3 Prioritizing Toxics: The Prehistory of Risk Management

The interest in risk as a legitimate design for administering environmental problems in the EPA did not materialize only among medical scientists, toxicologists, and statisticians with regard to the application of probabilistic analysis to chemically induced biological mechanisms. At about the same time as the health scientists of the ORD were articulating a standard risk assessment method and pushing it at the agency, the EPA administrator and some of the agency's policy analysts were grappling with another kind of controversy: incoherence caused by offices delivering divergent standards on the same chemical and risk. This incoherence stemmed from the differences among offices operating on the same generic regulatory object—chemicals—but with contrasting regulatory regimes and different modes of relationship with regulated industries. It gave substance to another form of uncertainty, as damaging for the EPA: that concerning the diversity of valuations of the risk, and the diverging preferences for tackling one or another hazard first. The diffusion of chemicals across environmental media, and thus across the boundaries of separate regulatory offices and their regimes, revealed this uncertainty, and created occasions for conflict, as the EPA was not designed to deal with chemicals in a coordinated manner. There was a major risk of controversy in this situation: divergent estimations of risk within the agency fueled disputes outside it about the reality and acceptability of chemical hazards and, most important, disputes about the appropriateness of the design of the agency and the legitimacy of its action toward chemical hazards—all of this occurring at a time when the debate on the excess of environmental regulation and the virtue of having put these new risk agencies in place became urgent.

This chapter explores the formal bureaucratic assemblage that emerged in this context. The agency's policy analysts, with support from the EPA

administrator, articulated a new, cross-agency discipline of risk-ranking. It did not reorder the agency in the way that quantitative risk assessment was in the process of doing. In particular, it did not create any strong base of knowledge across offices or coordination among them. But five years ahead of the installation of a new discipline of *risk management*, which risk-ranking preceded, the experiment helped establish the value of economic knowledge and of processes of centralizing information for the agency's policies, and showed the advantage of keeping economists and policy analysts close to the leaders of the agency in order to steer the agency and control the image of what it delivered overall.

EPA's Inborn Consistency Problems

The internal coherence of the EPA has been a problem ever since its inception in December 1970—and in fact, even before that. As the previous chapter recounts, after protracted negotiations, the Ash Council settled for creating an agency that assembled all regulatory programs aimed at combating environmental pollution under a single administrative umbrella. Whether a department or an agency, one question remained: Would this new governmental organization have new missions and powers, or would it simply gather those of existing services?

One of the organizational plans that the group contemplated was more disruptive than the others. It consisted in creating, from scratch, a functional agency in which the personnel of the units inherited from the various departments would be redistributed in newly formed, nonprogrammatic offices for dealing with abatement, monitoring, research, and standard-setting, separately. That plan had been devised by Alain Enthoven, a systems analyst and former adviser to the US Department of Defense, where he had been busy introducing systems analysis methods under the leadership of Robert McNamara. Enthoven introduced his functional scheme just two months before the EPA started its operations. Terry Davies pushed for an even more integrated design, with an agency structured around key functions, including disseminating information and performing analysis. Douglas Costle, who led the environmental committee that designed the new administration, was no enemy of this functional plan. In contrast to Enthoven, however, he feared, as an experienced bureaucrat, that too strong a disruption of existing bureaucratic structures would result in chaos

and opposition. He thus settled for an intermediary, incremental strategy: launching the agency on the basis of a program-office structure "with substantial continuity with its programmatic past" (Marcus 1980, 104), but subsequent reinforcement of integrative services.

William Ruckelshaus, upon being appointed as the first administrator of the agency, was sold on Costle's plan to make the agency evolve toward cross-program integration. He understood that the agency would be much more governable and project a united image to the public if offices were not separate, undirected fiefdoms. As Daniel Carpenter's work shows, agencies are seldom free of legitimacy, identity, and reputational challenges, notably at their creation (Carpenter 2001, 2010). Being federal bodies, they are necessarily assailed by positive and negative discourse that constructs their image and legitimacy. Image is, moreover, an instrument of management of these organizations. Administering them, therefore, implies the construction of a single image of their action and outcomes. After five months in office, following Costle's advice to proceed in various stages, Ruckelshaus outlined a new organizational chart, adding three functional offices to the existing program-oriented ones: Planning and Management, Enforcement and General Counsel, and Research and Monitoring (see figure 3.1). As the

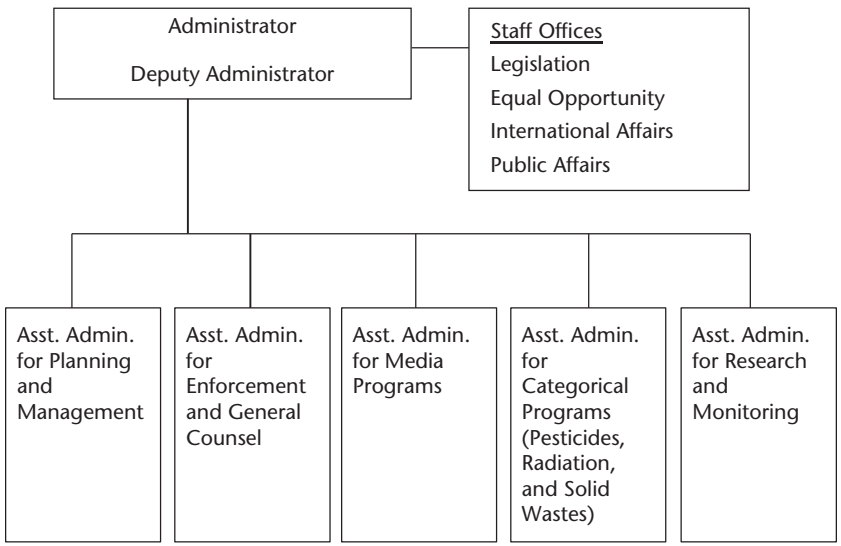

Figure 3.1
Ruckelshaus's second organizational plan (adapted from Marcus 1980, 105).

previous chapter illustrated, the first two were instrumental in constructing the EPA's authority, insofar as they were responsible for conceiving of two essential instruments: the cancer principles, first, and the risk assessment guidelines, second.

But Ruckelshaus did not fully apply stage 2 because he had planned to group all media-related programs under one umbrella office, Media Programs. He ended up, instead, with separate offices for Air and Water. He never implemented stage 3 of Costle's strategy—scrapping program offices to institutionalize a purely functional organization. According to Marcus (1980), combating the offices to create a whole new structure for the EPA was not of high enough importance to Ruckelshaus in the context of his chosen, litigation-oriented strategy for the agency. This strategy obviously corresponded to Ruckelshaus's inclinations and ways of working. As a lawyer, he could easily launch prosecution actions with top legal aides, which would make an impression on the public, industries, and states. It partly dispensed Ruckelshaus from going any further in implementing a reorganization plan for the agency. The organization of the agency along programmatic lines was thus never disrupted. By 1981, the agency's organizational chart mixed functional and programmatic offices, on top of regional ones (see figure 3.2).

During his first mandate, Ruckelshaus nevertheless experienced the negative effects of this organizational scheme for the deployment of his policies. He had felt frustrated early on due to not being able to count on dedicated scientific advisory services for reviewing the standards prepared inside the Air Office. He had only three days to review the proposed standards, with hardly any support. Marcus shows that this experience, coupled with pressure from the White House to factor economic implications into the EPA's decisions, forced Ruckelshaus to think about ways of controlling decision-making by program offices. The result was the "1000.6 approach" (named after the 1971 EPA order that describes it), which instituted a central decision-making steering committee designed to turn the standards prepared by program offices into options for consideration by higher-level decision-makers. With that approach, the program offices' work was only an initial sequence in a broader decision-making process involving ex post reviews of decisions drafted by ORD scientists and lawyers in the Office of Enforcement. In this way, the EPA administrator and associated decision-makers were afforded the possibility of choosing among options based on measured costs and benefits, as well as political and judicial opportunities.

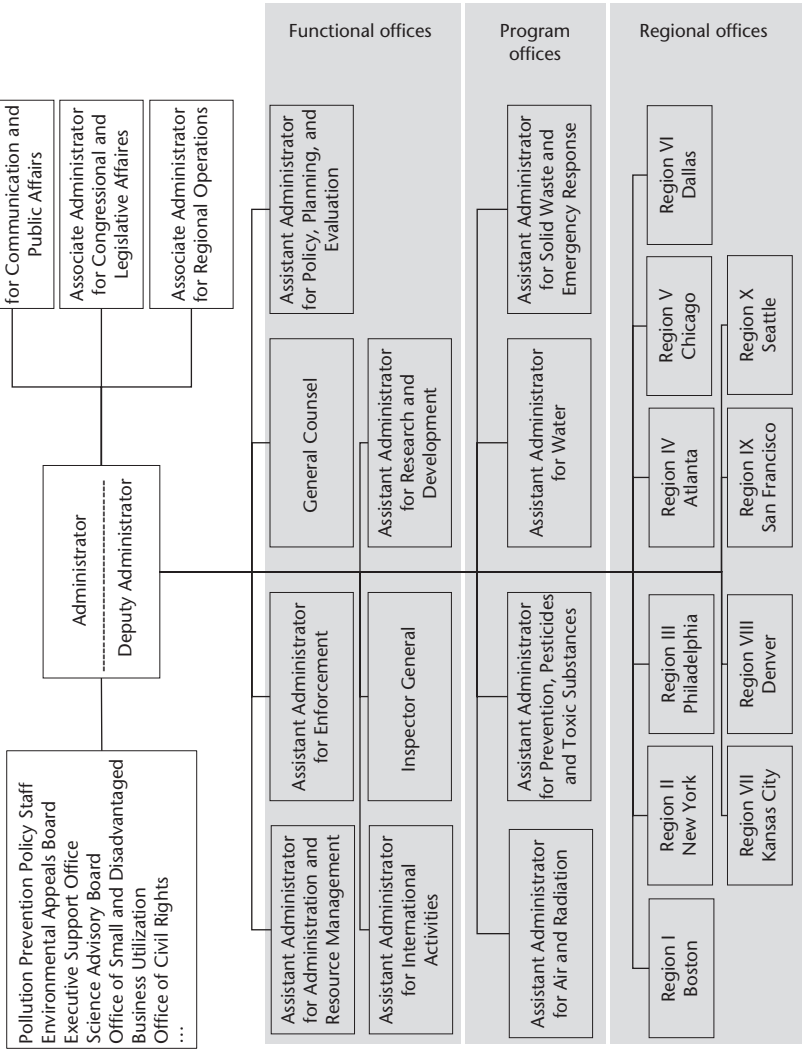

Figure 3.2
US EPA Organization chart circa 1981.

Unfortunately, the picture soon became even more complex, with the enactment of major laws throughout the 1970s containing distinct provisions, standards of safety, and regulatory instruments to address a similar regulatory object, chemicals. Chemicals were in the process of becoming the boundary object (Star and Griesemer 1989) of the EPA as a molecular bureaucracy (Hepler-Smith 2019): an object with a distinct identity, but dealt with differently by the various offices of the agency. Initially, the EPA had to implement preexisting laws, such as FIFRA, passed in 1947 and amended in 1972. Under that Act, the EPA had to review existing and new pesticides proposed for use in agriculture and manage their use in the fields. This mission was carried out by the Office of Pesticides, transferred from the USDA (while pesticide labeling came from the US Department of the Interior). Another was the 1970 Clean Air Act—specifically, the NAAQS program—that sets atmospheric goals for a number of specific pollutants (the so-called criteria air pollutants: carbon monoxide, lead, lead compounds, nitrogen dioxide, ozone, particulate matter 10, particulate matter 2.5, and sulfur dioxide), as well as creating a program to control emissions to reach these quality standards. The EPA was to define threshold levels for the presence of these pollutants in ambient air. Yet another program was the Hazardous Air Pollutant program, in which standards were set for the emissions of 187 listed chemicals. These standards prescribed the use of a control technology that was deemed appropriate to reduce these emissions. Until the EPA was formed, the Act was administered by the US Department of Health, Education, and Welfare, from which the Air Office inherited its staff.

The amendments of the 1972 Federal Water Pollution Control Act (better known as the CWA) aimed for the elimination of pollutant discharges from point-sources into surface waters. They also charged the EPA with drawing up a list of national standards for toxic water pollutants. The main instrument in this respect was effluent guidelines, encompassing a toxic effluent standard (a limitation for these effluents, including an ample margin of safety) and a prescription to use a given technology that could help to reduce the discharge to below the threshold. The amendments to the CWA that were passed in 1977 confirmed this approach of setting criteria for a list of 129 priority pollutants.[1] The exercise was called criteria formulation. Based on these criteria, the EPA would choose the best available technology to bring down these pollution levels. The criteria were set by EPA and the individual states, which could choose a different criterion for

each specific body of water. In practice, the EPA gave some discretion to the states, which at times adopted a more precautionary approach. The staff administering the CWA program came from the Department of the Interior and the Department of Health, Education, and Welfare.

However, with the creation of the EPA came multiple other new environmental policies and statutes. In 1976, the US Congress adopted the TSCA. As a result, the EPA had to look at many more chemicals that were about to be commercialized or already were so, independent of the dose and of the effects they produced in particular media. Part of the motivation for passing this Act was to include chemicals that were not already covered by separate legislation for air, water, waste, or pesticides. Sections 6 and 9 of the Act required the EPA to regulate chemical substances under the authority provided by other Acts, where possible. But it also established two huge new programs for reviewing the risks of existing chemicals and screening and licensing new chemicals (Boullier et al. 2019).

In 1977, Congress also reformed the Clean Air Act. The amendments soon set further ambitious precautionary goals for the agency (Graham 1985). First, they established a broad definition of "hazardous air pollutant" as "an air pollutant to which no ambient air quality standard is applicable and which in the judgment of the Administrator causes, or contributes to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness."[2] Second, it provided that the EPA administrator decide within one year (or two years for radioactive emissions) whether radioactive pollutants, arsenic, cadmium, and polycyclic organic matter were hazardous within the meaning of section 112.

In the same year, the RCRA was passed in order to expand the program for managing and regulating municipal and industrial waste, including toxic or hazardous waste. The program involved defining systems for managing the production and reducing the volume of waste, reducing the use of landfills, managing a permit program for producers and transporters of waste, and for managers of landfills, and so on. Finally, with the 1979 creation of CERCLA, also called the Superfund program, the EPA became concerned with the presence and effects of chemicals at local, contaminated sites. The Act provided for very wide-scale activity, covering an estimated 5,000 abandoned dumping grounds across the country that were deemed to be potential public health hazards. The Superfund program

Table 3.1
Main statutes administered by the EPA, listed by office

Office	Act/Regulatory Program
Office for Air and Radiation	Criteria air pollutants (NAAQS) Hazardous air pollutants (NESHAPS)
Office of Pesticides and Toxic Substances	Pesticides (FIFRA) Toxic substances (TSCA)
Office for Solid Waste and Emergency Response	Contaminated sites (Superfund/CERCLA) Hazardous waste (RCRA)
Office of Water	Drinking water (SDWA) Surface water (CWA)

involved emergency action in case of oil spills or other similar pollution, long-term remedial and containment action, and enforcement against parties responsible for hazardous waste and spills. It generated much more activity at the EPA headquarters and in EPA regions than any other program, and it obtained extensive political visibility through the Love Canal and Times Beach scandals.

The various Acts[3] that the various offices of the EPA had to implement by the end of the 1970s (see table 3.1) had little in common. They dealt with significantly different environmental problems, some of which were closer to conventional, well known, and hardly hazardous forms of pollution of natural resources, while others involved the management of the uncertain effects of toxic substances. Moreover, even where these substances were targeted for administrative action, the measures taken by the offices in the various programs would still differ. The programs were developed by coalitions of senators and congresspeople, under pressure from different interest groups and reacting to specific controversies and scandals, with little continuity among them. The result was very different standards of evidence and safety criteria, as well as different levels of authority and different levels of resources, for the EPA. The Clean Air Act required that the public be protected by establishing an adequate margin of safety, without regard for the costs or benefits of the use of the chemicals in question. The agency was not able to define a level of risk that would match measured benefits; rather, it simply had to aim for absolute safety. The CWA was technology-based: The agency had to prove that a given technology would reduce pollution to a

level deemed acceptable. The laws for pesticides and toxic substances were based on yet another standard: They were intended to secure safety in a relative sense, avoiding those risks that would be considered unreasonable in relation to a variety of costs and benefits associated with the regulated chemical. Such was the case for FIFRA and TSCA, which required the EPA to choose the least burdensome options of control.

Taking on the Chemical Revolution

The multiplication of these Acts that target chemicals in various forms and media was both an opportunity and a problem for the EPA. It was a political opportunity because it gave shape to a unified political agenda to which the agency could lay claim, and on which it could build its identity and legitimacy. This is the route that Costle chose to go down when he was appointed as EPA administrator, succeeding Russell Train in January 1976. Costle had worked in the OMB in the White House, and then was a member of the environmental committee inside the Ash Council. As mentioned previously, he had been instrumental in choosing to create the agency in the first place, and thus in departing from the original plan to create a cabinet-level Department for Natural Resources and the Environment. He was a proponent of a gradual integration of the agency for effective and comprehensive environmental management.[4] In the context of a multiplication of agency-forcing statutes that compelled the EPA to work on toxics from multiple perspectives, Costle initiated a strategy of greater integration, which had two aspects: working on a political agenda and working on integrative mechanisms inside the agency.

Costle took a stand on the terrain of cancer risk and health, defending a new identity for the EPA as a health-oriented agency. He developed the theme of the *chemical revolution,* insisting on the potential links between the diffusion of toxics in the natural and biological environments and the prevalence of cancer. This meant that the object of the EPA's overall action had to evolve from manifest pollution and identified chemicals to the more invisible and widespread health threat of toxics. Costle hammered down this theme in successive speeches in 1978. In an oral history interview, he retrospectively emphasized that the EPA was as much a health-protection agency as an environmental pollution agency: "In some ways, it was an

intellectual coming-of-age for the Agency to find itself suddenly dealing with a different universe of problems. It was never intended that we would drift away from the original environmental quality-of-life issue, but we did become preoccupied with health concerns" (EPA 2013).

Costle embraced toxic chemicals as the EPA's main issue for several reasons. One was that he felt that cancer and health were the right focus to keep the White House's support and to preserve the agency's budget, as well as its perimeter in the face of a new proposal to merge the EPA into the Department of the Interior (Landy et al. 1994). Train had a relatively high level of independence from the White House and cultivated ties with Congress, which gradually earned him substantial support from the key committees and subcommittees.[5] Costle was much closer to the president, Jimmy Carter, and to his agenda. Carter had made the war on cancer an explicit priority for his mandate. Eight months after the enactment of the TSCA in October 1976, Carter delivered an environmental message to Congress that embodied this new understanding of the problem of cancer and inaugurated a different policy based on comprehensive action on the toxic environment through the coordination of the FDA, OSHA, the CPSC, the EPA, and the USDA. By following up on cancer and health, Costle was showing that his agency would be instrumental to the president's priorities.

The other reason for embracing the chemical revolution and health agenda was that they constituted a plausible common agenda across the agency. Addressing toxics was what the multiple new Acts passed throughout the 1970s had in common. When speaking about the chemical revolution, Costle tried to instill the sense that these Acts were about the same thing: managing our chemicalized environment and its burden on public health:

> Substances show up, not just in one place, but across many media—air, water, land—often simultaneously. The public health concern then becomes the total body burden: what exposure are you getting? … So what is the nature of our job? It is to use common sense to reduce risk by reducing exposure, to take a harder look at new substances before we introduce them into commerce. But let's not kid ourselves that we are smart enough to know how to draw the bright line, or that there is a single scientifically sound way to do that.
>
> —Costle (cited in EPA 2013)

Toxics, compared to what a later report called the "grossest and most familiar forms of air and water pollution" (EPA 1981c, 1–5), or the pollutants already targeted in such Acts as the Clean Air Act or CWA (conventional

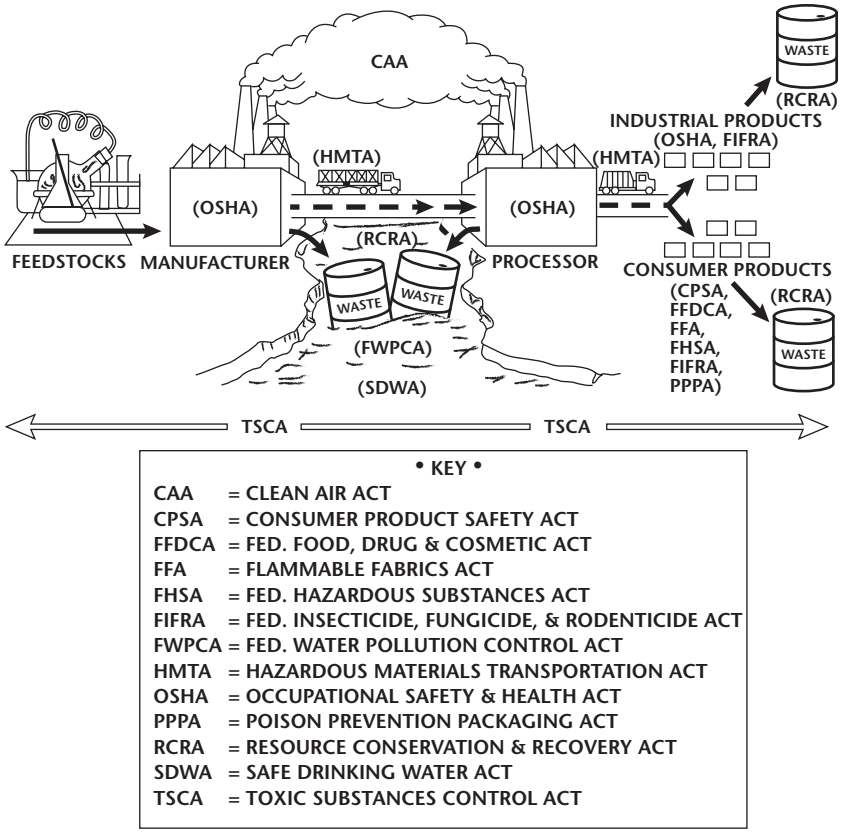

Figure 3.3
"Legislative authorities affecting the life cycle of a chemical" (adapted from EPA 1980b).

pollutants), could not be efficiently managed in only one environmental media. The same toxic could be regulated several times under several statutes because it was present in several media. The possible integration was nicely represented in the *EPA Journal* in 1979, with the representation of the life cycle of a chemical (see figure 3.3).

Balkanization and Credibility

In those days, then, chemicals became a generic risk object of the action and attention of the agency. The multiple statutes adopted over time to deal with chemicals of various kinds and with all environmental media

centrally "emplaced" this object in the network of preoccupations that the agency had to deal with (Hilgartner 1992, 48; see also Hutter and Power 2005; Lezaun 2006). Consequently, its reputation and legitimacy became dependent on its action toward this object.

Unfortunately, integrated action on toxics was orthogonal to the balkanized structure of the agency. In 1970, each office within the EPA was different, as all of them originated in departments with contradistinctive agendas and policy cultures. As new regulatory programs were set up, more offices were created, still with different cultures. Each office was headed by a political appointee and had its own weight and importance in the agency. The EPA was probably the most decentralized of all the agencies in the United States—no more than a set of "policy towers" placed side by side (Norton 2005, 20), with large professional cleavages (Landy et al. 1994) and administrative turf wars. Being part of the same agency meant competing for an adequate share of a budget, the administrator's attention, or getting the chance to blame a neighboring office to escape responsibility for a failing standard. The siloed structure of the agency and the weakness of its transversal, functional offices created uncertainty for the management of the EPA's credibility and overall reputation. The autonomy of these offices meant that decisions would be prepared autonomously and not reviewed at the level of scrutiny that they would receive once published. It was difficult for the person signing the decisions, and those called to Capitol Hill to be grilled in hearings about them, to justify a particular decision and to explain discrepancies and shifts in the agency's position on sometimes one and the same chemical.

The ubiquitous dioxin—in reality, a family of organic chemical compounds presumed to be among the most carcinogenic on Earth—was one such case. The EPA had acted early on in its existence to reduce the domestic use of 2-4-5-T, a pesticide in that family. In 1979, the staff of the Air Office suggested adding dioxin to the list of hazardous air pollutants—an action that the agency had not formally decided to take by 1983.[6] In 1981, however, the CAG had produced what should have become an agencywide risk value for dioxin. It estimated that, with a risk as high as $4.25 \times 10–5$ mg/kg/day, dioxin was one of the most potent carcinogens known. This rather alarming estimate went beyond anything the Office of Pesticides had reckoned, and it contributed to fueling the controversies that were unfolding at the same time in the media over the ubiquitous dioxin pollution in the country (Anonymous 1978, 1979).

During the 1979 presidential campaign, under the pressure of the ecologist and independent presidential candidate Barry Commoner, the problem of dioxin in municipal waste came onto the national agenda. With the discovery of high levels of dioxin in many sites, from Love Canal to Times Beach, Missouri (the latter was called the "Missouri crisis" in the press), the topic escalated into a nationwide issue (Shabecoff 1983). The subject was highly embarrassing for the EPA, though, because several of its offices were yet to address the topic.

In 1984, the Water Office of the agency issued a criteria document for tetrachlorodibenzo-p-dioxin (TCDD) as part of the CWA, with a different value from the ones advocated by CAG or the Office of Pesticides. As soon as this assessment was published, it triggered a revision, as the document had failed to factor in exposure to dioxin via media other than water, and therefore was useless for the Superfund office. All of this created much confusion around dioxin and made the EPA as much a part of the problem as a solution to it. A difficult hearing in Congress in October 1983 (US Congress 1984) made the EPA's embarrassment fully visible, as it had been with regard to other chemicals to which program offices had reacted, in urgency, and separately, in recent years, from vinyl chloride to the pesticide kepone.

Integration by Analysis: First Attempt

In October 1976, before Carter was elected and Costle began his mandate, the deputy administrator of EPA, John Quarles, had taken the decision to create an Integrated Toxics Strategy Work Group. The group's mission was to think about strategies to improve the agency's action on the problem of chemicals as a whole, as well as to motivate separate program offices to contribute to this goal, in addition to implementing their own statutes. This was the place for the formulation of the strategic problem of "toxics integration." The fate of the EPA, from the mid-1970s with the passing of the TSCA, appeared to be sealed by this double bind: the need to address toxics or chemical safety as a whole, but with insufficient resources to actually integrate what the various offices did. The paradox was defined, internally, as the "toxics integration" problem, a central and "unusually difficult" one for the agency: "[I]t represents the intersection of two problems, the toxic effects problem and the integration problem, each of which is difficult enough alone," and which "exacerbate one another" (EPA 1981c, 1–2).

The more the EPA set out to address toxics, the more it was confronted with its lack of control over its separate offices, their regulatory priorities, and corresponding ways of computing the risks (Beardsley 1987). The paradox and danger for the EPA as a whole were evident: The more a chemical substance spreads, the larger the number of program offices dealing with the substance would be, and the more the EPA would be evaluated overall for its action on the substance. Toxics accentuated both separate program offices' action and the agency's overall credibility.

During a four-month deliberation, the work group on integration identified one way forward: a ranking scheme. The diagnosis was that the EPA had been too much of an administrative victim of Congress's inchoate kind of priority-setting. Each law passed by congresspersons and senators targeted different sets of chemicals, forcing the agency to regulate them separately instead of earmarking global resources and leaving the agency to manage its priorities globally. It was time for the EPA to take control over its own priorities. The working group of the OPRM, with direct support from EPA Administrator Douglas Costle and from his deputy administrator, Barbara Blum, concluded that it should experiment with a ranking scheme (EPA 1981c). This ranking would proceed in two phases. First, an extensive threat list would be established based on unified assessments of the health effects, exposure levels, and ecological damages of many chemicals. Second, an action list would be drawn up in order to guide regulatory action concretely across the agency. In this second phase, elements other than just the science would be taken into consideration: costs, benefits of regulatory intervention, and feasibility also would be the criteria. The notion and design of toxics integration thus embedded the expertise of economists and policy analysts, expertise generally termed regulatory analysis, involving the combined analysis of the benefits of regulatory measures (including the reduction of health risks) and their costs, for a variety of alternatives. At that moment in time, this expertise was being promoted, and an attempt was made to materialize it in the organigram and functioning of the agency, in competition with the biological and biostatistical expertise promoted through the cancer assessment guideline of 1976.

The project was both ambitious and realistic. Computing common assessments of the hazardousness of many substances bordered on the unfeasible. The knowledge about many substances was simply incomplete, and therefore unequal. Establishing a common assessment of a substance

with people from across the agency, furthermore, would run into the difficulty of having people agree on the same set of assumptions regarding the linearity of the dose-response relationship, WOE, and the rest. There was, moreover, no evidence that costs, benefits, or feasibility could even be quantified and compared. But the plan was also realistic, and policy analysts adapted their ideals of commensuration to the context as follows: "[I]n view of the uncertainties in defining precisely the factors needed to make such a ranking (effects, exposure, abatement costs, benefits, data credibility, etc.), we recommend a coarse ranking, such as *high, medium* and *low* priorities, rather than a strict ordinal array for both the action and threat lists" (EPA 1977, 23, emphasis in original). Also, the ranking process would be less mechanical (i.e., follow a set scientific methodology) than judgmental and participative.

A major issue was where to locate such an activity in the agency. In a typical decision-science fashion, the economists outlined a number of recommended management options, including having a staff office for toxics integration, with political backing and substantive authority to ensure compliance with its ranking across the agency. The group advised that the new office be chaired by the assistant administrator for toxic substances, or by a college of relevant assistant administrators. Having one or several political appointees as its head, it thus would benefit from greater authority over program offices. The office would assess the hazards of substances independently, drawing from data contributed by individual offices and sending its assessment of priorities back to the offices for them in order to manage their own workload and crises in an informed way, compatible with other offices. It also would create an integrated annual work plan, with repercussions on the activities of all headquarters and regional offices, as well as on the ORD (which would be required, under this plan, to do its own planning only after the Toxics Integration office had drawn up its integrated plan). The EPA assembled according to this plan would look very different from the one designed in the guideline of 1976. It would be organized around the risk-ranking function and integrated thanks to comparative risk information, as in figure 3.4.

Three things happened in practice, none of which was really transformative. First, a Toxic Substance Priority Committee was formed inside the OPRM to monitor ongoing activities at the level of individual chemical substances. In 1979, it published a lengthy status report on EPA chemical

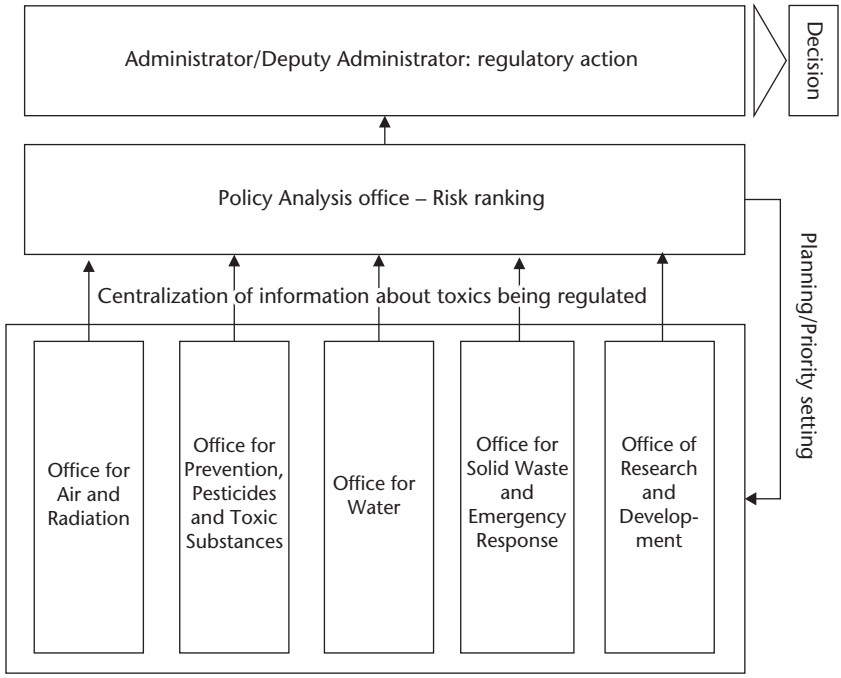

Figure 3.4
Design of an integrated EPA with a central risk-ranking function.

activities, listing the parallel activities in different offices for each substance (EPA 1979a),[7] including substances that mattered greatly to the EPA and to the industry because of their toxicity and the large volumes in which they could be found in the environment. The committee only had the capacity to gather information, and its function was purely advisory. It only barely succeeded in producing coordination among offices assessing the same substance at the same time. A subsequent report on toxics integration in 1981 noted that some chemical substances were assessed for their hazards and risks several times, in parallel, by separate offices. Between 1978 and 1980, for instance, ethylene dichloride was assessed by six offices of the EPA, all working simultaneously on information on its health effects, production and use, sources of release, and exposure. Other chemicals were included in this case, including highly controversial substances and key concerns for the administrators, such as arsenic (Powell 1999). Second, an Office of Toxics Integration was created inside the Office of Pesticides and Toxic

Substances (OPTS), which only covered the activity of the agency under TSCA and concerning pesticide products. It did not really contribute to coordination with other program offices. Third, a more original and shared activity of intermedia analysis was initiated. Groups were established that were tasked with experimenting with the integrated analysis of the toxicity problem, not at the level of individual substances, but on a chemical class basis by industry or by territory.

Toxics Integration as a Response to White House Supervision

In the short run, the impact of the Toxics Integration project was not substantial. But it did represent one of the first formal experiments in applying regulatory analysis as a decision-making discipline tentatively affecting the whole agency. Moreover, as regulatory analysis was being increasingly championed by the White House, the regulatory analysis personnel in EPA gained further support for their activities. Environmental and health regulation had emerged strongly in the 1960s, during a particular phase of American politics characterized by the strength of new public interest movements and greater political pluralism. But that period of intense regulatory change did not last beyond 1975 (Harris and Milkis 1989; Hoberg 1992). In the second half of the 1970s, environmentalism became less of a national priority and the control of regulation a much stronger one. In fact, systems to moderate regulatory interventionism were already in place. Richard Nixon, at the same time as he created the EPA, instituted inside the White House the office that would oversee its activity, the Council on Environmental Quality, and its process of quality-of-life review.[8] Regulatory quality later became an important leitmotif under Jimmy Carter, who embraced the theme of government efficiency and responsiveness during his presidential campaign (Graham et al. 2005).

After Carter's election, this materialized in the adoption of an executive order in 1978, requiring regulatory agencies to perform regulatory impact analysis, and the establishment of a Regulatory Analysis Review Group (RARG), comprised of representatives of the OSTP, the OMB, the Council of Economic Advisers, and the EPA, and tasked with reviewing regulatory proposals stemming from regulatory agencies) and of a Regulatory Council within the White House (with representatives of departments and regulatory agencies), chaired by Douglas Costle. The council had a variety of

projects aimed at increasing the use of innovative approaches to regulation and at coordinating regulatory efforts among agencies. It started a calendar of federal regulations and issued a set of pamphlets on innovative approaches to regulation. In this position, Costle pushed the rationalization of regulations development through regulatory analysis.[9]

Providing support to toxics integration was another aspect of this effort. The RARG was already an increment from what was called "quality review," which had been instituted under Nixon, and a process that was already delaying many EPA initiatives significantly (Anonymous 1976). Dan Fiorino, who was the OMB interface with the EPA, found out that the office asked for the revision of EPA rules much more frequently than those of other agencies and departments, and that it extended the review time for EPA rules in about a third of cases—far more frequently than for other agencies.[10] The EPA staff started to get frustrated about the OMB withholding major rules for months in order to conduct a review. But that was nothing compared to what was to come once Ronald Reagan was elected president and launched his "regulatory relief" program.

During the 1980 presidential campaign, this became a stronger theme than ever, particularly under Reagan's rhetoric of government as the source of all ills in American society, and so it needed to be rolled back. A few days before Reagan assumed office, the *New York Times* published an article proclaiming, "OSHA, EPA: The Heyday Is Over" (Anonymous 1981), listing the scathing criticisms of agencies that had accumulated during the past years, and explaining how the whole new social regulation drive was in fact a terrible mistake. Ann Gorsuch succeeded Douglas Costle as Reagan's EPA administrator in May 1981, and her job was to do the dirty work of correcting that mistake: essentially paralyzing any strong regulatory intervention coming out of EPA. Until then an assistant district attorney, Ann Gorsuch had virtually no experience in Washington policymaking or public administration. However, she was a Reagan enthusiast and a good soldier for his "budget-cutting and rollback of government" message. Most of her leadership of the EPA was inspired by the intention to curtail the agency's capacity to make decisions and issue standards by drastically reducing staff and budget overall, closing the enforcement office, encouraging regional offices to settle issues instead of going to Court, and requiring more detailed review—by senior officials or by the SAB—of the standards prepared by the various offices, and facilitating review of proposed EPA rules by the OMB (Layzer 2012, 110).

Reagan's other move was to institutionalize regulatory and cost-benefit analysis in two ways: through Executive Order 12291, requiring regulatory agencies to perform cost-benefit analyses for all proposed regulations with an anticipated impact of over $100 million;[11] and through the creation of a dedicated office to review the regulatory analyses of agencies, the Office of Regulatory and Information Policy (established within OMB in February 1980). Jim Tozzi, the head of the office and a longtime leader on the White House's regulatory reform agenda, dedicated a considerable amount of his time to environmental regulations, which were particularly prone to controversy and disagreement (Anonymous 1982).

The OMB used the mantra of toxics integration to instill regulatory analysis further into the processes of the agency. Although the budget passback does not generally entail policy directives,[12] in 1981, it was accompanied by a request to come up with a more decisive strategy for toxics integration. This forced the agency to continue the integration effort. Taking stock and going forward with it, Dan Beardsley, then in the Office of Policy—sometimes dubbed the "mini-OMB" for its role in helping or stimulating regulatory offices across the agency to perform regulatory analysis—put out a new report on the subject of toxics integration in 1981. He noted that the problems that he had diagnosed in 1977 remained unsolved: Duplication of analytical efforts continued, leading to inconsistent application of policies and standards; and the priorities of offices remained heterogeneous, leading to a bigger problem for the agency—that of ensuring "effective or measured" efficiency. In that 1981 report, the autonomy of program offices was attacked directly. The staff of program offices was described as excessively loyal to the regulatory regime that they operated and to the administrative culture of their service. On the other hand, the authority needed to impose agencywide standards or procedures on separate scientific assessments was lacking. Managers and staff scientists were reluctant or unable to criticize work done in other parts of the organization.

One of the short-term consequences was the institutionalization of the intermedia analysis performed in the "Integrated Environmental Management Division," reporting to Richard Morgenstern[13] in the Office of Planning. The division was populated by people from across the agency, with a variety of disciplinary backgrounds. Its industry work groups focused on calculating the regulatory burden for a given industry and computing cost-effectiveness curves, taking into account production processes and control

technologies, the transport and ultimate fate of pollutants, and the risk to exposed populations. The division was described as a stimulating place to work, where pioneering analytic work was performed, using such elements as nonlinear models and pollution geomapping. The integrated industry analysis demonstrated on several occasions that much money was spent chasing risks that appeared comparatively "trivial."[14] It showed that "few of the regulations under consideration at the time of the study lay on the cost-effectiveness curve for reducing additional risk" (Beardsley 1987, 144). In other words, the strict consideration of cost-effectiveness measurements would justify discontinuing many of the agency's actions. Gorsuch was enthusiastic about this promotion of joint analytic work, but she did not engage in any major reorganization, preferring instead to dedicate energy to implementing severe staff reduction plans.

Conflict over Guidelines: Assessment versus Analysis

Policy analysts and toxicologists found legitimacy in very contrasted kinds of bureaucratic designs. For the former, controversies surrounding chemicals surged from the uncertainty concerning the preferences of the public for tackling one or the other hazard. To govern those controversies, one had to render these preferences explicit, and show the process of ranking problems. From this perspective, policy analysts were to be at the center of the bureaucratic assemblage: they gathered all the necessary elements of information for the various decision criteria—from risk calculations to costs and benefits, making them available for the decision-maker. Proponents of quantitative risk assessment, as shown in the previous chapter, had a totally different design in mind: one in which uncertainty concerns the knowledge of a given individual risk, which needs to be reduced as much as possible, through various forms of data and calculation. Decision derives from these calculations and the choices among calculation methods. Toxicologists and exposure specialists come first; their calculations are provided directly to the decision-maker, who may balance calculations with other supplementary, contextual elements of costs and benefits to adjust the decision.

These two ways of assembling the agency and to produce credible decisions competed in the early 1980s in the agency through processes of reform and integration of the organization. The legacy of the Toxics Integration project and of economists was strong there, albeit unexpected and

indirect. The Toxics Integration group engaged in what was the first survey of analytical practices across the agency. The agency leaders had no synoptic vision of what the various offices were doing; they only had the experience of inconsistencies between health assessments, as revealed directly by the press and the courts. The CAG in the ORD was probably the only group in the agency that had some understanding of what was actually happening in various program offices. At least it was in a position to compare its own approach with that of the Air and Water offices, which it served most frequently.

So the Toxics Integration staff undertook a survey of the practices of various offices, showing that the uptake of quantitative risk assessment was uneven at best: Many offices were working with cutoff hazard criteria, leaving dose-response statistical curves and exposure considerations to others—the Air and Water offices, typically. Most offices remained substance-centered, while the OPTS performed mainly multimedia assessments. Finally, most of these offices failed to consider costs and benefits analytically, alongside risks. A few other program offices balanced the costs of controlling some substances against evidence of carcinogenicity—the pesticide program being a case in point.

That survey belied Office of Policy economists' belief that jointly developed analytical methods, coupled with strong political impetus, would solve the integration issue. The report notes that the agency would best fulfill its overall responsibility for the protection of public health and the environment by "comparing (whether analytically or judgmentally) risk among substances and across media, and adjusting Agency budgets and actions accordingly." The report envisioned decision-making structures to link policy with scientific findings and economic impacts: "integration should take place as early as possible in the analytical process on which Agency decisions rest" (EPA 1981c, I–2).

The convergence with the CAG's efforts through its guidelines was unmistakable, and both the CAG and Toxics Integration personnel converged on using notions of risk to integrate separate regulatory and epistemic cultures in the agency. In support of that effort to develop the agency's integration, and hence the consistency and credibility of its evaluations of chemicals, the Toxics Integration staff developed a standardized taxonomy of analysis that could apply to all offices. They picked the notion of "risk assessment" to name the analytic and evaluative work that the EPA performed as a whole.

The notion helped to embrace the set of analytic operations pertaining to the analysis of health consequences of toxic substances across offices: "[T]he most important tool used for evaluating toxic problems is 'risk assessment', a three part process that combines (1) an evaluation of the inherent hazard of a given compound through a given route of exposure (air, drinking water, surface water, food), at various levels, with (2) a quantification of current exposure levels (prevailing levels times the population exposed to each level), to produce (3) an estimate of total risk related to current exposures to that chemical. Human health risk assessments in EPA have tended to stress cancer effects, but teratogenic and other chronic health effects can also be accommodated. EPA also has considerable experience at estimating environmental risks, such as risks to fish, crops, and other biota" (ibid., x). Thus, the policy analysts of the agency were pushing the codification of expertise in the agency even further than the CAG had dared to do. In the EPA thus far (as discussed up to now), risk assessment had been used alongside other notions of health assessment, hazard assessment, or exposure assessment. It designated the quantitative, mathematical part of the evaluation of health effects. In no way was it used as the generic, organizing notion subsuming all other parts, including the more judgmental and qualitative parts of an overall process.

The report outlined several options to further integration,[15] all of which drew on *analysis* as a mechanism of integration, definition of generic analytic tasks, and preparation of guidelines for making flexible judgment. A few years later, recounting the effort, Beardsley (1987, 144) again noted, "We decided to use risk analysis—rather than more predictable bureaucratic approaches like reorganization—as the integrating theme because risk reduction, of either human or ecological health, is the best working approximation we have to describe EPA's general mission. Within limits, we believe it can be a common denominator for measuring many different actions, a sort of Rosetta Stone for opening up communication among the separate programs."

Even though the policy analysts did not necessarily get involved in the development of further guidelines for risk assessment or exposure assessment, their involvement in the work of separate program offices, as part of the need to prepare for OMB reviews, came with a more structured representation of the knowledge that the EPA should draw on to shape decisions. Essentially, they advocated the integration of knowledge on health effects

with economic analysis, with analysis embodying the most generic kind of competence in the agency. The Recommended Outline for Health and Environmental Assessment Documents of the Office of Drinking Water (EPA 1982) made it clear that a complete assessment had three parts: a health assessment, an exposure assessment, and a risk assessment. The document was meant for the associate assistant administrator of the Office of Water, a position invented by Gorsuch during her mandate to position more politically appointed people to supervise the work of regulatory offices. Like other assistant administrators, Merna Hurd was imposing on the staff a discipline of considering the risks, costs, and benefits of alternative regulatory options. The author of the document thus drafted an outline that, unlike most other guidelines, incorporated the consideration of control options for chemicals with negative effects into the very exercise of scientifically assessing those effects. That too was an exercise in assessing uncertainties—one that could justifiably be characterized as a risk assessment.

The same sort of forced consideration of cost and benefit knowledge in a standard, linear analytical process took place at the Air Office. A cancer policy task force there was asked to rethink the part of the guideline indicating the risk threshold that they considered significant. The group was led by Betty Anderson of OHEA and the CAG, with people from across the agency. It was to find a solution for such questions as: Should the agency decide on the basis of individual risk or total population risk?[16] Should it adopt a common "target risk level"? The 1976 cancer assessment guideline had put these questions aside, because so long as the OHEA developed guidance more or less alone, or in conjunction only with the Air and Water offices, in accordance with the precautionary statutes that they administered, these questions were irrelevant. But in a context where the agency as a whole was asked to consider the costs and benefits, as well as the proportionality of its regulatory decisions, they became unavoidable. The agency had to fashion a common response, matching the level of public contestation and OMB oversight that it had started to get in those years.

It soon appeared exceedingly difficult for the group to come up with generally applicable policy principles on these issues. The toxicologists leading the assessment of health effects kept in mind the uncertainty inherent in their assessments, and they needed to err on the safe side. To compensate for this controversial, de facto precautionary policy, they tried not to standardize or mechanize it too far, applying strict guidelines. This attitude

contrasted with that of economists and policy analysts, who had confidence in their cost and benefit measurements. They found less uncertainty, and firmer ground for decisions, than health scientists. Anderson reported the difficulty to an administrator at the Office of Policy in the OPRM, asking him to arbitrate and to give directions on resolving the question.[17] The group agreed that it was necessary to use estimates of the magnitude of the cancer risk *along with* other factors to make sensible regulatory decisions, such as the costs and feasibility of control, benefits of the compound, and impact on the controlled industry and the economy—which is a major shift compared to the past, when generic cancer policies were restricted to considerations of health and science. But they did not manage to standardize a decision-making process using these various elements of knowledge, or to clarify the relative importance of health scientists and policy analysts in the forging of these decisions.

Conclusion

Economic analysis, under the guise of comparative analysis of the levels of the costs, benefits, and risks associated with actions on series of chemicals, and prioritizing these chemicals, emerged as early as other kinds of scientific expertise within the EPA. This rationale for decision-making, after all, was present in the group that designed the agency, including Alain Enthoven, the economist and systems analyst, and Terry Davies, the political scientist and advocate of integrated action on the environment. The agency they had imagined at the time of the Ash Council, for Nixon—featuring a central planning and management function—never saw the light of day. There were plans to organize the agency around this kind of decision-making mode based on a synoptical function of information collection and systematic comparison, turning the policy office into a central functional element of the agency. However, these plans did not materialize.

But the ideas underpinning such a design remained alive inside the agency. It reemerged during the mandate of EPA Administrator Douglas Costle because of a new political configuration. The many new regulations introduced in the 1960s and 1970s to regulate environmental problems and health risks started to be perceived as a problem. In the nascent era of regulatory reform, the agency was under pressure to speak with one voice, justify each new regulatory intervention, and avoid duplication. The problem

of the impregnation of the environment with chemicals constituted the other facet of this configuration of evaluation of the agency's action. The effects of individual chemicals did not present the only issue. Their accumulation and dispersion across the totality of the environment constituted a new, more complex version of the problem. The focus of the controversies concerning the agency shifted. They were less about being wrong for one chemical than about being wrong about which hazard it was regulating in the first place. The orientations given by the administrator—addressing the chemical revolution across environmental media—encountered the thinking of economists in order to produce an emergent bureaucratic technology of risk-ranking. Still, giving greater power to economists in the definition of the agency's priorities meant placing them above toxicologists in the hierarchy of expertise of the agency, and above the leaders of individual regulatory programs. In a context in which the public continued to expect that the agency protects against chemical risks—rather than optimally distribute its resources between a variety of issues—this was a difficult organizational reform to make. For the time being, the economists' proposed design and bureaucratic assemblage was not fully instituted. The risk-ranking process did not become an obligatory, cross-agency process, involving the leaders of each program office. It did not lead to any formal reorganization of the agency. It was not used to project a new identity. The political imperative of optimizing regulatory intervention, as Reagan campaigned to become the president of a leaner, smaller government, only grew stronger from this moment onward, though. And so did the ambition to inform the decisions of the agency through economic analyses.

The Science of Bureaucracy

Risk Decision-Making and the US Environmental Protection Agency

By: David Demortain

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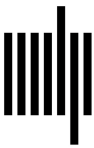

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