2 The Invention of Quantitative Risk Assessment

Rational decision-making at the EPA is influenced by the hope that enduring controversies could be resolved and legitimate decisions advanced. It is shaped through a process that involves scientists and their rationales for reordering knowledge and administration. In 1976, a group of medical scientists and toxicologists, brought together on the initiative of the EPA administrator, engaged in the creation of a procedure for computing and regulating the risks of getting cancer from exposure to chemicals—namely, the cancer assessment guidelines (EPA 1976). This technology for making decisions, still in use today, structures judgment of the hazards posed by chemical substances and helps to arrive at regulatory measures concerning them. The technology involves a series of steps to devise estimations of the level of concern, truncating uncertainty as much as possible to provide a firm ground for decision-makers. This process rests on the assemblage of various people and expertise: biochemists and statisticians, but also policy analysts and administrative officials making the final decision.

The common narrative of the invention of quantitative health risk assessment links it to the rise of risk science and the expansion of engineering methods for probabilistic risk analysis in this sphere of the medical and biological sciences (e.g., Nash 2017). But the history of the EPA's cancer risk assessment guidelines shows that this bureaucratic technology reflected a particular political situation, namely, the agency's difficulty in establishing noncontroversial facts concerning cancer risks before the courts, in the context of the medical disputes raging around carcinogenesis. This circumstance provoked the design of a new, probabilistic organization: one in which a decision emerges from the examination of data and the ascertaining of a level of risk. This technology was conceived by a network including

the agency's lead economist and policy analyst, Alvin Alm, and toxicologists from inside and outside the agency. It was to produce long-lasting effects on the internal organization of the agency, as well as its credibility as a regulator of cancer-causing substances, putting together an organization that could govern risks according to degrees of certainty and harm, in a legible manner. Ideally, this was an organization in which cancer risk assessors acted transversally, informing the action of officials in the diverse regulatory programs of the agency.

The Delaney Problem

The environment made it onto President Richard Nixon's agenda under pressure from the public environmental movement that had built up in the 1960s in the United States, culminating in the first incarnation of Earth Day on April 22, 1970. He was also forced to move forward on this issue because of the popularity of Senator Edmund Muskie, head of the Public Works Senate Committee and future Democratic candidate for president, who was championing the environment. The 1969 National Environmental Policy Act was the first piece of general environmental legislation applying across all sectors of government. It required all agencies of the federal government to consider the detailed impacts of actions that were expected to have an effect on the quality of the environment, and it established a Council on Environmental Quality in the White House. Nixon also decided to add to the program of the White House Council on Government Reorganization, chaired by Roy Ash, formerly head of Litton Industries (a company developing military technologies and equipment, and a contractor to the US Department of Defense), a project to institute a new department for all matters related to nature and the environment (Landy et al. 1994).

Both Ash and Nixon were in favor of creating a large, new Department for Environment and Natural Resources. An environmental committee inside the Ash Council was appointed to design this department. The group was headed by Amory Bradford and also included Douglas Costle, a future EPA administrator (1977–1981),[1] and J. Terry Davies, a political scientist and future EPA assistant administrator in the 1980s. It soon developed a set of original ideas, which differed from the plan to create a new department. It argued that such a new department would be too heterogeneous and

unwieldy, with imbalances between its environmental and developmental perspectives. Moreover, it would tend to disrupt the distribution of subjects among committees in the US Congress. They pushed instead for a global approach to the environmental problem. A notion of *comprehensive environmental management* implied doing away with the separate treatment of different kinds of pollution in order to sensibly improve the overall state of the environment. The new administration was thus envisaged as an agency rather than a department so that it could approach the environment as a whole and embody public policy in this regard.

That plan was finally accepted by Ash, and by Nixon. When it was formally inaugurated in December 1970, the EPA thus compounded the bureaus that administered statutes relating to the environment in a handful of departments. Tellingly, the act of creating the new agency was a reorganization or redistribution of fifteen existing offices and groups from the previous departments to the new agency. The US Department of Health, Education, and Welfare contributed the groups in charge of air, solid waste, radiological health, water hygiene, and pesticide tolerance. The US Department of the Interior conceded its unit for water quality and pesticide label review. The Atomic Energy Commission and the Federal Radiation Council transferred its service for radiation protection standards. Pesticide registration came from the US Department of Agriculture (USDA). The creation of the EPA was not accompanied by a revamping of all of these statutes and offices. So the legislative tasks, goals, resources, and processes of each bureau, as well as their personnel, remained in place.

These choices had two major implications for the EPA's authority. One was that because the EPA was an agency, not a department, the EPA administrator was not a member of the president's cabinet. This has been a recurrent problem over the life of the agency, and Congress debated elevating the agency to cabinet status on several occasions (in 1992, 2001, and 2012), but it never occurred (though the administrator of the agency has cabinet-status rank today). This meant that the EPA administrator was kept out of a number of strategic policy choices made by the White House, which saw it as a lower-ranking administrative body to be supervised. From the very start, the EPA was a targeted candidate for supervision by the White House Council of Environmental Quality, the Regulatory Council, and the Office of Management and Budget (OMB), and attempts at displacing agency decision-making toward other parts of the executive (Percival 2011).

The other implication was that an environmental protection agency was simply very difficult to steer. Its administrative infrastructure was made of separate bureaus, each implementing regulatory statutes with distinct rules and supervised by different congressional committees, all intent on pushing through "agency-forcing" legislation. The strategy was one of legislative micromanagement, leading to the definition of often-ambitious goals and tight schedules for the agency to meet in order to ensure delivery and minimize the risk of capture of the regulatory body by the regulated industries (Stigler 1971; Rosenbaum 1995). In practice, this meant that the various offices of the EPA had very different objectives, constraints, patterns of staffing, and expertise (McGarity 1991), as well as different regulatory cultures. Some were seen as more inclined toward protective policies, and others as closer to the industries they regulated. It also meant, however, that they were largely autonomous and difficult to steer from the top. They were fiefdoms that could easily frustrate the deployment of the administrator's chosen policies.

The agency's first administrator, William Ruckelshaus, chose an "activist suit strategy" (Marcus 1980, 88) to build up the newly created institution's credibility. His ambition was to quickly amass a number of successes on the legal front, taking on polluters. The strategy was meant to break with the image of its constituent part and to avoid falling captive to businesses' and interest groups' symmetrical criticism, through radical, unambiguous actions. This was announced forcefully by Ruckelshaus in December 1970, when several cities were threatened with prosecution if they failed to stop the discharge of pollutants into rivers within 180 days, and when several corporations were charged with pollution control violations (Marcus 1980, 88–90). Ruckelshaus also decided to opt for a case-by-case litigation strategy, through which he tried to cancel registrations of pesticides based on the argument of cancer effects. This litigation strategy, operated directly from the Office of the General Counsel, had in part been chosen against the Office of Pesticides. The latter, which had been transferred from the USDA, was oriented toward product registration, not driven by public health or environmental protection concerns, and was reputed to be relatively close to the industries it regulated (Landy et al. 1994; Powell 1999). It was one of the offices that seemed less easy to merge within a new environmental agency. To advance his strategy of establishing the EPA's reputation in high-profile litigation, Ruckelshaus decided to circumvent the Office of Pesticides

and to have his general counsel run so-called cancellation hearings against a number of pesticides, including dichlorodiphenyltrichloroethane (DDT), aldrin/dieldrin, mirex, and heptachlor.

Cancer Policy: From Fixed Principles and Facts to Flexible Judgment Guidelines

Cancer had emerged as a major national public issue long before the EPA was set up. The question of the widespread effects of various chemicals on the environment and human health lay at the heart of the nascent modern environmental movement in the 1960s. The cancer issue was also a policy issue. Even before the collective mobilization of the 1960s, lawmakers had moved boldly on it. For instance, an amendment to the Pure Food and Drug Act adopted in 1958, pushed by Representative James Delaney, prescribed that any food additive shown in animal tests to be carcinogenic may not be approved. The Delaney amendment, of course, was a radical regulatory intervention and an unmistakable sign of the rise of a new kind of regulation, soon known as *social regulation*: a form of public intervention on industries and markets that is similar to competition regulation, but motivated this time by health, environmental, or social concerns. The rise of social regulation was deeply linked to the growing influence of public interest groups in the 1960s, reflecting a new, more open pattern of interest group politics (Vogel 1988; Bardach 1989; Harris and Milkis 1989). Cancer became an object of official federal policy with the adoption of the National Cancer Act in 1971 (establishing a fund to research possible ways to cure cancer). The Mrak Commission's report "Pesticides and Their Relationship to Environmental Health" (1969), a report of the US surgeon general in 1969 (also on the evaluation of environmental carcinogens), and the 1971 report of the Council on Environmental Quality confirmed the "war on cancer" agenda. They also contributed to changing the framing of the cancer problem. From a focus on finding the medical "silver bullet" for eradicating the disease, it became one of controlling toxics as the silent, environmental cause of cancer and of acting preventively instead of curing. The EPA was thus born in this atmosphere of environmentalism under political pressure from members of Congress, environmental groups, and public demands for regulatory intervention against polluting, health-damaging chemicals.

Establishing a generic cancer policy applicable to all cases and meeting the high levels of protection and safety that the statutes imposed, as Delaney had, proved immensely difficult. The EPA was soon confronted with the challenge of proving in court what was immensely controversial in science and medicine: the causal link between exposure to chemicals and the development of cancer. The dominant assumption in medicine was that exposure to carcinogenic chemicals could bring about cancer effects at any dose. But for some carcinogens, nongenotoxic ones in particular, it appeared that the existence of a threshold was still a possibility. And there was no definitive standard of proof to establish the existence of this threshold in the dose-response relationship. It was a matter of choice between statistical methods to extrapolate between tested doses.

That whole issue aroused strong emotions. It turned into a full-blown medical and toxicological controversy, compounded by legal challenges and doubts about whether administrations had sufficient authority to decide this threshold question, which has a direct impact on decisions on whether to regulate a chemical. Because of this problem, the Delaney amendment was particularly hard to implement for the FDA. It faced strong opposition on the grounds that the economic activity associated with the production and use of these chemicals was often substantial, and it seemed difficult to ignore the benefits associated with a substance, even though there were also risks.

Opponents of the amendment argued, on the contrary, that regulatory measures on products and substances should be based on the doses to which people were actually exposed. In other words, they should be regulated according to the risk, which was a function of the hazard. Harm mattered, but it was assumed to be more appropriate to ban things only when they were proved to be regularly or frequently harmful under one or the other condition. The pharmacology division of the FDA developed a procedure for establishing not absolute, but acceptably safe, levels of chemicals (Lehman et al. 1955; see also Rodricks 2007; Carpenter 2010), sketching out a kind of risk-based procedure for ruling chemicals. The procedure consisted of drawing dose-response curves based on experimental results. The curve normally was supposed to have a threshold corresponding to a dose that was conceptualized as the *No Observed Adverse Effect Level (NOAEL)*. To take into account differences between experimental animals' and humans' reactions to a similar substance, as well as to define a dose that it was deemed

acceptable (by toxicologists at least) to expose humans to, the dose was divided by 10, 100, or 1,000. (The convention was to divide by 10 the safe dose found in animals, to determine the safe dose for humans, and/or by a supplementary factor of 10 to determine the safe dose for the most sensitive human, and/or by yet another factor of 10 to protect the most sensitive human against potentially lethal and irreversible effects). The resulting calculated dose was called the *acceptable daily intake*.

With regard to the EPA, the Criteria Office, one part of the Office of Health and Environmental Assessment (OHEA) of the ORD, was routinely performing this sort of assessment for noncarcinogenic substances. This was, in essence, the basis of what was then starting to be called risk assessment, in lieu of the former, more qualitative exercise of "safety evaluation" (Weill and McCollister 1963, 486). But for substances with a cancer effect, the EPA devised a less flexible policy, abstracted from the arguments used by its legal counsels in the first procedures to cancel the registration of pesticides. The cases resembled each other and raised the same kind of questions and challenges for the EPA (namely, the scientific challenge of proving scientifically the existence of a link between exposure to the pesticides and risks of cancer). The EPA's associate general counsel of the Office of Pesticides asked Umberto Saffioti, a scientist in the National Cancer Institute, to abstract principles that could serve as a standard of legal proof of carcinogenicity. Choosing Saffioti was by no means neutral, because he had chaired a scientific panel under the auspices of the National Cancer Institute a few years earlier, which had concluded that no safe level of exposure to carcinogenic substances could be established.[2] Saffioti's principles were still used in the proceedings of the EPA for cancellation of the registration of the pesticides aldrin and dieldrin. The principles were particularly precautionary and represented an aggressive legal strategy. In formulating them, the EPA's attorneys had clearly taken strong stances in medical toxicological debates to ascertain the following facts that were immediately convertible to legal strategies:

1. A carcinogen is any agent that increases tumor induction in humans or animals.
2. Well-established criteria exist for distinguishing between benign and malignant tumors; however, even the induction of benign tumors is sufficient to characterize a chemical as a carcinogen.

3. The majority of human cancers are caused by avoidable exposures to carcinogens.
4. While chemicals can be carcinogenic agents, only a small percentage are.
5. Carcinogenesis is characterized by its irreversibility and long latency period following initial exposure to a carcinogenic agent.
6. Individual susceptibility to carcinogens varies greatly.
7. The concept of a threshold exposure level for a carcinogenic agent has no practical significance because no valid method of establishing such a level exists.
8. A carcinogenic agent may be identified through analysis of tumor induction results with laboratory animals exposed to the agent, or on a post hoc basis by properly conducted epidemiological studies.
9. Any substance that produces tumors in animals must be considered a carcinogenic hazard to humans if the results were produced in a valid carcinogenesis test.

These principles and supposed facts about pesticides and cancer were as scientific as they were policy-based (Jasanoff 1982). They were developed by leaving aside many gray and controversial areas regarding the determination of carcinogenicity, under the concerted search for effective legal arguments. They were meant to determine mechanically how the EPA would now treat chemicals, as well as securing victory in court. Moreover, because there were hundreds (or even thousands) of them, the combined impact of these decisions on health or the economy could become substantial. They were also an essential instrument for representing the EPA's posture toward the toxics problem as a whole; an image that could supplant variations and inconsistencies across ad hoc responses to individual, controversial chemicals like DDT. In short, they were a bureaucratic technology to bring closure to controversial issues.

They were not, however, a very effective technology because they elicited controversy in turn. First, it was not that easy to defend these principles before the courts. Although credible, these facts could very well be countered by other scientists or medical researchers, whom the industry readily cited in court to counter the EPA. They were, moreover, insufficient to close legal cases. Mirex, for instance, was not formally banned until June 1978, and only after the manufacturer, Allied Chemical, decided to suspend its production because of the high costs of defending its use in court, and

after the state of Mississippi, which bought the main unit manufacturing Mirex from Allied Chemical, agreed to rescind the license to manufacture it in exchange for stopping the cancellation hearings. The scientific case constructed by EPA's attorneys did not seem to have been as effective as the successive scandals in the media about the presence of Mirex in the Niagara River (Severo 1976).

Reactions to these principles had appeared within the agency. Scientists in the Office of Pesticides, one of the EPA's program offices that counted a large group of scientists, were frustrated that scientific and medical issues were being arbitrated by lawyers in search of firm legal ground to argue their cases. Other officials in this office simply deemed the principles inappropriate in the context of FIFRA, which mandated weighing the benefits of pesticide use for agricultural production against the risks. Even in legal terms, the principles were not necessarily the right instrument because blanket principles overlooked the wide diversity of types of cancer and modes of cancer onset, and making such blanket judgments could easily be found to surpass the agency's delegated authority under the law it was administering.

At the time, Alvin Alm was managing the Office of Planning and Management,[3] having moved there from the position of chief of staff of the Council of Environmental Quality in the White House in 1973. He was a public administration graduate from Syracuse University, and he already had had ten years of experience in public administration of environmental programs. People who got to know him and worked with him closely describe him as "a 'let's get things done', let's be rational, let's get things organized, a managerial sort of a person"[4] and an "astute analyst" (Fiorino 1995, 56). He was, above all, a staunch proponent of ex ante policy analysis and of the sort of comprehensive synoptic analysis that informed the policy analysis school movement of those days in the United States. At the EPA, Alm assembled an effective team of policy analysts, as described by his administrator, Russell Train: "Al Alm had put together a top-flight economic analysis staff, and the analytic data on costs, both to business and to the public health, that we were able to present were outstanding. In fact, we won many an argument simply because of the quality of our data" (Train 2003, 180). It was Alm who advised the administrator to move from a strategy of asserting definitive cancer facts in courts in aggressive legal strategies. Alm, who was to have a major influence ten years later on the formal adoption of risk assessment methods throughout the agency (see chapter 6),

recommended a formal strategy of measuring the risks and benefits of products, as well as the establishment of a scientific group inside the agency to perform these assessments. With these recommendations, Alm was in fact instituting a move from a system of black-and-white decision-making (is a substance carcinogenic or not?) to a system in which the reality to be regulated is captured through a scale of risk, or shades of gray. This implied complex organizational and cognitive changes, such as the explication of decision options, and the complicated design of cross-agency reasoning procedures, to collectively choose among these options. Alm was, at this point in time, sketching out the elements of a probabilistic organization.

The EPA administrator, Russell Train, refused to produce the official notice for the cancer principles (Dickson 1987) and withdrew his support for the Office of the General Counsel's litigation strategy. His reaction was in part guided by the fact that he was spending long hours in hearings before Congress justifying the agency's actions in these legal cases. He followed Alm's recommendation to clarify flexible modes of judgment about toxicity through a *guideline,* a new kind of instrument that aimed less at establishing determinate rules than at clarifying options that rule-makers could use in developing a rule. A guideline, ideally, was to be comprehensive and detailed, to cover the manifold options that decision-makers could resort to under various statutes. In effect, it was a tool to assemble the necessary elements to make the organization more probabilistic: one that could adjust its strategy to the level of risk emerging from the calculations and the level of certainty underpinning these calculations—a flexible organization in which decisions were produced by a chain of actors along which information was transmitted to design the decision, rather than a pyramidal organization implementing a fixed strategy defined at the top. This tool was particularly welcome at the EPA, which had to decide on the carcinogenicity of substances that were regulated under different Acts, some of which required the setting of ample safety margins, and others the balancing of risks and benefits associated with the use of a substance. A guideline, thus, could fit in the interstices of different laws. Adaptable and flexible, it would cover "the whole class of chemical carcinogens" (Rushefsky 1986, 209) and ensure the consistency of the approach, its scientific soundness, and fairness to various chemicals and companies.

By the time the EPA started to formally develop guidance, the U.S. Supreme Court had effectively allowed regulatory agencies to set this kind

of informal generic policy (meaning that they were issued through a procedure involving giving notice in the Federal Register and public comment; see McGarity 1979, 752). A guideline, however, also had to demonstrate the EPA's commitment to be as protective as the "zero-risk" Delaney amendment or the "principles" previously used in courts by EPA lawyers could be (US Congress 1983b, 372). The decision mechanism designed in the guideline—one in which a variety of information was considered in order to shape predefined decision options—was the way to ensure this.

The Interim Cancer Assessment Guidelines of 1976

Train opted for the instrument of the guideline, and furthermore, he agreed to establish a Carcinogen Assessment Group (CAG) within the ORD, as Alm had also suggested. The CAG was established as a branch of the OHEA. A sign of the group's policy centrality was the fact that it was based in Washington, D.C., at the agency headquarters (as opposed to the two other branches of the OHEA, based in Cincinnati and in Research Triangle Park in North Carolina). The group was comprised of scientists with a specialization in mutagenicity and reproductive toxicity. It was managed by Elizabeth Anderson, a chemist and toxicologist. The group chair was Roy Albert, a medical doctor and scientist from New York University who also had experience in research on radiation hazards at the Atomic Energy Commission. As part of an agreement with the EPA, he participated in the CAG's activities a couple of times every month, thus giving it scientific medical support and lending it credibility.

The group published its interim guidelines for cancer assessment in May 1976. The structure of reasoning that the guidelines recommended was not immediately apparent from the text. It curtly indicated that the assessment should have a summary that answered two main questions: "(1) How likely is the agent to be a human carcinogen? (2) If the agent is a human carcinogen, what is the estimated impact on human health?" (EPA 1976, 2). Anderson later got into the habit of converting the questions into steps, structuring an integrated, linear process of assessment.[5]

The first question was solved by applying a particular assessment technology abstracted as a *weight of evidence (WOE)*. In this exercise, the assessor decided what weights to grant various kinds of studies relating to the same chemical, yet mostly employing different methodologies and producing

different results. A WOE essentially created a hierarchy of knowledge. Studies indicating the presence of tumors (i.e., negative studies) were supposed to be granted more weight than those that did not (i.e., positive studies). If two studies were available to the risk assessor, with one study on rats indicating cancer, and another on mice indicating no cancer, then the assessor was to continue working on a cancer hypothesis and not let the negative study overturn the hypothesis. The judgment about the carcinogenicity of the substance was to be "firm," or backed by "substantial evidence," if malignant tumors were found in several animal species. The evidence was to be considered "suggestive" if the only tumors that were seen were benign and "generally accepted as not progressing towards malignancy" (EPA 1976, 2).

The WOE method addressed rather than ignored the uncertainty or interpretive flexibility inherent in the consideration of experimental studies. Such studies, unfortunately, were rarely entirely positive, and were themselves rare. They failed to establish firm causal relations between exposure to a given substance and cancer incidence in an individual or group. Experiments were not devoid of ambiguity, moreover, for tumors could be interpreted in various ways: "Different substances act at different stages in the process. Some carcinogens may act as initiators, others as promoters. Still others may be complete carcinogens, capable of acting at both the initiation and promotion stages" (Harrison and Hoberg 1994, 24). There were also different kinds of tumors, benign or malign, and the interpretation that benign tumors were a sign of carcinogenicity was contested. Carcinogen identification depended on the capacity to interpret these tumors in animal experiments. WOE did not assume that the studies provided unambiguous results, and it admitted that contradicting signs would be available to the assessor. Neither did it assume that the assessor would be able to decide on the basis of only one study, for evidence was clearly an assemblage. This approach, couched in the scientific language of proof, was in fact a powerful strategy of legal demonstration: a standard of legal proof that the courts soon agreed to follow (McGarity 2003).[6]

The second question involved some quantitative analysis, employing mathematical and statistical techniques. In those days, when EPA staff described the approach, the overall carcinogenicity assessment task was called a "health assessment" or "effect assessment," with sporadic references to the production of "risk assessment documents." Risk assessment, or quantitative risk assessment, covered only the second step of the process,

or the quantitative measurement of the impact.[7] With these guidelines, the CAG was extending risk assessment beyond what any other agency was effectively doing.

Much like the WOE, quantitative risk assessment was both computational and judgmental. It involved assessing, first, the number of people exposed to the chemical in the environment. Precise, unambiguous data were missing to determine this. For instance, numbers indicating what percentage of the population was exposed to a given dose of the product were generally absent—there was no system in place that allowed empirical information on this topic to be collected. Therefore, estimates were needed to define an exposure pattern: Who is exposed, and for how long? Are kids and pregnant women more exposed than others?

Second, quantitative risk assessment involved drawing a dose-response curve. Only high doses of the chemicals (not the doses that people are normally exposed to in daily life) were tested in animal experiments. Therefore, the toxicity of the substance was known only at these doses. Mathematical models were used to extrapolate from these points to lower doses, or to the doses that one could realistically expect to find in the environment. The so-called dose-response curve was the line linking the resulting toxicity points. The guideline mentioned just two available mathematical models to perform this extrapolation: the linear model and the probit model.[8] The linear model "assumes that there is a finite, though diminishing, risk at all doses above zero" (Harisson and Hoberg 1994, 23). In other words, when applying the mathematical equation constituting the model, one would obtain dose-response points that, linked to one another, would produce a linear curve, showing no level at which the substance would seem to be safe.

Two mathematical models were mentioned in the guideline, leading Rushefsky to call it very flexible (Rushefsky 1985). In practice, however, CAG members generally used the linear model. As Dickson notes, agencies have generally embraced the no-threshold hypothesis, or at least refused to engage in extensively researching and deciding the issue of whether dose-response relationships could exhibit a threshold in some situations. They have also generally concluded that a nongenotoxic mechanism (wherein a threshold may be found) had not been adequately proven (Dickson 1987). The linear approach was soon institutionalized at the EPA.

An OHEA report of 1980, explaining how it would calculate unit risk estimates for air pollutants as part of the criteria-setting exercise that the

Air Office had to perform under the Clean Air Act, put forward what will henceforth be known as the *multistage model*, developed by the biostatistician Kenny Crump under contract with the agency (EPA 1980a). The exposure calculation and dose-response combined would lead to the expression of a cancer risk in terms of excess lifetime incidence. The implicit EPA guidance was that an excess incidence of one cancer in a population of 1 million people justified intervening. Altogether, the guideline expressed a policy, not just a scientific method, or what the document calls a philosophy: "Evidence has accumulated that indicates that the non-threshold concept can also be applicable to chemical carcinogens … We, thus, have a comparable conceptual basis for the regulation of chemicals as for ionizing radiation where the philosophy has been to eliminate or reduce exposure to the greatest extent possible consistent with the acceptability of the costs involved" (EPA 1976, 2).

There are various ways of explaining why the EPA opted for a *conservative* (the term that engineers were using to denote a model including wide margins of error) policy of this sort, most of which are related to the need to make choices in the presence of uncertainties. It was not known in detail whether substances with a promoting or initiating effect behaved differently; it was not known for sure which individual substance exhibited a threshold and which would not (Harrison and Hoberg 1994, 25). By applying a linear model, the EPA was sure that it was erring on the safe side. But the other influential reason was the experience available in the area of radiation, where so-called low doses had been a major debate for decades, resulting in the adoption of the ALARA (meaning "as low as reasonably achievable") principle concerning exposure to radiation. In the absence of certainty of where safety precisely lies, one should derive a measure of protection from plausible levels of risk. Roy Albert, who had experience in the area of radiation, consistently defended the application of this reasoning to environmental toxicants.[9] In effect, the guideline was not very detailed (indeed, it was quite short). It largely preserved and valued the judgment of the CAG scientists.[10]

With this guideline, it became official EPA policy to consider, due to the need to protect the population, that there was no safe dose for carcinogenic substances, and that exposure to them should be reduced as much as possible. As a design, it assembled the expertise of toxicologists and biostatisticians, with the choices of other administrative and policy officials of the

agency, to stay on the safe side. It was computing as many numbers as possible, aiming to be precise and reliable by reviewing wide sets of data. With these guidelines, the science was becoming more sophisticated and scientists began to challenge diagnoses. It was a long way from the days when regulators and judges faced with making decisions on cancer risk simply asked if the compound in question caused cancer in a lab animal. But the EPA was also acknowledging the existence of uncertainties, and at least provisional limits on the science, and constructing uncertainty-compensation rules out of consideration of its public health mission.

The substantial choices laid down in the guideline were protective, but the procedural design offered protection for the industry too, as well as a measure of the EPA's awareness of what was due process and the limits of its authority. The two steps of risk assessment represented only the first half of a decision-making procedure—described in the preamble of the guideline by the EPA administrator—wherein the decision-maker may balance the risk estimate with a consideration of the costs and benefits of the future regulatory intervention. Again, this had been the suggestion of Alvin Alm, and Russell Train had followed suit to give reassurances to the regulated industries. In his preamble, Train states that the decision-making procedure described in the guideline separated the more robust biological and biostatistical aspects from the rest: "I believe it is important to emphasize the two-step nature of the decision-making process with regard to the regulation of a potential carcinogen. Although different EPA statutory authorities have different requirements, in general two decisions must be made with regard to each potential carcinogen. The decision is whether a particular substance constitutes a cancer risk. The second decision is what regulatory action, if any, should be taken to reduce that risk" (EPA 1976, 3). A footnote in the risk assessment part of the guideline pointed out that "[t]his health risk assessment is part of the risk-benefit analysis [which is performed] after a determination that a health risk exists" in the case of pesticides. It was a trace of the intra-agency conflict on cancer principles, and it showed that the guideline had been devised to resolve the issue. To better articulate the whole risk and benefit assessment strategy, the guideline included a second facet for the economic impact analysis of proposed actions on carcinogenic pesticides.

The EPA documents of the mid-1970s did not feature the graphs that later documents of the 1980s would typically include, but if one had been

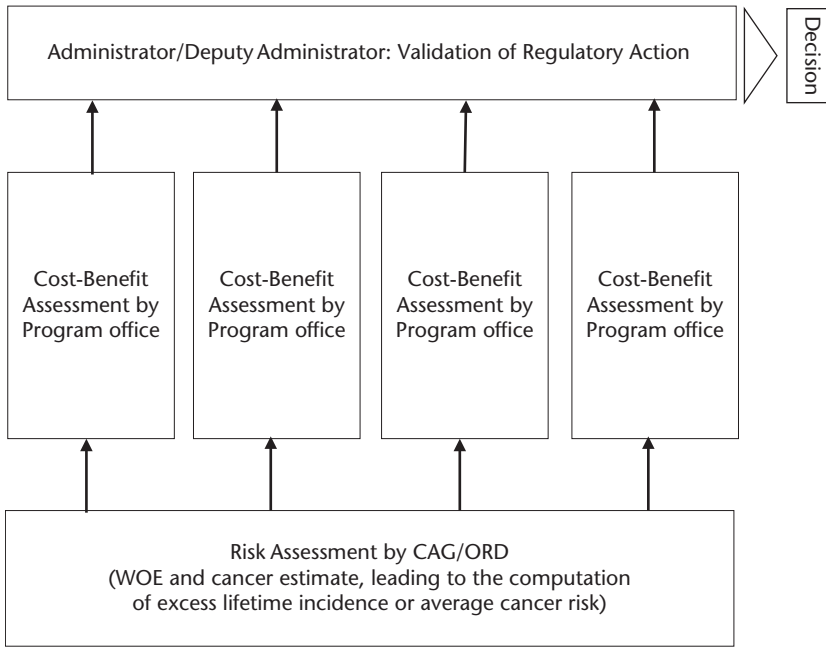

Figure 2.1
A graphic representation of the decision-making system in the EPA (1976) interim guidelines.

produced, it would have looked like figure 2.1. In the bureaucratic assemblage described in the guideline, CAG and the scientific assessment of the risk has a transversal role, feeding regulatory offices with a computation of the risk. Regulatory offices then construct the regulatory decision adapted to the Act that they implement.

The assemblage thus gave the EPA several advantages. It would instill various options in risk assessment and demonstrate its flexibility. At the same time, it also worked as a bureaucratic screen, protecting EPA's internal capacity to overcome uncertainty through expert judgment, as opposed to further research. It also helped to flexibly combine two separate modules for risk assessment and cost-benefit assessment: the cost-benefit part was an integral part of pesticide assessment. It could be left out in other cases. Such was the technology for decisions in a probabilistic organization. Instead of compelling a scientific fact (any chemical producing a tumor is hazardous) to impose a decision (they should be banned), it used an algorithm to

produce several informed judgments, in sequence, from which a legitimate decision seemed to flow. The algorithm was a legitimizing design, in that the person who had authority (the administrator) built on the judgments of medical scientists and policy analysts.

Guidelines of Controversy

The cancer assessment guideline was adopted as part of an informal rule-making procedure involving official notice and consideration of public comments. They were not reviewed by external scientists, however. They were still defended as being based on a broad scientific consensus that the linear, no-threshold hypothesis was the most plausible one, as well as being a reasonable one to apply in the context of health protection.

But this was not sufficient to turn it into a standard practice across the agency. Its application was impeded by interoffice disputes, rooted in differences in the degree to which they embraced conservative assumptions. The Air Office was the first program office to implement the guideline. As mentioned previously, an OHEA report drawn up in 1980 explained how it would calculate unit risk estimates for air pollutants, as part of the criteria-setting exercise that the Air Office had to perform under the Clean Air Act (EPA 1980a). In that document, the OHEA outlined the multistage model. As a result, a substance with either "best evidence" or "substantial evidence" would be listed as a hazardous air pollutant, on the grounds that there was a "high probability" that it was a human carcinogen. Quantitative risk assessment was thus a preliminary indication of significant risk (EPA 1979b, 25). The office proposed "National Emission Standards for Identifying, Assessing, and Regulating Airborne Substances Posing a Risk of Cancer" (Federal Register 1979). The "assessment group" formula underpinning the CAG was replicated in the form of a series of teams, each of which would carry out the corresponding analyses for regulatory offices: the Exposure Assessment Group, Mutagenicity Assessment Group, and Teratogenicity Assessment Group, which engaged in the experimental development of more guidelines. By 1980, three guidelines had been developed and were in use (EPA 1976; Federal Register 1979, 1980b, with a fourth in the making [EPA 1983a]). They routinized the assessments performed by scientists in regulatory offices or in ORD, though without harmonizing them strictly.

The practical work remained quite literally case by case, with the guidelines providing directions for treating more ambiguous cases.

The Air Office was the main client of the OHEA, but the relationship with other program offices was less cooperative. Certain offices were doing their assessments independently, without drawing from the science available in the ORD or using its guidelines. The Office of Pesticides was particularly autonomous for scientific evaluation purposes: by law, agrochemical companies were required to test their products and provide data and studies to the office. The office, therefore, had plenty of knowledge for reviewing and did not need to have the ORD labs perform such tests. It also had a substantial scientific staff inherited from the USDA, including toxicologists and health scientists, allowing it to analyze the industry data and perform many screening assessments, day after day. It produced more assessments than any other program office of the agency. The nature of the Act, which allowed the EPA to take into consideration the costs and benefits of registering a product as a pesticide, as well as the regulatory culture ingrained in many of the staff (including those that transferred from the USDA), meant that their safety assessments were regularly less protective than those of the more health-oriented people in CAG.

The modus vivendi, for many years, was not to question the fact that OHEA was not involved in the health and environmental assessment of pesticides. The Air Office was in the opposite situation, relying quite strongly on the scientific forces of the ORD.[11] The Water Office, finally, was intermediate. Interoffice problems were particularly acute for more controversial chemicals, particularly cancer-causing chemicals found in air, water, or contaminated sites across the country. Each office was led to make its own assessment of the safety of chemicals, specifically when caught in the crossfire of the many public controversies on the subject. In those years, gross, highly symbolic pollutants were addressed, leading to a short list of "chemicals of the month" regularly making the headlines, and which the agency was forced to address. The inconsistencies were particularly problematic where the EPA was actually setting risk levels for states to act on, as under the water legislation, or the EPA's own regional offices, as in the Superfund program.

The guideline drew up a cross-office process, linking scientists in the ORD to regulatory bureaucrats, lawyers, or policy analysts in program offices. In practice, changing the organization to reflect this natural liaison between

various sorts of knowledge and competences was hard to obtain. A reform of the ORD was attempted to address this issue. In the 1970s, the ORD budget was in the region of $200 to $300 million, well within the range of the research budget of departments with large scientific programs, such as the US Department of Energy or US Department of Defense. In those years, the ORD was the largest department of the EPA,[12] but it was not integrated with the rest of the agency. The EPA inherited laboratories from various existing departments; it never actually designed the ORD, its research orientation, or the actual laboratories. The problem of the relevance of the research carried out in the ORD for the work of program offices emerged almost immediately during the early life of the agency.

A report by the NRC (1977) pinpointed the problem. Despite its title ("Decision-making in the EPA"), the report focused to a large extent on the question of the science that the EPA used for its regulatory work, and put its finger on problems that were there to stay: namely, the need to have a system in place to review the data and scientific studies that regulatory offices used, to ensure that all of the science was used; and that leaders of the agency must have direct access to the science.[13] In August of the same year, the SAB of the agency published its own report on "the research, development, monitoring, and technical support system of the US EPA" (SAB 1977). A "dangerous ally" (Jasanoff 1990, 85) of the agency, the board did not spare it from criticism, noting the continuing problems that plagued the relationship that various parts of the agency had with science and research. It highlighted a lack of communication between natural scientists and lawyers and recommended that the former present their data and translate their information into adapted formats—meaning that the technical information should be organized in the form of a cost-effectiveness comparison of various control options. It found a lack of logical connection between the research performed by laboratories and the needs of the regulatory offices; questionable value of some of the research performed in labs; duplication of research among the various laboratories; laboratories functioning like autonomous empires; and a lack of assessment of the uncertainties, costs, and benefits (SAB 1977). In other words, the ORD laboratories did not appear to be functioning as laboratories of a regulatory agency, and their activities seemed to be steered to some extent by the leaders of the various program offices or of the whole agency. A reorganization of the laboratories was eventually decided, leading to the creation of

five "megalaboratories." The OHEA was promoted to that status, in which the CAG took on a prominent position.[14] With this decision-making guideline, cancer-causing chemicals were in the process of becoming a generic object for the agency, and CAG was virtually becoming a transversal office, providing science to the various other offices of the agency. Science-based decision-making was becoming a new, virtual organigram for an agency otherwise made of regulatory siloes.

The guidance developed by the EPA found confirmation in a multiagency document that was soon compiled by an interagency group, the so-called Interagency Regulatory Liaison Group (IRLG). The origins of that group go back to May 1977, when the EPA, FDA, and Consumer Product Safety Commission (CPSC) held a joint press conference on chlorofluorocarbons that helped the leaders of each agency to realize the benefits of such occasional coordination and common action, and also led to the idea of having more regular meetings. The IRLG was formally created in September 1979 as a "systematic, but short-lived, attempt at comprehensively coordinating regulatory policy" (Gore 1993, 19), with eight working groups, including one on risk assessment. It developed common cancer guidelines based on that of the EPA and the comparable approach developed by OSHA.[15] The risk assessment work group, which included Elizabeth Anderson of the CAG, decided to focus on cancer and produce a state-of-the-art methodology.

The first draft of the document threatened the generic cancer policy of OSHA, which had not embraced quantitative risk assessment as the EPA had done (Landy et al. 1994). Saffioti, who was instrumental in the development of cancer policy in that agency, regarded quantitative risk assessment as spuriously precise and certain. He only agreed to the inclusion of a short discussion of quantitative risk assessment in the document, highlighting uncertainties much more than the former draft had done. Roy Albert, who had joined the group for the revision of the first draft, did not facilitate the rewording. Although they were proponents of quantitative risk assessment, he (and Elizabeth Anderson) considered the EPA and CAG to be ahead of any other agency and were wary of the difficulties that the interagency policy could create for the CAG's work.

The resulting document was entitled "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks" (IRLG 1979). It reflected both the composition of the group, which read "as a list of prominent cancer

researchers and advocates of risk-averse cancer policy" (Rushefsky 1986, 94), and the tensions spawned by each one's defense of the agency's guidance. The former led to a broadly conservative, cautious guideline, which erred in all choices on the side of caution in order to avoid false negatives; the latter resulted in a lack of discussion about the range of available options (e.g., on the weight to grant to different kinds of negative or positive studies, or the choice of sample size and statistical confidence levels in animal tests). With such lack of detail and flexibility in the options, the guideline hardly reflected the uncertainty in the exercise of carcinogenic identification, and thus the policy nature of many of the determinations involved. The reason for this was clear: the group had explicitly been instructed not to address policy. So the inherent policy dimension of the technical choices laid out in the text could not be assumed explicitly. It led the group to forge an ad hoc distinction between science and policy. The draft work plan of the IRLG, back in 1977, had already stipulated, "Whether a particular type of risk may have to be accepted in certain circumstances is a policy decision, but the issue should not become entangled with the scientific problem of risk measurement" (IRLG 1977). At the end of the day, the guideline was seen as disguising policy choices in scientific terms (Landy et al. 1994).

The White House Regulatory Council still endorsed the report. It argued that agencies should deal with cancer risks quantitatively and use the IRLG report as a guideline. But the guideline, like OSHA's generic principles or EPA's interim guideline of 1976, proved to be "exceptionally controversial" (Rushefsky 1986, 89). At the very least, the chemical and oil industries had decided to engage in a forceful debate about conservative policies. A number of large chemical and petrochemical businesses banded together in 1977 to form the American Industrial Health Council (AIHC), a vehicle used to counter the development of guidelines by the social regulation agencies. The main threat, for the industry, was that guidelines would in effect distort the regulatory frameworks, taking a precautionary stance toward all chemicals, beyond the letter of the Acts. The 1977 Clean Air Act, for instance, addressed a few extraordinary air pollutants. As guidelines represented implicit extensions of regulatory policy to potentially unlimited numbers of chemicals, they had to be stopped.

The AIHC pointed to the confusion in the IRLG report between methodological and regulatory considerations to debunk its conservative preference. It accused the working group of not admitting its policy biases

1.	Identification of the hazard Epidemiology Toxicology In vivo tests
2.	Characterization of risk Potency Exposures Susceptibility
3.	Reduction of risk Information Regulation Substitution

Figure 2.2
OSTP's 1980 linear decision-making process for carcinogens (adapted from Faustman and Omenn 2010, 1083).

and of hiding them in arcane technical language (Landy et al. 1994). The industry pushed instead for the application of guidelines developed by another group under the aegis of the White House Office of Science and Technology Policy (OSTP). The group worked under the leadership of Gil Omenn, a medical doctor and scientist, professor of medicine at the University of Washington in 1979, and deputy science advisor to President Jimmy Carter between 1979 and 1981.[16] Omenn had been associated with the work of the IRLG's risk assessment group, but he was seen as defending a position that was contrary to OSHA's approach. The OSHA official in the IRLG spread the word that Omenn was the industry's mouthpiece within the group and that he should be dissociated from its work. He stopped being formally invited to the meetings and thus practically left the group. He was thus free to work separately on OSTP's own guidance document.

The OSTP document, published in the medical literature as Calkins et al. (1980), differed markedly from that of IRLG. First, it addressed regulatory questions, whereas the IRLG had decided from the beginning to leave policy out of its scope. The report presented cancer assessment as a component of a two-stage approach: first research, and then assessment by regulatory agencies of the significance of the risk and benefits behind the findings. In operational terms, the framework contained three steps: *identification* of carcinogenic substances and *characterization* of their risks by scientists, followed by the act of *reduction* (see figure 2.2). While similar in appearance to

the two-step approaches of the EPA and the IRLG, this guideline introduced much greater flexibility in its design, with the request for information (presumably from the manufacturer of the substance) being a possible regulatory outcome.

The OSTP guideline was also much more positivistic in the identification of carcinogens. It did not recommend any juggling with positive and negative studies, as in the weight of evidence judgment. It argued that classifying a substance as carcinogenic should happen only if preponderant scientific evidence indicated as much. Furthermore, the text did not recommend any model for extrapolation. More crucially, the OSTP recommended that all authority for cancer risk assessment be consolidated under the national toxicology program—including the research performed by the EPA and OSHA[17]—much as the industry advocated. This guideline, in essence, disassembled the EPA: in a typical scientistic, predictive fashion, it saw no uncertainty, and no need to create a particular organizational space, within which judgments could be formed. Graphically speaking, the linear, step-by-step process exhibits no boundaries. It does not allow delimiting, crafting a legitimate space of intervention of the agency.

Industry Campaign

The chemical and petrochemical industries waged a concerted battle against OSHA and EPA guidelines, coordinated by the AIHC and supported by other groups such as the Chemical Manufacturers Association. Every EPA publication was met by counterpublications. Also, all the public consultation meetings organized by the EPA for air or water pollutants were crowded with industry representatives forcefully denigrating, in particular, the generic and default conservative approach embedded in the agency's 1976 guideline. In 1980, for instance, the EPA organized a public hearing on the proposed standards for air pollutants, established in the framework of the Clean Air Act and based on the work of the CAG. The AIHC sent several people to speak at the hearing, and dozens of representatives of its member-companies filled the auditorium. Industry people took issue, first, with the WOE approach, arguing that the EPA was in essence classifying chemical substances as carcinogenic or not based on a single study. Wayne Jaeschke, head toxicologist at Stauffer Chemicals, repeatedly referred in his talk to the supposed "one mouse criteria" that the EPA was applying

in its assessments: "The one mouse criteria that EPA has set up is totally unsound, that this is a matter where there are no rationalized clear-cut principles. That's been made abundantly clear by the litany of testimony here on metabolism and other factors, and it certainly seems to me that this is a matter of scientific judgment … You must have the best scientific judgment" (EPA 1980c, 22). The CAG's Anderson countered this, showing that the decisionistic system designed in the guideline was not applied without judgment or lack of adaptation to the circumstances: "Any information we have about mechanisms of action, short-term test data, all of the information is put together to see what sense we can make of the entire picture, so there is no search in a haystack for one study that happens to show a positive signal and then just action going straight ahead on that basis" (ibid., 24).

The AIHC had also sent Richard Wilson, a Harvard University physicist, to the hearing. As an early proponent of cost-benefit analysis, Wilson discarded the no-threshold hypothesis, along with the lack of flexibility in the guideline: "I don't say that you should automatically let the risk assessor choose what he wants, but you should not rule him out by some legal process saying, you must take the linear hypothesis. Take the linear hypothesis, if you can accept something, fine, but don't leave out the possibility of someone coming back in this particular case … it should be allowed, and I think there would be such cases." Anderson, at this point, countered that the current IRLG guidelines and EPA's general approach recognized that "where such data can be generated, it certainly would be used" (ibid., 34–35). Wilson also advanced his own estimates of cancer risks at the population level in the United States for the purpose of deconstructing that of the EPA. There were, in his view, no more than ten cases of cancer per year that one could associate to industrial chemicals in the air, such that EPA's conservative policy was not warranted.

These acrimonious exchanges showed the interest of the guideline as a bureaucratic technology. It provided a reference point for audiences that wished to engage with the agency and criticize its expertise and decisions. But they also left a lot of flexibility inside, for agencies to shape decisions case by case. It worked as a screen, giving something legitimate to see outside ("The EPA uses this or that method of extrapolation"; "Health scientists assess, managers decide"), but concealing some of the details of what was happening inside for each substance. This, of course, created frustration on

the part of these actors who wanted to control what the agency was doing and reduce its autonomy, leaving them to complain that the agency was not doing what it was pledging to do or that it was applying a cookbook approach,[18] blindly following linear extrapolation methods, and so on.

The regulatory agencies' efforts to establish guidelines had diverse fates. Despite great initial enthusiasm around the IRLG guidelines (Clark 1979), the agencies failed to formally adopt them (see Landy et al. 1994). From this point onward, the agencies parted company.[19] The White House Regulatory Council continued working on a possible cross-agency platform for risk assessment, resulting in the later publication of its principles for chemical carcinogens (Federal Register 1979). Still, the EPA effort earned it some legal security for its regulatory actions. The key court case in that period was the Supreme Court's 1980 ruling on benzene, following the OSHA's adoption of a workplace exposure standard for the chemical of one part per million. According to the majority opinion of Justice John Paul Stevens, no exact quantification of the risk was expected, but the agency "does have an obligation to find that a significant risk is present before it can characterize a place of employment as 'unsafe'" (448 U.S. 607, 656).[20] Throughout its judgment, the Court took the establishment of a quantitative dose-response curve as the main way to demonstrate this significance. The judgment promoted quantitative risk assessment as a means of executing protective regulatory decisions.[21]

With the benzene decision, the Supreme Court effectively required agencies to use a quantitative or numerical measure of the risk to decide on whether to regulate a substance. A system of classification based on qualitative expert judgments was no longer sufficient. These measures of the risk were needed for agencies to distinguish between significant or insignificant (de minimis) risk. In 1979, the court ruling in the *Monsanto v. Kennedy* case, involving the FDA, essentially authorized the agency not to ban a carcinogenic substance—despite the Delaney amendment that ordered it to do so—if the insignificance of the risk were demonstrated in a quantitative risk assessment. The Supreme Court, in this case, decisively promoted quantitative risk assessment as a tool for finding criteria—if not thresholds in a dose-response curve, or at least qualitatively appreciated levels of significance—and constructing decisions.

The CPSC was next in line. In a 1983 decision, the Fifth Circuit Court of Appeals ruled against the agency's decision to ban a kind of foam insulation

using formaldehyde.[22] The court established several important rules applying to risk assessment: Agencies should not base their risk assessments on a single study; risk assessments should yield a most probable estimation, rather than a range of values, using the upper value to define its standard; agencies should not use a single model (like the multistage model of the EPA) for their extrapolations; and finally, they should use real exposure data rather than worst-case assumptions.

On the whole, the EPA's decisions were spared from criticism in court. In an essentially supportive Supreme Court ruling,[23] the agency was granted the right, in areas where risk assessments are needed, to make policy judgments when findings of fact could not be made with absolute certainty. The ruling did not "speak to the content of the policies that may fill the factual void" (McGarity 1979, 781), but it still supported the agency in the belief that the guidelines were a legally acceptable benchmark of analysis and decision for the courts, and that therefore, it could extend their use across regulatory programs. It provided a reference for the courts to examine, and in a context where the courts only reviewed the procedures applied by agencies without scrutinizing their scientific reasoning and interpretations, they found nothing to argue against.

By providing a clear benchmark of scientific analysis to the courts, the EPA facilitated the institutionalization of what has come to be known as the hard-look doctrine: a doctrine in which courts are supposed to take a hard look at whether and how agencies applied the intentions laid out by Congress in the statutes they administer, and considered all aspects of the problem and the contentions of all parties (Glicksman and Schroeder 1991; Foster and Huber 1999; McGarity 2003; Freeman and Vermeule 2007). Counterintuitively, the hard-look doctrine also recognized the fundamental lack of the courts' expertise to substantively review the science used by agencies in their decisions, as well as their lack of legitimacy to prescribe agencies' criteria for their decisions, in cases where Congress's intentions were unclear. The hard-look doctrine justified applying the "arbitrary and capricious test," originating in the Administrative Procedure Act of 1946, whereby agency regulations were generally upheld so long as the agency demonstrated that it had applied a minimal standard of rationality. Risk assessment guidelines provided just such a standard of rationality, and wherever the EPA could convince the courts that it had formally applied

its own guidelines, it stood a good chance of not losing its case in court—a good reason for not altering its frameworks.[24]

Conclusion

Risk assessment, in the form of a guideline, emerged as way of making decisions in the EPA in the 1970s in order to defend the goals and legitimacy of the agency in difficult contexts of uncertainty, close supervision, and intense industry opposition. In the words of Terry Yosie, staff director of the EPA's SAB in the 1980s, the guideline "represented one of Washington's most venerable principles: be sure that your potential adversaries (be they industrial firms, environmentalists, Congress, or the OMB) debate your ideas, and your agenda" (Yosie 1989, 3).

The risk assessment methodology, standardized in the guideline, even if not properly and systematically applied in all corners of the agency on all chemical substances assessed, provided a bureaucratic screen, both representing to the outside what the agency was holding as its ideal form of assessment—decisions adjusted to degrees of risk and certainty emerging from consideration of data and calculations, but also guarantees of "objectivity," "consistency" or "feasibility" (Stephan et al. 1983)—demonstrating its commitment to approximation of this ideal, *and* concealing, in the meantime, the individual decisions that did not follow the model. The guideline deflected accusations of poor science and biased regulatory decision-making. It helped tone down the level of judicial scrutiny. It became a focal point in the ongoing discussions with the industry, helping the agency set these debates and negotiations on its own terms. In all these respects, it was an effective bureaucratic tool that acted to durably reflect within the agency. It did not solve all of the EPA's problems though, particularly not the continual lack of consensus among the agency's diverse offices. Other designs were needed for this problem of integration of the organization and of its knowledge that economists and policy analysts took care of articulating.

The Science of Bureaucracy

Risk Decision-Making and the US Environmental Protection Agency

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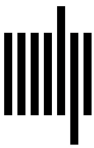

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