

10 Beyond the Risk Paradigm

The EPA has been a risk-based agency during a large part of its nearly fifty years of existence. Around risk has emerged a whole set of formalisms—of the knowledge in use in the agency, and of the right way of producing decisions—that were instrumental to assemble the agency and construct its identity and legitimacy. These formalisms emerged from diverse disciplinary networks, with diverging views about what the source of the uncertainty was, and which knowledge should be used to forge credible decisions. A decisionistic bureaucratic design (carried by toxicologists, embodied in the technology of quantitative risk assessment and defaults) combined with a commensurative design (that of economists and policy analysts) to give form to EPA's standard way of governing problems. This EPA was defended by administrators and other political appointees, who enjoyed a reasonably high level of support from the key audiences of the agency, from courts to the OMB to the White House. The preceding chapters of this book have shown how the framework started to unravel—not all at once, but piece by piece, starting around ten years after the publication of RAFG. Comparative risk analysis lost momentum under the leadership of Carol Browner. Risk assessment was heavily influenced by scientists' and industry's efforts to fold this practice into a strict scientific definition, as if science could inform exact decisions. The reaction to all this was the need to recreate a design that allowed the explication of the limits of science and the definition of its boundaries with policy determinations. Those evolutions were captured and codified in a series of reflexive reports (NRC 1994, 1996; Presidential and Congressional Commission 1997) that accelerated the move from the risk assessment–risk management dualistic representation in order to promote risk characterization.

Moving forward another decade, these trends have only strengthened. Risk is nowadays much less present in the whole of agency discourse

concerning the EPA's goals, science, and processes. It is more frequent to hear that the agency has risk-based programs, and that risk assessment is but one instrument among many, than to see the EPA administrator invoking risk reduction, safety, and health protection as the overall organizing policy principles. Thirty years after William Ruckelshaus's commitment to the idea of risk, which portrayed the EPA as a risk bureaucracy, other designs have emerged—namely, a new kind of bureaucratic technology termed “problem formulation, planning, and scoping.” Like other concepts that previously gave form to the agency, these were in great part invented at the EPA, notably in those parts of the agency that were dealing with complex, systemic ecological issues. These concepts are now being pushed forward to show that the action of the EPA is not driven by what it is able to measure and calculate, but by what it decides to achieve. It is less acting on pre-defined objects of action—such as the risks of individual chemicals—than promoting indirect outcomes—sustainability of the environment—using the science that it needs to reach that end. That design helps the agency promote a new, autonomously defined agenda and keep control over the definition of the right science for policy. It serves to move away from the terrain of risk, one on which the agency has more and more difficulty actually imposing its policies, given the continued pressure that it is under to adopt more scientific methods and always reduce scientific uncertainty.

Like previous episodes of formal redesign of the EPA, this involved its share of public controversy about its scientific capacity and its share of conflict to control the ground of science and to control the agency more generally. As in other episodes, the National Academies, the NRC in particular, is the site on which competing actors converge, and in which the controversy was reframed and new formalisms advanced. The 2009 report called *Science and Decisions* is, from this point of view, similar to *Risk Assessment in the Federal Government* from 1983: a turning point in the political life of the bureaucracy, a shift from dispute to design and an attempt for the agency to restore a capacity to govern the environment credibly through terms and technologies it owned.

A New Coherence: Sustainability

The shift from risk to sustainability as the overall framework of action and identity of the EPA was never as clear as during the first administration of President Barack Obama, when Lisa Jackson headed the agency. As Andrews

(2011, 247) recalls, “Jackson’s stated goal has been to restore momentum to EPA’s core programs—healthier air and water, and reduced risks from toxic substances—while also tackling emerging challenges such as climate change.” Risk was not the way that the administrator defined EPA’s approach and overall goals. Like the previous Democratic administrator, Browner, who stressed such objectives as environmental justice, Jackson placed climate change, environmental quality, and sustainability at the center of her agenda. Sustainability goals and adaptation became the new overarching imperatives for environmental action (Ostrom et al. 2002; Wennerston and Fidler 2007; Sexton and Linder 2014).

In those years, the representation of EPA’s knowledge and of its typical, integrated way of making decisions also evolved. Paul Anastas, Yale University’s prominent chemist and celebrated visionary behind “green chemistry,” rationalized this change during his tenure as Jackson’s chief of science (2009–2012). A couple of months after his nomination, he wrote to the entire staff of the ORD of the agency to announce a paradigmatic change. The goal of sustainability was now the “true north,” for the agency in general, as well as for its science and research effort in particular. The path forward was to embrace technological innovation and to “couple our excellence in problem assessment with an equal excellence in solving problems” (Anastas 2010, 2012). According to his vision, risk would cease to be the methodological tool for the agency’s science and decision-making: “[T]he issues of risk characterization, risk assessment, and risk management will be essential building blocks in all of the work that we do. But we’re also going to ask ourselves: ‘Is it possible to use our reductionist tools to characterize, assess and manage risk in ways that may be unsustainable?’ I’d suggest the answer is yes” (Risk Policy Report 2010a). Anastas created transversal research programs, from which the various laboratories of the ORD get their funding. One of the eight research programs is dedicated to human health risk. At the same time as he changed the name and composition of the Science Policy Council (turning it into the Science and Technology Policy Council), Anastas got rid of several risk-related policy projects led by it.¹ The RAF ended up unanimated in those years and was essentially brought to a halt (Risk Policy Report 2010a).

The risk focus did not disappear, but it was demoted to just one kind of operation of the agency. Anastas commissioned a study from the NRC on the adoption of a new integrated sustainability perspective for the EPA. The study, dubbed the “Green Book” from the inception of the committee,

explicitly aimed to replace the “Red Book” (RAFG) of 1983—not amending the paradigm, as previous NRC reports claimed to do, but replacing it entirely. The NRC committee was chaired by Bernie Goldstein, who saw sustainability as the new horizon for the agency.² The NRC 2011 sustainability report considers that risk assessment should be preserved as a key tool for decision-making. It should even be further developed, such as to address problems of cumulative risks. But it represents only one option or tool in the task of managing environmental problems.

In any regulatory process in the agency, risk assessment should now be preceded by a new exercise of “problem formulation, scoping, and planning”: “At the early planning and scoping stage, project managers and analysts diagnose the issue or problem to be addressed. Upfront review of the nature of the problem, credibility of the science, and the decision and legal context helps in considering the nature of the assessment and decision process (Goldstein 1993; NRC 1996, 2007)” (NRC 2011). Only after this stage would analytical activities start, employing a variety of possible methods, including but not limited to risk assessment.³ To naturalize this new framework of sustainability and help articulate these two sets of organizational reference points, the committee mapped the risk assessment–risk management framework onto their own sustainability flowchart (figure 10.1).

Each component of the sustainability framework, in practice, corresponds to a phase of the process of assessing and managing risk. For instance, the second phase of this process, in which risk assessment is planned and executed, maps onto this moment of the sustainability management process when other assessments addressing social, environmental, and/or economic dimensions would be performed alongside that of risk. In conclusion, risk assessment is not the fundamental, central process that RAFG presented, but its technical components are still the same, and they constitute it as a tool that should be employed to make decisions that enhance sustainability.

“Organizing Information” to Attack “Environmental Conditions”

The initiatives around sustainability resonated with an earlier, impactful study by the NRC published in 2009. *Science and Decisions: Advancing Risk Assessment* (referred to just as *Science and Decisions* hereafter) was written on request from the EPA directly [more specifically, by the National Center for Environmental Assessment (NCEA) inside the ORD] to review the risk

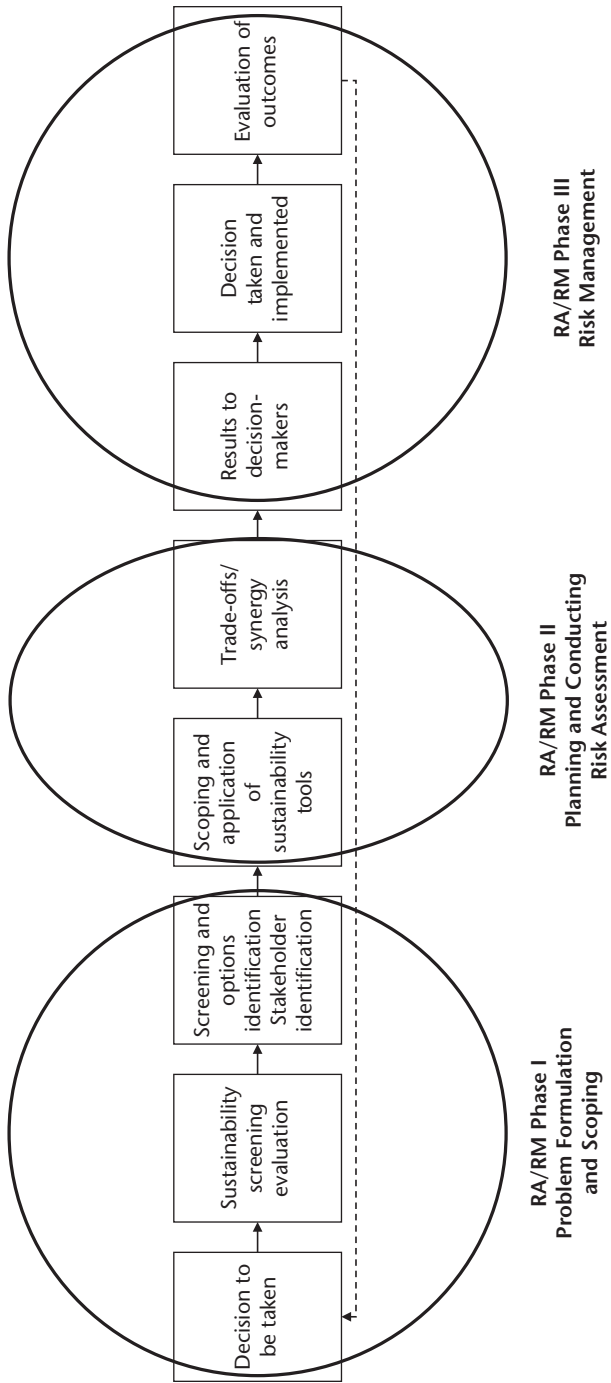


Figure 10.1 Correspondence between sustainability assessment, management elements, and the risk assessment–risk management (RA/RM) framework (adapted from NRC 2011).

assessment practices of the agency, evaluate progress achieved in the past several years, and point to directions for further evolution. The Committee on Improving the Risk Analysis Approaches Used by the US EPA, assigned to write this report, had the massive and ambitious task to “conduct a scientific and technical review of EPA’s current risk analysis concepts and practices” (NRC 2009, 281), covering contaminants across all media, as well as health and ecological risk analysis. The panel had to formulate short- and long-term recommendations on probabilistic risk analysis, alternatives to default assumption choices, quantitative characterization of uncertainty, cumulative risk, risk variability, PBPK and biologically based dose-response (BBDR) modeling, and derivation of uncertainty factors. The cost of the study also gave a measure of the extension of risk assessment in the past thirty years and the ambitious charge of this new committee. RAFG had cost the NRC \$500,000 in 1983 (around 1 million in 2009\$), *Science and Judgment* \$900,000 in 1994 (1.3 million in 2009\$). This time, the budget reached \$1.7 million.

The 403-page report advanced many new bold recommendations: developing a common approach to evaluate the risk of cancer and other effects based on the mode of action of the chemical of interest, being more precise and tailored in the analysis of uncertainty and variability, continuing to explicate default assumptions and defining standards for departing from them, and addressing simultaneously all sources of risk, in the spirit of cumulative risk assessment. All these technical recommendations were unified by a framework proposal: Risk assessment should technically be designed and tailored to the problem at hand. It should respond to the problems facing risk managers rather than being self-initiated and unguided. Taking stock of the practical limits experimented in the EPA with RAFG and the risk assessment–risk management framework was the easiest for the group. The limits were well identified by now: slowness of the one-substance-at-a-time approach, risk assessment as a central process leading to risk management, and lack of interaction between risk assessment and risk management. They were all the more easily recognized, as Joseph Rodricks, the former FDA toxicologist and chief of science, a member of the committee that wrote RAFG, and the supposed author of the fourfold scheme of risk assessment, was part of the committee. Rodricks could recall the genealogy of RAFG and its use at the EPA, as well as the particular context that motivated it—the political intrusions in the health assessments of benzene, formaldehyde,

and bis(2-ethylhexyl) phthalate (DEHP) by political appointees in the first years of Ronald Reagan's administration (see chapter 5).

Like Anastas's sustainability initiative unfolding at the same time in the ORD, this panel lent weight to a new exercise of problem formulation, planning, and scoping. It pushed the integration of various streams of science away from partitioned disciplines of human health risk assessment and ecological risk assessment, or of cancer risk assessment and noncancer risk assessment. It pleaded against the use of "bright lines": defined doses, thresholds, and the like, below which risks are not supposed to materialize. Too much time is spent defining these limits for individual chemicals when instead the agency should be driven by the aim to improve overall environmental conditions and the effects of global exposure to chemicals in the environment. It suggests advancing further in the inclusion of considerations of variability of risks among populations. It also criticizes the use of uniform risk management measures, which leave the most exposed populations unprotected.

The report is called the "Silver Book," as if a sequel to RAFG. At the start of this work, James Reisa, a former EPA staff member and longtime director of the NRC's Board on Environmental Studies and Toxicology, who oversaw this panel, argued that the future report had the potential to become "the new Red Book"—a new gold standard for risk-based decision-making. The chair of the panel now recounts that "the joke is that we got silver!"⁴ Indeed, the report advances a framework, and dutifully developed its own distinct graph, to contrast with the paradigm of yesterday (see figure 10.2).

The group capitalized on the formalisms developed at the EPA, particularly in the context of environmental assessments, to come up with a synthetic graph that leaves risk assessment intact at its heart, but flanks it with a planning stage, a risk management stage, and permanent stakeholder involvement. The framework tones down the importance of risk as the primary and overall object of the agency's action, choosing to promote a less specific action of decision-making to attack environmental conditions. Modules are defined to design useful risk assessment against the tendency to continually deepen scientific understanding of risk at the expense of timely intervention.

Compared to what was presented in the original definitions of risk assessment and risk management in the 1980s, the shift is clear. The process of governing a risk does not start with risk assessment. Options for decision-making should not derive from risk assessment alone. Risk assessors cannot

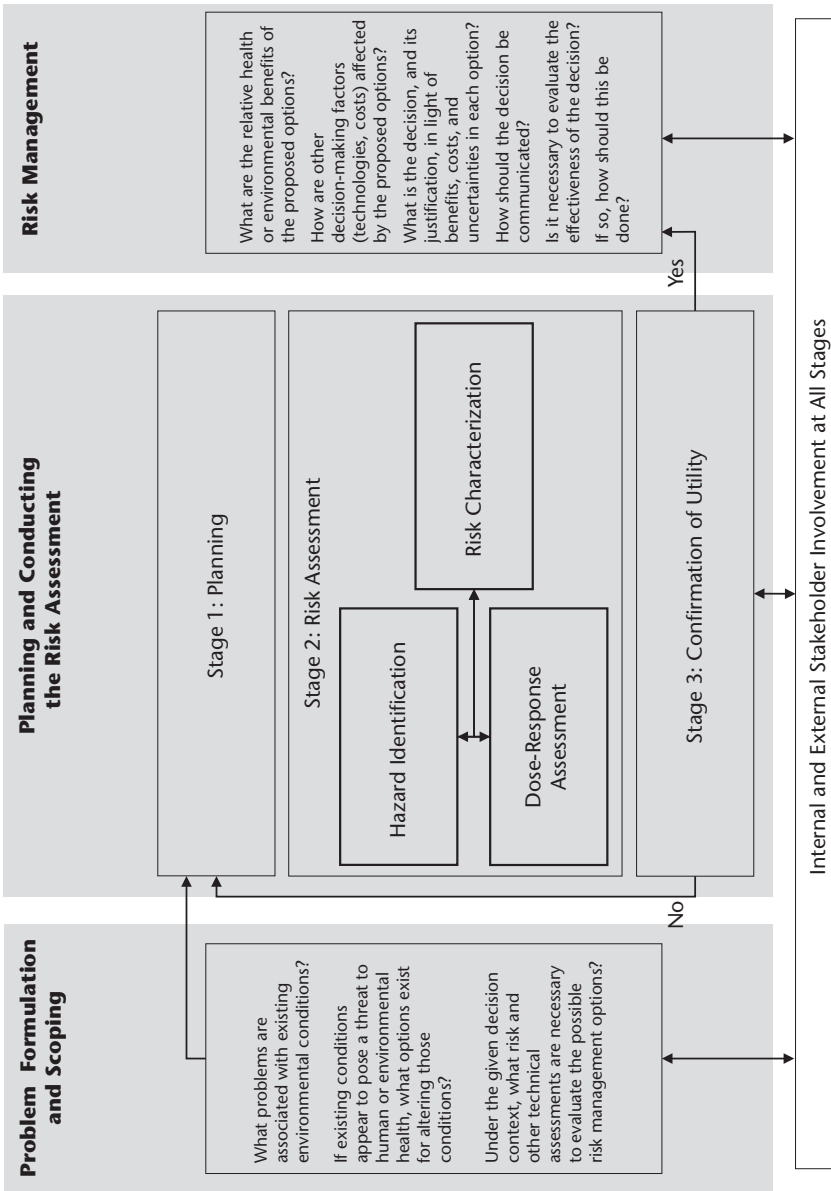


Figure 10.2
A framework for risk-based decision-making (adapted from NRC 2009).

use the assumptions, parameters, or models that they alone deem better. Rather, these elements should be chosen to improve the capacity to finally implement the decision. Also, risk assessment is defined more generically as the organization of information for decision-making.⁵ The risk assessment-to-risk management algorithm is undone: Risk assessment does not so much forge decision points as it brings information to the decision-maker. By the same token, the framing of what the decision-maker does in terms of risk also recedes. The fact is: If one deletes just a couple of terms from the graph—mainly the words in the central box, like *risk*, *hazard*, or *exposure*—a framework is obtained that can be applied in literally any organization.⁶ The image of the EPA as an agency that is concerned with risk and organized to deal with such an object is omitted from the design.

The agency soon responded to the NRC by holding a colloquium in 2010, with approximately 120 risk assessors and risk managers focusing on the lessons to extract from this and other concomitant NRC reports.⁷ The colloquium was the occasion of a vast exercise of review and stock-taking of the agency's internal practices and approach of risk assessment: 116 agency risk assessors and risk managers were interviewed during the preparation of the event. A task force was then created under the Office of Science Advisor and the RAF. From *Science and Decisions*, it emphasized those recommendations that the agency was already actively working on (addressing the variability of exposure to risks, performing more uncertainty analysis, expanding the use of science to support or revise default assumptions, etc.), and the adoption of a "Framework for Risk Based Decision-Making," with elements on "Planning and Scoping" and "Problem Formulation," a focus on "Informing Decisions," and formal stakeholder involvement. The group thus favored a high-level response through new, generic designs and concepts applying to decision-making.

The working group offered a draft framework for human health risk assessment to inform decision-making (EPA 2012), with the overall objective "to improve the utility of risk assessment in the decision-making process." The document was not intended to supersede existing EPA guidance (which does not use such language as "utilization of risk assessment" in "decision-making"). It is meant instead as a supplementary reference for interpreting existing guidelines, helping agency staff assess the weight to give to the newly promoted concepts of "problem formulation, planning, and scoping" that were already mentioned in some of these guidelines. As

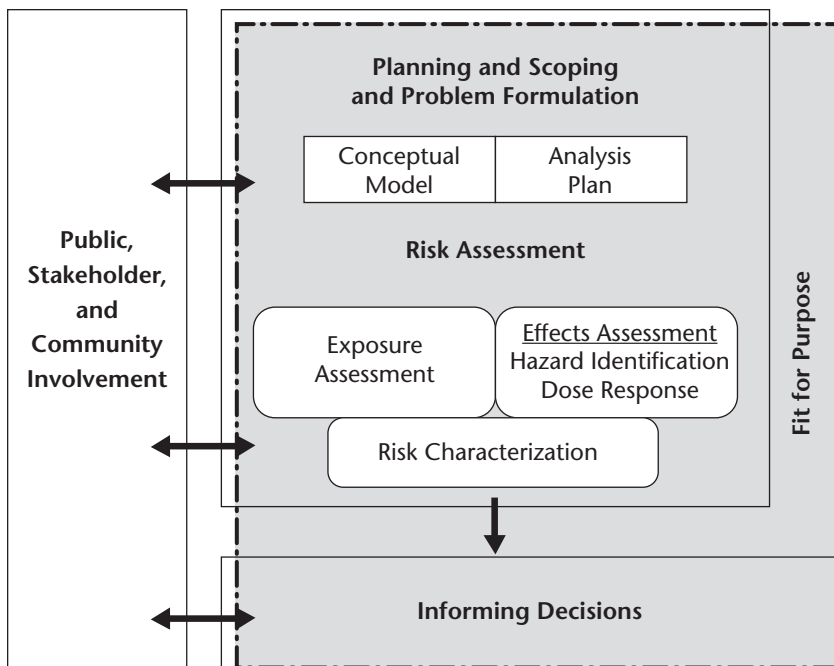


Figure 10.3

Framework for human health risk assessment to inform decision-making (adapted from EPA 2012).

before, these concepts are conveyed together by a graph (figure 10.3), in which the scientific process of assessing risk is incorporated into a broader process of production of knowledge to solve environmental problems.

From this date onward, the bureaucratic technology of *problem formulation* continued to be elevated as an agencywide discipline. The framework of 2012 was reedited in 2014. In that document, the 2012 flowchart was shoe-horned into a wheel (figure 10.4) in an attempt to stress the permanence of a cyclical process in which one decision act feeds further reformulation of the problem, and to find a place for such principles that do not translate into linear bureaucratic operations, such as engagement with stakeholders.

The framework also accumulated a number of schematic lessons of the past⁸—the compatibility among assessments of health problems and ecological problems, and the need to produce a full risk characterization, qualifying the uncertainties and variabilities inherent in the final risk estimation. And in accordance with long-standing agency policy, it also emphasized

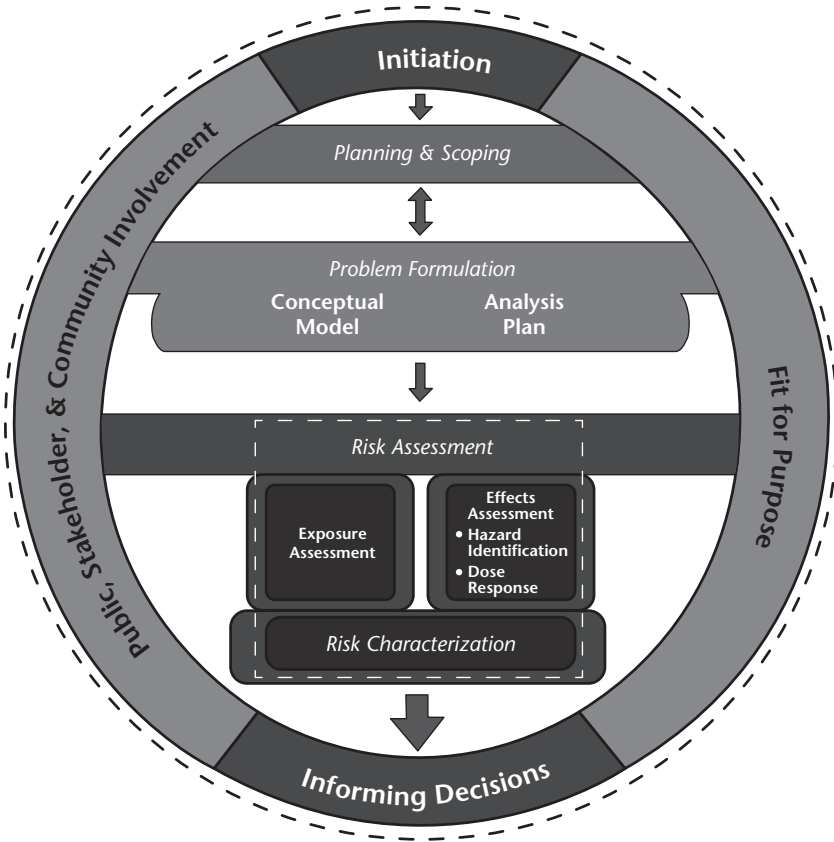


Figure 10.4

Framework for human health risk assessment to inform decision-making (adapted from EPA 2014).

the importance of scientific review and public, stakeholder, and community involvement (although it does not translate these principles into recognizable sequences of action).

Problem Formulation as a Bureaucratic Response to the Republican Assault on the EPA

This new design applying to the goals, processes, and objects of the agency did not emerge from the minds of detached academics. Neither were they imposed by the management of the agency. The various formalisms that were

advanced here—*environmental conditions*, *problem formulation*, and *organization of information* as essential operations; *sustainability* and *environmental quality* as an overall rubric defining the objective of the organization—were selected in the context of a particular controversy about the EPA (notably its treatment of uncertainty and a continued accusation of being too conservative and not scientifically robust enough). They responded to the new “wave of attack” on the agency (McGarity 2012, 205) and its science in the early 2000s.

Despite evidence to the contrary during the campaign,⁹ the election of George W. Bush as president in 2000 opened “another anti-regulatory era” (Andrews 2011, 247). The new president had chosen a relatively moderate Republican for the job of EPA administrator. Christine Todd Whitman, formerly the governor of New Jersey, was inclined to embrace the tradition of risk and cost-benefit analysis as other Republican administrators before her had done. She announced a shift back to “long-standing traditions” of “precaution, science-based risk analysis, and sound risk management, including consideration of benefit/cost” (Gibb 2001, 57), putting the battle between Congress and the EPA on risk analysis on hold. She resurrected the Policy Office (now the Office for Policy, Economics, and Innovations) and its role in reviewing regulatory proposals from other program offices, particularly those related to energy issues. But environmental policy in the new administration was made at the White House as much as at the agency. Whitman resigned after only two years, officially citing her desire to return to New Jersey but unofficially reacting to being frequently overridden by the White House and Vice President Dick Cheney in particular.¹⁰

Her successors, Michael Leavitt and Stephen Johnson, strengthened a number of environmental standards (e.g., standards for ozone and diesel emissions). But they also urged program offices to abandon the development of several important standards and policies and revived the kind of political interference in the work of EPA scientists that made headlines in the early 1980s. This time around, the EPA leadership edited scientific reports that alerted to the need to regulate industries to reduce global warming, as well as other technical reports on oil extraction or particulate matter pollution (US House of Representatives 2003; UCS 2008; see also Freeman and Vermeule 2007; Rest and Halpern 2007; Rich and Merrick 2007; Shulman 2008; Shapiro 2009).

The Bush administration also used the OMB to counter or impede environmental regulation and the science supporting it. George Bush appointed John D. Graham, a longtime critic of environmental policy and of the EPA, as head of the OIRA. This appointment was heavily criticized by environmental and public integrity groups (Hume 2001; Rampton 2001). At OIRA, Graham resurrected the kind of aggressive oversight and critical review of EPA practices that OMB had done during most of the administrations of President Reagan and the first President Bush, stalling many assessments or rules the agency proposed (Tomkin 2016). He won praise from his infamous predecessor, Jim Tozzi, who played this role under Reagan, before becoming an industry lobbyist (see chapter 9; Vogel 2012).

Graham was no newcomer to the field of risk regulation and risk analysis. Indeed, he had a whole career in this field, starting with his first job at the NRC, assisting Howard Raiffa when the statistician chaired the Committee on Risk and Decision-Making. He then got a PhD from the Heinz School at Carnegie-Mellon University, with a dissertation assessing automobile safety technologies, and did postdoctoral research at the Harvard School of Public Health. A specialist in risk-benefit and uncertainty analysis, he is a past president of the Society for Risk Analysis (1995–1996). Graham, as well as the colleagues whom he trained and mentored at the Harvard Center for Risk Analysis, have been remarkably consistent critics of the actions of such agencies as EPA and OSHA, demonstrating through numerous reassessments of agency decisions (many of which were funded by companies on the board of the center) that they were wrong in what they were doing, inflicting more costs on industries than creating health benefits for the society and the environment at large.

At the OIRA, Graham started by releasing a vast review of the costs and benefits of environmental and energy regulations (OMB 2003). As part of this exercise, the office requested comments on the practice of risk assessment to help the working group in its task. The survey was aimed less at assessing the value of whatever innovative risk assessment method and more at resetting the debate about the supposed precautionary approach that EPA perpetuates via its risk assessment practices—specifically via the default parameters and models that it applies during risk assessment when data are missing. The text of the notice builds on the themes that Graham typically defended while heading the Harvard Center for Risk Analysis: the

precautionary nature of EPA's preferred conservative risk assessment methods; the unintended negative effects of risk reduction efforts, which often result in augmenting other risks that were not being targeted (the so-called risk-risk trade-offs); the need to reduce uncertainty as much as possible, and to calculate risks as precisely as possible, before making any decision.¹¹

The agenda for the public consultation left no chance to the agencies: The notice called for comments about "how conservative defaults used by the EPA embed a precautionary approach" and "examples of approaches in assessment and management that appear unbalanced" (Federal Register 2003, 5499). The OMB made the numerous comments it received available to the EPA, specifically the more critical ones coming from the American Chemistry Council (formerly the Chemical Manufacturers Association). Most of them were critical of the EPA's work. They portrayed a decidedly conservative agency in its assumptions about risk (too inclined to be protective rather than to be right in its assessments), its persistent neglect of the uncertainties inherent in risk, and distortions of the science by its precautionary stances.

While the criticism was "not radical or particularly new" (EPA 2004, 8), the fact that it was channeled by the OIRA to lend support to its project of supervising the agency's risk assessments was sufficient to trigger a clear response from the EPA. Three political appointees of the agency decided to form a task force to produce an internal evaluation of risk assessment practices and "set the record straight."¹² The resulting staff paper on risk assessment was almost 200 pages long, mobilized seventy-four people across the agency, and was organized as a clear rebuttal of the criticism the agency received. The context was so important, and the substance so critical, that this staff paper, though not a guideline in any formal sense, had a major status inside the agency. It constituted a moment of coming together and of collective assertion of the policy of the agency in a moment of adversity. It was, thus, a key moment of codification and explication of its bureaucratic knowledge, recalling all that had been ingrained and practiced in the organization since its foundation, and perhaps even more so since its refoundation in 1983.

As in other places in the report,¹³ the staff recaps the history of risk assessment practices and the numerous, evolving guidelines developed over the years for the exercise. Referring to the practice of "examining data before invoking defaults," of using modes of action, explaining defaults better, using uncertainty factors, clarifying choice of a "point of departure" from

observed experimental data, and using environmental models, the panel demonstrated that at the EPA, “the derivation of risk estimates improves continually with the addition of newer techniques and relevant data” (EPA 2004, 141). This was essentially a way of saying that the OIRA was off the mark—many of the critical comments concerned practices that were no longer current in the EPA—and that it was making up controversy, so it was illegitimate to propose a refashioning of the agency.

The staff paper was produced right when the agency was finalizing its new carcinogen risk assessment guidelines—another fragment of bureaucratic knowledge that reflects the EPA’s response to the controversy manufactured by Graham over the agency’s supposed political distortion of science. Following the publication of the proposal for a new cancer guideline in 1996, a public debate emerged, and in response, an SAB review was performed, to which the agency fashioned a reply. A new draft was issued in 1999 and a final adoption occurred in March 2005. The process concluded the evolution that took shape in the 1980s and 1990s, such as definition of alternatives to the default linear approach; recognition of the need to analyze more data and use biological models; refined uncertainty analysis at the level of model choice or, within a given model, at the level of parameters; refinement of exposure calculation, particularly for sensitive populations (with a module for children exposure included, capitalizing on progress made separately on this issue); and revision of the WOE narrative classification. Overall, the evolution was linear, with less expert judgment allowed and more formalized criteria made available to choose among predefined analytical options. In short, and given the evolution of guidelines away from default conservatism, the EPA deflected the accusations of Graham and the OMB.

Graham’s attacks continued, though. He created an Interagency Work Group on Risk Management, cochaired by the White House Council on Environmental Quality, using the need for consistency among agencies as an excuse to restrict the autonomy of the EPA—as Reagan had already done, in fact. The group prefigured a new procedure of reviewing the agency’s assessments of chemical hazards, whereby the OMB would officially be allowed to comment on the risk estimates developed by the scientists of the EPA for the IRIS database on behalf of all other agencies and departments. It was designed to enable the US Department of Defense, the US Department of Energy, or the National Aeronautics and Space Administration (NASA) to intervene in the EPA’s doings.

The process was implemented. It contributed to block the publication in the IRIS database of estimates for controversial substances,¹⁴ some of which soon became the object of new federal-level policy drama—notably concerning perchlorate.¹⁵ More crucially, Graham and Tozzi launched a two-pronged attack on EPA guidelines. Graham launched the *Risk Assessment Bulletin* (OMB 2006), which articulated principles and standards that the agency had to comply with in its risk assessment. The strategy was similar to what OMB, Vice President Quayle, and Jim Tozzi had attempted back in 1992: prescribing and framing how agencies calculate risks, address uncertainties, and develop regulatory measures on this basis. In that publication, he advanced the same agenda that he pursued while director of the Harvard Center for Risk Analysis, advocating analytical practices that mechanically minimize risks, such as providing central estimates of risk in addition to high-end estimates, requiring robust evidence of the adverse nature of the effects being targeted in risk assessments, and using ranges of risk obtained through probabilistic assessment instead of single risk estimates. The bulletin argues at length about the inherent, structural problem of uncertainty in health and environmental risk assessment and emphasizes the need to perform quantitative analysis of uncertainty, as well as sensitivity analysis of models, all to avoid finding risks where there were none—the so-called false positives.

Graham's launch of the bulletin was in all likelihood done in concert with Tozzi, who maneuvered to have the Information Quality Act implemented (Mooney 2004). That legislation created extra requirements for transparency of information in regulatory agencies, as well as justifications for industries to challenge agencies in court, after several failures of businesses to access large studies central to the EPA's decisions (on particulate matters and ETS) (McGarity 2003, 912–913). The *Risk Assessment Bulletin* was in essence using this imperative of transparency of regulatory information to justify imposing new analytical obligations on the agency.

A review of the bulletin—which Graham had required in the hope of giving a scientific imprimatur to it and propelling its recommendations into practice in the agency—was prepared by a panel of the NRC that included academics, but also several scientists with experience in risk assessment at the EPA or elsewhere.¹⁶ Sally Katzen, the person responsible for the OMB's Principles for Risk Analysis of 1995, was a member, as was Joseph Rodricks, a member of the committee that had written RAFG.¹⁷ The panel could not

tell what problem the OMB was trying to fix, and it suspected that Graham was trying to rein in the EPA, particularly its actions on such issues as perchlorate and many other issues that, he thought, were being unduly considered for regulation based on indeterminate science.

The panel framed its review in less politicized but no less effective terms, fending off the new prescriptions by outlining the departure that they would create from the patient history of improvement of risk assessment methodologies in the agency (NRC 2007). The NRC panel pointed out that the bulletin insufficiently considered the state of risk assessment as performed by regulatory agencies, or the structure on which these risk assessments are based, including RAFG. The NRC review panel also stated that the suggested rules were unclear or confusing, which betrayed the fact that the OIRA was out of touch with the actual ways in which risk assessment was done in agencies. The conclusion of the NRC review report was a cruel assessment of the OIRA's effort: "The committee began with the working assumption that its role would be to recommend modifications [to what was being asked for], if necessary. After digging deeply into the bulletin and after extensive discussion, the committee reluctantly came to its conclusion that the bulletin could not be rescued" (ibid., 7).

The proposed bulletin is thus remembered as a "spectacular failure" (Shapiro 2007) of the OIRA/OMB, as well as a personal defeat inflicted on Graham, once known as the "regulatory czar" (Nakashima 2002, 35). The OIRA withdrew the bulletin, replacing it by a less controversial update of the 1995 risk analysis principles, developed under President Bill Clinton by Katzen (OMB 2007).

Science and Decisions as a Compromise

At about the same time as Graham left OIRA and launched the *Risk Assessment Bulletin*, his former colleague at the Harvard Center for Risk Analysis, George Gray, was in line to become the next chief of the ORD, as well as its science advisor.¹⁸ It was Gray's turn to push uncertainty analysis and use the uncertainty argument to justify more extensive, repeated reviews of the EPA's assessment documents, but this time the efforts came from inside the agency.

As part of his candidacy as chief of the ORD, Gray had suggested creating a standing body, under the dual authority of the OSTP and OMB to

review the EPA's scientific assessments. That proposal, which revived old projects of having a review board established within the NAS board, went under close scrutiny during Gray's confirmation hearings, and Gray had to backtrack under the pressure of Democratic senators (US Congress 2006). The EPA did not reject the new scheme entirely, though; it entered into talks with the NAS for setting up a standing panel (that risked overshadowing the agency's own SAB). The NAS was already playing a review role for the agency. In those years, more and more risk assessments were referred there: it dedicated panels to reassessing the EPA's work on dioxin, trichloroethylene (TCE), phthalates, tetrachloroethylene, and formaldehyde (NRC 2006a, 2006b, 2008, 2010, 2011).¹⁹ With these reports, the NAS was now hosting controversies that originally had set the EPA against the OMB (not to mention other opponents of the agency's supposed conservatism). The cumulated impact of these reports was to push the EPA to think about revising the standard process for setting IRIS values, both procedurally and scientifically.

In nearly all these cases, uncertainty analysis was a bone of contention. On TCE, for instance, Gray in 2006 had asked the staff of the NCEA (formerly the OHEA)—an arm of the ORD and the main risk assessment shop in the agency—to perform a quantitative uncertainty analysis instead of a straightforward linear extrapolation. The NCEA staff and its director, Peter Preuss, resisted, arguing that the evidence did not support such a hypothesis, and that the exercise would lead in effect to relaxing the risk estimate. Producing a range of risk points, as Gray advocated, would not help risk managers, who needed clear decision points to determine whether to initiate the costly clean-ups of contaminated lands. For the risk assessors of the agency, running ten different models to get a shape of the curve at low doses was highly impractical. The choice of considering which model was supposedly right was purely arbitrary anyway in the absence of underlying biological experimental data. Using more models did not reduce the uncertainty that the risk manager had to face, making policy determinations. Rather, it was a theoretical exercise that only confused, and in practical terms, postponed, the decision (Freudenburg et al. 2008).

The staff of the NCEA resisted the calls to embrace uncertainty analysis because this scientific agenda was so closely associated with some areas of the academic field of risk assessment—namely, the Harvard Center for Risk Analysis—as well as with the OMB and with the Republican agenda on

environmental policy. The refusal of the staff delayed the assessment and the planned review by the NAS. EPA eventually released its health advisory in 2008, proposing a smaller reference dose than in its last assessment ten years earlier. Although the assessment included a range of reference doses and made some strides toward uncertainty analysis, the NAS panel reviewing the document found that too many precisions were missing to allow for evaluating the quality of the application of the method.

The NRC, just as in the days of RAFG or Science and Judgment (NRC 1994, see chapter 9), became the new battlefield—the space in which the controversial redesign of the EPA's operations was fought. In the 2000s, the council had been assigned more and more frequently to review the EPA's risk assessments, gradually taking up the role of the SAB. The adversaries of the agency's decision-making autonomy frequently used the NRC to try and constrain it. In return, the EPA developed over the years a capacity to liaise with NRC panels, interpret reports, and negotiate the application of its recommendations,²⁰ to nearly turn the NAS into an ally. But with every new report, whether the NRC would eventually come out in support of the agency or of its adversaries was an open question.

In 2006, the Academies were approached concurrently by two different parts of the agency. Gray went to the IOM for a study of uncertainty analysis, hoping to get an authoritative request from that institute to the EPA to embrace uncertainty analysis much more. For their part, NCEA officials sought to enlist the support of the NRC to undertake a broad review of the risk assessment practices in the agency, particularly its evolution since the days of the RAFG. The initiative was meant to counter the controversial OMB bulletin and transform the climate that it had established. The initiative had another advantage: It would consolidate the conventional risk assessment approaches of the agency by bridging health risk assessment with the now fully developed ecological risk assessment approach. That the initiative for the report came from the “defending” part of the EPA—the one under pressure from OMB on IRIS—is confirmed by the fact that the funds for the study came from the NCEA itself. The expectation and hope was that the NRC review would bolster the credibility of risk assessment methods in the agency.

The IOM study on uncertainty was delayed by the EPA's refusal to appropriate funds for the study,²¹ so Gray could not formally endorse it: He left the agency in 2009. The report requested by Preuss, of the NCEA, was released

as *Science and Decisions: Advancing Risk Assessment* that same year. It seems that both Preuss and Gray closely followed the setup of the study. They had the chance to give precise input on the charge and to take a look at the preliminary selection of panel members. As ever, the panel composition balanced environmental and public health perspectives—contributions from scientists who were associated with NGOs or industry and had a great deal of experience in toxicology and risk assessment, as well as engineering and biostatistics. Two former colleagues of Gray and Graham in the Harvard Center for Risk Analysis were part of the group. Tom Burke, a medical doctor, epidemiologist, and former public health official in the state of New Jersey, and at the time a professor at John Hopkins University, chaired the group. People such as Bailus Walker, Joe Rodricks, and Lauren Zeise had much experience in the area of chemical risk assessment, including by regulatory agencies. Burke was someone who was very aware of the methods of risk assessment and the risk assessment–risk management framework. Back in 1983, when he was working for the state of New Jersey, he had been trained by Rodricks on the then-new approach at a national conference of state environmental and health officials.²²

Given the issues on the agenda of the committee and its “eclectic”²³ composition, there was potential for controversy, and even failure. The committee that produced *Science and Judgment* in 1992–1994 had never managed to get everyone to agree on the same argument about defaults, leaving the NRC staff with a bitter taste in their mouths. And there was another potential disagreement this time, surrounding the extent to which agencies should pursue scientific sophistication in risk assessment instead of closing uncertainties and knowledge gaps by default science-policies, as it had always done. For some panel members, this quest for scientific precision, which the EPA had come to accept (embracing the paradigm of chemicals’ “mode of action,” BBDR modeling, but also attempting to apply more probabilistic risk analysis and Monte Carlo approaches to reducing uncertainty), was what prevented the EPA from actually delivering more and quicker assessments of substances to use to fill in the IRIS database. Others thought that the calculation of a reference dose, or bright line below which no risk can be expected, was outdated. It needed to be repealed in favor of new scientific methods, including quantitative uncertainty analysis. The latter seemed to be Gray’s preferred perspective on the debate, as he came to ORD in October 2005 with an agenda on uncertainty analysis and

more frequent recourse to nonlinear modeling. But with this issue, which “falls right on the US political divide,”²⁴ complicated discussions could be expected. The NRC staff wanted to avoid a repetition of the failure of *Science and Judgment*.

The various recommendations that came out of the group bear the mark of these oppositions, as well as of the interventions of the chair in order to come up with formulations that everyone could sign on to. The chapter on uncertainty and variability analysis clearly stated that there remained more to do for the EPA in this regard. But the chapter did not push formal, quantitative uncertainty analysis all the way. Rather, it defined different degrees of sophistication in uncertainty analysis and a tiered approach, recommending that the agency be clear as to how and why it chooses to analyze uncertainty qualitatively or quantitatively. It did not attack the EPA on risk-risk trade-offs, but it did argue that this risk-risk dimension and benefit-cost comparisons could be encouraged via dedicated guidelines.

Chapter 5, on the reference dose concept, and chapter 6, on the use of defaults, were most difficult for the panel to complete. Chapter 5 did not actually recommend getting rid of the reference dose idea, even though some in the group considered it a “lame duck.”²⁵ But some methodological perspective on the improvement of the concept helped soften the language and saved the reputation of the concept, while still pushing the EPA to evolve. The chapter argued for a harmonization of cancer and noncancer assessment—and specifically for the need to compute an overall measure of the risk of noncancer effects (comparable to the “there is a 10–6 risk of developing a cancer from exposure to chemical x ”), in such a way that the policy office could include noncancer effects in their analysis of economic impacts. Chapter 6 recommends the agency go further in the development of explicit risk management considerations underpinning the use of defaults, or the search for further quantitative evidence of risks. The next major chapter is chapter 8, which pushed concepts of “problem formulation, planning, and scoping” to denote the preliminary work pertaining to risk management and framing risk assessment. It was not controversial, though the committee had to decide whether to introduce other concepts, such as that of “solution-focused” risk assessment, which was tabled by Adam Finkel.²⁶ Under great pressure from the NRC and EPA officials monitoring the work of the group and reviewing the report, staunchly opposing any form of too radical organizational revision, the group did not go in that

direction. Finkel did not try to have an appendix included in the report to outline the concept, as was in *Science and Judgment*.²⁷

The final scheme bears no trace of the *solution* language advocated by him; it falls back on the more neutral language, already ingrained in the EPA, of *problem formulation*. In the text of the report, it is converted into a language that has been spoken for decades already, including in RAFG: that of “options.” Risk management options should be on the table *before* a risk assessment is undertaken, so that this assessment focuses on informing these options. The context in which the panel worked—a request from the EPA for a report that would review, rationalize, and essentially give support to ongoing changes in the agency—contributed to polishing the recommendations to make them more agreeable in the agency: The risk assessors of the agency could argue that they already were doing problem formulation.

Bureaucratic Lineages: The Internal Origins of “Problem Formulation, Planning, and Scoping”

Overall, it seems, the uptake of these external suggestions was limited, or it was slow and incremental, subject to political impetuses at a later stage. Most suggestions were discussed in a specially established forum called the Alliance for Risk Assessment, put together with the not-for-profit risk assessment consulting company Toxicological Excellence in Risk Assessment (TERA), founded and managed by ex-EPAer Michael Dourson.²⁸ The dioxin assessment, for instance, was split in two parts (the cancer, and non-cancer parts), preventing the use of unified dose-response methodologies for cancer and noncancer effects, and the calculation, by economists of the cost of the latter. Uncertainty analysis, though expanding, remains a limited practice. In combination with the NRC reassessment of the EPA’s report for phthalates (NRC 2008), *Science and Decisions* contributed to accelerating the work on cumulative risk assessment, balancing the large investments in more sophisticated dose-response research, and following the new biological, mechanistic paradigm of “toxicity pathways” (NRC 2007).

There was great activity around the IRIS process after 2010. Several actions were done to relaunch the program, following the controversies of 2006–2010 concerning the credibility of the estimations and the delaying effects of the OMB’s and other departments’ comments on the agency estimates. The proposals for reform after 2010 used suggestions presented

in *Science and Decisions*, notably those surrounding “problem formulation,” a conceptual stage that now became more official in the new IRIS process developed after Obama’s 2008 election. But the staff appeared to resist the idea of making this problem formulation stage an area for more explicit considerations of risk management options in order to improve the utility of IRIS assessments. The IRIS staff within NCEA also feared that turning problem formulation into an occasion for interaction with stakeholders, would offer the industry too much access to the assessment process. In short, the experts and bureaucratic specialists of human health risk assessment—once the flagship bureaucratic technology for an EPA in search of credibility—were using the same strategies than those that led, back in the 1980s, to promoting risk assessment. But this time, in a context in which risk assessment was definitely owned by specialists and other prescribers of methods that they no longer controlled, it searched in house again for those formal techniques that restored, or maintained, its capacity to act.

The fact is that, like risk assessment in 1983, “problem formulation, planning, and scoping” already pertained to the agency’s bureaucratic knowledge and decision-making technologies. It was simply that until that time, these concepts were limited to certain parts of the agency. Only the political context—the new Republican assault on the agency beginning in the 2000s—explains why these concepts were used by the leadership of the agency to evolve a new organizational identity. The controlled response of the EPA to *Science and Decisions* in terms of “problem formulation, planning, and scoping,” greater uncertainty analysis, and greater tailoring of risk assessment to decision-making needs is the result of a slow institutionalization of new practices and policy visions. The agency leveraged concepts that had been forged in the ORD throughout the 1990s for two main purposes: the reorganization of the agency’s research programs and of its laboratories, and the development of methods to calculate ecological risks.

The design of the agency’s research programs is a continuing problem. On several occasions at the end of the 1970s, during the second term of Ruckelshaus as EPA administrator (see chapter 7), the agency had to tackle this major, inborn problem of integration of its research and regulatory missions. In the early 1990s, a new series of reform started. The first episode was, as ever, the agency’s internal design effort, materializing as the 1992 report *Safeguarding the Future: Credible Science, Credible Decisions*. The committee that produced this report had advanced a framework to enable the EPA to adjust

its research plans to the characteristics of environmental problems in a broad sense. The problem of the agency's research soon deepened, becoming the subject of congressional hearings. The many years of budget decline, the loss of 400 employees since 1980, the rate of retirements, and the growing perception in the agency that ORD scientists were too detached from the realities of regulatory work (see Powell 1999 on this) all compounded to generate a feeling of crisis within the EPA's research.

Following a request from Congress to Browner, the MITRE consultancy did an assessment (MITRE 1994), reviewed by the Research Strategies Advisory Committee of the SAB (EPA 1994e). In parallel, a NRC report (NRC 1993c) and a Carnegie Commission report (Carnegie Commission 1992) came into the picture, advocating the creation of megalaboratories. An internal EPA steering committee then considered recommendations stemming from these reports and chose to follow the path recommended by the Carnegie Commission, with one key adaptation: The four laboratories should be based on the risk assessment–risk management paradigm because so much of the science of the agency was defined by the four broad categories of the framework, as illustrated by the thinking applied in health risk assessment and ecological risk assessment guidelines.

In a major reform in 1995, the head of ORD at the time, Robert Huggett, decided to align the structure of EPA research on the “blueprint” of RAFG (Patton and Huggett 2003, 1337): One laboratory focused on hazard identification, one on dose-response, a third on exposure research, and the last on risk reduction technologies under the rubric of risk management (EPA 1994d). Before this reform, the ORD was organized into five offices along disciplinary lines²⁹ (EPA 1990a). After the reform, all research activities were reframed as a building block of risk management. The 1996 *Strategic Plan for the Office of Research and Development* offers the diagram shown in figure 10.5 (EPA 1996b, 4), where “The risk assessment process is one component of the overall process of risk management” (2), a process initiated by the identification of the problem. Such was the basis of the “new risk-based organization” of the ORD (EPA 1996b, 51).³⁰

In 1995, a couple of years after this major reorganization, the new Republican-dominated Congress reopened this issue. It pushed the agency to rethink its research programs. As part of the Departments of Veterans Affairs and Housing and Urban Development Appropriations Act of that year, it requested that the EPA obtain an independent review of the overall

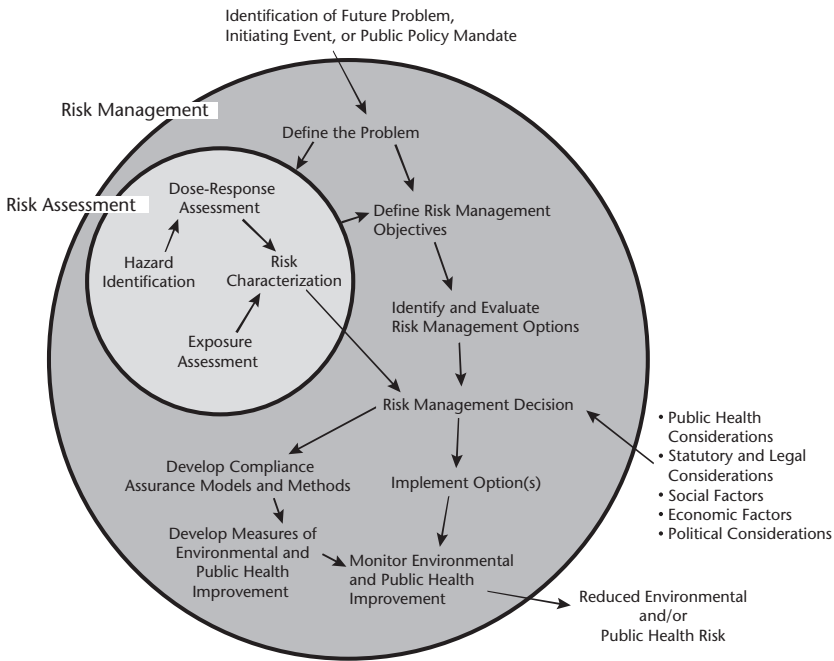


Figure 10.5

The scientific and technical contributions to risk management (EPA 1996b).

structure and management of its research program and evaluate the scientific peer-review procedures that it used. Once more, the NRC was called upon to perform this review, which resulted in a report called *Building a Foundation for Sound Environmental Decisions* (NRC 1997). It argued for the need for another organizing principle besides risk: “Not all environmental issues can be assessed and ranked within the risk paradigm. The more complex and global the problem, the more difficult the task of risk assessment will be. While the risk-based research strategy is sound, it must be augmented and adapted to encompass potential and emerging risks as well as current ones” (ibid., 11). The report puts forward the theme of ecological complexity. The utility of performing risk assessment is assessed in the context of this new horizon and overarching goal: knowing and addressing complex environmental issues. The report introduces a framework in which research and science developed by the agency is coupled with the regulatory process and “problem-driven research,” but not conducive to it in a linear and mechanical fashion (see figure 10.6).

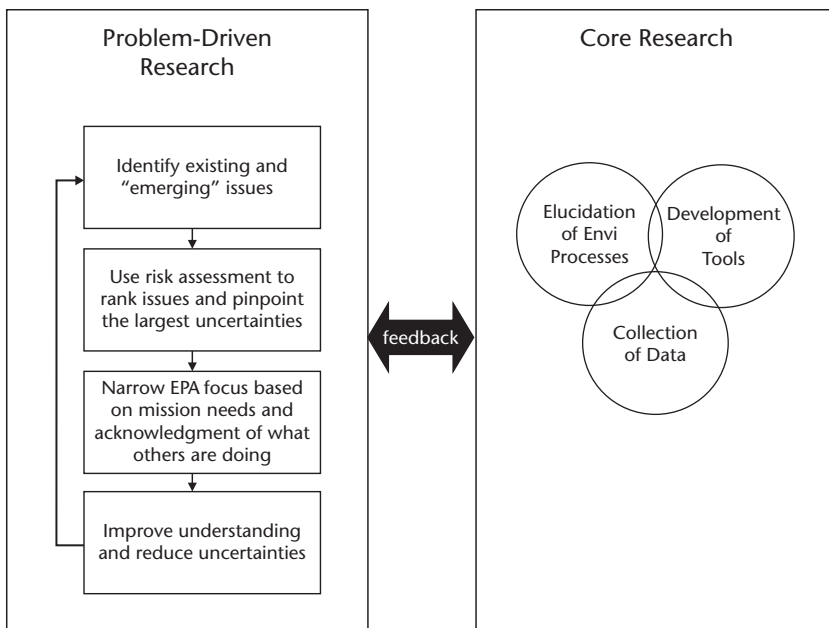


Figure 10.6

A framework for research at the EPA (adapted from NRC 1997).

The report defends the use of risk assessment as a priority-setting tool, not as an uncertainty-eliminating or predictive one: “[R]isk assessment currently is the most satisfactory approach for setting research priorities in the environmental arena. It is particularly valuable in identifying areas of uncertainty that need to be resolved in order to achieve more accurate assessments” (NRC 1997, 46). To reframe the EPA’s science and go beyond the reductionist focus on risk, Paul Anastas picked up on some of the ideas introduced by an NRC report of 1997, which similarly argued that risk assessment was too much of a reductionist method to approach complex problems that the agency typically would have to face. Problem formulation was inherited from the work in the agency on ecological risk assessment. That concept was essential to the relatively marginal formal discipline of ecological risk assessment. In that discipline, the collection and analysis of data are preceded by a stage where the chemical of interest is considered to be diffuse in the environment, and a number of stress effects in this environment are created.

Before anything else, a plan of analysis must be laid out to define which stresses are actually relevant to consider, and with what data and modes of calculation they may be captured and measured. Such was the major difference that the specialists in the national Oak Ridge Reference Laboratory had emphasized when asked by the ORD back in 1983 to produce an ecological risk assessment of synthetic fuels on the basis of the RAFG.³¹ Ecological issues then were not subjected to risk assessment methods. The Oak Ridge National Laboratory had extensive experience in nuclear risk analysis and associated methods of fault-tree or event-tree analysis. Glenn W. Suter II and his colleagues had to innovate because these methods that calculate the probabilities of a predefined event are reductive: “We found it was not really applicable to ecological systems. Because they are not affected in terms of a ‘component’ failing, causing failures in other components. You could force ecology into this formalism, but it was not the sort of formalism that we thought was natural and logical for ecological issues.”³² Their approach was a more relaxed formalism, in which complexity is embraced through a problem formulation stage, leading to employing a range of possible analyses, including the more quantitative, model-based risk assessment. The whole discipline, in their view, did not correspond to a rubric of risk analysis. They coined their own disciplinary category, “Technical support for decision making under uncertainty,” and emulated the just-published RAFG by producing something generic, and framework-like,³³ as in figure 10.7.

The method was not taken up in the EPA immediately both because it came from outside the agency and because it was not in line with the emerging routine of how to link such an assessment process to decision-making, which the framework did not address at all—after all, Suter and his colleagues were not working in a regulatory agency. People in the agency already had their own ways of doing assessments, and they were not sure what they would gain from a new concept and terminology. So it took a while for the EPA to actually elevate the methodology of ecological risk assessment to a broader, cross-office status.

The early 1990s saw concrete advancements on the topic, with the RAF taking care of developing a framework for ecological risk assessment in which risk assessment disappeared in a broader analysis step, succeeding problem formulation (see figure 10.8). This concept was coined by the

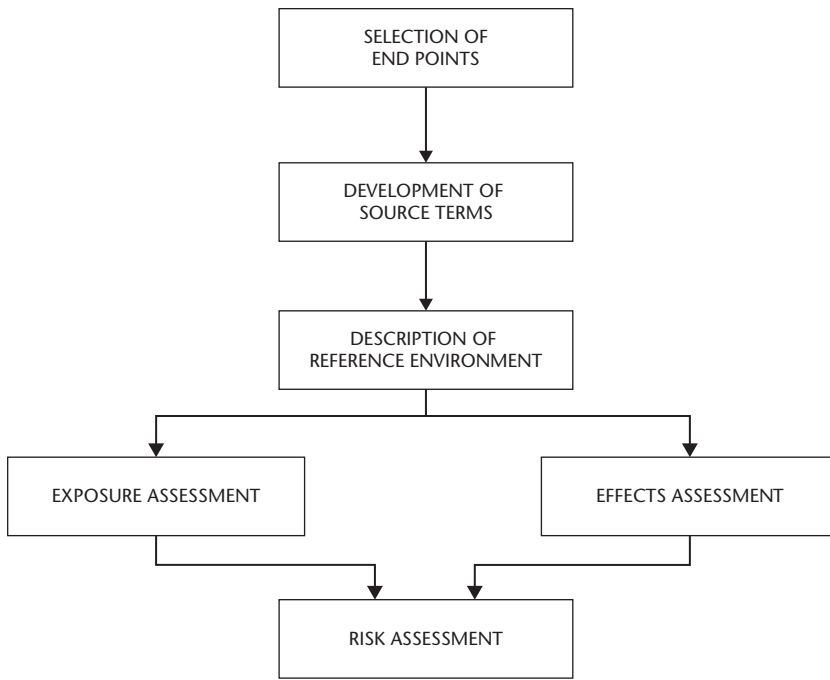


Figure 10.7

Flowchart for ecological risk assessment of toxic chemicals; developed by researchers at the Oak Ridge National Laboratory for the EPA (adapted from Barnthouse and Suter 1986).

dedicated group of the RAF, not by the Oak Ridge researchers, out of the need to organize the link between science and policy.

The agency adopted a formal guideline for ecological risk assessment in 1998 that incorporated the notion of problem formulation, replacing the reductive risk assessment process by a more integrated³⁴ exercise of analysis that assembled the necessary data and calculations to respond to the problem. It did so right after other prominent reports advocated the importance of “problem formulation”—the NRC’s *Understanding Risk* (NRC 1996) notably, but also the report of the Presidential/Congressional Commission on Risk Assessment and Risk Management (Presidential and Congressional Commission 1997).³⁵ That commission had set risk management as the overall goal, context, and framework of environmental policy, within which analysis of risks was to be performed. In its report, it insisted that the challenge consisted of making risk assessment a substance-by-substance,

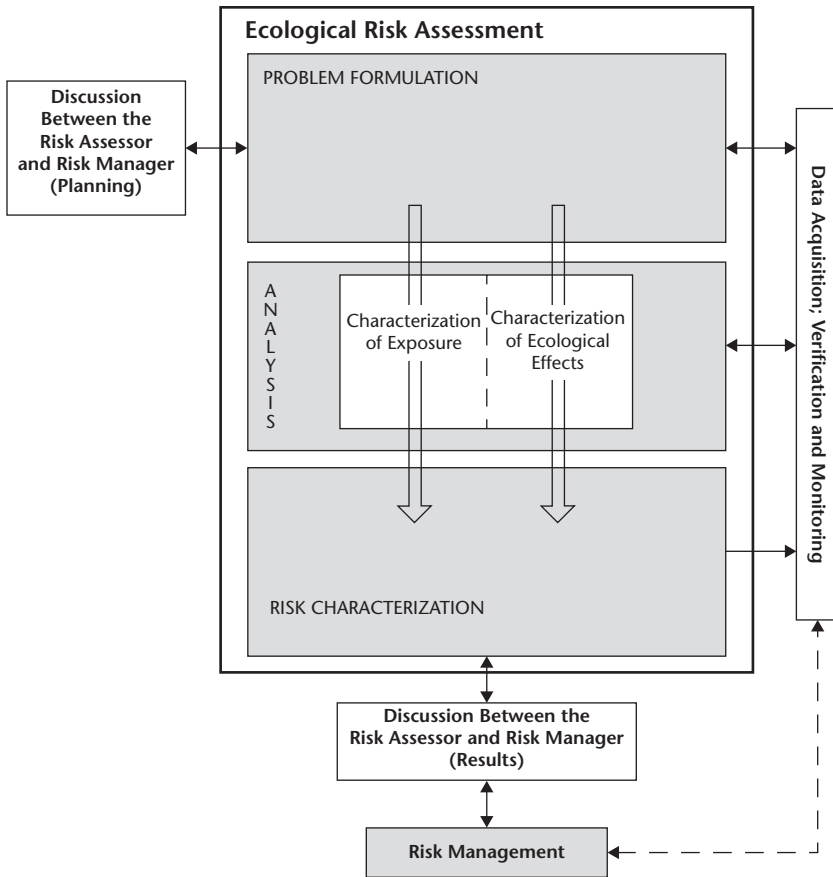


Figure 10.8

A framework for ecological risk assessment (adapted from EPA 1992a).

reductive approach to risk that was better suited to effective intervention global public health issues. Reasoning graphically in terms of a decisional wheel (at the initiative of the physicist and engineer of the panel)³⁶ helped select, generalize, and give coherence to the whole set of prescriptions (see figure 10.9).

A formulation of the problem and clarification of the context in which it is posed comes first. Before engaging in an analysis of the risks posed by individual agents or substances, the problem/context stage must clarify the multidimensional elements and complexity of the problem. Stakeholder engagement is a constant task throughout the cycle.³⁷

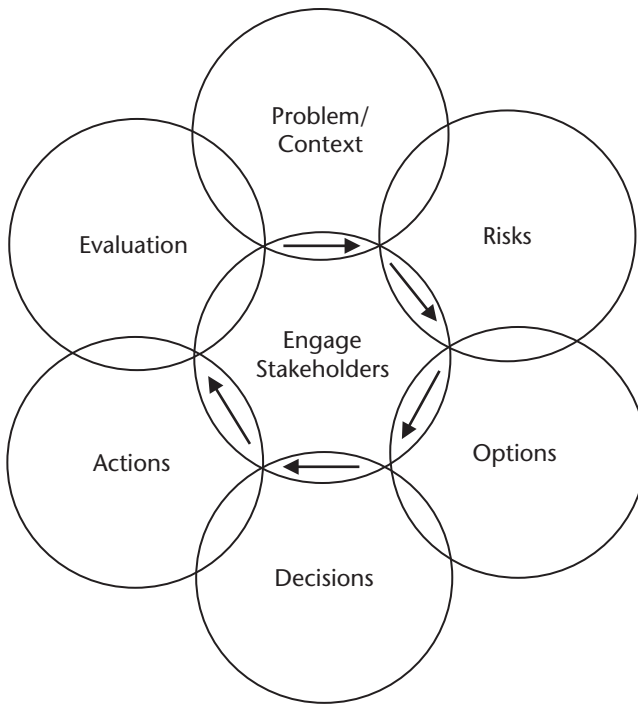


Figure 10.9

The circular design of the Presidential and Congressional Commission on Risk Assessment and Risk Management (adapted from Presidential and Congressional Commission 1997) decision wheel.

Conclusion

In the 2000s, the controversies surrounding the handling of risk by the EPA have shifted to its failure to actually regulate chemicals and reduce risks, and particularly the slow pace at which it concludes scientific assessments of chemicals and makes management decisions. As the introduction of *Science and Decisions* makes clear—as do many other NRC reports during this period—the knowledge and technologies applied to make decisions on these objects seem imperfect. This observation was both realistic and manufactured. It is realistic because the sum of the chemicals to regulate, and the time it takes to agree on the risks of any single one of them, make it impossible for the agency to simply envisage that it could finish the work someday. But it is also manufactured because, over the years, risk assessment has

grown more complex, infused with propositions to always know the risks with greater precision and predict them more accurately before attempting to decide anything. This scientization, fueled by the scientific capacities of the regulated industry, causes the inability to decide, the continuous delaying of the moment of decision—paralysis by analysis. The failure to regulate chemicals individually is compounded by the more and more compelling observation, in several corners of environmental and health sciences, that health risks are not determined by exposure to one substance at a time. Risks would be reduced, and environmental health preserved, by analyzing and treating biological and ecological systems in their full complexity, taking into account the set of stressors and factors affecting them.

This means that the 2000s represented an entirely new design configuration—one in which the standard knowledge and technologies embedded in the agency lost credibility; one that evoked the ambition and competence of many actors inside and outside the agency in order to refashion its processes so that it appeared capable of addressing complex, long-term issues. Science, again, lay at the heart of these dynamics. It was both the object of the controversy and the source of a new design. At the heart of the controversy was the EPA's continuous reliance on default, protective assumptions. As explained several times in this book, defaults help the agency make decisions. They are the cornerstone of a particular way of designing itself, of formalizing a way to move from a necessarily uncertain and inconclusive science to environmental policy decisions.

This decisionistic, protective design, however, was discredited by demands to use ever-more-refined uncertainty analysis and discover true risks—a strategy of elimination of rather than compensation for uncertainty. “Problem formulation, planning, and scoping,” in turn, embodies a more pragmatic and holistic design to defect the latter predictive, scientific approach. What was essential to the progressive, pro-environment proponents of “problem formulation” was to avail themselves of an organizational mechanism by which ambitious protective goals are defined every time a new issue emerges, since science could no longer ensure the legitimacy of protective decisions by itself.

At this time, the outcome of this new configuration is unclear. A new design has emerged, which is driving the reform of the organization now and probably will do so for many years, though slowly and contentiously.

Science remains at the heart of a conflict between progressives, who argue that it should be used pragmatically to help achieve goals of environmental and health protection; and conservatives, who insist on moderate administrative intervention and, accordingly, maintain that we should wait to make any decision until we can predict the outcome with absolute certainty—a daunting criterion. Today, President Donald Trump’s EPA is being redesigned in exactly this way.

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