise (Risk Policy Report 1997).

31. When considering more diffuse cause-effect relationships, as in the case of environmental hazards affecting species or milieus, the logic of risk assessment remains, but the preliminary, qualitative steps for identification of the hazard become more sophisticated. As noted by Suter (2008, 286), "The ORNL ERA framework differed from the Red Book framework in having 3 preliminary steps that differed from the hazard identification step in the Red Book framework. The first, defining the endpoints, was necessitated by the diversity of ecological entities and attributes that might be at risk (Suter 1989). The second, development of source terms, was neglected by the Red Book, which focused on human exposure processes. However, the synthetic fuels case studies clarified the importance of determining where, when, and how pollutants are released to the environment. The third, description of the environment, was necessitated by the recognition that ecological risks are determined by the environmental context."

32. Interview with the author.

33. Ibid.

34. The idea of addressing a variety of risks in an integrated manner also draws on a longer history of codification of the methods of the agency. It belongs specifically to what the agency specialists called *cumulative risk assessment (CRA)*. The EPA produced its first synthetic document about CRA in 1997, approximately ten years after the Committee on Pesticides in the Diets of Infants and Children of the NRC started to sensitize the agency to the problem of multiple exposures. That guidance, drawing from the experience of the Office of Pesticides, produced a new vision of risk assessment, incorporated into a broader dialogue to plan the assessment and future actions stemming from it. It stipulated that risk assessment should not be performed as a matter of habit, on isolated risks or hazards presumed to be the source of the problem. That problem should be appreciated for its complexity: A risk is a risk because the chemical hazard often compounds with such factors as "existing health condition, anxiety, nutritional status, crime, and congestion" (EPA 1997, 2). Rather than risks, these are stressors. In pinpointing the problem and planning for the analytic task, the "needs of risk management," fed back from previous decision points, are an important point of reference. In terms of practical innovation, the report suggested establishing the "analysis plan," or conceptual model that identifies the stressors, the exposed populations, and the end points that will be addressed in the risk assessment, as well as the relationships among them. The report recalls that the analysis plan can simply use and quote existing guidance (Ibid., 3). Again, the practice is borrowed from ecological risk assessment work, where the development of a conceptual model was already an old practice, rooted in the very first formalized plans for ecological risk assessment in the 1980s at the Oak Ridge National Laboratory.

35. The establishment of this risk commission was mandated in the Clean Air amendments of 1990, with the goal of reviewing the NRC report that these same amendments ordered the EPA to obtain in order to review its risk assessment methods. The commission did not start its work until 1994, however, because of the presidential election of 1992 and House and Senate elections of 1994. Gil Omenn, a former member of the OSTP under President Jimmy Carter in the 1970s and a coauthor of RAFG, was nominated by Congress and became chair. Alan Kessler, nominated by the White House, cochaired the group. Bernie Goldstein, a professor of environmental medicine and former head of the ORD during Ruckelshaus's second term as EPA administrator, was nominated by the NAS. Omenn and Goldstein had particular influence on the group and the ideas presented in the report.

36. Interview with the author.

37. The report also distanced itself from RAFG. Volume 1 does not cite RAFG; rather, it starts from the definition of risk management that is given in this report and goes on to broaden it: "Risk management is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions

that reduce or prevent risks while taking into account social, cultural, ethical, political, and legal considerations. Our definition of risk management is broader than the traditional definition, which is restricted to the process of evaluating alternative regulatory actions and selecting among them" (Presidential and Congressional Commission 1997a, 1). Volume 2 of the report, however, mentions RAFG as the source of the "now universally recognized four-step framework for characterizing the likelihood of adverse health effects from particular chemical exposures" (Presidential and Congressional Commission 1997b, 4).

The Science of Bureaucracy

Risk Decision-Making and the US Environmental Protection Agency

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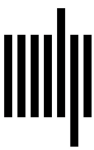

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