6 Risk Management: The EPA as a Decision-Making System

Risk Assessment in the Federal Government: Managing the Process (RAFG) is often presented as the source of the risk assessment–risk management framework and the inspiration for William Ruckelshaus's policy of publicly separating science from policy in the agency—but that is a misreading of the report (North 2003) because it explicitly recommended distinguishing these things intellectually, and forced thinking about their interaction. But the single most important material consequence of the risk assessment/risk management knowledge representation was the capacity that it granted to the administrators of the agency to design a joint decision-making process involving the various programmatic and functional offices of the agency, and assembling the expertise and specific conceptions of uncertainty of toxicologists, economists, and policy analysts. In other words, the framework supported a redesign and integration of the agency, in the form of a decision-making process that attended to the various dimensions of an environmental issue, and concerns of EPA's audiences. All of this was evident in Alvin Alm's decision to pursue the Toxics Integration effort of the late 1970s, the gradual acculturation to the knowledge representation borne by RAFG across the agency, the ensuring design of a sophisticated "options tracking system," and the creation of multiple analytical guides and formats for application by all the agency staff.

The Agencywide "Risk Projects" of 1983

Given the loss of credibility of the EPA and the diminishment of staff morale during Ann Gorsuch's stint as the administrator, Ruckelshaus and Alm wanted to reenergize the agency quickly. Alm came up with the formula of the "task force" in his first week back at the agency in May 1983. He

believed that the swift launch of several task forces was important for the agency to be able to deliver quickly in a context of high internal and external expectations. The task force formula was instrumental, the manager thought, in getting people involved and revitalizing the EPA. It was also a way of demonstrating, without delay, that the days of Gorsuch's autocratic style were at an end.

The day before he delivered his NAS speech, Ruckelshaus signed off on the decision to create ten task forces. The first concerned dioxin and other complicated cases of pollution, such as nonpoint-source pollution and groundwater pollution, and others tackled structural institutional difficulties concerning the enforcement of EPA decisions. Each of the task forces had ten to twenty members drawn from around the agency and mobilized more staff in the different offices as necessary in order to produce memos and reports. But the most generic task force was the so-called Toxics Integration Task Force (TITF), designed to continue the efforts initiated in 1977 to establish agencywide processes for comparative analysis of risk, ranking, and prioritization across all offices.

There was no splitting of the Toxics Integration effort among offices this time (see chapter 3): the entire exercise was located in the OPPE and chaired by Richard Morgenstern, the director of the Office of Policy Analysis there. Its agenda became more ambitious. Its mandate now was to address various problems "that can be grouped under the general heading of 'risk assessment' and 'risk management.'"[1] RAFG and its proposed definitions helped the managers and policy analysts in the agency to align the various offices on common descriptions of bureaucratic processes and problems. As in RAFG, all other terms—from risk evaluation to hazard assessment, in passing by technology assessment—were obliterated in this simplified picture of what the EPA should deliver. The risk assessment and risk management categories were defined in task force documents as they were in RAFG: as generic processes summarizing all actions aimed at controlling risk. And while until 1983, the Toxics Integration work groups had had limited agendas, this time around, the task force had an extensive reach across the organization and its subjects of interest.

The objectives of the TITF were to create consistency—a favorite goal of the economists of the OPPE—at all levels. The agenda of the first meeting of the task force had the following points: "consistency in risk assessment" (developing methods and guidelines for application across the agency);

"consistency in risk management"; "high-visibility chemicals"; "intermedia inconsistencies" (improvement of coordination between offices managing water, air, contaminated lands …); "interagency coordination."[2] The fact that the risk designs were already en route to becoming normal bureaucratic knowledge and technology across the EPA, beyond the pockets in which it had first been tried such as the CAG, enabled Morgenstern to advance this streamlined, integrated agenda affecting the entire organization. Not only was most of the Washington, D.C., regulatory community abreast of this new representation of agencies as structured around scientific risk assessment or risk management, but the EPA itself was structured by it. Notions of risk assessment were already employed in the agency, notably at the CAG.

RAFG, given its high profile and recognized quality, further helped to structure this knowledge and spread it across the EPA. The report had penetrated the agency through the various offices and at the level of political appointees and program managers.[3] John Todhunter, the head of the OPTS (then in his final weeks at the agency) was at the dinner event for the launch of the report. He soon wrote back to Gil Omenn, whom he had been seated next to, that he had instructed his staff to develop options for implementing the recommendations of the report. He stressed the need to act on the recommendations with regard to peer review—recommendations that were "meritorious and fully consonant with policy positions that I have expressed in the past."[4] Don Clay, also of the OPTS, wrote to Lee Thomas when the latter was acting EPA administrator (March–April 1983) to stress the merits of the report. Clay considered the report "a fine piece," and went on to suggest that each office in the EPA comment on it and submit their evaluations to a single source in the agency.

Several senior scientists that Ruckelshaus and Alm had picked for the agency in 1983 concurred to promote the RAFG framework and further install risk assessment and management in the agency. John Moore became the assistant administrator for pesticides and toxic substances in October 1983, but he had worked as a consultant for the agency starting in May 1983. He had a doctorate of veterinary medicine and was a certified toxicologist. Before joining the EPA, he had spent fourteen years (1969–1983) at the National Institute for Environmental Health Sciences, as head of toxicology research and testing and deputy director of the National Toxicology Program. He fully understood the benefit of RAFG's redefinition of science-for-regulation as risk assessment. He was called to the agency to attempt to

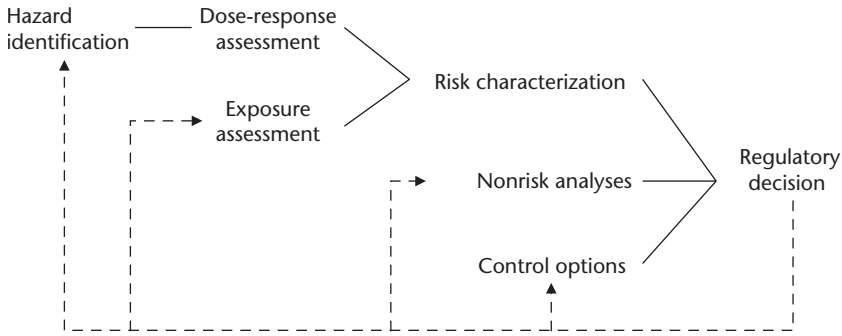

Figure 6.1
Graphical representation of a regulatory decision-making nosology proposed for the EPA.
Source: Richard Hill, Office of Toxic Substances, memorandum to John Moore, assistant administrator for the OPTS, "A Regulatory Decision-Making Nosology," US EPA, January 12, 1984, Milton Russell Special Collection.

institute risk assessment in the programs, and RAFG laid out the path to do just that. The document had the advantage of being "not this huge document, it was readable, it could be used as a guide," so Moore told people to get it and read it.[5]

In his office, he circulated a memo by one of his staff members, entitled "Regulatory Decision-Making Nosology," based on the definitions of RAFG. The document was meant to develop common definitions of risk terms because some confusion was noted within the agency as to what *risk assessment* meant. A graph converted RAFG's proposals into a decision scheme (see figure 6.1). Richard Hill, the author of the paper, sent it to Moore and to the ORD's OHEA with a note saying that "in the carcinogenicity guideline work-group [Alm's Toxic Integrations A-1 effort] it was apparent people were using terms in different ways. The appended is my draft to help demystify matters. There may be merit in getting general agreement across the agency."[6] Moore agreed to this and sent the paper to Milton Russell, thus supporting the ongoing process in the EPA of acculturation to this new knowledge representation and technology of decision-making. This design work, prompted by RAFG, shows that the report did not impose a new framework on the agency, as much as it helped disambiguate a knowledge representation that was already emerging in the agency, and that its officials were ready to apply.

Finally, Bernie Goldstein,[7] who became assistant administrator for research and development at the agency in October 1983, was also very much alerted to what was in RAFG, even before it got published. He knew several panel members and frequently interacted with them professionally.[8] Much like Moore, he was perceived as a person of high intellectual stature, a "solid thinker"[9] who quickly saw the interest of this framework for constructing a bigger picture of what the EPA was actually doing and could deliver to the public. His office, the ORD, was also aware of these notions. The OHEA, of course, was already partly organized along some of these lines. But RAFG emerged there as a new and authoritative manner of defining regulatory work.[10] This was especially the case for the version that stressed the scientific potentiality of risk assessment and its neat separation with policy, through a well-demarcated exercise of clarifying the science policies of the agency.

So, perhaps for the first time since the EPA was set up, the whole team of assistant administrators was renewed. Special talents in science, law, and management were brought in. They were picked by the EPA administrator, synchronized to bring about major changes to the agency, and aligned on a similar set of intentions for the development and application of risk assessment techniques in order to improve the science and policy interface. All of them were aware of the RAC's efforts and had read the report. RAFG showed many of these people the directions in which to take the agency, both to consolidate its expertise in risk assessment or risk ranking and to eliminate the controversy-prone practices of the recent past (conflicts between offices, intervention by program managers into the science, etc.). It helped to align people from different offices, as well as the people in these offices and top leaders of the agency, to a common set of notions that had started to be diffused throughout the organization and corresponded to its key operations.

Designing an Options-Generating System

Perhaps the most decisive change that the risk assessment–risk management framework brought about is the unified representation of the agency as a machine to produce decisions and of its internal structure as an organic system to develop these decisions. How risk assessment and risk management effectively became a framework embracing the activities of offices

across the agency in order to become more integrated can be seen in the establishment of an options tracking system.

Like Ruckelshaus, Alm had worked at the EPA in the early years of the agency. After leaving the EPA in 1973, he went on to work for President Gerald Ford on energy policy, based in the OMB, and he stayed on under Ford's successor, Jimmy Carter. During the second half of Carter's term, he became assistant secretary for policy and evaluation in the US Department of Energy. When Ruckelshaus asked him to come back to the EPA to be his deputy director, Alm was the director of Harvard University's energy security program. Everywhere he worked between 1973 and 1983, Alm introduced further policy analysis and economic and regulatory analysis to design and deploy public policy programs effectively, and he received credit for that.[11]

Coming back to the EPA after the years of Gorsuch's politicized and error-prone management, Alm introduced his own personal management philosophy, essentially a mix of discipline, stimulation of personal involvement, and intensive analytics. In a memo dated August 18, 1983,[12] addressed to all the agency's political appointees, and particularly the assistant administrators and regional administrators, he clarified that his philosophy was to set clear goals and schedules and to hold people accountable for meeting them once they were agreed to. He wanted "professional commitment and motivation to get the job done." His expectations of the EPA staff were high—and he noted that they were one of the best and most professional teams. On the other hand, he announced that he would apply a more inclusive and participatory decision-making system, thus giving staff opportunities to use their experience.

In his approach, it was analysis that brought people together in a disciplined decision-making system that respected their autonomy and experience. Alm wanted environmental results to be monitored, based on reliable data, and to be periodically evaluated to avoid succumbing "to day-to-day demands." More important perhaps, one of his stated principles was that "[a]long with good data, we need high-quality scientific and policy analyses. As the Administrator recently stressed to the National Academy of Sciences, we must make the scientific and policy assessments behind our decisions clear so that the public understands what we have done and why."[13]

Alm worked hand in hand with Milton Russell, whom he had recruited to become head of the OPPE at the agency (as discussed in chapter 5). Upon

his arrival at the agency in May 1983 as a consultant to the administrator,[14] Russell received a copy of RAFG from Ruckelshaus and Alm, with the mission to create a new approach to decision-making for the environment—a more structured and integrated one: "The issue was, how could we in effect create a new approach, a new image, a new analytical, objective basis for regulation and environmental issues in the USA? And consequently, Mr. Ruckelshaus was looking for, my office was supposed to, impress and create an analytical framework, which was risk analysis, risk management, and so forth. And my job was to promote that, not only within the group there at EPA, the office, but across the EPA and outside."[15] Ruckelshaus and his deputy Alm pushed Russell to search for the elements of that generic and harmonized decision process in the risk assessment–risk management architecture and in the generic thought processes articulated in RAFG. The report and its architecture of terms were used to continue the effort of agency integration that was attempted at the end of the 1970s, but that did not lead very far. In 1983, the EPA looked very much like it did in 1981 and in the early 1970s, as a compound of offices dealing with separate matters (see figures 3.1 and 3.2, chapter 3).

Starting in the summer of 1983, Russell and Alm worked on a process that could help track each and every dossier and decision in-the-making in the agency, filtering out the most important and politically problematic decisions so that they would rise to the deputy administrator and administrator levels for them to focus on. The options-tracking system was very much a political process because its function was to detect and channel policy issues that had the potential to become controversial or litigious, either inside the agency or toward the industry, environmental groups, or at the OMB. The options review and the risk assessment–risk management framework were closely linked: "[T]he options selection process was the implementation of the risk analysis/risk management operation. It was the way we organized, structured, enforced, and regulated if you will, made it part of the normal flow of the system."[16]

So the system was there not only to track operations routinely, but also to create the conditions to address issues that were in the process of becoming controversial and politically salient. In more operational terms, the goal was to make sure that everything flowed smoothly, to be able to track delays caused by staff offices, including the twelfth floor where the administrator was, and also to make sure that the administrator and deputy administrator

were on top of issues and ready to make decisions, with all information in hand. The system, furthermore, was intended to ensure that someone was there to question the decisions favored by program offices. The OPPE had the role of scrutinizing the decisions shaped in the program offices and being a "third pair of eyes"[17] on decisions in preparation.

In practice, the system was run by the Office of Management Systems and Evaluation inside the OPPE. It would track on average 200 to 250 operations at a time. More important operations, designated level I, were those that were likely to have an economic impact of over $100 million, and were subject to cost-benefit analysis as per the 1981 Presidential Executive Order 12291, enforced by the OMB. The decision of how important an operation would be was made by a workgroup involving people from the program offices. A level II or level III operation issue was handled directly in the program office and signed off by Russell. For operations of greater importance, discussions were held in a meeting with Alm every month.

The staff would meet with Alm and the various program offices to go over any of the problems in the procedures and to deal with delays and controversies. Following these troubleshooting meetings, an option selection meeting would be held. The meetings brought together around twenty people, including members of the OPPE, people from the Office of the General Counsel, the Enforcement Office, a representative of the ORD, and the assistant administrators of program offices. The day-to-day logic of individual program offices could not simply be carried into these meetings in which the functional offices played a key role—something that Alm ensured would happen. A representative of the OPPE would often lead those meetings, or Alm himself. A protocol for conducting the meetings was put in place, institutionalizing cross-office debates on decision options, thus diminishing again the possibility of one program office or another having a unilateral influence on a dossier. Recommendations from each office would be discussed, explicitly considering options and alternatives that were compared using notions not only of cost, risk, and benefit, but also of alignment of the criteria of each legal statute. Ruckelshaus, Alm, or Russell would then select the preferred option. A final decision meeting in the administrator's office would be held before the final sign-off on the regulation.

What was being resumed there was the older attempt to resolve internal conflicts stemming from irreconcilable statutes, thanks to a transversal

process of analysis. According to that plan, the OPPE would finally receive the sort of mandate that it should have had under Douglas Costle's third phase of EPA structuration, along functional lines (see chapter 3). The options review system was fitted to the previous institutionalized practices of the steering committee and the so-called workgroup. Both had been gradually introduced during the 1970s, not least because of the Toxics Integration efforts. This time, the political circumstances allowed Ruckelshaus to stress analysis and management as central functions of the agency, and thus to put the OPPE in a central position. The fact of placing a political appointee at the head of this nonstatutory office reflected the novel political status accorded to policy analysis in this EPA. This office, now under the direction of Russell, was to become "the premier analytical office."[18] Its task would be to develop, with the contribution of all offices, a preparatory basis for making decisions—and a reliable, robust one at that. The thing that Ruckelshaus and Alm, as the top decision-makers in the agency, wanted from the OPPE was to ensure that they would never have to question an analysis or a set of recommendations submitted to them. What was necessary to achieve this was a controlled, uniform decision-making process across the agency.[19]

However well institutionalized it may have been, the options system still relied on the political importance that the leaders of the agency granted it. Between 1983 and March 1985, while Ruckelshaus and Alm were there, the system functioned effectively. The fact that it worked meant that it forced those people in a position to release standards and rules to the public to detect whether the decision they contemplated would be challenged outside. It prompted them to perform a sort of political opportunity analysis of upcoming decisions and participate in the construction of an internal agenda that would reflect external controversies. For such issues, the options selection meeting was a kind of preliminary test of the proposed decision—an internal peer review that anticipated the deconstructive pressures that the decision and its scientific foundations would undergo after public release. John Moore, head of the OPTS at the time, recalls that options tracking was "not an automatic system for generating decisions, but really a way of asking people 'tell me how much you thought about this really' … rather than accepting the automatic 'one in a million cancer risk'. It was not necessarily a system to challenge the risk assessment; instead, Alm was saying 'I accept that the risk is such, but what are the management things you defined that lead to this, what did you give credit to … ?'"[20]

So long as there were leaders in the various offices that understood and agreed with this point, the system worked. Even after Ruckelshaus and Alm left the agency, the system lived on, notably because key political appointees would still be there to defend and run it.[21] Moore understood that better than anyone else. His office was the source of many potentially controversial decisions: The Pesticides Office made many decisions every year, on widely used products, and had to run the complicated cancellation procedures; the toxic substances office, at least for the "existing chemicals" part of its activity (Boullier et al. 2019), made few decisions, but it dealt with controversial, embattled chemicals, many of which came under more than one office. Moore duly worked within the framework of options selection to identify the issues that should be elevated to level I interest—those that had a large "magnitude of effects and costs," and hence a "high degree of controversy," and could potentially become a "policy precedent,"[22] such as formaldehyde.

Those meetings also helped to discuss regulatory procedures under particular statutes, such as the special review procedure run by the Pesticides Office for withdrawal of pesticides from the market.[23] As mentioned previously, the special review procedure was complicated because it was difficult to find proof that the product in question was definitely the cause of a hazard, and the burden of proof to reverse a decision to authorize a product was high. These procedures often lasted several years, which created another difficulty: As the procedure unfolded, more scientific data appeared, changing the basis of the decision. The OPPE developed routines for these special reviews that frequently involved touchy legal questions. The options meeting was an occasion to work out how to make these procedures more collective, without automating them through formal rules and procedures. On all these aspects, the particular interest of Alm and the OPPE was for extra clarification of the motives and basis of the office's decision, with a view not to develop more "automatic decision rules," but rather to put in place a series of screens to detect upcoming political problems.[24] Again, this meant that the process was dependent on professional engagement and political support because the meetings were moments of collective analysis of political, regulatory, and scientific issues, not a mechanical decision point in a set procedure. It belonged to a team model and a bureaucratic-pluralistic style of decision-making (McGarity 1991; Furlong 1995) that continued to inform the way the EPA

was working, even after the options selection process lost the energy that Alm and Russell had injected into it.

Risk, Costs, Benefits, and Regulations: The EPA Analyzed

The options tracking and selection system was the product of a particular way of seeing the agency: as an organization plagued by internal discrepancies in regulatory cultures and political agendas, and thus was unable to collect, share, and integrate information about the problems that the public expected it to treat. But it was also the product of the sets of categories that surfaced in 1983–1984, and which allowed for the almost-ontological redefinition of what the agency was and how it should operate to respond to these external demands and legitimacy criteria. In the framework of risk assessment and risk management, the agency was an organization that turned out decisions by forcing those who knew about risks and those who knew about costs and feasibility of regulatory interventions to confront one another. Alm and Ruckelshaus, effectively, were making decisions by arbitrating among them. They had the help of OPPE economists and regulatory analysts, who were there less to force offices to count, measure, and calculate everything—indeed, OPPE people frequently reminded others that not everything could be measured and that there was no point in establishing automatic procedures for decisions based on data—and more to prompt them to clarify the political judgment, or science policies, underpinning the proposed rule. The risk assessment–risk management framework, the design that then best embodied the legitimate way of evolving decisions using various scientific inputs, served as the template and was reflected in a series of tools.

Numerous tools came out of the office of the deputy administrator and of the OPPE at the time to "allow the agency to apply the risk assessment/risk management discipline in a more orderly way."[25] Alm first developed his criteria for an acceptable "decision package" to bring to his and Ruckelshaus's consideration, particularly for level I regulation.[26] Thus, the chosen regulation should provide the greatest net benefits to society; allow flexibility in compliance; induce innovation in the regulated community; be consistent and complementary with other federal programs and agencies; impose the least possible burden on the public in terms of reporting, information collection, and recordkeeping; and disrupt competitive markets as

little as possible. These criteria, overall, implemented the regulatory reform program and took an economic view of regulation. But they were meant to inform one overarching public principle and element of agency reputation: "The Agency's primary goal is to develop standards and rules that protect human health and the environment." The package was to include analyses showing that all options had been considered on the basis of the best data available, and "clearly present: the costs, risks, and benefits of the options"; present a range of assumptions, including a "best estimate" as well as a "conservative case"; and give a comparison of the action's cost-effectiveness with that of similar regulatory actions. In terms of presentation, the memo required the decision package to include "a clear formulation of the problem" and "conclusions flowing logically from basic information"; "a clear, consistent, and logical rationale for the proposed action"; and a "presentation of risk analysis information in a clear and consistent format."

In the memo, risk analysis was the generic rubric for all information, data, numbers, and calculations that had been produced through an analytic effort, be it about costs, benefits, or risks. Risk analysis, in other words, was the overarching process encompassing risk assessment. And while the tools for risk analysis still implied a large degree of trust in the competence and professional judgment of the health risk calculation experts, they also explicitly rejected reliance on one preferred mode of analysis and too much monodisciplinarity. Natural and social scientists, biologists and economists, needed to work at constructing decision options. Risk analysis pushed for a greater number of analytical options, thus introducing more flexibility into the process, and partially replaced implicit and contained professional judgment by a collective, organized process of options selection. This generic notion of analysis helped the at least nominal integration of the organization, the assemblage of various internal expertise.

The OPPE complementarily revised and extended the use of regulatory impact analysis guidelines, absorbing the OMB's own guidelines developed in the aftermath of President Ronald Reagan's adoption of Executive Order 12291. This new Regulatory Impact Analysis (RIA) guidelines (EPA 1983c) had timelines, methodologies, criteria, and procedural sequences for performing RIA and introduced a number of methodologies that would remain in place in the agency for a long time. The guidelines stipulated that the problem should be formulated clearly, with all options outlined, including nonregulatory ones.[27] Benefits and costs should then be examined in

turn. Its novelty was to incorporate, under the term *benefits*, prescriptions for when and how to perform a quantification of health effects. For the very first time, the guidelines recapped the bureaucratic knowledge available in the EPA to address standardized regulatory objects: risk (defined in the guidelines as "the probability of experiencing an adverse health effect from the pollutant under consideration"—this was essentially the agency's first document ever to define the term *risk*); cancer risks; and noncancer risks. Noncancer risks were to be assessed using the conventional methodology of computing a NOAEL, divided by a "safety factor." Cancer risks were be evaluated following CAG's approach: a weight of evidence assessment to define how dangerous a substance may be and a quantitative risk assessment based on an extrapolation of dose effects observed in animals, combined with whatever existing exposure data. Those flexible instructions were soon reasserted in the OPPE's "risk documentation paper," which was an optional paper to be prepared when the assistant secretary wished to review the significant risk information developed by the staff.

All these analytical prescriptions were reflected in Alm's final tool: the risk management information reporting format, introduced in May 1984. The purpose of this format was, according to Alm, "to present risk data in a manner allowing comparison across rules and programs in a way more accessible to decision-makers. Because this form will accompany regulatory packages, it will provide the Administrator, me, and other reviewers with easy access to this critical information." It should be used for "all 'major' rules, and all 'significant' rules which specifically involved the management and control of environmental and human health risks." The office responsible for filling it in was given the status of "Lead Office." A format had to be made available to Alm with options selection review packages, completed to the best possible extent, "as part of the steering committee review." The format was prepared by the OPPE's Office of Policy Analysis, and an OPPE analyst checked that it was completed correctly.[28] The tool was meant to promote coordination across the agency, again, but also to prepare for the OMB's review of these rules. The OMB created a lot of uncertainty by keeping EPA rules under review for long periods of time, without clear timelines. It also had the tendency to talk to various EPA officials across the agency, sometimes with different information about their review of one given decision, thus creating more confusion among offices. To counter this, Alm had selected the OPPE to be the OMB's interface. The

OPPE was supposed to become the agency's internal "mini-OMB,"[29] helping the offices prepare for OMB review and coordinating the responses to the White House office.[30] At the end of the day, most of the rules developed by the agency were accepted, given the underlying process for developing them and the procedural guarantees put in place by Alm to consider costs and benefits properly. If he had an issue with the OMB, Moore (who managed the pesticides and toxic substances program) simply held his ground, waiting for the administrator to take his position at the White House. In his experience, the OMB generally backed down.[31]

Taking Options on High-Visibility Chemicals

Several decisions in the mid-1980s showed that the overall organizational structure for analysis, where risk, cost, and benefit were formalized as logically interdependent items of decision, naturalized cost-benefit analysis. In July 1983, the issue of the control of arsenic emissions in the air was on the agenda of the EPA again—the subject of the now-famous Tacoma meeting (see chapter 5). The agency revised its rule in light of a balance between the excessive number of cancer cases (believed to be one per year), and the reduction of the risk that the depollution technology would allow. Imposing such technologies at a cost, for reducing this small number of excesses cases seemed unbalanced. So nine out of the twelve smelters initially subjected to the rule were exempted from it (Pasztor 1986). Environmental groups were massively critical of that cancer calculation and of the weighing of costs and risks.

Ruckelshaus had little time to save the agency, and a complicated legacy to handle around a few hot, complicated dossiers, notably those issues that had embodied the failure of Gorsuch and that symbolized its faults: dioxin, benzene, formaldehyde, and EDB mainly. The scheme in RAFG was not just a good way to present to the public what the EPA was doing; it was also a good key to interpret what had been done wrong in these cases. The problem was not so much that politicians had distorted the science—for, what would undistorted science mean, and by what standard would a pure, objective science for risk assessment be judged? What had gone wrong was that Lavelle and Todhunter pretended that the science was straightforward. They grounded their actions on this supposed, deceptively objective state of the science in order to advance their preferences, not anticipating that

their actions would be discredited by the questionability of the science, its fundamentally disputable nature.

Again, RAFG provided the key to understanding this by making it clear that risk assessment was shot through with assumptions, that program managers necessarily carry into their standards, unless such assumptions were made explicit at some point in the decision-making process. Ruckelshaus understood that scientific uncertainties were in fact quite difficult to overcome, and impossible to do away with in the short time span the EPA had to issue a regulatory measure. But he could reduce the political uncertainty associated with those measures made on the basis of uncertain science—that is, the potential that these decisions had to be contested through the science employed to buttress them—if uncertainties were assumed. What that translated into, in decisionistic language, was: options. Scientific uncertainties would not preclude acceptable decisions if they appeared transparently as a factor in the choice among options.

In 1983 and 1984, Ruckelshaus took a number of decisions on the controversial, convoluted dossiers that his predecessor had failed on, many of which had been on the agency's agenda since its establishment. One was dioxin. Ruckelshaus and Alm, reviewing all the hot issues that would have to be dealt with quickly with other leaders of the agency, came to the conclusion that an agencywide task force was needed for this topic alone. By December 1983, the task force had concluded its work, not with a decision to launch more studies or revise the existing health assessment, but with an announcement of a multimillion-dollar program for the assessment of health risks linked to dioxin contamination, with sampling or monitoring in a hundred new sites across the country. If doses higher than one part per million would be found, then a clean-up would be ordered and executed under the Superfund program.

EDB was another such long-lasting controversy that embarrassed the agency. In 1975, the Environmental Defense Fund had petitioned the EPA to do something about this product used as a fumigant, which a National Cancer Institute study in rats and mice had found to be carcinogenic. The agency had followed suit, initiating a so-called Rebuttable Presumption Against Registration (RPAR) process, or special review, to assess whether to ban the product. The preliminary decision to ban EDB was issued in December 1980, but that process was stalled by Ann Gorsuch, while the head of the OPTS was redrawing the health effect assessment with his own

back-of-the-envelope calculations.[32] After Todhunter resigned from the Office of Pesticides, his successor, Don Clay, acted quickly on the matter, issuing an emergency suspension of the registration of the soil fumigant, justified by the recent discovery of high levels of groundwater contamination in California and Hawaii. The case became more complicated as a public panic set on, after discovery of residues of EDB in food products, with consumers calling EPA staff directly to know whether they would die from eating this or that product, and asking for advice on what to do. States pressed the EPA to develop a specific guidance on use of the product—to which Ruckelshaus first responded that he did not want to act in emergency. When the Natural Resources Defense Council threatened a new lawsuit on the EDB decision, Ruckelshaus changed his mind and held a press conference to launch an accelerated study, leading to an emergency suspension for fumigant in grain, and a six-month phase-out of treated fruits (Anonymous 1984c).

Formaldehyde was another controverted case of chemicals regulation in which the EPA was embroiled. It was one of the chemicals for which John W. Hernandez, Gorsuch's deputy administrator, held a so-called forum with the industry, which created one of several scandals during Gorsuch's tenure. Hernandez and Gorsuch had limited themselves to creating a research clearinghouse for studies concerning the chemical, even as the CPSC was banning the use of formaldehyde foam insulation in February 1982 (Mosher 1983). The official rationale behind the EPA not pursuing the regulation of formaldehyde was that animal tests demonstrating carcinogenicity should not be given too much weight as evidence of risk in humans—against the established guideline and WOE methodology. In July 1983, with Ruckelshaus back at the EPA, the Natural Resources Defense Council and the American Public Health Association sued the agency, accusing the EPA of setting an unreasonably high standard for meeting health hazard criteria in TSCA and of violating its own conservative scientific principles in assessing the chemical's carcinogenicity. The lawsuit pressured Ruckelshaus to put his new approach to the test: letting scientists work, on the basis of established guidelines, to construct a set of possible regulatory options. The EPA did just that: Ruckelshaus reverted to the application of its cancer policy, considering substances found to be animal carcinogens as being carcinogenic in people as well, and announced that the agency would consider regulatory options on formaldehyde, ranging from ban to partial ban or no

ban. The move seemed bold and was greeted in just that way by the press (Pasztor 1983, 1984). The agency was seen to be performing its mission of protecting the public's health, following a graduated scientific and regulatory response that seemed credible.

On all these issues—a March 1984 proposal to establish a rule applying to particulate matter, blocked since 1978, offered yet another example—Ruckelshaus capitalized on the dual advantages of a flexible and generic framework for decision-making: transparency concerning the criteria on which the agency was making its decisions, including scientifically, but also the right and legitimacy to develop and adopt different regulatory options for variegated chemicals, in a way that was comprehensible to the public, even when those decisions allowed greater exposure and risks for the public (Shabecoff 1983f).

Anticonsistency

The development of these tools for risk analysis had important consequences—namely, that of enabling the administrator, deputy administrator, and assistant administrators overseeing functional offices (research, policy, legal affairs) to take control of the development of major rules and standards. The creation of a cross-office process covering risk, cost, benefit, or options analysis was a soft, legitimate intrusion in the business of program offices. But now that there was an internal, transparent, and informed process for taking into account costs and benefits alongside risks, legitimized by a global knowledge representation defining the act of making decisions at the EPA in terms of a sequential consideration of numbers and uncertainties concerning risks, costs, and benefits. The agency was organized to produce these considerations and also to produce arguments justifying them. With differences among offices, regulatory analysis in the Ruckelshaus years was fully institutionalized (McGarity 1991), to the point that it was becoming a standard part of the decision-making and options generation process, including in legislation that (whether formally or by interpretation) discouraged taking cost considerations into account, such as the Clean Air Act.

There was some resistance to the introduction of more formal regulatory analysis. Alm and Russell were not unaware that most offices would resist requests to perform such analysis. For many offices, these innovations were too numerous in 1983–1984. The many guidelines introduced,

on top of the options selection process, were resented, and complaints were becoming more frequent by the end of 1984 that the review process was causing delays, and that the OPPE did not demonstrate enough flexibility in implementing it. Russell denied the problems, emphatically defending what had been initiated in the past year: "My point is simply this—that under your (Alm's) leadership during the past year we have established a decision system that is the best in EPA's history, and the best for an agency of this kind in the government, and I don't want us to undermine what we have achieved."[33] A retreat with his senior staff to reflect upon these issues led to the conclusion that the OPPE was spending less energy on developing rules to be applied at a distance than on helping offices to improve and working with them directly. Still, the OPPE was not abandoning its vision of expanding analysis in the agency, getting more done by program offices, and "pushing risk assessment/risk management."[34]

But the language of "consistency" was frequently called into question by people outside the OPPE, as were the benefits of the forceful creation of central analysis and decision-making channels across the EPA. In the early days of the interagency risk management initiative, driven by the OPPE and largely centered on common analytic methodologies, Don Clay, the head of the OTS, wrote to Dan Beardsley, one of the leaders of the interagency effort, that "optimization of costs and benefits may not and should not in all cases define the ultimate goal for all agency activities related to chemicals."[35] To which Beardsley replied, as sanguine, that "I know you folks in OTS [Office of Toxic Substances] think OPPE wants to optimize every environmental problem which passes before our eyes, from personnel decisions to TSCA amendments. We suspect you would want us to coordinate the Second Coming … No matter how unique the specific chemical problem, it seems reasonable to try to respond to that problem in as organized and structured a manner as possible."[36]

While the acrimonious correspondence focused on the program of interagency coordination, it illustrates program offices' resistance to the OPPE's strategy of promoting integration through analysis. In the summer of 1984, the assistant administrator of the OPPE and two of his aides were busy writing the flagship report *Risk Assessment and Management: A Framework for Decision-Making*. The report was envisioned by Ruckelshaus, Alm, and Russell as the first major agencywide document explaining how the managers of the agency planned to create a presentable structure of the EPA and

demonstrate its capacity to produce credible decisions on uncertain, controversial issues. It was projected as a "potentially significant statement of further policy direction of the Agency."[37]

The report was eventually endorsed by all assistant administrators and subsequently published. But in the process of writing it, Joe Cotruvo, the head of the Water Office, found that it was "overly optimistic about the changes that would come about in decision making when the risk assessment/risk management process becomes universal in the agency."[38] Moore, the assistant administrator for toxic substances and pesticides, noted that the report did not clearly define what was meant by consistency—"why it is an improvement, and how it will foster a strong base of public support as the report asserts"—and strongly recommended that the agency carefully evaluate whether consistency was desirable and under which circumstances it should be applied, given the differences between regulatory statutes and offices.[39] Much of the discomfort among the reviewers of the draft report came from the fact that the people in the OPPE described the methods of risk assessment and policy analysis as too standardized and mechanical. They did so to uphold the image of the EPA as a unified agency identified by its transparent procedures. But people involved in the development of regulatory decisions in program offices found that the economists misrepresented their work and the role of professional judgment in decision-making.

John Moore and the managers of the OPTS were particularly resistant to the way that the economists of the OPPE used science as an instrument to integrate the whole agency in a cross-program decision-making system. For the OPPE, risk assessment was a transversal process that could lead to differentiated risk management decisions in separate offices. But the OPTS had always produced its own science and performed risk assessment in house. At the very moment when Alm and Russell were describing risk assessment as a cross-office process, the OPTS was busy organizing itself along the lines of RAFG too, defining its own internal scientific and regulatory decision-making stages. In the offices that were implementing the TSCA, the people in charge of both existing and new chemicals were busy outlining a process based on RAFG, with scientists and types of data assigned to the three key steps of hazard assessment, exposure assessment, and risk characterization (Zeeman and Gilford 1993; Boullier et al. 2019).

The report was finally accepted by all the managers of program offices once it was rewritten to look like a proper framework: a set of generic

principles that described to the outside world how the agency functioned, not a set of instructions to be applied uniformly by the professionals in the various program offices.

Risk Assessment and Risk Management as Culture

The guidelines and tools developed by Alm and the OPPE would not be sufficient to eliminate potential disputes inside the agency on chemical uncertainties so long as they continued to work in isolation, applying the criteria written down in their legislation. The staff of program offices needed to realize what they were part of—namely, that the standards they were developing would eventually appear to the outside world as decisions of the agency. The OPPE embarked on the design and delivery of a training course on risk assessment and risk management for all agency staff, "trying to get that whole framework deeply understood inside the agency."[40] This training policy was inaugurated at a major conference on risk assessment in early 1985, with a list of prominent speakers from both inside and outside the EPA, attended by a chosen list of participants from across Washington, D.C. Soon after this first public event on risk, the OPPE tested its new "generic course on assessment/management/communication"[41] in June 1985 with about 100 staff from the EPA headquarters and regional offices.

Goldstein and Moore taught risk assessment, while Russell took care of explaining risk management and regulatory analysis. All drew from the graph in RAFG, which provided the new informal structure of agencywide operations: a sort of mental organizational chart that was disseminated to replace the policy towers that people had in mind. The graph had changed into a Venn diagram and flowchart hybrid, perhaps to accommodate people's affiliations in the organization (see figure 6.2). The large circles and the space offered to every subdiscipline seemed to indicate the self-sufficiency of these various jobs and forms of expertise in the organization. But the arrows inside the circles drew a decision flow. They characterized the interdependence among the types of expertise and redefined their action identities with regard to an institution- and interest-free decision-making system (specific offices were not represented).

The training included hands-on session learning through case studies. Over time, thousands of EPA staff became acquainted with the famous—albeit entirely fictitious—controversy over the "widely used chemical

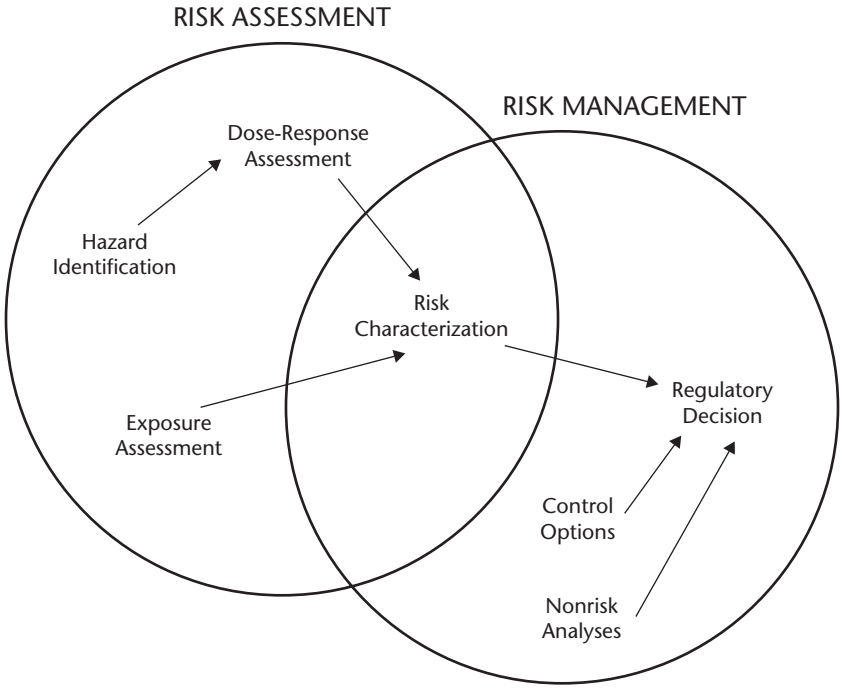

Figure 6.2
The NAS paradigm, as represented in EPA training material.
Source: Bernard Goldstein, "The Elements of Risk Assessment," EPA Workshop on Risk Assessment, March 17–18, 1985, Easton, MD; Milton Russell, "The Elements of Risk Management," EPA Workshop on Risk Management, April 13–14, 1986, Easton, MD. Milton Russell Special Collection.

dinitrochickenwire," which participants in the training had to approach in the role of either risk assessor (being instructed, as appropriate, not to ask themselves questions about what to do with the situation from a regulatory point of view) or risk manager. By the end of 1985, the OPTS and ORD had trained fifteen facilitators to conduct the "famed RAW" (Risk Assessment Workshop) involving the "notorious dinitrochicken-wire."[42] During the months of October and November 1985 alone, the OPTS and the ORD conducted fifteen separate RAW sessions at the EPA headquarters for the enforcement office, the OPPE, the ORD, and the OPTS.

The training was offered several times a year, to around 100 participants every time, leading to thousands of staff being exposed to an integrated knowledge representation of what the EPA as a whole was supposed to

produce. By 1992, more than 18,000 people in the agency had attended a risk assessment training of some kind (Anonymous 1992). Information about the many workshops organized across the country on risk assessment, characterization, communication, or management was disseminated through a dedicated internal newsletter that started to be published in 1986 by the OHEA. This bimonthly publication, *Risk Assessment Review,* had been initiated by the newly formed network of regional risk assessors. It was an important instrument, too, as it circulated information across a wide range of offices concerning risk studies performed in any office or region about any substance or risk. It decreased, by a small proportion, the number of duplicated studies and contradictory assessments in the agency. It also gave form to a "risk assessment community" across the agency.[43]

Conclusion

The problem of the use of science to forge environmental decisions, insofar as it resulted in the articulation of an original design termed *risk assessment and risk management*, fostered the birth of a new kind of administration. In those years, a set of bureaucrats drew on the notion of risk management as the consideration of policy options to adjust decisions to the knowledge of risk in order to design a more integrated EPA—an entity that could smoothly involve scientists, policy analysts, and lawyers from various offices in processes of risk assessment and risk management. These processes were generic: They applied across the offices that comprise the agency and link the bottom of the organization with its top—the political leaders of the agency, recast as the ultimate decision-makers. These processes, furthermore, were scientific in style; they were defined in terms of the knowledge and information that was necessary to construct policy options and shape good decisions. In those days, it was the risk decision-making of economists and policy analysts—in which risk decisions can be optimized, so long as an adequate, homogenous level of information is reached on all aspects and objects of a decision—that prevailed.

It was their particular discipline of making decisions sequentially, through explicit criteria and completeness of information, that was disseminated across the EPA: a particular sort of bureaucratic science that incorporated and redefined the utility of the scientific calculation of health and environmental risks of toxicologists, biologists, health scientists, and

statisticians, in a rare moment of collective redefinition (both symbolic and material) of the objects, knowledge, and processes of the agency. The most notable aspect of this transformation is that science was, at this moment, brought under the purview of the leaders of the agency. Risk assessment, now closely coupled with risk management, became an object of explicit interest and policy for them. A framework linking risk assessment with risk management meant, in essence, the possibility of managing risk assessment.

The Science of Bureaucracy

Risk Decision-Making and the US Environmental Protection Agency

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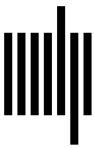

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