# Science and Policy in Regulatory Decision Making: Getting the Facts Right about Hazardous Air Pollutants


## Ken Sexton

Environmental and Occupational Health, School of Public Health, University of Minnesota, Minneapolis, Minnesota



Hazardous air pollutants are regulated under Title III of the 1990 Clean Air Act Amendments. The Amendments replace the risk-based approach mandated in the 1977 Amendments with a prescriptive, technology-based approach requiring that maximum achievable control technology (MACT) be applied to all major industrial sources of 189 hazardous air pollutants. The change reflects political, rather than scientific consensus that the public health benefits justify the costs. The choice is put into perspective by looking at the interface between science and policy that occurs as part of regular decisionmaking. Particular emphasis is given to examining the interrelationships among facts (science), judgments (science policy), and policy (values) in the context of the risk assessment paradigm. Science and policy are discussed in relation to Title III, contrasting the political consensus for action with the scientific uncertainty about risks and benefits. It is argued that a balanced research program is needed to get the facts right about hazardous air pollutants, including research to meet statutory requirements, to reduce uncertainties in risk assessment, and to address strategic issues. — Environ Health Perspect 103(Suppl 6):213–222 (1995)



Key words: risk assessment, regulatory decisions, science policy, hazardous air pollutants, Clean Air Act


## Introduction

In the United States, there is a longstanding societal commitment to safeguarding people's health from the adverse effects of toxic agents in the environment. This is reflected in the missions, mandates, and actions of federal regulatory agencies like the U.S. Environmental Protection Agency (U.S. EPA), U.S. Food and Drug Administration (FDA), U.S. Occupational Safety and Health Administration (OSHA), and U.S. Consumer Product Safety Commission (CPSC). At the state level, there are also numerous regulatory agencies that share responsibilities for regulating risks from toxic exposures. Regulatory decision making is defined here to mean the kinds of decisions that these regulatory agencies must make to balance trade-offs between economic and societal costs of government intervention on one hand and corresponding benefits to public health or environmental quality on the other.

This article looks at how science is used in making regulatory decisions and examines Title III of the 1990 Clean Air Act Amendments as a case study. The discussion is divided into two major sections: a general survey of regulatory decision making with emphasis on the role of science and an examination of the hazardous air pollutant provisions of the Clean Air Act.

## Survey of Regulatory Decision Making

It is useful, at the outset, to examine the conceptual framework for regulatory decisions, keeping in mind that practical realities often intervene to make real-world decisions more complicated and harder to analyze.

### Science Policy: The Interface between Science and Policy

In the process of regulatory decision making, there is a direct interface between science and policy. Science is used here in its broadest sense to encompass research and development, technical and research support, monitoring and data collection, review and interpretation of technical investigations, and assessments of health and environmental risks. Policy is used to mean decisions both about the acceptability of risks and about the tradeoffs between the costs and benefits of intervention to prevent and reduce unacceptable risks. The interface between science and policy has been called science policy, and in the context of regulatory decision making, it has two complementary meanings (*1,2*): the use of science to make judgments about the formulation and implementation of policy (e.g., quantitative risk assessment), and the development of policy specifically for science (e.g., setting priorities for research directions and funding).

As depicted in Figure 1, science and policy can be conceptualized as existing on opposite ends of a fact–value continuum. Science is portrayed as primarily factual, with a smaller but important value component, while policy is comprised primarily of values, with a smaller but important factual component. Science policy exists at the intersection between facts and values, often functioning in the area where scientific knowledge and understanding are incomplete. This means that judgments, inferences, and extrapolations are a necessary aspect of most, if not all, science policy decisions.

### Relationships among Research, Risk Assessment, and Risk Management

According to the National Research Council (3,4) and the Office of Technology Assessment (5), regulatory decision making


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Address correspondence to Dr. Ken Sexton, Environmental and Occupational Health, School of Public Health, University of Minnesota, Box 807 UMHC, 420 Delaware Street, SE, Minneapolis, MN 55455. Telephone (612) 626-4244. Fax (612) 626-0650.

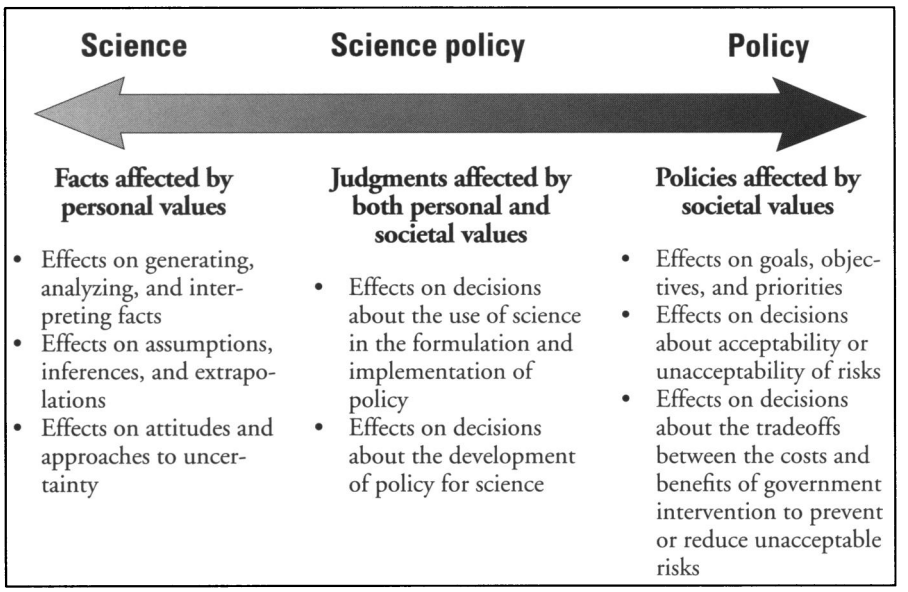


**Figure 1.** Conceptual framework for the interrelationships between science, science policy, and policy (fact–value continuum).

can be thought of as occurring in three phases: *a*) research to provide necessary scientific information and understanding; *b*) risk assessment, either qualitative or quantitative, to estimate the likelihood, magnitude, and uncertainty of risks; and *c*) risk management to make determinations about the risks that are unacceptable and what, if anything, to do about them. A fourth element, risk communication, is becoming increasingly important, and refers to the need for regulatory agencies to enter into a dialogue with stakeholders to explain risks and risk-related actions, and to respond to their concerns and questions (*6*).

In a landmark 1983 report, Risk Assessment in the Federal Government: Managing the Process, the National Research Council (NRC) argues against organizational separation but calls for clear conceptual distinctions between research, risk assessment, and risk management (*3*). In the NRC view, research provides the factual, presumably valueless, basis for risk assessment. Risk assessment uses scientific facts to estimate risks, but because the scientific database is incomplete, there are "decision points where risk can only be inferred from available data." These decision points require "scientific judgments and policy choices" to select among alternative inferential bridges. The NRC calls these choices risk assessment policy. Risk management integrates the results of risk assessment with engineering data and social, economic, and political considerations to weigh policy alternatives and to select an appropriate course of action. The NRC labels these choices risk management policy.

The NRC suggests, "At least some of the controversy surrounding regulatory actions has resulted from the blurring of the distinction between risk assessment policy and risk management policy." The Council notes, however, that the most important contributor to the conflict and controversy surrounding regulatory decisions is the differing values placed on the relative importance of economic costs versus health benefits by different segments of society.

Because of the contentiousness of many regulatory decisions, the NRC expresses concern "that scientific interpretations in risk assessment will be distorted by policy considerations." Partially in response to these concerns, the Council recommended "reorganization to ensure that risk assessments are protected from inappropriate policy influences and development and use of uniform guidelines for carrying out risk assessments." The NRC made it plain that "The importance of distinguishing between risk assessment and risk management does not imply that they should be isolated from each other; in practice they interact, and communication in both directions is desirable and should not be disrupted."

Although the NRC pointed out the problems associated with organizational separation and emphasized the need for communication among researchers, risk assessors, and risk managers, the 1983 report has served as the rationale to justify compartmentalization of regulatory decision making. As summarized in Figure 2, the NRC made clear conceptual distinctions between research and risk assessment and between risk assessment and risk management. Both conceptual and organizational distinctions among these different phases are now well-entrenched within many federal bureaucracies.

Nevertheless, an increasing number of observers question (or reject outright) this separation of facts (science) and values (policy). They argue that, in reality, science and policy are inseparable, and they find no rational basis for the existing compartmentalization, which they view as artificial, arbitrary, and counterproductive. These critics contend that formal integration of science and policy is necessary to foster better and more consensual societal decisions about environmental health risks (*2,7–10*).

An alternative to the more traditional approach (Figure 2) for conceptualizing the key aspects of regulatory decision making is pictured in Figure 3. In this conceptual model, the three phases are not portrayed as either completely separate or wholly integrated. Instead, they are pictured as overlapping spheres, each with its own focus. The role of values, both personal and societal, is acknowledged and made explicit within the context of each sphere. The emphasis shifts from facts to values as one moves from science to policy (left to right) along the research–risk assessment–risk mangagement continuum.

This alternative paradigm explicitly emphasizes that interrelationships among scientific research, risk assessment, and risk management should form a feedback loop to foster more informed judgments (*11,12*). The feedback loop requires that information, including facts and values, flow in two directions. First, the information needs identified as part of risk assessment and risk management must drive the direction and nature of supporting research. Second, the information and understanding generated by the research program must directly improve the scientific basis for decisions.

## Different Roles for Scientists and Regulators

Science is an integral part of regulatory decision making and its role is 2-fold: to improve the quantity and quality of scientific information and to enhance our ability to interpret the available scientific database for risk assessment, risk management, and risk communication decisions.

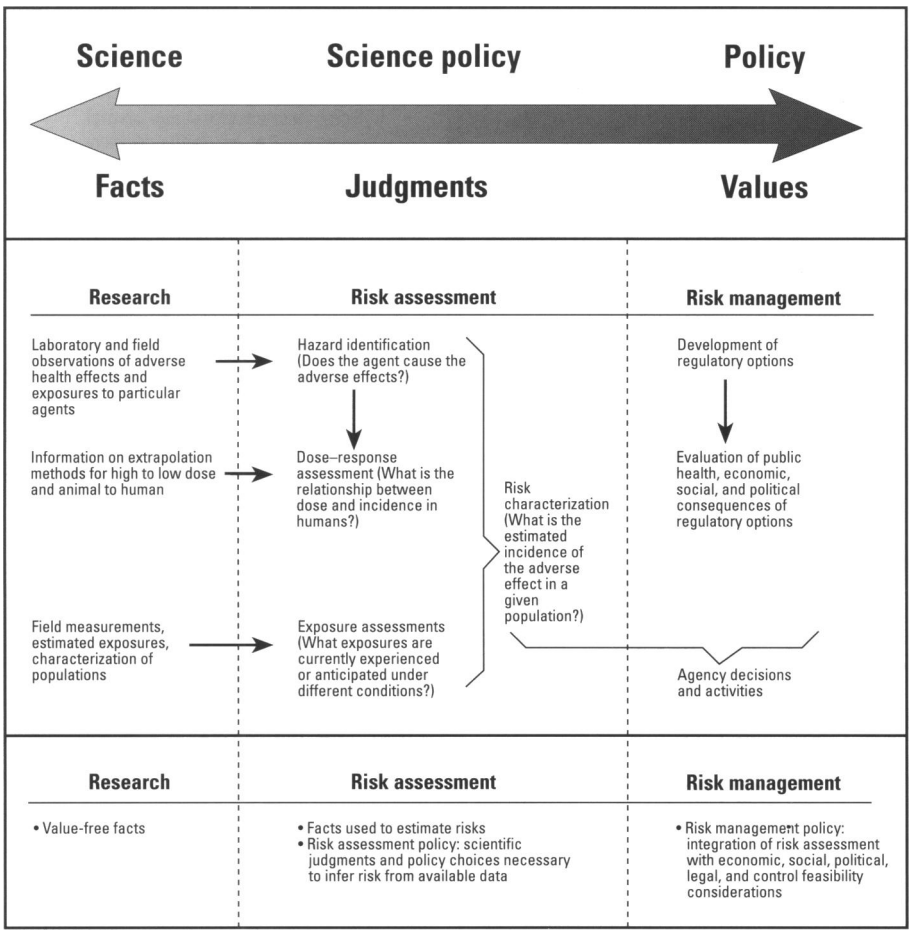


**Figure 2.** The traditional risk assessment paradigm and its relationship to the fact–value continuum. Adapted from the National Research Council (*3*).

Scientists not only conduct research (generating facts), but many also play a critical role in science policy (judgments about the use of facts) by serving as technical consultants, peer reviewers, policy advocates, and mediators (*2*).

A major role of scientists in the regulatory process is to provide expert advice about science policy issues, e.g., validation of long-term research strategies, certification of study protocols and analytical methodologies, definition of standards of adequacy for scientific evidence, and approval of inferences from studies and experiments (*2*). The lack of scientific certainty normally associated with science policy issues puts a premium on scientific consensus. In the face of significant uncertainty regarding issues such as the adequacy of scientific evidence and the appropriateness of inferences from existing data, consensus among a diverse spectrum of respected scientists functions as a stabilizing factor and intellectual anchor; it focuses attention on critical, unresolved technical questions and lends credibility to both the process and its products.

In contrast to the scientist, the regulator must go beyond consideration of the scientific facts supporting the decision process. The challenge of regulating risk involves balancing science, values, and economics. Other factors such as legislative mandates and political considerations can also play a major role in shaping regulatory decisions. Six major categories of information essential to risk managers are (*13*)

- Science
  - public health and ecological risks
  - technical feasibility of risk management options
- Law
  - legislative mandates
  - regulatory options
- Economics
  - costs and benefits
  - economic feasibility of risk management options
- Public Values
  - public sensitivity to risk
  - credibility of risk management options
- Communication
  - public and stakeholder involvement
  - communication strategy for risk management options
- Politics
  - political importance of risk
  - political acceptability of risk management options.

Ideally, science (along with public values and economics) is an important factor in regulatory decision making. When scientific knowledge and understanding are insufficient to answer important regulatory-related questions, there is typically a controversy about "whether regulators have the facts right." Moreover, there is typically widespread concern that without a firm scientific foundation, regulatory decisions can be more easily driven by political agendas, media pressure, special interests, legal challenges, and bureaucratic inertia.

An obvious solution is to invest adequate resources in targeted research and surveillance to reduce the most critical scientific uncertainties that currently limit our ability to estimate risks realistically. Although the roles of the scientist and regulator may be different, it is clear that they share a common goal—the reduction of scientific uncertainty to improve the assessment of health and environmental risks (*14–16*).

## Viewpoints on the Value of Science

Focusing on the practical realities of real-world regulatory decisions, divergent viewpoints have emerged about the intrinsic value of science in the politically and emotionally charged atmosphere that surrounds many environmental health issues such as neighborhood cancer clusters, Alar-contaminated apples, and asbestos in schools. Generally speaking, opinions about the relative importance of science (e.g., data on exposure and toxicity) in regulatory decision making can be grouped into three broad categories (Figure 4): *a*) science is a critical, often central, factor in decisions (*17–20*); *b*) science plays a marginal and often insignificant role in what are basically political decisions (*2,21–23*); and *c*) science is one of several factors in a multifactorial decision-making process (*8,9,21,24*).

The traditional view, consistent with the risk assessment paradigm (*3*), has been that science (research) is an essential driving force underpinning regulatory decisions, and that better science (facts) leads directly to better decisions about

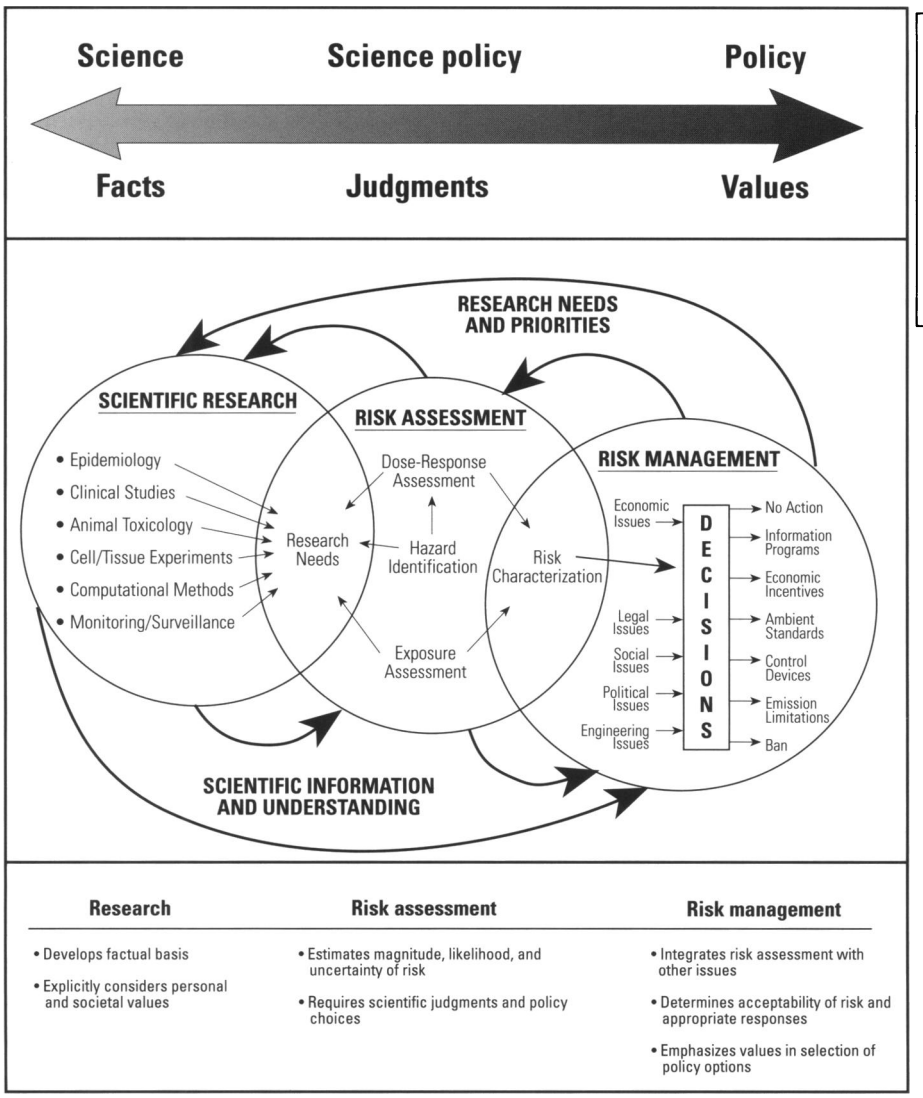


**Figure 3.** An alternative risk assessment paradigm and its relationship to the fact–value continuum. Adapted from Sexton et al. (*12*).

**Science in regulatory decision making**

**Science is essential and pivotal**
Better science → Better decisions

**Science is marginally significant**
Science → Politics → Decisions

**Science can inform the debate**
Better science → More informed and more credible decisions

**Figure 4.** Different viewpoints about the role of science in regulatory decision making.

management of risks. Some observers, however, have taken a more skeptical view, seeing decisions about risk as essentially a political (value) exercise wherein science rarely plays a decisive role. These observers remind us that science cannot provide definitive and timely answers to most of the crucial questions confronting decision makers, and they argue that science can be fragmented and polarized by the beliefs and values of special interests being used to legitimize political agendas rather than to illuminate and inform the debate.

A third, more middle-of-the-road viewpoint is that science is just one of many important factors in regulatory decision making. According to this view, the major contributions of science to decision making are its unique capabilities to structure and describe critical technical issues, especially as they relate to other important decision variables, and to identify and address key scientific uncertainties in risk assessment. Scientists are seen as vested with a special responsibility to guard against distortions and misuse of scientific evidence, which might unfairly bias the process.

Whether science is the central factor or only a marginal consideration in the final regulatory decision, it should be an explicit part of the public debate about the seriousness and acceptability of environmental health risks. Scientific evidence can enhance and inform the debate and lend credibility to regulatory decisions.

## Factors Affecting the Role of Science in Regulatory Decisions

The role that science plays in regulatory decision making depends on certain characteristics of the situation. Although this issue has received little attention, it is evident that situational variables such as media scrutiny, public outrage over perceived risks, political pressure to do something, legal requirements and deadlines, and the degree of scientific consensus about risks and remediation measures affect how and to what extent science influences decisions. Three of the potentially more significant situational variables are the age of the relevant public policy issue, the boundary-crossing implications of the science, and the bureaucratic realities of real-world pressures and demands on regulatory decision makers.

Conceptually, public policy issues can be thought of as passing through a four-stage lifecycle: identification, politicalization, legislation, and litigation (Figure 5). Science is apt to play different roles depending on the age (life-cyle stage) of the policy issue at hand. For example, in the identification stage, science usually provides a sense of the magnitude, scope, and uncertainty of the problem, while in the litigation stage, science primarily documents compliance or noncompliance with established guidelines, standards, and regulations.

Another factor of likely importance is the potential for science (or scientific consensus) to displace estimates of risk from one region of social acceptability to another (Figure 6) (*25*). Science can be thought of as having boundary-crossing implications when it could alter risk estimates in a way that makes them either more or less acceptable according to prevailing societal norms. For example, research might precipitate a change in an estimated risk such that it moves from

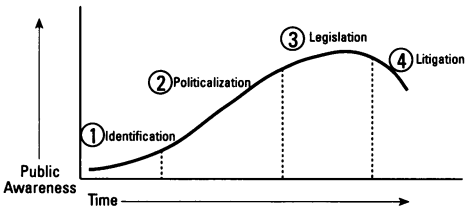


**Figure 5**. Simplified life cycle of a public policy issue.

being socially acceptable (e.g., probability less that one in a million) to being selectively unacceptable (e.g., probability greater that one in a million), or vice versa. Science with boundary-crossing implications is more likely to play a central role in regulatory decisions and, for that reason, to be more contentious.

Finally, as a practical matter, regulatory decision makers respond to the realities imposed on them by a complex and constantly changing environment (Figure 7*A*) (*26–29*). Among the more important factors that can affect their decisions are political pressures, statutory mandates, institutional constraints, scientific and technical issues, public perceptions, and special interests. The exigencies created by confrontations between these often conflicting forces have fostered an informal decision process that is, among other things, subjective, messy, uncertain, unstructured, intuitive, pressured, contentious, and chaotic (Figure 7*B*).

The people who staff and run this "adhocracy" tend to exhibit common bureaucratic tendencies, which can have significant ramifications for the final outcome;

- A tendency to make conservative decisions (err on the side of safety);
- A reluctance to change (subject to bureaucratic inertia);
- A tendency to seek/build consensus (credibility depends on consensus);
- A reliance on codified rules (prefer standard, published procedures);
- A tendency to delay decisions (don't decide until forced);
- A dislike of surprises (fear that revelations can only be bad);
- A tendency to act in self interest (consider impact on career); and
- A response to personalities (prefer working with certain people).

In a recent study (29) of the kinds of information that U.S. EPA decision makers want to have when making a decision, it was found that they wanted data on risk assessment issues such as numerical estimates of risk, magnitude of adverse effect, level of exposure, and confidence in data. In addition, they also want to have a sense of the bureaucratic context and possible institutional ramifications of their actions (or inactions). For example, they want to know the consequences of doing nothing; reactions of stakeholders to recommended options; costs and economic impacts; what has been done in previous, similar situations; and positions of other U.S. EPA offices and the Office of Management and Budget.

In the final analysis whether science is a force or has any effect at all depends to a large extent on this real-world calculus involving conflicting forces, informal and ad hoc decision processes, and bureaucratic tendencies of decision makers. Because the dynamics of these complex interactions are constantly changing, the role of science can vary dramatically from one situation to the next. Understanding when and why this is true is important for identifying ways to increase the utility of regulatory-related science in decision making.

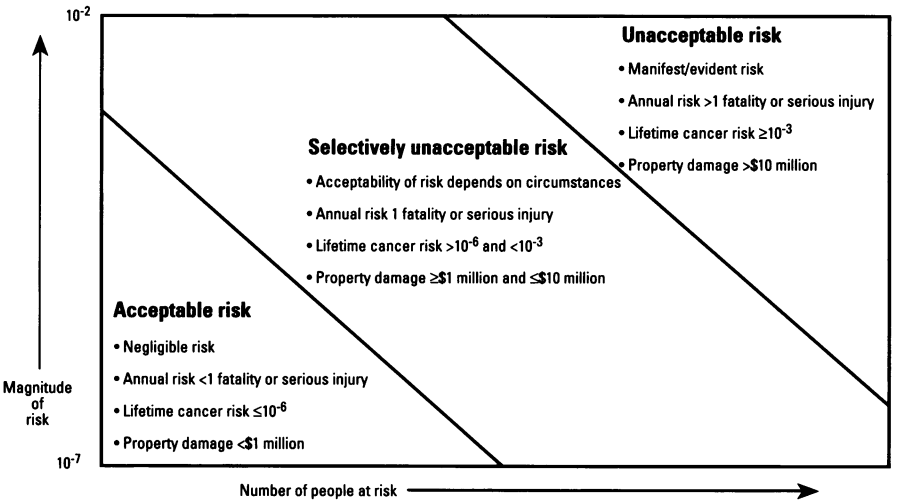


**Figure 6.** Conceptual framework for the boundaries between different levels of socially acceptable risk. Adapted from Kolluru (*25*).

## The Science and Policy of Hazardous Air Pollutants: A Case Study

The hazardous air pollutant provisions of the 1990 Clean Air Act Amendments offer an example of how politics can dominate the debate when there are inadequate facts about risks and benefits.

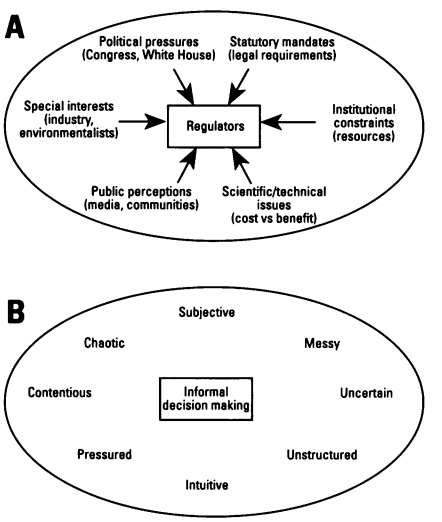


**Figure 7.** Schematic representation of (*A*) the diversity of forces affecting regulatory decision makers and (*B*) the informal, ad hoc process for making regulatory decisions.

### Practical Realities of Title III

With relatively little fanfare, the 1990 Clean Air Act Amendments (CAAA) were signed into law by President Bush on 15 November 1990 (*30*). The passage of the CAAA by the U.S. Congress involved intense and protracted negotiation over complex political issues and ultimately was dependent on political compromise among powerful members with diametrically opposed views, interests, and constituencies (*31,32*). The result is a complicated and detailed piece of legislation that combines

traditional approaches such as command-and-control with some new innovations like market-based incentives (*31–35*).

The CAAA provide a comprehensive regulatory framework for clean air. They take a primarily prescriptive approach and mandate an immense, technology-based, regulatory effort driven by tight deadlines for compliance. The 1990 regulations create new or modified programs to address acid rain, stratospheric and tropospheric ozone, vehicle emissions, and hazardous air pollutants as well as establish a uniform national permitting system. Eventually the requirements associated with implementation of the CAAA will affect virtually every industrial source in the United States and are expected to fill 6000 pages of U.S. code books, compared with 9000 pages for all other environmental codes combined (*34*).

Title III of the 1990 Clean Air Act Amendments addresses the issue of hazardous air pollutants from stationary and urban area sources. Hazardous air pollutants are those not defined as criteria pollutants under Title I. Among the more significant provisions of Title III are *a*) a list of 189 substances (and classes of substances) deemed to be hazardous air pollutants; *b*) requirements to identify and prioritize major sources of these chemicals; *c*) a mandate to apply maximum achievable control technology (MACT) to major sources over the next 10 years; *d*) specification that, subsequent to applying MACT, an analysis of residual risk must be performed to determine if further actions are needed to protect human health; *e*) establishment of an area source program aimed at reducing the incidence of cancer attributable to urban area sources by 75%; *f*) formation of a risk assessment and management commission composed of 10 scientific experts to examine how risk assessment and risk management are used to make decisions about clean air; and *g*) initiation of a National Academy of Sciences (NAS) study on risk assessment (*4*).

The political decision behind Title III is apparent: emissions of hazardous air pollutants pose a threat to public health that is sufficient to justify the costs of applying MACT. This suppostion is not founded on hard scientific evidence or rigorous cost–benefit analysis but rather on a political consensus that instead of waiting for a body count, it is prudent public policy to take regulatory action to reduce postulated, if highly uncertain, air pollution health risks. The approach taken in Title III, to apply MACT and then see if residual risks are unacceptable, reflects congressional frustration with what it perceives to be the slow pace of hazardous air pollutant regulation under the risk-based provisions of the 1977 Clean Air Act Amendments; only seven hazardous air pollutants were regulated prior to 1990.

In contrast to the political consensus that hazardous air emissions represent an unacceptable health risk, the scientific basis for estimating risks from outdoor exposure to hazardous air pollutants is fragmented and sparse. Preliminary estimates by U.S. EPA suggest that as many as 2500 cancer cases per year may result from outdoor exposure to 45 of the 189 hazardous air pollutants (*36*), although some researchers have criticized that estimate as being too high (*37*). In addition, it has also been suggested that noncancer health effects from outdoor exposure to hazardous air pollutants, including nonmalignant respiratory disease, hematopoietic abnormalities, neurotoxicity, renal toxicity, and reproductive and developmental toxicity, may be widespread. Approximately 50 million people live near emission sources where estimated ambient concentrations of one or more hazardous air pollutants exceed levels of concern for noncancer health effects in humans (*38*). Overall, however, a paucity of data exists to support accurate estimates of actual exposures, doses, and health consequences for either the general population or for communities potentially at greater risk.

The available data on the 189 hazardous air pollutants regulated under Title III are summarized in Figure 8. Based on an analysis conducted by U.S. EPA (*39*), adequate data are currently available on only a small percentage of these chemicals. For example, fair or better evidence exists to estimate emissions for only 17 substances, ambient concentrations for 43, noncancer health effects for 27, and carcinogenicity for 88. Inadequate data are on hand to estimate emissions for 137 substances, ambient concentrations for 112, noncancer effects for 149, and carcinogenicity for 81 (*39*).

Given the inadequacy of the scientific database, the resulting uncertainty about air pollution health risks, and the enormous costs of implementing the regulations, there has been surprisingly little criticism of the 1990 Clean Air Act Amendments in general and of Title III in particular (*33,34,40*). Currently, both critics and supporters of the amendments appear to see them as a significant step toward achieving the goal of clean air. As the costs become more apparent, however, the benefits of the CAAA will come under increasing scrutiny (*41–46*).

Insight into the regulators' perspective on the public health benefits of the CAAA is provided by the following quotes. Lydia Wegman, Deputy Director, Office of Air Quality Planning and Standards, Office of Air and Radiation, U.S. EPA, states that

> ...The [hazardous air pollutant] program will substantially decrease the number of cancer cases caused by air pollution, and it will reduce many other health effects. Consequently, medical costs associated with these effects will be substantially diminished (*47*).

Robert Brenner, Director, Office of Policy Analysis and Review, Office of Air and Radiation, U.S. EPA, said

> ...I'm confident that the act is going to be, if not fully implemented, virtually fully implemented....All significant emission reductions will be attained....55 billion pounds a year of emission reductions when the [Clean Air Act] is fully phased in after the year 2000. That is enough, we believe, to have a pretty dramatic effect on people's health (*34*).

According to Mary D. Nichols, Assistant Administrator, Office of Air and Radiation, U.S. EPA,

> Today is the third anniversary of the Clean Air Act Amendments of 1990. In the course of those 3 years, the Act has noticeably improved public health and the environment (M Nichols, personal communication).

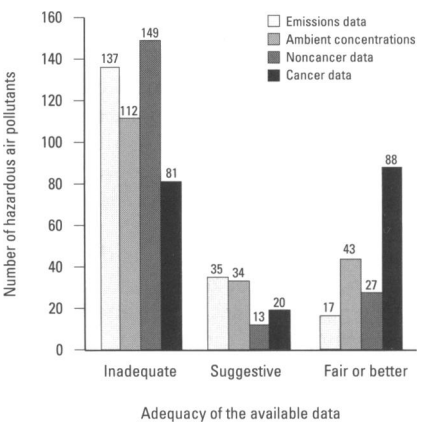


**Figure 8.** Summary of the adequacy of available data on 189 hazardous air pollutants. Adapted from U.S. EPA (*39*).

Despite the scarcity of data, these regulatory officials seem confident that improvements in public health have occurred already and that they will continue to acrue in the future from implementation of the CAAA. Their optimism appears to be based on the assumption that a direct relationship exists between regulatory actions and related emissions reductions and between emissions reductions and reduced health risks (Figure 9). Under this assumption, keeping score of the public health benefits is possible by tallying the number of major regulatory actions taken (Figure 9*B*), summing the estimated reduction in emissions related to these actions (Figure 9*A*), and then calculating the estimated decrease in cancer risk based on standard EPA approaches (Figure 9*C*). This assumption may, however, have no basis in fact and, without appropriate data, cannot be verified (*4,48,49*).

All this suggests that it would be difficult to argue that Title III of the 1990 Clean Air Act Amendments is science driven. The scientific information and understanding necessary to quantify the risks from outdoor exposure to hazardous air pollutants with a reasonable degree of certainty are simply unavailable in most cases. In their absence, adequate political concern and consensus among elected officials is sufficient to drive regulatory action. Although the public health benefits are uncertain, a political decision has been made to get on with the business of cleaning the air.

## Research in Support of More Informed and More Credible Decisions

Within this milieu, what is the role of scientific research in Title III? One way to think about this question is to envision a continuum of relevant research (Figure 10*A*) covering: *a*) routine testing and monitoring to meet statutory requirements; *b*) research aimed at reducing uncertainties in risk assessment; and *c*) research focusing on broad strategic issues. Keeping in mind that these three research directions are not mutually exclusive, characteristics generally associated with each are listed in Figure 10*B*. A combination of all three research approaches is necessary to establish a firm and credible foundation for informed decision making (Figure 10*C*).

Research to meet key statutory requirements is usually the top priority for regulators since theirs is the task of implementing the statutes. Typically, this type of work consists primarily of filling key data gaps by testing for cancer or noncancer effects

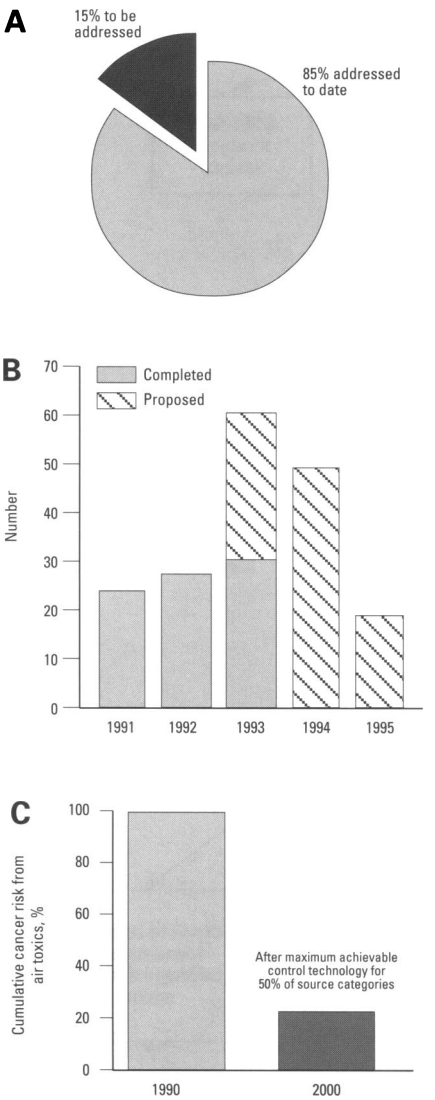


**Figure 9.** Summary of U.S. EPA perspective on the 1990 Clean Air Act Amendments: (*A*) air emissions reductions to date in billions of pounds per year; (*B*) number of major regulatory actions; and (*C*) effect of technology standards on cancer risks from stationary sources. (*A,B*) from U.S. EPA (*52*); (*C*) from Wegman (*47*).

in animals, measuring or estimating emissions, and monitoring ambient concentrations to determine compliance. This type of research is generally of short duration and the emphasis is on doing things right.

The need for research to reduce uncertainties in risk assessment is pervasive, long standing, and widely acknowledged (*3,4,15,16*). Without progress in this area, health-related benefits of risk reduction or prevention remain largely speculative. Quantitative risk assessment is impeded in most cases by two persistent problems; lack of data and lack of understanding. These problems contribute to uncertainty in risk assessments by causing errors in estimating important parameters accurately, in identification of relevant hazards or causal pathways, in specifying the functional form of models, and in extrapolating from one set of conditions to another. Research to address the first problem (lack of data) emphasizes improvement of the quality and quantity of the scientific database, while research to address the second problem develops and applies mechanistically based methods and models (*12,16*).

Research to address strategic issues examines whether we are asking the right questions and how science can be more effective in informing the debate. The emphasis is on doing the right things and typically requires a long-term commitment of resources. This type of research is important because it can challenge existing dogma, cause paradigm shifts, and create the need for new priorities and directions.

In a mature program such as Title III, late in its lifecycle as a public policy issue (Figure 5) regulatory emphasis is likely to be on research to meet statutory requirements. This may be tempered somewhat by the fact that Title III also has several provisions that seem to create an explicit need for research to reduce risk assessment uncertainties, including regulatory requirements to *a*) list or delist chemicals (Section 112(b)); *b*) prioritize source categories (Section 112(c)); *c*) delist source categories (Section 112(c)); *d*) establish regulations for modified sources (Section 112(g)); *e*) implement the urban area source program (Section 112(k)); *f*) promulgate standards to protect public health and the environment (Section 112(f)); and *g*) promulgate accidental release regulations and guidance (Section 112(r)) (*50*).

At this stage, regulatory enthusiasm for research to address broad, strategic questions appears to be minimal. Given the political consensus behind passage of the CAAA and the regulators' apparent confidence that the benefits are worth the costs, and considering inherent bureaucratic tendencies toward caution and inertia (Figure 7), there are few incentives for regulatory officials and policy makers to encourage this kind of research. For example, no comprehensive research program is in place to determine whether the list of 189 hazardous air pollutants in Title III is appropriate or relevant from a public health perspective or to evaluate whether risks from outdoor exposure to toxic air pollu-

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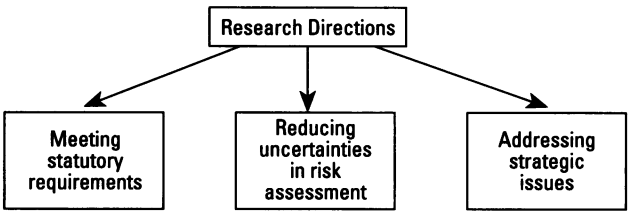


B

| | Addressing statutory questions | Addressig assessment questions | Addressing strategic questions |
|---|---|---|---|
| Goal: | Satisfy statutory requirements | Reduce uncertainties in risk assessment | Influence decision making |
| Focus: | Narrow | Intermediate | Broad |
| Approach: | Fill key data gaps | Develop mechanistically based models | Use science to ask and answer the right questions |
| Time frame: | Short-term | Combination of short- and long-term | Long-term |
| Emphasis: | Doing things right | More realistic risk assessments | Doing the right things |

C

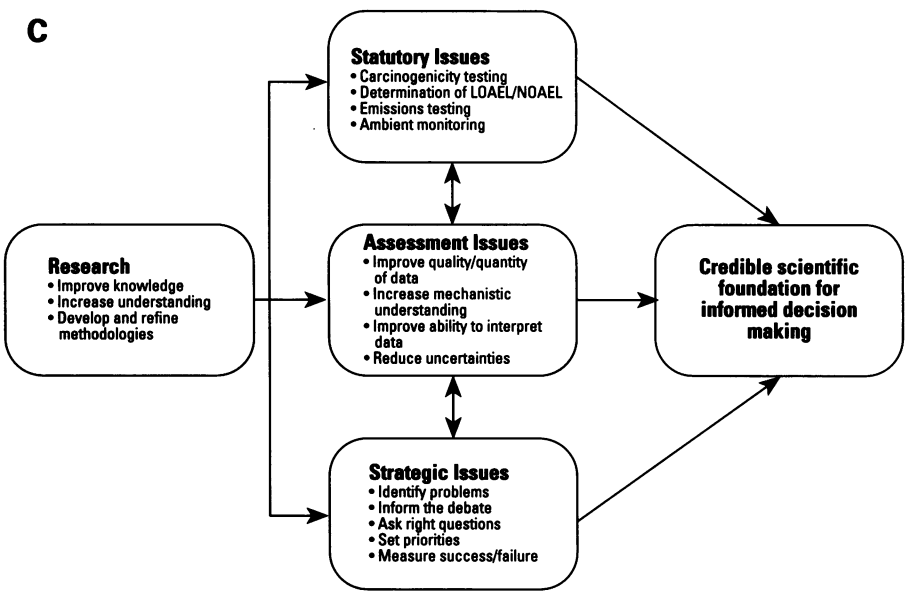


**Figure 10.** Conceptual framework for research to strengthen the scientific basis for Title III of the 1990 Clean Air Act Amendments: (*A*) directions, (*B*) characteristics, and (*C*) framework.

tants justify the costs of technology-based controls.

Research notwithstanding, the philosophy and approach to controlling hazardous air pollutants embodied in Title III may remain fixed well into the 21st century. As the costs of regulating scientifically uncertain health risks become better defined and more understood, questions of whether we are doing the right things become pivotal (*41–46*). Just because the political issues seem to be settled does not mean that we should walk away from the crucial scientific issues. By failing to address the critical strategic questions now, we ensure that in the future we will continue to lack a sufficient scientific foundation for determining whether we are doing the right things for the right reasons.

Developments outside or only peripherally related to the CAAA, including scientific and technical innovations, new developments in science–policy judgments, or changes in policy positions, could potentially disrupt the existing political consensus about hazardous air pollutants. Among the types of changes that might have significant ramifications for Title III are the following: the expanding technical capability and feasibility to measure biological markers of exposure, susceptibility, and dose in humans; advances in our understanding of the etiology of currently ill-defined and poorly understood chemical sensitivity syndromes such as multiple chemical sensitivity, sick building syndrome, and building-related illness; breakthroughs in our ability to measure or estimate the health effects of chemical mixtures; increasing emphasis on risk-based priority setting (addressing the worst risks first) to establish budgetary, regulatory, and research priorities; improvements in methods and models to determine total exposures to air pollution, thereby allowing us to apportion the contribution to exposure of various sources and pathways; and better information and understanding about the extent to which economically disadvantaged communities, including many ethnic and racial groups, are disproportionately at greater cumulative risk from air pollution exposures (e.g., issues of environmental justice).

## Summary and Conclusions

Facts and values are important building blocks of regulatory decisions. Regulatory decision making incorporates these elements into an interconnected series of overlapping phases—research (science), risk assessment (science policy), and risk management (policy). These three phases should form a feedback loop, with risk assessment and risk management driving research directions and research providing scientific knowledge and understanding as the basis for more credible and informed decisions.

Views about the utility of science in regulatory decision making cover a wide spectrum, from those who see science as central and decisive to those who believe it is marginal or insignificant. As a practical matter, science is one of several variables in a multifactorial decision process. Its utility varies according to certain key situational variables such as the age of the public policy issue, the boundary-crossing implications of the science, and the bureaucratic realities of regulatory decision making.

The hazardous air pollutant issue provides an illustration of political consensus about the need for regulation despite the lack of scientific evidence about risks and benefits. Hazardous air pollutants are regulated under Title III of the 1990 Clean Air Act Amendments in a two-stage process. First, technology-based standards to limit emissions are applied to important sources. Second, residual risk characterization is conducted after installation of maximum achievable control technology to determine whether further emission reductions are necessary. This regulatory approach is not based on hard scientific evidence of health risks or on rigorous cost–benefit analysis. Instead, the approach is based on a political decision by Congress that to wait for a body count before taking action would not be in the public interest.

Because political consensus, which is often tenuous, is not necessarily synonymous with scientific consensus, research should not be stymied by the politics of clean air. In the face of significant uncertainties about the public health benefits of Title III, a comprehensive research program should be undertaken to establish a solid, credible scientific basis for decision making. This would necessarily involve a balanced approach that includes research to meet statutory deadlines, to reduce uncertainties in risk assessment, and to answer key strategic questions.

Because strategic research has the potential to challenge dogma, shift paradigms, and reorder priorities, it may not engender much political and bureaucratic support. Nevertheless, the need for strategic research is getting stronger as concerns mount about the relative costs and benefits of regulating uncertain health risks. Informed, cost-effective protection of public health requires a blending and balancing of facts and values. If we are to get the facts right, investing in sound science is essential.

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