
RISK AND THE ENVIRONMENT
IMPROVING REGULATORY DECISION MAKING

JUNE 1993

A Report of the
CARNEGIE COMMISSION
ON SCIENCE, TECHNOLOGY, AND GOVERNMENT



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EXECUTIVE SUMMARY

THE NEED FOR INNOVATION

The nation's environmental and risk-related regulatory agenda* has changed dramatically over the past twenty years, and it will undoubtedly continue to evolve in the decades ahead. Since the establishment of the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and the Consumer Product Safety Commission (CPSC) in the early 1970s, the cost and complexity of federal programs have increased as environmental and risk-related problems have become less amenable to straightforward solutions. In response to public demands for cleaner environments, healthier workplaces, and safer food and commercial products,

* We define "environmental and risk-related" regulation as regulation conducted by CPSC, EPA, FDA, and OSHA. The basis for the Task Force's decision to examine the environmental and risk-related subset of regulation, and to focus in particular on EPA and FDA, is discussed on pages 30-33.

policymakers are striving to develop innovative solutions to increasingly subtle and intractable problems.

We stand at a crossroads in environmental and risk-related regulatory policy, facing critical organizational and procedural questions about the future at a time of large budget deficits and escalating demands on the regulatory system. In order to address the challenges of the present and to anticipate and ameliorate the problems of the future, the nation must develop a more comprehensive and integrative decision-making infrastructure while maintaining the flexibility to adapt to the new challenges of the next century. Our report focuses on the interactions of science, technology, organizational dynamics, and law in environmental and risk-related regulatory policy and attempts to identify potential reforms. (See pages 35-36 for a "roadmap" to the report.)

FINDINGS AND RECOMMENDATIONS

EXECUTIVE OFFICE OF THE PRESIDENT: POLICY FORMULATION AND REGULATORY REVIEW

■ **The Executive Office of the President should expand its capacity to formulate broad environmental and risk-related policies and should better integrate these policies with other national goals (see pages 43-48).**

Federal policies to address environmental, health, and safety hazards are often inconsistent and fragmented. The need to develop comprehensive environmental and risk-related regulatory programs and to integrate them with the nation's economic, energy, and national security goals is paramount.

As the only entity in the federal government with a view of the whole regulatory landscape, the Executive Office of the President (EOP) is a logical focus for regulatory reform efforts. In recent years, unnecessarily high tension has existed between White House staff and agency regulators. The EOP has been accused of trying to "micromanage" technical details of rules that experts in regulatory agencies have prepared. Since the early 1970s, environmental and risk-related policymaking in the Executive Office has been largely reactive and at times, some have charged, obstructive. Policy activities in the White House have mainly focused on the economic impacts of regulatory actions, and the Executive Office has developed relatively few forward-looking initiatives to control threats to public health and the environment.

The Executive Office must have the capacity to undertake several fundamental tasks in the environmental, health, and safety policy arena

(see Box 4, page 42). Of paramount importance is the capacity to identify and analyze issues of "presidential" significance; to develop integrated policies consistent with statutory mandates; to communicate these policies to responsible agencies, states, the public, and industry; and to monitor policy implementation.

In developing environmental and risk-reduction policies, the Executive Office should rely on the analytical capabilities of departments and agencies whenever possible. It should help the President to define the broad contours of the Administration's environmental and risk-related policy, but must take care to leave implementation details and day-to-day regulatory decisions to the regulatory agencies.

■ *A focal point should be created in the Executive Office of the President for developing environmental and risk-related policy in the context of other national policy goals (particularly economic) and for helping federal departments and agencies to integrate sustainable development and risk reduction objectives into their activities. By strengthening the existing Office of Environmental Quality (OEQ) and redefining its mission, this can be achieved without new legislation (see pages 43-45). (On February 8, 1993, the White House announced its intention to abolish CEQ, and to replace it with an "Office of Environmental Policy." The new Office is to be staffed at approximately one-third the level of CEQ. It will be headed by a Deputy Assistant to the President.)*

■ *The Executive Office's analytical and policymaking processes should complement and not supersede the capabilities in departments and agencies (see pages 45-46).*

■ *Cabinet-level working groups should be established to formulate and oversee the implementation of federal policies for environmental protection and risk reduction that cut across departmental boundaries. Standing groups should be created to address persistent concerns, such as the relationships among energy, environment, and the economy. Ad hoc groups should be created to address challenges that can be resolved over a limited period of time. (see pages 46-47).*

■ *The Office of Science and Technology Policy (OSTP) should play a leading role in developing environmental and risk-related policies by becoming more directly involved in policy decisions involving scientific and regulatory issues, promoting consistency in the scientific aspects of risk-based decisions, and ensuring that federal R&D programs are directed to the missions of the environmental and risk-related agencies. OSTP's work in these areas should be conducted in close cooperation with the Office of Environmental Quality (see pages 47-48).*

- Executive Office review of regulatory decisions made by the presidentially appointed administrators of federal agencies should consist primarily of an examination of the extent to which decisions are consistent with statutory mandates and broad Administration policies (see pages 51-52).

Within broad statutory constraints, the approach a President takes to governing is largely a personal choice. Therefore, we do not recommend a precise mechanism for overseeing the activities of federal regulatory agencies. Nonetheless, general principles of good government should guide the executive review process in whatever form it takes (see pages 51-52).

The President should select appointees with whom a relationship of mutual trust can be established, and the President should be able to rely on the judgment of these appointees in implementing policies. If dissatisfied with the actions or progress of federal agencies, the President should either work with Congress to modify their legislative mandates or make changes in agency management. The Executive Office should not second-guess agency interpretations of statutes. It should appraise its capabilities realistically and should not review complex scientific or technical issues where it lacks the necessary expertise.

The Executive Office should have a minimum of regulatory review points, and the review process should be clearly described. Except for communication directly related to presidential deliberation, the executive oversight process should be open to public scrutiny. Economic analyses should take place chiefly at the agency level in the context of clearly stated procedural guidelines developed by the Executive Office.

CONGRESSIONAL, EXECUTIVE, AND JUDICIAL INTERACTIONS

- Mechanisms should be devised to promote informal communication among the branches of government with respect to environmental and risk-related issues (see pages 59-63).

Congressional-Executive gridlock and other interbranch conflicts have impeded effective policymaking at times in the past. Although politically divided government has often contributed to this friction, interactions between Congress, the Executive, and the Judiciary can be contentious regardless of partisan differences. Increased informal communication among the branches could help alleviate some of this conflict. We propose two models designed to increase communication and foster better understanding among the branches.

- *A forum should be created in which Members of Congress, executive branch officials, and judges can meet informally to discuss broad*

issues raised by the interaction of science and policy in environmental and risk-related regulation (see pages 61-62).

■ *Informal working groups at both the principal and staff levels should be organized more frequently to foster communication between the executive and legislative branches in developing and implementing environmental policy (see pages 62-63).*

INTERAGENCY COORDINATION

■ Mechanisms are needed to improve consistency in federal regulatory decision making and to facilitate interagency cooperation. One approach to meeting these needs is to establish a Regulatory Coordinating Committee comprised of the administrators of the environmental and risk-related regulatory agencies and representatives of the Executive Office of the President (see pages 71-72).

The environmental and risk-related regulatory agencies have mandates that overlap in some areas and leave gaps in others. To ensure that agencies do not duplicate their efforts to reduce some risks while not attending to other hazards, a Regulatory Coordinating Committee should identify problems that necessitate or would benefit from the involvement of multiple agencies. Agency staff members should seek to build consensus on means for coordinating their efforts, and agency heads should review coordination issues that staff members cannot resolve. The committee should

■ Examine the relative risks posed by problems or categories of substances and attempt to identify problems that need additional attention; ensure that major risks that cross agency jurisdictions are addressed and that sufficient data are developed to rank them appropriately; and see that relative risk rankings are updated regularly as more information becomes available (relative risk analysis is discussed in more detail in the next section).

■ Develop and articulate a coordinated federal response to high-priority cross-cutting problems and set common risk reduction goals and strategies across agencies for these problems.

■ Develop methodologies and guidelines for risk assessment and risk management and promote the exchange of information among regulatory agencies. In areas where fully consistent approaches are found not to be appropriate, committee publications should explain why this is so and clearly describe the different approaches used by each agency. All committee publications should be readily available.

■ Identify research needs and determine the proper roles of indi-

vidual agencies in meeting those needs, with agencies utilizing the research strengths of other agencies to the extent possible.

SCIENCE, RISK, AND REGULATORY DECISION MAKING

■ Agencies should place problems in broad risk categories and develop strategies to address risks of high priority. To do this, each regulatory agency addressing environmental and risk-related issues should develop a broad-based risk inventory. The agencies should use the inventories' output to help develop multidimensional risk rankings. The agencies should experiment with methods to integrate societal values into relative risk analyses where statutes do not supply all the value judgments necessary to rank risks. Agencies should repeat relative risk analysis initiatives periodically, readjusting the process at each iteration in light of lessons learned, new information, and progress in addressing high-priority risks (see pages 75-90).

Setting priorities is the fundamental problem in regulatory decision making at the agency level, as at the presidential and interagency level. Comparing and ranking individual risks, families of risks, and risk reduction opportunities present great challenges for science-based regulatory agencies. The public, the media, industry, the Executive Office of the President, legislators, and the courts all exert pressure on these agencies, and their decisions often appear equal to the vector sum of these forces. While our regulatory agencies should be responsive to government institutions and the public, setting priorities on a "chemical of the month" basis may result in overregulation of some hazards, underregulation of others, and decreased agency credibility.

We see relative risk analysis as a promising way to promote scientifically sound decision making about risk. Nevertheless, we recognize that the technique is still in its infancy. To enhance the accuracy and credibility of the process, two components of relative risk analysis must be strengthened: scientific data must be better collected, organized, and evaluated, and more attention must be devoted to integrating societal values into the process.

■ *We recommend that other agencies working to reduce risk conduct relative risk analyses of the type done by EPA in Unfinished Business and Reducing Risks and that both EPA and these agencies periodically update their findings and methodologies (see pages 81-82).*

■ *We recommend that each agency develop a risk data inventory that reflects the agency's mission and that agencies coordinate their efforts to facilitate exchange of information and interagency comparability of risk rankings (see pages 84-86).*

■ *Congress and regulatory agencies should consider modifying provisions and practices directed at protection of confidential business information in order to produce a better balance between industry's need for proprietary secrecy and the need for efficient use of environmental, health, and safety data by governmental agencies, the scientific community, and the public (see pages 86-87).*

■ *Regulatory agencies should report a range of risk estimates when assessing risk and communicating it to the public (see pages 87-88).*

■ *Agencies should experiment with different mechanisms for integrating societal values into the process of setting risk-based regulatory priorities (see pages 89-90).*

■ **Regulatory agencies should critically evaluate and take deliberate steps to improve their internal scientific capabilities and their means of integrating scientific and technological considerations into agency decision-making processes (see pages 90-94).**

The Environmental Protection Agency recently convened a group of distinguished nongovernmental experts to examine its internal scientific capabilities and recommend approaches to improving the Office of Research and Development and its intramural laboratories. This analysis yielded many thoughtful recommendations. We believe that other agencies should undertake similar exercises.

■ *Regulatory agencies should seek advice from other government agencies where appropriate expertise is available (see page 91).*

■ *Individuals with both public policy and scientific expertise should be appointed more frequently to senior positions in regulatory agencies (see pages 91-94).*

■ **The federal government should use its existing personnel authority to create opportunities for selected individuals to rotate in the early years of their careers through environmental and risk-related regulatory agencies, Congress, the Executive Office of the President, and, in some instances, administrative offices of the Judiciary (see pages 94-95).**

Regulatory policy results from a dynamic interplay among politics, economics, law, ethics, and the physical and natural sciences. But relatively few scholars or practitioners of regulatory policy have a truly broad view. By providing new opportunities for promising staff members to rotate among the branches, the federal government will develop a highly trained and experienced cadre of individuals with a unique perspective that will eventually prove a valuable asset to the regulatory process. The protection

accorded by the civil service system would help insulate these individuals from political influence.

LONG-RANGE GOALS AND STRATEGIES FOR REGULATORY PROGRAMS

■ Regulatory agencies should establish specific long-term research and regulatory objectives and regularly report their progress toward achieving these goals to the President and Congress. Congress and the President should mandate that regulatory agencies justify annual budget and program plans in the context of explicit long-term regulatory goals. Furthermore, Congress should work more closely with federal and state regulatory officials and experts in nongovernmental organizations to devise realistic regulatory goals and deadlines for meeting them (see pages 99-102).

Strategic planning is an essential but exceedingly difficult task for federal regulatory agencies. Congress and the agencies have traditionally been reactive rather than proactive in addressing environmental, health, and safety risks. We encourage Congress and the President to take a longer-range view in devising broad policy mandates and to give regulatory agencies more freedom to conduct internal strategic planning exercises.

In setting goals for federal agencies and mandating actions, Congress should match responsibilities with resources to ensure that objectives can be attained. Regulatory agencies should devise work plans and secondary goals to meet these long-term goals and should monitor progress in achieving them.

■ Regulatory agencies should enhance their long-range planning capabilities by strengthening the linkages between research and regulatory policy-making efforts and by undertaking policy planning exercises in the context of relative risk analyses (see pages 102-104).

The extent of linkages within regulatory agencies between research and development capabilities and the planning efforts of regulatory offices varies considerably. We believe that each regulatory agency should establish an anticipatory research program, closely linked with its regulatory program offices, to identify emerging problems and ways of addressing them.

■ *Regulatory agencies should strengthen their anticipatory research capabilities and establish and maintain effective linkages between these efforts and regulatory planning activities (see page 103).*

■ *Regulatory agencies should undertake long-term planning exercises in the context of the risk-based decision-making processes described in Chapter 5 of this report (see pages 103-104).*

■ *Regulatory agencies should sponsor extramural policy studies to*

expand and enhance agency intramural long-range planning processes (see page 104).

RULEMAKING PROCEDURES

■ Regulatory agencies should experiment actively with the variety of means available under existing authority to reduce rulemaking ossification. Care should be taken with all experiments to preserve adequate opportunities for analysis and public participation (see pages 109-111).

The rulemaking process appears to have "ossified," becoming so time-consuming and expensive that agencies increasingly turn to perfunctory vehicles for promulgating policy, like policy statements, manuals, and regulatory letters. Any solution to the problems of "rulemaking ossification" must balance two sets of factors. Increased public participation and careful analysis of all aspects of a policy is desirable, but can lead to lengthy procedures—the very length and complexity of which may defeat the desirable ends of rulemaking itself. Although no "perfect" balance exists, providing a range of choices and criteria for making the proper choice would allow agencies to select the appropriate approach for each rule on a case-by-case basis.

The drafters of the Administrative Procedure Act intended it to provide agencies with a great deal of flexibility. Although judicial interpretations of the act have yielded a series of procedural requirements that somewhat constrain agency freedom, the zone of discretion remains wide. We present a set of suggestions for using this discretion to de-ossify the rulemaking process.

■ *Regulatory agencies should create a "menu" of procedures, ranging from highly simple to more complex, calling for various degrees of public participation and comment, which may be subject to varying degrees of judicial review, and whose legal status may also vary. Agencies could choose the kind of procedure they believe best fits the type of policy problem at hand from among the menu's options (see page 110).*

■ *Agencies should search for ways to diminish the complex, time-consuming nature of the informal rulemaking process (see pages 110-111).*

■ *Agencies should attempt to negotiate rules where it is possible to do so without prejudicing unrepresented third parties (see page 111).*

■ Mechanisms should be explored to keep appropriate congressional committees informed of the interpretation made and ambiguities found by courts in the statutes that authorize rulemaking (see pages 111-112).

Such efforts show promise in promoting clarity in the drafting of statutes. One approach is to have nonpartisan analysts periodically apprise relevant committees of statutes or statutory passages that have given rise to divergent interpretations. Another possible method is for committees with jurisdiction over regulatory statutes to devote one or two days per year to informal conferences with representatives of the agencies or the Executive Office of the President for this purpose.

- Executive Office officials should communicate less formally, earlier, and more directly with agency officials (see page 112).

The current process—agencies submitting rules to the Executive Office, followed by EOP review for compliance with presidential policies—can create an adversarial relationship between the agencies and the White House, sometimes resulting in delay. Increased informal consultation and discussion earlier in the rulemaking process among staff members of agencies and the Executive Office would prove beneficial and would likely lead to faster approval of more effective regulations.

ROLE OF NONGOVERNMENTAL ORGANIZATIONS

- The extensive capabilities of nongovernmental organizations (NGOs) should be used more frequently to evaluate the regulatory process, suggest ways to improve existing regulatory strategies, and aid federal agencies in establishing regulatory priorities. Nongovernmental policy research organizations should establish stronger ties with scientists and engineers in universities to bolster their capacities to examine issues pertaining to environmental and health risks (see pages 115–116).

Nongovernmental policy research centers can be particularly effective in convening a diverse group of practitioners and scholars for sustained reflection on problems of organization and decision making in environmental and risk-related regulation. The immense environmental challenges and health risks we face in the future, coupled with existing and anticipated constraints on the federal budget, will necessitate a considerable expansion of activity in the nongovernmental sector. Nongovernmental policy research organizations should establish stronger ties with scientists and engineers in universities to bolster their capacities to examine issues pertaining to environmental and health risks.