Summary, Issues and Options 1

Health risk assessment provides a systematic approach to evaluating and estimating risks to human life and well-being. Risk, as it pertains to the health effects of toxic substances, is the probability of injury, disease, or death for individuals or populations who undertake certain activities or are exposed to hazardous agents. It is sometimes expressed numerically (e.g., one excess cancer death in 1 million exposed people is termed a 10^{-6} risk of cancer). If quantification is not possible or necessary, risk may be expressed in qualitative terms such as low, medium, or high risk. Health risk assessment is a synthesis of the following four steps: hazard identification, dose-response analysis, exposure assessment, and risk characterization (figure l-l).

The primary sources of data for assessing risks to human health are from epidemiologic, toxicological, structure-activity relationship, and exposure studies. But those data are usually incomplete, failing to describe the risk from the exposure being considered. The incompleteness of the data requires the use of extrapolations to make predictions. Common extrapolations are from measured effects in people exposed to high concentrations of substance to the effects expected at lower exposures, from the results of animal tests to predictions of effects in humans, and from observations of effects from one route of exposure to estimates of effects from another route.

To perform those extrapolations, Federal agencies use assumptions or science policy choices to bridge gaps in data or knowledge. Because assumptions and policy positions contain value judgments and a substantial measure of scientific uncertainty, they are the main areas of controversy in risk assessment.

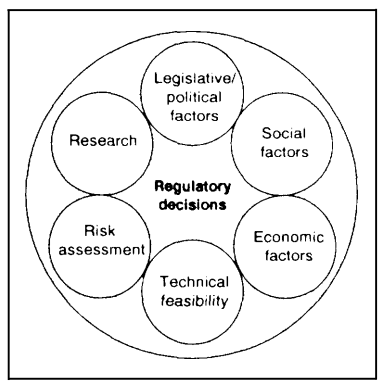
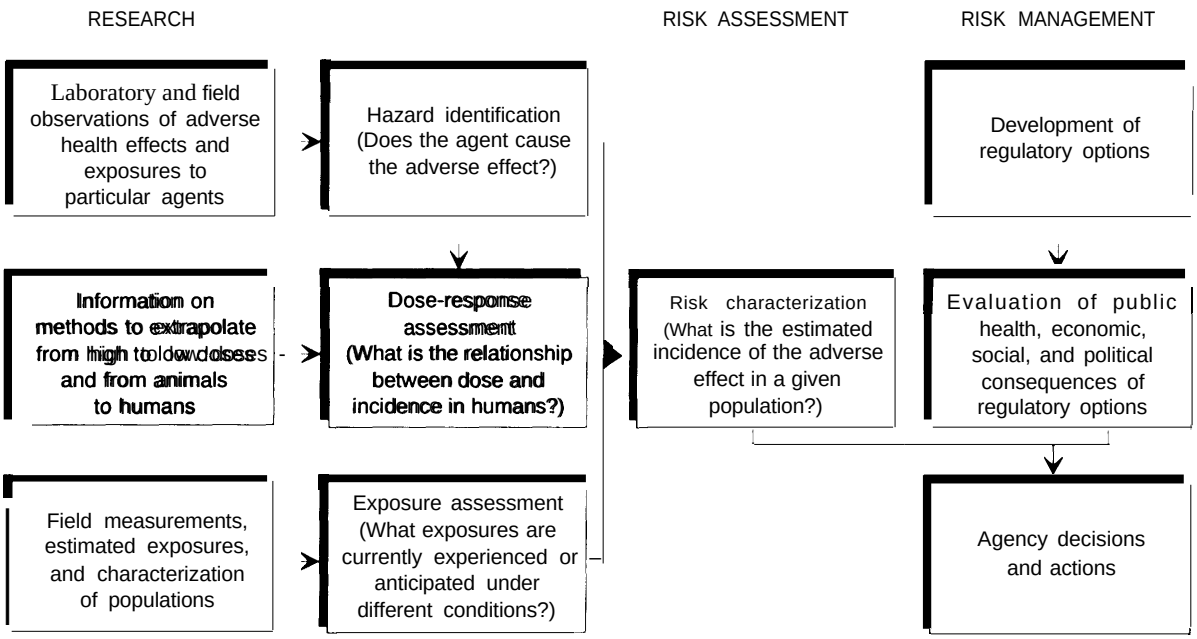


Figure I-I—Elements of Risk Assessment and Risk Management



SOURCE: National Research Council, *Risk* Assessment *in the Federal Government: Managing the Process, 1993.*

But, however uncertain the results of health risk assessments may be, they provide the foundation for health risk-based decisions (e.g., emission standards for incinerators). Those decisions affect expenditures for complying with regulations and medical expenses for exposure-related diseases that can total billions of dollars.

With so much at stake, it seems fitting to seize opportunities to use scientific research to narrow the scope of uncertainty in health risk assessment. In its landmark 1983 report, the National Research Council (NRC) concluded that improving the quality and comprehensiveness of knowledge is by far the most effective way to improve risk assessment. The decade following the publication of the NRC report saw impressive advances in the biological and biomedical sciences and provided regulatory agencies with considerable experience in conducting risk assessments and applying risk assessment methods. This report reviews Federal research efforts to harness those advances and experiences and develop abetter knowledge base for health risk assessment.

In this study, the Office of Technology Assessment (OTA) analyzed the nature and organization of federally supported research on health risk assessment and examined whether such research was adequately supported and managed. The first section of the report summmizes the results of the survey OTA conducted of Federal programs and identifies the resources, research priorities, trends, and gaps of current research in this area Subsequent sections describe the linkage of research to decisionmaking and the limits of research-based information in making social decisions, using management of the risks associated with radon exposure as a case study. A final section describes prospects for the future, including promising areas of research on risk assessment and factors to enhance the chances of success in the endeavor.

Table l-l-Categories of Health Risk Research

Methods Development

Method and model development-Developing tests and structure-activity analysis for identifying toxicants; developing models for predicting human exposures; developing methods for extrapolating effects, dose, and dose-response from laboratory study results to humans. Activities for method and model development include:

- Toxic effects identification and extrapolation
- Exposure extrapolations
- Dose-response extrapolations
- Uncertainty analysis

Methods *evacuation and validation--The* iterative process for validating new methods by comparisons to methods of known and established veracity. When validated, methods can be applied to risk assessments.

Basic Research

Toxicity mechanisms--Research to determine the nature, sequence, and combinations of events that result from exposure of test animals or humans to toxicants. This includes the study of the concentration of the toxicant or its metabolize that reaches the site **of action,** the rates and nature of the reactions with target organs or tissue that are causally linked to disease or the development of toxic effects, and an understanding of how the toxic effect comes about.

Biological and biomedical--Research on the structure and function of molecules, ceils, organs, physiological systems, and organisms. The resulting knowledge of comparative genetics, biochemistry, and physiology can be used to guide studies on toxicity mechanisms or reduce uncertainty in effects, dose, and **dose-response extrapolations.**

Chemical and physical sciences--Research on physical and chemical properties that govern absorption, distribution, fate, transport, and transformation in the environment and in biological systems.

Chemical-Specific Data Development

Toxic effects--Research designed to identify the toxic effects of agents and the nature of dose-response relationships under defined conditions of exposure. Activities include:

- Human studies
- Whole-animal studies
- Mammalian tissue, organ, and cellular studies
- Microorganism and other studies

Human exposure data--Measuring toxicant levels in different media or commodities and biological materials to test predictive models and to validate measurement methods.

SOURCE: Office of Technology Assessment, 1993.

HEALTH RISK ASSESSMENT RESEARCH AT FEDERAL AGENCIES

OTA surveyed Federal programs that conduct research on the toxicity of environmental pollutants, occupational toxicants, and toxic contaminants in food. It collected information through written requests for data, following up those requests with interviews of agency representatives and visits to agency laboratories.

Survey of Federal Research Activities

To narrow its range of inquiry, OTA restricts risk assessment research **to two types** of activities: 1) generalizable research to improve methods for assessing the risks of adverse health effects from food contaminants and environmental and workplace exposures, and 2) research to improve estimates of risks from exposure to specific agents. Because of the controversies that surround the methods for evaluating and estimating risks from exposure to agents suspected of causing cancer, this report frequently uses research to improve the assessment of risk from potential carcinogens to illustrate the directions and needs of research on health risk assessment in general.

Given that framework, OTA divided health risk assessment research into three key areas (table l-l). Two of the areas encompass more general research, and the third encompasses chemical-specific research. Methodological research, the first area, is specifically aimed at

improving the approaches and methods used for assessing risks. The second, basic research, contributes to an understanding of how environmental agents perturb normal biological functioning. The third category involves research that expands the database about specific chemicals for use in risk assessments. The results of all three types of research are crucial; inadequate development in any one area could impede progress toward the overarching objective of making risk assessment more credible and its results more widely accepted. For instance, the models developed in methodological research depend on the results of basic research and chemical-specific data development.

RESEARCH TO IMPROVE HEALTH RISK ASSESSMENT METHODS

OTA sees the goal of research on health risk methodology as development of better methods for extrapolating results: from animal models to humans, from high to low exposures, and from emission data to predictions of population or individual exposure. It also encompasses efforts to estimate uncertainty and develop new methods for toxicity testing. An important and often overlooked part of methods research is evaluating and validating the methods with experimental data.

Many scientists argue that methodological research holds the most immediate promise for substantive improvement of risk assessments. To begin with, generic methodology research, in contrast to chemical-specific studies, can have considerable impact on assessing the risks from exposure to many different chemicals and radiation. Moreover, when the methods are directed at the most uncertain aspects of risk assessments (extrapolations from high to low doses and from animal models to human populations and predicting the risk of chemicals for which few or no toxicity data exist), they can reduce the range of uncertainties in current risk assessment approaches. Because of a number of characteristics, methodological research falls in between basic and chemical-specific research, making it a bridge between basic and applied efforts. In other respects, however, this research is sufficiently unique that its practitioners refer to it as "risk science.

BASIC RESEARCH TO SUPPORT RISK ASSESSMENT

For the purposes of this report, basic research is separated into two types: basic health risk research and basic sciences research. Basic health risk research investigates the mechanisms of disease associated with exposure to toxic agents. These studies examine the fate and transport of chemicals and physical agents, the avenues of exposure, and interactions with living systems and biological tissues, all of which feed into health risk assessment research. The focus of basic health risk research on the application of results to risk assessment problems and opportunities sets it apart from the basic sciences.

Basic sciences research encompasses the basic biological and biomedical, chemical and physical sciences. Although some research in the basic sciences contributes to risk assessment research, basic sciences research is a very broad endeavor, and it is not included in OTA's analysis of relevant research. These studies examine the structure and function of molecules, cells, organs, and physiological systems and their relationship to the functioning organism, as well as the properties of chemicals and physical agents.

Of the three types of health risk assessment research, findings from basic research usually require the most time to be incorporated into decisionmaking. The research has also been generally characterized as having the lowest probability of success. Nevertheless, it can serve as the foundation for developing new methods in generating or applying primary data for health risk assessment and affect risk assessment in a far-reaching way, as it does other applications of science. Recently, techniques and findings from basic research have been rapidly incorporated into health risk research. Within the past several

years, for example, many molecular biological principles and techniques have proliferated throughout the field of toxicology.

CHEMICAL-SPECIFIC DATA DEVELOPMENT

Chemical-specific data development identifies the toxic effects of agents and characterizes dose-response relationships under defined conditions of exposure. Efforts to identify toxicants probably constitute the broadest and most diverse type of data development. Usually, they involve testing agents in laboratory animals, sometimes complemented by results from epidemiologic studies. This type of research also includes collecting data on exposure of humans to environmental agents. Some scientists dismiss the idea that collecting or gathering data using "routine" tests or monitoring methods is research. In contrast, the majority of scientists who advised OTA in the study and who reviewed drafts of this report voiced the opinion that such activities are properly classified as research. In OTA's evaluation of research funding, only two Federal agencies reported collection of exposure data as a research activity, but many included toxicity testing in research activities. The programs that carry out toxicity tests do more than provide the basic information for risk assessments, they also do research that leads to better tests and basic research on mechanisms of disease causation.

Resources and Priorities for Research

The Federal Government's support of research on health risk assessment extends from basic studies in the biological and biomedical sciences to toxicity testing and methods for extrapolating observations from one setting to another. That breadth was evident during OTA's attempts to evaluate the funding devoted to improving health risk assessments. Under the broadest definition of research that affects health risk assessment, a significant portion of the Federal Government's obligations in health research and development (R&D) generally can be considered as contributing to the effort.

OTA used the research objectives and the three categories of risk assessment research discussed above, which parallel the categories used by the executive branch,[1] as the framework for the analysis of the research funding. OTA's call for information from the various Federal agencies resulted in estimates of resources that were highly dependent on how the responder classified agency research activities. OTA concluded that reliable estimates of expenditures for health risk assessment research had not been obtained; nonetheless, OTA was able to discern some general trends and directions.

using Summary data issued between 1981 and 1991 from the National Toxicology Program (NTP) review of research related to toxicology as a surrogate for health risk R&D,[3] OTA determined that total support of health risk assessment research increased from $336 to $520 million, a 55 percent increase before adjusting for inflation. During the same period, Federal obligations for health R&D, as reported in the National Institutes of Health data book, increased from $5.0 to $10.7 billion, a 123 percent increase before adjusting for inflation (figure 1-2).

Using the above data, OTA estimated health risk R&D's share of total Federal health R&D dropped from 6.8 percent in 1981 to 4.9 percent in 1991. Moreover, this relative decline in health risk R&D took place during a period of expanding Federal legislation and responsibilities to protect

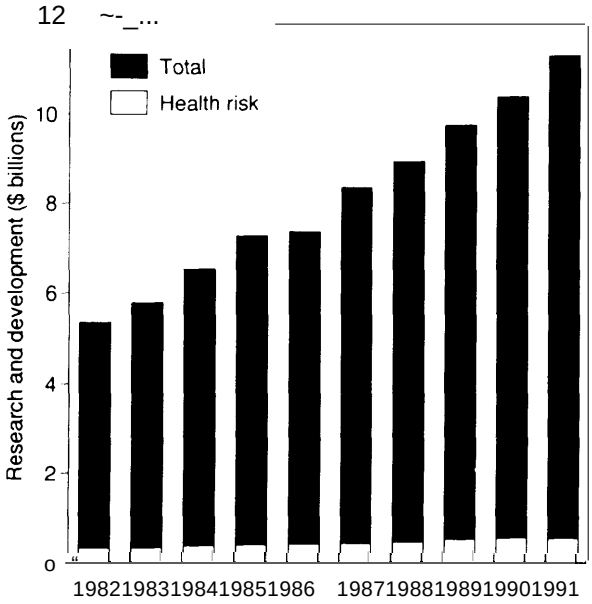
---

[1] The NTP Reviews of DHHS, DOE, and EPA Research Related to Toxicology compiles data 011 agency programs in the categories of Basic Toxicology Research, Toxicology Testing, and Toxicology Methods Development.

[2] The NTP review also includes human studies as research related to toxicology.

[3] OTA's survey in 1993 indicates health risk research is also carried out by the Department of Defense, Department of Agriculture, the consumer Product Safety Commission and Nuclear Regulatory Commission. NTP data did not cover resources for those agencies. However, their contributions are small relative to the agencies covered in the review.

Figure 1-2-Funding fo Federal Health Research and Development, Fiscal Years 1982-1991

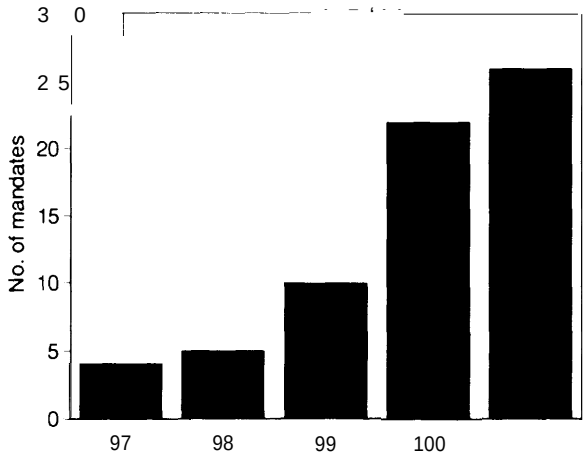


SOURCES: National Institute of Health Data Book, 1992; Review of Current DHHS, DOE and EPA Research Related to Toxicology, Fiscal Years 1982 through 1991, National Toxicology Program, U.S. Department of Health and Human Services.

human health from environmental pollutants. During that period, the number of environmental legislative mandates increased with each successive Congress-horn 4 in the 97th Congress (1981 and 1982) to 26 in the 101st Congress (1989 and 1990) (figure 1-3).

In addition the NTP data also illuminated trends in how the various agencies apportioned support and resources for methods development, basic toxicology, and testing (data development) (figure 1-4). In general, over the 1980-92 period, research agencies such as the National Institute of Environmental Health Sciences (NIEHS) and the National Cancer Institute increased the percentage of basic toxicological research that they conducted. In contrast, regulatory agencies such as EPA and the Food and Drug Administration (FDA) devoted a larger proportion of their health R&D to methods research than did the research institutes.

Figure I-3-Environmental Legislative Mandates



SOURCE: Office of Technology Assessment, 1993.

The personnel figures, in full-time equivalents (FTEs), devoted to this research reflect the size of the intramural program. In general, the regulatory agencies have sizeable intramural programs compared to their R&D budgets, while the research agencies support relatively larger extramural programs. For example, these data show that NIEHS devotes the most resources, in both dollars and FTEs, to health risk research. EPA, in contrast, has FTEs nearly equivalent to NIEHS, but only about one-third of the R&D budget.

Based on fiscal year 1993 estimates in the OTA survey of research (table 1-2), less than 11 percent ($65 million) of the total R&D budget of $600 million for environmental and occupational health and food safety is devoted to research on methods. It is possible only to estimate roughly the total amount that was actually spent on methods research during the period, because of the difficulties in categorizing the research. Nevertheless, the small size of the risk research analysis programs at the National Center for Toxicological Research of FDA and the National Institute of Environmental Health Sciences, and the reported part-time participation of researchers at the regulatory agencies, support a conclusion that methodological research is underfunded.

Table 1-2—Health Risk Research and Development Estimates, 1993 **(In millions of dollars)**

Agency	Health risk research*		Agency total: health or biomedical research**
	Total	Methods	
National Institute of Environmental Health Sciences.	129.0	14,0	251.2
Department of Energy	10.0[a]	3.0[a]	90.0"
Department of Defense	19.6	2 . 5[b]	300,0'
U.S. Department of Agriculture . . . . . .,	11.5	0.5	11 .5[nd]
Agency for Toxic Substances and Disease Registry	16.9	0.0	16.9[nd]
Environmental Protection Agency	32.0	21.3[d]	49.0[e]
Food and Drug Administration (other than NCTR)	13.0[a]	3.5a	1 3 .[nd]
National Center for Toxicological Research	33.6	7.6	38.9*
National Institute for Occupational Safety and Health.	49.0	6.1	49.0*
National Cancer Institute ., ...	82.0[a]	4.4[a]	1,981.4
Other NIH	140.oa	2.2[a]	6,929.9
Alcohol, Drug Abuse, and Mental Health Administration . .	64.0[a]	0.0[a]	1,164.1
Total	600.6	65.1	10,894.5

a Estimat,based on agency's 1992 funding for research on toxicology as reported in the National Toxicology Program Review of current DHHS, DOE, and EPA Research Related to Toxicology, Fiscal Year 1992.
b Calculated as 13 percent of agency R&D for health.
c Steinberg, 1993. *Journal of NIH Research* 5:35. Data on biomedical research, which excludes $210 million for breast cancer research.
d Research t. Improve Health Risk Assessment program estimated to be $5 million; $21.3 million is sum of funding for human exposure, health effects, and risk assessment methods.
e Figure represents Health Effects Research Laboratory total budget: EPA-wide data are not available.
nd No data (research related to toxicology was used).
● Based on data from the OTA survey of agency resources.
● "U.S. Congress, CRS, 1993. Research and development funding; fiscal year 1993; issue brief (IB2062).

SOURCE: Office of Technology Assessment, 1993.

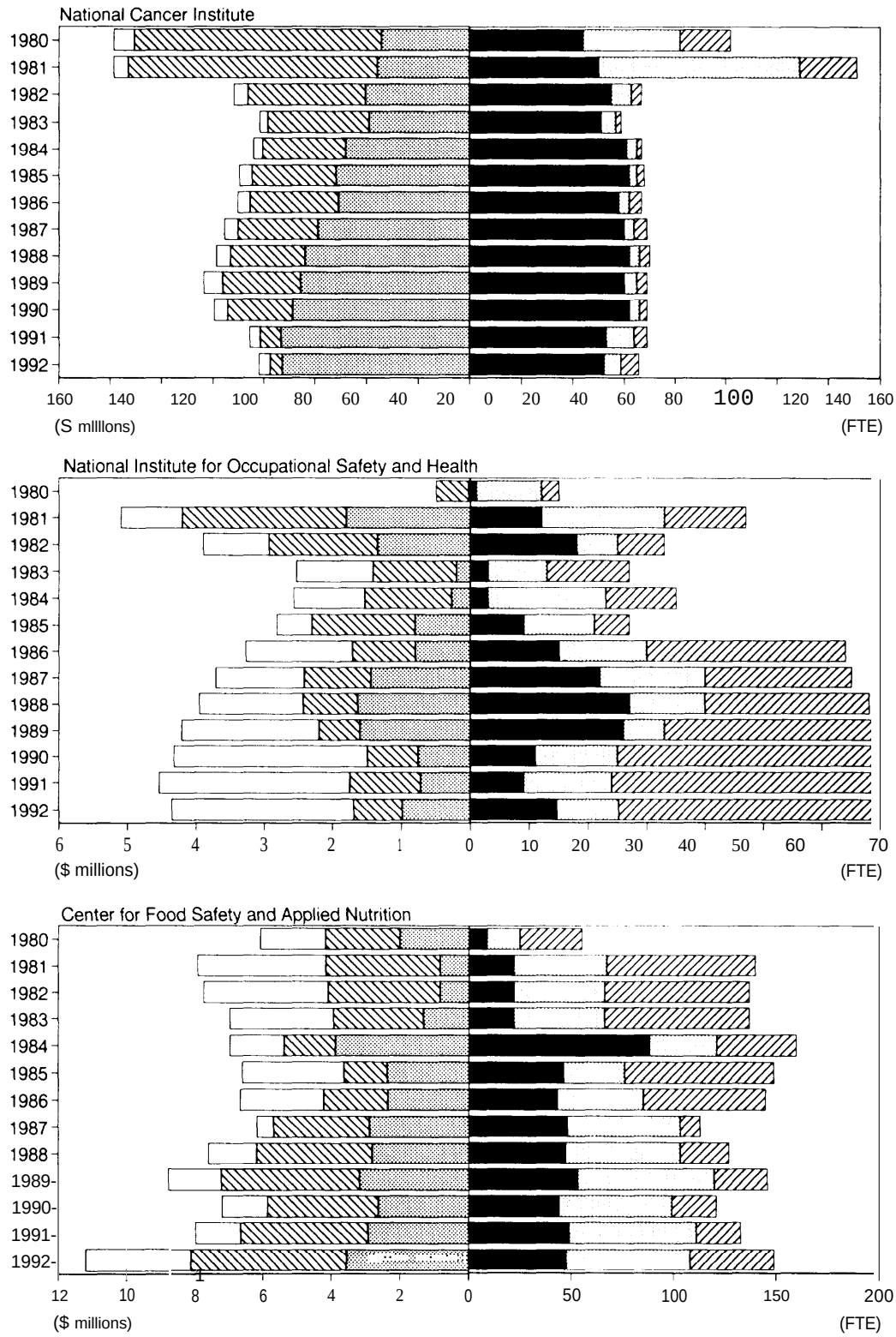
As would be expected for activities as broad as risk assessment research, some fields of inquiry have received more funds, some fewer. However, environmental health research funding has neither kept up with the increase in health research nor increases in environmental mandates that depends on that research for decisionmaking. Methodological research, in particular, seems inadequately supported, despite the most immediate promise that OTA sees for this research to improve risk assessment.

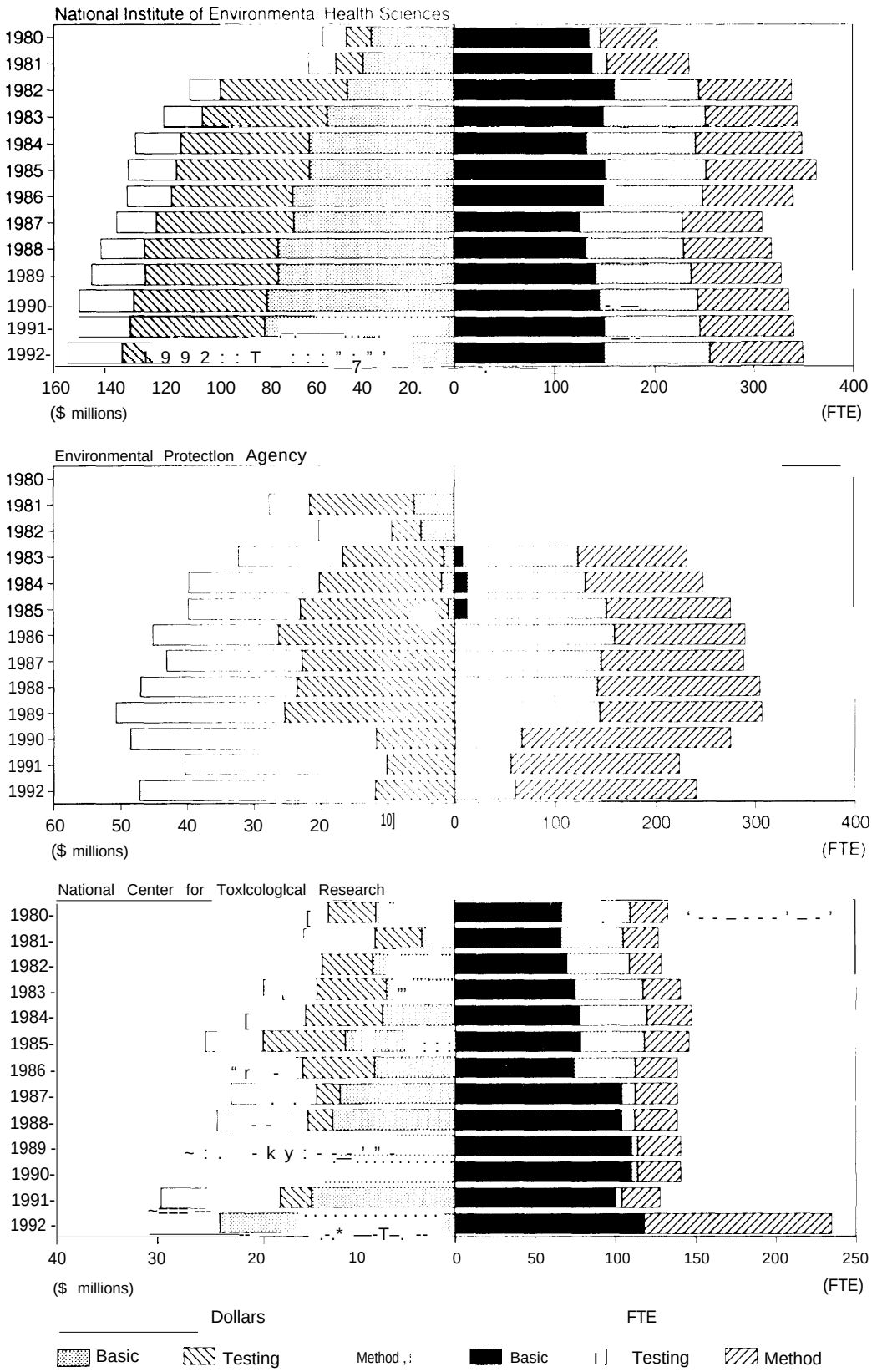
Setting Priorities for Research

Charting a course for improving risk assessment research requires Federal agencies to work at several organizational levels. OTA examined the priority-setting process for such research at three different levels: national, agency, and program. Each level uses different processes and methods. OTA's analysis indicated that priority-setting at the program level uses the most formalized, systematic processes; the national level, the least. In addition, OTA identified various factors that influenced the choice of one type of research over another.

National priorities for research, based on national needs and goals, are influenced by prevailing economic, social, and political conditions. Federal research to improve risk assessment is largely decentralized and uncoordinated. The work of Federal researchers is almost entirely in support of the agencies and departments that sponsor the research. Except for the NTP, which sets priorities for toxicity testing, OTA observed few national priority setting efforts. One of those is the Federal Coordinating Council on Science, Engineering, and Technology (FCCSET), an interagency body within the Executive Office of the President (EOP). However, participants and nonparticipants alike displayed little enthusiasm for or optimism about the recent FCCSET process as it relates to risk assessment or risk assessment

Figure 1-4--Federal Research Related to Chemical Toxicology, 1980-1992
(In millions of dollars and full-time equivalents)





SOURCE: ***Review*** *of Current DHHS, DOE and EPA* **Research** *Related to Toxicology,* Fiscal Years 1980 through 1992, National Toxicology Program, U.S. Department of Health and Human Services.

research. In any case, the Clinton Administration plans on eliminating FCCSET and creating a National Science and Technology Council.

The priorities for risk assessment research vary with the mission and function of an agency—especially whether or not the agency's responsibilities include risk management. The research conducted by the regulatory agencies, and the Departments of Defense and Energy, is mostly chemical-specific data development; the research agencies, by and large, conduct basic research.

Setting priorities at the program level is generalIy a more developed—that is, both a more systematic and a more formal-process than priority-setting at the agency or national levels. One of two distinct types of management methods is used to determine priorities for individual research projects. The style termed ''bottom up' depends on researchers to develop research ideas and priorities and to communicate those ideas and requests for research support to their superiors or to grant managers. In contrast, ' 'top-down' management has the most senior decisionmakers in an agency deciding the priorities for research. OTA observed both styles of management used separately or in combination in its survey of risk assessment research. In general, research priorities for programs at the regulatory agencies are more frequently decided by top-down management, whereas program priorities at the research agencies are determined through a bottom-up process. EPA and DOE have used a combination of these styles in managing their research programs.

Trends and Gaps

Over the course of this study, OTA observed several major trends in Federal research activities that support health risk assessment. To begin with, agencies are expanding their research horizons to include not only cancer but other adverse effects on health. Many scientists interviewed by OTA expressed the belief that research on health effects other than cancer has the potential to influence regulatory policy significantly. But they also believe that the current science base is not sufficient for adequate assessments of noncarcinogenic health effects. One reason that such research may have a great impact on policy is that health risk issues about noncarcinogens do not usually lead to the acrimonious policy debates associated with carcinogens.

Many agency research programs, along with expanding the breadth of their research, have been restructuring. In most of those cases, the restructuring reflects a greater emphasis on social relevance. As agencies link their research activities more closely to social needs, their research becomes, by necessity, increasingly multidisciplinary. No one field of academic training or research encompasses all aspects of health risk research, which ranges from basic biomedical research to computer modeling. The increasing complexities of the science involved and the need to incorporate more science into rulemaking have made it clear that multidisciplinary research is required to provide the requisite scientific underpinning for future risk assessments.

Yet overall, few incentives exist for long-term multiagency, multidisciplinary research on health risks, and very few resources are allocated to this work. Scientists from all of the environmental health disciplines, such as toxicology, epidemiology, biostatistics, environmental chemistry, and clinical studies, make contributions to health risk assessments and are the mainstay of agency research to improve the risk assessment process. Nonetheless, those fields remain disparate, and collaborative studies remain the exception rather than the rule.

Without more incentive to collaborate, disciplinary myopia may continue and grow more pronounced and entrenched. Compartmentalization by agency or discipline can only hinder progress and retard the infusion into risk assessment research of newly developed techniques and knowledge arising out of the rapid advances now occurring in the biomedical sciences. Ironically,

dwindling agency resources may actually be spurring some collaboration: evidence indicates that decreasing budgets have catalyzed some interaction as the need for cooperation becomes apparent. Setting aside turf battles, Federal agencies are beginning piecemeal approaches to promoting multiagency, multidisciplinary research.

Today, Federal Government risk assessment research support is spread out across at least 12 different agencies. That dispersion has both positive and negative consequences. On the one hand, agencies can monitor their agency-specific research without having to overcome additional hurdles, and they can target their activities to the areas they consider of highest priority. On the other hand, work is fragmented and diffuse. Those characteristics may hinder progress with risk assessment problems that are common to several agencies.

OTA finds a particular lack of emphasis on collaborative research to evaluate and validate new methods and models, especially in the important area of corroborating experimental results from animal studies with studies in humans. Admittedly, this is a most difficult undertaking, but it is critical to elevating the level of confidence to be accorded to risk assessment results. OTA also found little research under way to examine or attempt to validate extrapolation models for general use or for use with specific chemicals.

The basic building block for much of the critical research-chemical-specific toxic effects data—is generally obtainable, although the Federal Government supports fewer toxicology tests than in years past. The number of tests carried out by industry is uncertain. Regardless of the number of tests, what is missing is funding for studies to use those data in combination with expanding knowledge in toxicity mechanisms and biomedical sciences to examine various extrapolation models in order to learn which models are more predictive. With additional resources, Federal agencies could conduct those bridging studies. For instance, the Federal Government has collected toxicity information in response to mandates for registering or approving drugs and pesticides. Both animal and human data have been collected in those efforts, and they could be used in attempts to evaluate and validate existing models as well as develop new ones. However, such research requires better collaboration between and among agencies and research disciplines. Although it remains to be seen how much such analyses would cost, gathering of data is typically the largest cost, and that has already been accomplished.

The past decade has witnessed nearly revolutionary developments in the biological sciences. Researchers are poised to use those advances to improve health risk assessments. Yet despite the potential for progress, the present Federal risk assessment R&D infrastructure maybe an impediment to moving forward. Many scientists interviewed by OTA claim that the research system is "broke." Resources, they argue, are squandered on a system that is incapable of setting priorities. Consequently, the perception exists that the areas of research of highest priority-those most likely to improve risk assessment approaches—are not being funded or studied, to the benefit of lower priority or even irrelevant research. Even the $65 million spent on methods research may not be targeted correctly. Instead, according to some scientists, there is a tendency to fund projects that may yield improvements on current methods but that are unlikely to open new avenues of research or application.

The absence of an identified central leader in risk assessment research contributes to the pessimistic viewpoint and to the current level of funding and disciplinary and agency fragmentation in the effort to improve health risk assessments. A nationally recognized leader could provide leadership and assurances about political support for research, promote multiagency collaborations, and provide incentives for overcoming bureaucratic hurdles and turf battles. A national leader in the White House in a position equivalent to the "Drug Czar" or "AIDS Czar,"

could bring national visibility and unify and coordinate research activities across agencies, in addition to articulating the needs of the field to Congress and the President. Furthermore, this central figure could instill a sense of common purpose among researchers and program managers.

LINKING HEALTH RISK RESEARCH TO DECISIONMAKING

The complex relationship between research and decisionmaking demonstrated in figure 1-5 deviates from the conventional representation of a unidirectional flow of information from risk assessment to risk management. It is, however, a reasonable evolution of the conventional model put forward in a 1983 report by the National Research Council. Part of the reason for the unidirectional information flow was the desirability of the compartmentalization of the risk assessment process from risk management. In the 10 years since the publication of the report, the importance of information sharing to increase the efficiency of research for decisionmaking has become apparent. Thus, OTA's figure highlights the bidirectional flow of information as well as the integration of the various disciplines and types of research. In addition, it shows that evaluating and validating methods can be the focal point for integrating different lines of health risk research, since anew model or method should be examined and compared with methods of known and established veracity. The figure also indicates OTA's stress on the interdependency of research activities, the risk assessment process, and policymaking.

Moreover, the interdependence of health risk research and decisionmaking limits the capacity of agencies to structure long-term solutions to problems posed by toxic substances. As research identifies potentially adverse health effects of an agent, the public conveys its concern to Congress, and Congress considers and passes laws to address those concerns. By necessity, agencies' addressing those more immediate concerns restricts their opportunities to continue research to decrease the reliance on science policy assumptions in risk assessments.

The Impact of Research

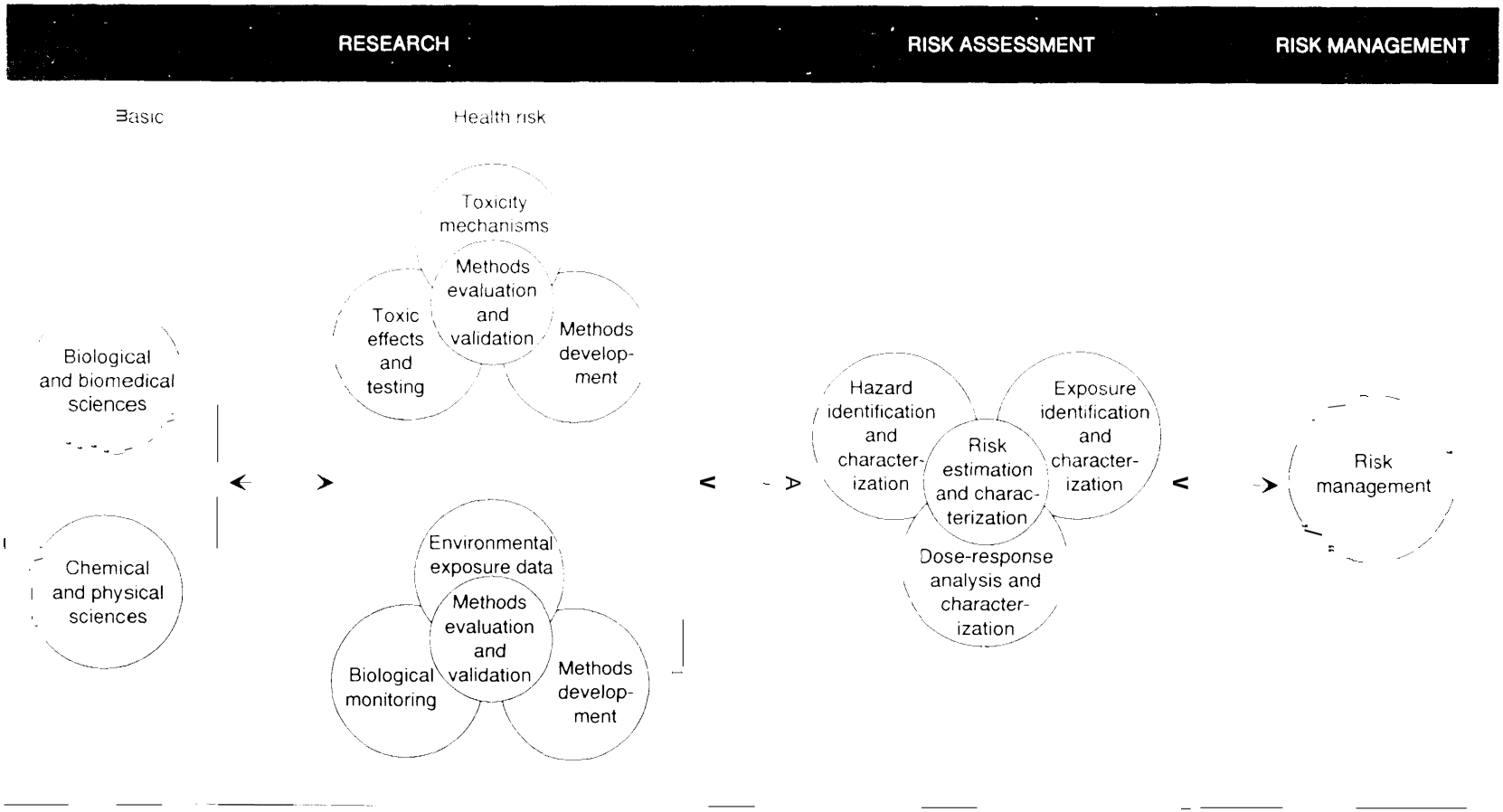
Science and policymaking are uneasy partners. Nevertheless, the primary criterion for health risk assessment research is that it be useful for decisionmaking. OTA examined three questions about the relationship of research to decisionmaking:

1. How has research influenced Federal risk assessment guidelines and risk assessment practices?
2. What impact has research had on decisionmaking?
3. How can research be designed to make risk assessment more useful in decisionmaking?

To answer those questions, OTA reviewed the evolution of Federal risk assessment guidelines and risk assessment practices and some of the comments and criticisms made about them.

Research findings from many scientific fields provide the basic data for health risk assessment. But those data are never extensive enough for answering questions about exposure, effect, and the people who are likely to be affected. Agencies frequently confront questions that science cannot answer, and in order to make decisions they have adopted so-called science policy assumptions to bridge the gaps in the available information. The assumptions have some grounding in science-they don't contradict accepted scientific conclusions and opinions at the time they are adopted—but they necessarily incorporate other ideas that are based on policy rather than science. For instance, choosing the risks of the maximally-exposed individuals as a basis for regulatory decision is a policy decision, as is the decision to include 24-hours/day exposure for 70 years in calculating maximum exposure. Those decisions

Figure 5—Linking Research on Health Risks to Decisionmaking



SOURCE: Office of Technology Assessment, 1993.

can be set aside, but as matters of policy, not science.

The assumptions that are used in health risk assessments can be divided into two general types: those that bridge gaps in scientific knowledge and those that compensate for a lack of agent-specific data.

After reviewing the evolution of EPA's risk assessment guidelines, OTA concluded that research has had only a modest effect on the agency's efforts to revise the science policy assumptions adopted in its risk assessment guidelines. The controversary generated by EPA's current efforts to revise its 1986 cancer risk assessment guidelines underlines the importance of policy-based decisions. Research has, however, had a substantial impact on chemical-specific risk assessments and consequently on regulatory actions,

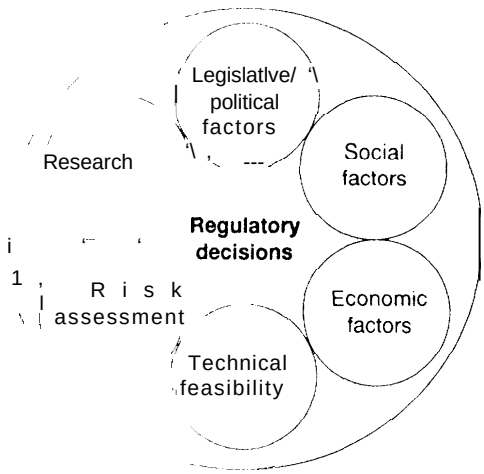
Three interacting factors account for the limited impact of new scientific research on EPA's science policy assumptions: the nature of the assumptions, the importance of the assumptions to regulatory approaches, and the policy reverberation from changing specific default assumptions.

The Limits of Science

Whatever is expected of risk assessment in any given circumstance, it is only one of the elements in formulating regulatory actions. Legislative mandates, social values, technical feasibility, and economic factors may take a more prominent role than expert assessments of risk (figure ***1-6).***

The limits of science are manifest at different levels. Uncertainty in measurements and observations constrains science at the most fundamental level, and the scientific underpinnings of risk assessment are more subject to those limitations than the experimental sciences. At a higher level of complexity, the interpretation of data and observations to predict outcomes introduces other unknowns. And risk management actions can themselves produce uncertainty. Solving the problems in health risk assessment goes beyond more and better science; it also requires building trust among government, industry, and citizens.

Figure 1-6-Research as an Element of Decisionmaking



SOURCE: Off Ice of Technology Assessment, 1993.

Radon as a Case Study of Research and Decisionmaking

The controversy developed around EPA's proposed regulation of radon in drinking water illustrates some of the interplay between science and decisionmaking. When radon gas, which originates in the Earth's crust, is emitted into an open space such as outdoor air, it is rapidly diluted to the low "background" or "outside" levels found around the world. But when it is emitted into a home, a school, or another type of building, dilution is slower. As a result, the concentrations of radon inside structures are usually higher than the concentrations outside. These higher levels raise concerns about health because studies have revealed higher rates of lung cancer among miners and other workers exposed to radon on the job than are found in the general public. (All estimates of risk from indoor radon are based on extrapolations from the results of studies of miners.)

Responding to those concerns, Congress and EPA have considered ways to reduce the risks posed by indoor radon. Most indoor radon enters buildings directly from the soil, and efforts to lessen those exposures have included EPA programs to inform homeowners about the risks from radon and about methods to reduce radon inflow into buildings. The private sector has also acted on the problem by imposing requirements for measuring and, if it is deemed necessary, reducing indoor radon as a condition in real estate contracts in some localities.

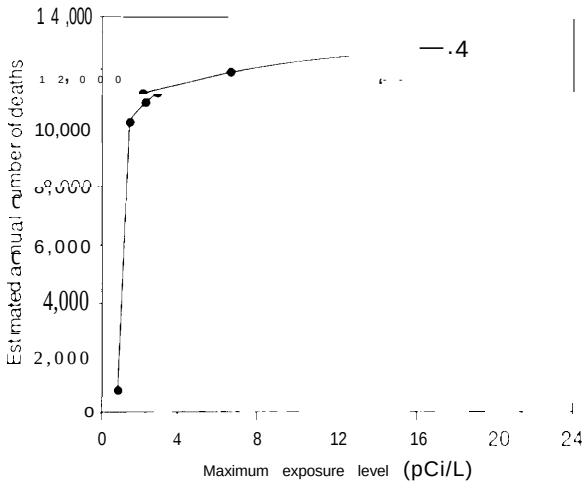
EPA cannot, of course, regulate radon from the soil because radon from that source enters homes directly, without passing through any entity that can be regulated. Some radon, however, enters buildings through the water supply, and the agency can regulate radon in water just as it regulates other contaminants under the Safe Drinking Water Act (P.L. 93-523 and P.L. 99-339).

Some Members of Congress, including the Chairman of the House Committee on Science, Space, and Technology, asked OTA to examine an ''inconsistency'' in EPA's approach to radon. That request arrived at OTA after this study to examine health risk assessment research was in progress. OTA officials decided to include the office's response to the request as a case study in this report.

REGULATORY APPROACHES

EPA divides its regulatory programs along media lines: air, water, industrial wastes, and so forth. It has approached the issue of indoor radon as a media problem, and has different policies toward radon entering buildings directly from the soil and through water. The agency has not proposed regulating radon emitted directly from the soil, but it has proposed regulating water suppliers. Some scientists, Members of Congress, and other policymakers have recognized that indoor radon is only a single part of the larger issue of indoor air pollution. The question of risks to health from indoor exposures presents assessment, remediation, and regulatory difficulties that differ from those associated with pollutants in outside air.

Figure 1-7—Estimates of Deaths From Lung Cancer at Different Levels of Radon Exposure

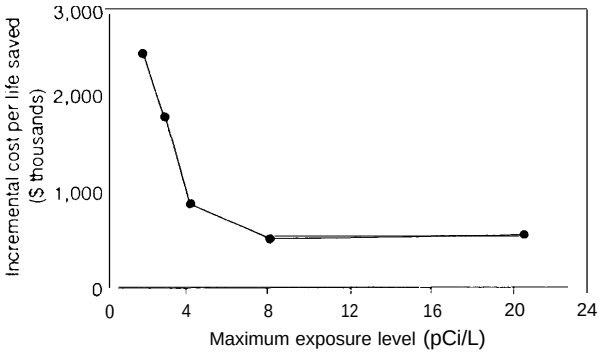


SOURCES: Office of Technology Assessment, 1993, based on Environmental Protection Agency, 1992. Technical Support Document for the 1992 Citizen's Guide to Radon. M. Reimer, U.S. Geological Survey.

Air—Based on its National Residential Radon Survey, EPA estimates that about 5.8 million homes (6 percent of all U.S. homes) have concentrations of radon in air above 4 pico curies per liter (pCi/L), the level at which EPA would recommend remedial action. The agency estimates that the average home has a concentration of around 1.25 pCi/L.

As figure 1-7 shows, the bulk of cancers that are associated with exposures to radon occur in the population exposed to low levels, below 2 pCi/L. The primary reason is that many more people are exposed to those levels than to higher levels, Given EPA's conclusion that it is impossible to reduce levels below 2 pCi/L in some houses, the practical lower limit on the number of deaths associated with radon may be as high as 10,500. That estimate is based on extrapolations from studies of miners who were exposed to radon. Refining those extrapolations might re-

Figure 1-8-Cost-Effectiveness of Different Action Levels for Reducing Indoor Radon Exposures



SOURCE: Office of Technology Assessment, 1993.

duce or increase the estimate of the number of cancers.

Because radon is present in all air, both inside and outside, it is impossible to have zero exposure to radon. Thus, some risk of death from radon-associated lung cancer is always present, if one assumes that there is no threshold for radon-associated lung cancer deaths. Exposures to radon in outside air is estimated to be associated with about 500 deaths from lung cancer annually.

EPA's ***Technical Support Document for the 1992 Citizen's Guide to Radon*** provides the agency's reasoning behind choosing 4 pCi/L as the level at which homeowners should obtain more information about exposure and take steps to bring the level of radon in their homes below that concentration. But because EPA does not regulate radon in air, the Federal Government is not required to provide an administrative forum to debate whether the projected benefits of reaching 4 pCi/L of radon justified the associated costs. Figure 1-8 summarizes EPA's cost-effectiveness analysis for reducing concentrations of indoor radon to various levels. Reducing exposures to 8 pCi/L is expected to save lives at a cost of less than $0.5 million per life; the cost per life saved just about doubles (to a little less than $1.0 million) at 4 pCi/L and increases further at lower action levels.

Water—The Safe Drinking Water Act (SDWA) Amendments of 1986 require EPA to develop regulations for toxic chemicals in water. The agency has decided to regulate radon like any other waterborne carcinogen; it calculates that radon in water is associated with 30 to 600 cancer deaths a year. That single radioactive element accounts for most of the total risk from radiation in water, and the upper bound on its risk exceeds the total risk from all chemicals in water (table 1-3). The regulatory process can be considered in two time periods. Before the summer of 1992, EPA was developing the regulation under its usual procedures, but at that time Congress intervened in the process and mandated that EPA reassess its estimates of risks and costs in relation to radon in water and imposed a one-year moratorium on any regulation of radon in water.

The SDWA imposes a goal of zero for concentrations of carcinogens in water, which is unattainable for radon. Extensive aeration of radon-bearing water would discharge the radon into the air, but there would always be radon at least at the concentration found in outside air. EPA determined that the lowest "practical quantification level" for radon in water was 150 pCi/L, and in 1991 it set the regulatory maximum contaminant level at that value in its proposed rule. Because of the decay of radon over time, the "quantification level" translates to a concentration of 300 pCi/L. Differences in the procedures for measuring radon in air and water account for the fact that measurements of 2 pCi/L or less of radon in air are routinely obtained, whereas EPA contends that measurements below 150 pCi/L in water are not practical.

Scientists generally agree that 10,000 pCi/L of radon in groundwater results in 1 pCi/L of radon in air from volatilization. Therefore, if the 300 pCi/L limit on radon in water were imposed, it would mean that no more than 0.03 pCi/L of radon in indoor air would result from the waterborne radon. That concentration is 10 percent or less of the radon in outdoor air, and it would contribute about 5 percent to total indoor expo-

Table 1-3-Cancer Risks From Water

Source of risk	Estimated annual cancer mortality
Radiation in drinking water	37 to 730'
All chemicals in drinking water.	215 to 430

a her EPA estimates vary within this range.

SOURCES: Office of Technology Assessment, 1993, based on M. Gough, 1989. Estimating cancer mortality. *Environmental Science and Technology* 23 S25-930, based on USEPA. 1987. Unfinished Business. Washington, DC: USEPA.

sures. EPA has carefully examined such things as how much radon is released into the air from water during showering, laundering, and flushing the toilet in order to estimate the contribution of radon from water to indoor air.

"Inconsistency" in EPA's Approach to Radon

The letter that requested this OTA examination of indoor radon cited the concerns expressed in 1992 by EPA's Science Advisory Board about inconsistencies in the agency's approach to reducing risks from radon. It contrasted the goals of the Indoor Radon Abatement Act (IRAA) with EPA's action level for indoor radon and its proposed level for regulating radon in water under SDWA. The IRAA goal is to bring indoor radon levels down to those commonly found outdoors (0.1 to 0.5 pCi/L). EPA, however, urges that remediation be undertaken to reduce concentrations of radon in homes to 4 pCi/L or less and acknowledges that it is infeasible to reduce concentrations below 2 pCi/L in some homes. In contrast, EPA's proposed regulation under SDWA would set 300 pCi/L radon in drinking water as the highest permitted level, limiting radon in indoor air to 0.03 pCi/L from this source. Clearly, the goal, the action level, and the proposed regulation set different exposures as acceptable levels of risk (box l-A).

These inconsistencies are not surprising, given the way that the goal, the action level, and the regulation were derived. Congress in the IRAA acknowledged that the level of radon in outdoor air is unavoidable and that concentrations cannot be reduced below it. At the same time, it maintained that reducing concentrations indoors to that level would be as protective of health as possible.

EPA, in setting the 4 pCi/L action level for indoor radon, accepted a risk of cancer from radon that is far higher than the 1 X 10^{-6} (one excess cancer per million people) that the agency routinely uses as a goal in regulating exposure to toxic chemicals. A 10^{-6} cancer risk is equivalent to about three excess cancer deaths annually; thus, the risk of 7,900 excess cancer deaths at exposures of 1.25 pCi/L, which is the national average for indoor exposures, is about 2,600 x 10^{-6} or 3 X 10^{-3}. ***The Citizen's Guide to Radon,*** a publication issued jointly by EPA and DHHS, provides some examples of comparative risk; for instance, the risk that a nonsmoker bears from constant exposure to radon at 4 pCi/L is roughly the same as that person's risk of drowning,

The level of 300 pCi/L of radon in water, set at what EPA had determined was the practical limit on quantification, was projected to reduce risks to about 2 X 10^{-4}. In its preamble to the proposed rule, EPA raised the question of the significance of waterborne radon to total exposure to radon: "In evaluating the various alternatives for proposing a radon MCL [maximum contaminant level, which is the regulatory standard], EPA considered the critical policy questions of whether radon in water should be regulated like other drinking water contaminants, or whether it should be regulated more in accord with its importance compared to overall radon exposure. EPA decided to regulate radon as it does other waterborne contaminants, but its Science Advisory Board in 1992 criticized that action because of the small contribution that waterborne radon makes to overall exposure to radon.

As a result of Congress's mandating the multimedia risk assessment in 1992, EPA's risk and cost assessment changed slightly, but whether it will make a difference in regulation remains to be seen. The risk estimate of about 200 cancer

Box I-A–Reducing Exposures to Radon: A Goal, an Action Level, and a Regulatory Standard

Nazaroff and Teichman (1990)[1] calculate that current exposures to radon are associated with about 15,700 lung cancerdeaths annually. They estimate that 97 percentof those deaths are expected in smokers with 3 percent in nonsmokers. Concentrations of indoor radon are higher than those outdoors, and the Federal Government has directed several initiatives at reducing indoor exposures. As a result, there is a goal for the reduction of indoor concentrations of radon, an action level to guide voluntary reductions, and a proposed regulation to reduce concentrations of radon in water.

A Goal

The indoor Radon Abatement Act sets the goal of reducing indoor concentrations of radon to the concentrations found outdoors-that is, 0.4 pCi/L. Currently, the average indoor concentration is about 1.5 pCi/L, with about 6 percent of all houses having concentrations greater than 4 pCi/L. EPA states that it is difficult to reduce indoor levels below 2 pCi/L (apparently for houses with current levels greater than 4 pCi/L). if, however, the goal of 0.4 pCi/L could be reached, it would reduce EPA's estimated annual number of radon-associated lung cancer deaths to about 3,100 (a reduction of about 80 percent).

An Action Level

EPA recommends that indoor radon concentrations be reduced to 4 pCi/L or below, a level considered technologically feasible for all houses. Reducing ail indoor radon concentrations that are now greater than 4 to 2.7 pCi/L is expected to eliminate about 3,500 deaths (a reduction of about 17 percent). (The 2.7 pCi/L figure is the mean between the national average of 1.5 and the action level of 4 pCi/L.)

A Regulatory Standard

Under the provisions of the Safe Drinking Water Act, EPA proposes regulating radon in drinking water so that the concentration of radon in air that is the result of the volatilization of radon from drinking water is no more than 0.03 pCi/L. According to EPA, reducing all higher concentrations of radon in water to this level would eliminate 80 radon-associated lung cancer deaths annually (a reduction of about 0.5 percent).

---

1 W.W. Nazaroff and K. Teichman, Indoor radon. *Erw/romnenta/Science and Technology* 34:774-782, 1990.

SOURCE: Office of Technology Assessment, 1993.

deaths expected from waterborne radon changed hardly at all, and radon in water remains associated with a risk greater than 10^{-4}, which is the usual upper limit on the risk that EPA finds tolerable.

Despite EPA's revisiting its risk assessment and making only small changes, there is little consensus about the certainty of the estimate of risks or the costs of addressing them. As the Science Advisory Board of the EPA pointed out in its review of the multimedia risk assessment, substantial questions remain about the validity of EPA's estimate of the risk from ingested radon, about the number of water suppliers that will exceed the regulatory limit, and the costs of regulation. As of October 1993, EPA's multimedia risk assessment had not been released, pending the agency's development of responses to the Science Advisory Board critiques. Congress in 1993 again intervened in the regulatory process and imposed an additional one year moratorium on any regulation of radon in water.

The specific questions raised by radon maybe answered by congressional or EPA decisions that impose new regulations or leave the current approaches intact. New epidemiologic results may inform those decisions by revealing more certain evidence of the level of risk posed by

indoor radon. And it is possible that research into mechanisms of carcinogenesis may shed some light on such risks. More generally, however, radon is a case that illustrates the difficulties posed by an environmental risk of uncertain size that reaches human beings through different media.

PROSPECTS FOR THE FUTURE

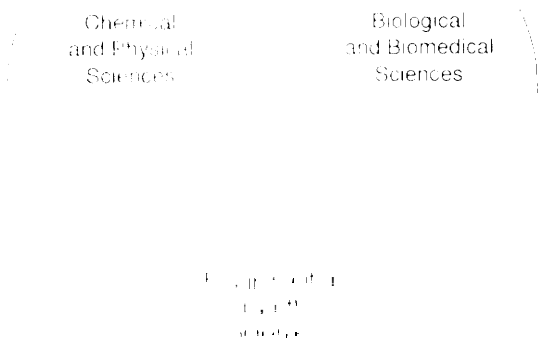
In its study, OTA noted several qualities that characterize common to high-quality research programs that should be considered in structuring the future of health risk assessment research. These include leadership, well-defined objectives, investigator initiation of projects, competitive awards and peer review, planning and criteria for evaluating success, collaboration and coordination, training, and advisory input.

OTA also identified several areas of research that promise to advance health risk assessment: new methods for toxicity studies, biomedical and molecular epidemiology, mechanistically bawd dose-response extrapolation methods, improved methods for measuring or estimating human exposures, mechanistic studies, data development and management to support toxicity evaluation and methods evaluation and validation.

The exploration of the many promising areas for research requires establishing linkages not only among various scientific disciplines but also with decisionmakers. No one category of research can be classified as the most useful for decisionmaking. Instead, risk assessments will increasingly require multidisciplinary approaches and analyses of available information. The nature of the health risk being addressed, the nature of the information already at hand, and the other factors that affect decisionmaking should all be considered when structuring a research program for health risk assessment.

Research linkages and collaborations offer enduring benefits to all participants. They bring together researchers with different strengths and expertise, foster the dissemination of knowledge,

Figure 1-9--Linking Scientific Disciplines in Health Risk Research



SOURCE: Office of Technology Assessment, 1993

and permit the sharing of resources. Research linkages also allow researchers to undertake projects that might otherwise not be possible. Linkages can occur within and between Federal agencies as well as between Federal and nonfederal institutions.

The link between health effects research and basic biological, chemical, and physical sciences has often been neglected (figure 1-9). More recently, however, bridges are being constructed between basic and health risk research in response to calls from Congress and the private sector to link science to social needs. Although basic scientists may respond grudgingly at first, some may actually find it rewarding to modify and redirect their research to serve the requirements of health risk assessments.

Analogous to the Human Genome Project, in which collaborations have been formed among scientists working to sequence the human genome, researchers from a plethora of disciplines could work together to improve health risk assessments as a desirable social and scientific goal.

In addition to scientists' collaborating to improve risk assessments, researchers who study

health risks can transfer knowledge to the private sector to foster economic growth, now a vital part of the mission of many research agencies. Revenue raised in technology transfer could be used to bolster research in this area. Such a contribution would be an important source of funds since, as this report describes, few resources are allotted for long-term funding of research to improve risk assessments despite the amounts of money involved in decisions that depend on risk assessment.

Risk assessment involves the analysis and synthesis of the entire knowledge base on the risk at hand, such as a specific chemical or class of chemicals. A substantial amount of reasoning and judgment is required in determining g whether the composite data on toxic effects, exposure, and dose-response characteristics as a whole make the hypotheses of risk tenable. This line of questioning and reasoning weighed against scientific principles and data is an iterative process, not unlike conducting experiments. It is a process different from the frequent practice of summing up the data that indicate risk and downplaying or ignoring contradictory information. When applied, questioning and reasoning can reveal the strengths and weaknesses of the evidence for risk and identify additional research needs.

Health risk assessments, by their very nature, require extrapolations from current information to estimates of effects under different circumstances. Scientists contribute to those extrapolations, but the science policy decisions that guide the choices of models include assumptions with embedded value judgments. The process of selecting the science policy assumptions (e.g., extrapolation models) may benefit from involving practitioners of disciplines other than the biological, chemical, or physical sciences. In this, OTA agrees with analyst Sheila Jasanoff, who argues for ‘‘bridging the two cultures of risk analysis’—the “hard” quantitative sciences and the soft’ nonquantitative disciplines such as the behavioral and political sciences.

The objectives of this OTA report are more limited. They are to describe current research, how research contributes to decisionmaking, and the limits of research and science in decisionmaking. Accepting those limits, it remains clear that improvements in scientific understanding from research will produce better risk assessments, which are mighty contributors to decisions about how much society will pay to cleanup pollution, how many resources will be expended on pollution prevention, and judgments about the extent of environmentally related illnesses.

INTRODUCTION TO ISSUES AND OPTIONS

This OTA study finds that health risk assessment research is itself ‘‘at risk:

- The attention and resources allotted to health risk assessment research are not commensurate with its impact on public health and the economy. Moreover, the proportion of funds devoted to environmental health R&D relative to health R&D declined from 6.8 to 4.9 percent in the decade from 1982 to 1991, despite expanded congressional mandates for Federal environmental responsibilities. The research being conducted is fragmented within and across at least 12 Federal agencies, resulting in the inefficient and ineffective use of resources.
- Inadequate resources are devoted to research on risk assessment methodology, the area likely to have the most far-reaching effect on policy. Methodological research receives about $65 million in 1993-only about 11 percent of the $600 million of Federal spending on risk assessment research.
- Not enough attention is given to linking research to decisionmaking.
- Opportunities to link government, university, and industry research are not being exploited.

OTA raises six issues related to health risk assessment research (box l-B). Four interrelated

Box I-B-Summary **of Issues and Options**

HEALTH RISK RESEARCH, STRUCTURE AND FUNDING

ISSUE 1: Given what is at stake, inappropriate attention being paid to health risk assessment research?
- . Option A-Continue with present policies.
- . Option B-Create a national initiative for health risk assessment research.
- . Option &Expand resources for health risk assessment research by redirecting funds, raising tax revenues, collecting user fees, or increasing funds.

ISSUE 2: How can Congress foster research on risk assessment methodology?
- • Option A--Continue with **present policies.**
- • **Option B--Promote or mandate** more interagency coordination of methodological research.
- . Option C-Establish a risk assessment research agency.

ISSUE 3: Should Congress mandate more targeted research to improve risk assessment?
- . Option A-Continue with present policies.
- . Option B-Mandate programs of targeted research at some Federal agencies.
- • Option C-Provide incentives for programs of targeted research.
- * Option D--Support research priority-setting based on level of risk.

ISSUE 4: How can Congress promote research linkages and technology transfer among the Federal Government, universities, and Industry?
- . Option A--Continue with present policies.
- • Option B-Establish more academic centers for health risk assessment research.
- . Option &Promote technology transfer from health risk assessment research.
- . Option D-Encourage industry support of health risk assessment research.
- • Option E—Provide incentives for collaborative research.

LINKING RESEARCH *TO* DECIS1ONMAK1NG *(RADON* AS A CASE STUDY)

ISSUE 5: Can epidemiologic studies confirm, reject, or sharpen estimates of the risk posed by indoor radon?
- . Option A--Accept the results of a meta-analysis as sufficient to answer questions about the level of risk posed by exposure to indoor radon.
- . Option B-Convene a planning group to consider a study to answer questions about risks from exposure to indoor radon.

ISSUE 6: Can there be a consistent approach to reducing radon exposures?
- . Option A—Accept the inconsistency and let the Environmental Protection Agency (EPA) deal with exposures to radon under existing laws.
- . Option B-Use the reauthorization of the Indoor Radon Abatement Act to direct EPA to integrate all routes of exposure in considering activities to reduce exposure to indoor radon,
- . Option C-include radon in a comprehensive law for regulating indoor air.

issues address the Federal research infrastructure: 1) deciding on the appropriate level of health risk assessment research; 2) fostering research on health risk assessment methodology; 3) targeting research to improve health risk assessment; and 4) promoting research linkages and technology transfer among and between Government, universities, and industry.

Two issues are related to understanding risks from exposures to radon and controlling them. They involve research, risk assessment, and regulatory decisionmaking. This example typifies

the issues relating to the limitations of science for resolving policy questions. The issues for radon are: 1) using epidemiologic studies to confirm, reject, or sharpen the estimates of risk posed by indoor radon, and 2) developing a consistent approach to reducing radon exposures.

OTA has provided options for congressional consideration for each of the issues raised in the OTA report. The options are not mutually exclusive; in many cases, they are complementary and can be integrated to improve health risk assessment research.

ISSUES IN HEALTH RISK RESEARCH, STRUCTURE AND FUNDING

ISSUE 1: Given what is at stake, is appropriate attention being paid to health risk assessment research?

Health risk assessment research provides the scientific foundation for health risk-based regulatory decisions (e.g., emission standards for incineration). Those decisions affect expenditures for complying with regulations, cleaning up contaminated sites, and treating exposure-related diseases that can run into the billions of dollars.

EPA estimates that complying with its regulations costs more than $150 billion annually. Compliance with FDA and Consumer Products Safety Commission regulation of food and product safety adds to the above estimate as does compliance with Occupational Safety and Health Administration regulations. Moreover, although estimates of the total health costs from environmental exposures are not available, a number of studies suggest that the costs of some environmentally related illnesses-such as lead poisoning and pollution-related respiratory conditions -could reach well into the billions of dollars.

Yet OTA finds that health risk assessment research is not high on the national research agenda. To elevate this research to a priority level consistent with its impact on health and the economy, requires leadership from higher reaches of government, strategic initiatives that incorporate and respond to the needs of many Federal agencies, and funding commensurate with the magnitude of the problem. Currently, health risk assessment research, according to this OTA study, has none of those hallmarks. Only about $600 million-less than one-half of 1 percent of the costs of complying with EPA regulations alone-is spent annually on health risk assessment research.

With adequate support, research can develop informative, cost-effective toxicity testing, better evaluations of human exposure, and health risks. The results will improve health risk-based decisionmaking and strengthen public confidence in environmental decisionmaking.

The expected health, environmental, and economic benefits from health risk assessment research warrants the consideration of raising it to a higher level of research priority. OTA explored several options for improving leadership and providing additional funding.

Option A: Continue with present policies.

If Congress takes no action, the present piecemeal approach will probably yield slow, incremental progress in health risk assessment research. In the absence of congressional action, Federal health risk assessment research is likely to remain focused on carrying out individual agency priorities, responding to specific legislative mandates, or being based on the culture and talents of agency researchers. This is not a completely undesirable outcome, Research by its very nature is a foray into the unknown, making progress difficult to predict.

However, continuing with present policies means that advances in research on health risk assessment are left very much to chance. In particular, little research is devoted to finding solutions to problems with overarching impact or tailoring solutions to meet risk assessment needs that cut across the boundaries of discipline, agency, or risk assessment issue.

Risk assessment research has not kept abreast of the needs of our modern society. It is estimated

that more than 1,500 new chemicals are introduced into U.S. commerce each year, adding to the more than 62,000 chemicals already in use. Studies suggest that only 10 percent of chemicals existing worldwide have adequate toxicity data. New insights from research can produce better tools to decide which chemicals require more investigation and which require regulation. But without better tools, Government agencies and private companies will never eliminate the backlog of chemicals needing testing or unanswered questions about their risk to human health.

Regulatory agencies attempt to protect the public's health by counterbalancing uncertainty and incomplete information with conservative assumptions. From the standpoint of those that must comply with Federal regulations (e.g., industry and government entities and utilities), that orientation leads to unnecessary costs that must be passed on to consumers and citizens. Although their points of view may differ in some respects, representatives from both regulatory agencies and the regulated entities would agree that resources are misspent if risks of greater magnitude are not handled earlier and with more resources than risks of lesser magnitude. Both would argue for adequate resources for health risk research to take advantage of progress made in science (e.g., cellular and molecular biology) to reduce uncertainty in health risk assessments.

Finally, without national leadership and a commitment to health risk assessment research, the public's support for environmental protection may erode.

Option B: Create a national initiative for health risk assessment research.

If the decision is reached that current activities in the area of health risk assessment are too fragmented, Congress can consider methods to centralize the planning and evaluation of Federal health risk assessment research. Some areas of health risk assessment research would benefit from a multiagency approach. A national initiative would focus attention on such research and make it more responsive to national needs. It would provide a forum to debate, develop, and plan research. In particular, it would identify problems in risk assessment that cut across the agencies and distinguish which of those problems are addressable by research and which remain essentially policy choices. It would also provide guidance of Federal policy that is open to scrutiny by the public and Congress, and its plans and operation would reflect the overall needs of the Nation. It can be accomplished by:

- setting up crossagency strategic planning,
- providing leadership from the White House, or
- directing the Department of Environmental Protection (should it be established) to develop a program.

CROSSAGENCY STRATEGIC PLANNING

Crossagency strategic planning can be designed to bring agencies together to establish common research goals-for the short, medium, and long terms. On paper, the benefits of crossagency strategic planning appear within reach, but formidable obstacles lie in the way of securing them. Most agencies have a deeply rooted commitment to their own priorities, based on historical or legislative imperatives. Their resistance to change can thwart the setting of national goals. The most typical forms of resistance are to set objectives that are so broad as to be meaningless or to repackage existing programs to make them appear to be meeting objectives for which they were not actually intended. The nature of health risk assessment research and the breadth of disciplines that support it lends itself to those kinds of deception.

One way to enlist agency cooperation in strategic planning is to offer financial incentives for participation, such as additional research resources that are earmarked for research tailored to meeting government-wide objectives. The Bush Administration used such a mechanism,

called a ‘‘crosscut,’’ to augment funding in priority areas of research under the auspices of the Office of Science and Technology Policy’s Federal Coordinating Council on Science, Engineering, and Technology. Given the currently tight Federal budgets, providing additional funding will be difficult. However, another way to enlist agency cooperation is through strong and well-respected leadership.

LEADERSHIP FROM THE WHITE HOUSE

Leadership at the pinnacle of the executive branch can provide accountability, authority, and responsibility for risk assessment research. Furthermore, a nationally recognized leader can elevate the stature of programs for health risk assessment research, instill a sense of common purpose, and persuade agencies to cooperate in attaining national objectives. Such a person within the Executive Office of the President (EOP), similar to the “Drug Czar” or the “AIDS czar,” would provide a focus for discussing research needs across agencies. The President’s Science Adviser might fill this role; he or she could certainly spearhead the important function of cross-agency strategic planning. Similarly, the Carnegie Commission recently proposed that the EOP become the focal point for developing environmental and risk-related policy and coordinating the activities of the Federal agencies. One potential pitfall, however, in assigning this responsibility to a political appointee in the White House is that it will engender fears, warranted or unwarranted, about the politicization of science.

In contrast to a designated leader, a Center for Research Policy could serve within the EOP, most likely in the Office of Science and Technology Policy, as a neutral forum for linking research to decisionmaking. Such a forum could assist Federal agencies in identifying important gaps in research, setting crosscutting research objectives, and monitoring whether those objectives are being met. Another of the center’s functions could be to distinguish issues of policy from issues of science. Those distinctions are necessary because the high stakes and commercial interests involved in health risk assessment research virtually guarantee controversies about the scope, interpretation, or application of research. The center could help to educate policymakers and the public about the nature and limitations of research; it could also help identify which areas of controversy involve unverifiable assumptions and which are amenable to resolutions by further research.

The center may well be unnecessary, however, because it would be performing the same functions that existing agencies could perform by working together.[4] However, as the center would evaluate the potential impact of research on policy, it would require an analysis of cultural and social factors as well as scientific merit. Commingling science and policy may be viewed unfavorably by some communities: keeping policy separate from research has been seen as essential to maintaining the credibility of scientific research. It may also be problematic to assign the job of developing and monitoring objectives to a center without also giving it the responsibility or the capacity to implement those objectives. All of these issues require a discussion of the scope and scale of the center and the source of its resources, which is not attempted here.

PROGRAM IN THE DEPARTMENT OF ENVIRONMENTAL PROTECTION (SHOULD IT BE ESTABLISHED)

As part of the responsibilities for a new department, the much discussed Department of Environmental Protection could be instructed to establish a high-level program in health risk assessment research. Such a program could be made to provide a collaborative atmosphere for Federal research and to include private sector initiatives.

[4] A working party under the auspices of FCCSET had been attempting to Identify government-wide gaps in health risk assessment research. However, the effort apparently has been abandoned before the release of its results.

Option C: Expand resources for health risk assessment research by redirecting funds, collecting user fees, raising tax revenues, or increasing appropriations.

Congress could increase the level of support for health risk assessment research through several mechanisms. For example, it could use any of the following approaches:

- redirecting funds to risk assessment research,
- collecting user fees,
- raising tax revenues, or
- increasing appropriations.

New legislation could channel special taxes or user fees to finance health risk assessment research. Unlike many areas of science, health risk assessment research is so closely linked to regulatory action that a strong argument can be made for the appropriateness of finding such research through charnels related to regulation.

REDIRECTING AGENCY FUNDS TO RISK ASSESSMENT RESEARCH

Congress could redirect existing Federal resources toward research programs with potentially high dividends for health risk assessment. The funds could be secured from Federal agencies that support health risk assessment research or from agencies whose programs depend critically on the results of such research. DOE, for example, relies on the results of research in its vast program of environmental cleanup, which is larger in scope than EPA's Superfund program. Yet DOE lacks a targeted, coordinated research program that could help it set priorities among cleanup sites on the basis of the risk to human health. Redirecting a portion of the funds appropriated for remediation of its sites would provide a substantial increase in research funding. Even a comparatively small 2 percent redirection of the $5.4 billion allocated to DOE's cleanup activities would expand risk assessment research by more than $100 million. That figure is substantially larger than the estimated $65 million this country spends on health risk assessment methodological research and is more than double the entire health effects research budget at EPA. Based on its research, OTA agrees with those who point out that DOE's own national laboratories have the expertise and laboratory capacity necessary to absorb an infusion of funds for methodological research. Given EPA's experience with the types of research necessary to improve policy decisions, Congress may want to consider joint EPA/DOE projects.

Redirected funds could be used either to bolster existing programs in health risk assessment research or to create a new program. They could be channeled within the agency or to another agency that is already supporting health risk assessment research. In any case, this approach is viable only if the redirected funds are sufficient to support a meaningful level of research.

RAISING TAX REVENUES

The Superfund law is an example of Federal legislation that provides funds for research from directed tax revenues—in this case, from a tax on the petrochemical industry.[5] The tax revenues are deposited in the Superfund trust fund, which finances cleanup, compliance, and research.[6] Research receives the smallest share of the funds, and the exact amount is not a fixed proportion or set-aside. Of the 1992 Superfund appropriation of $1.6 billion, Congress appropriated about $116 million for research, of which only a small portion was devoted to health risk research. In fiscal year 1994, Superfund research programs are being cut 13 percent.

At the State level, California has enacted a cigarette tax of 25 cents per pack that specifically

[5] The Comprehensive Environmental Response, Compensation and Liability Act of 1980.

[6] Superfund appropriations also come from general revenues. In 1992, for example, $250 million of the Superfund's appropriation of $1.6 billion came from general revenues.

sets aside a flat percentage of tax revenues for research. Proposition **99,** passed in 1988, earmarks 5 percent of collected revenues for research. As a result of this legislation, $30 million was set aside in 1989 for a competitively awarded grants program of research on tobacco at the University of California.

There are many arguments, pro and con, over the use of such 'sin' taxes. On the one hand, they can raise substantial revenues for desired programs and can promote socially desirable behavior, such as reducing pollution and reducing smoking. On the other hand, these taxes are often levied on those individuals who can least afford them. Moreover, the earmarking of tax revenues can be seen as a license for agencies to raise money for their own ends. Many in Congress adamantly oppose earmarking of tax revenues, insisting that collected money go into the general revenue.

COLLECTING USER FEES

To augment the resources available for research, Congress could enact legislation authorizing user fees for regulatory review of industry products. The money collected in fees could be earmarked for research on health risk assessment.

The concept behind a user fee is that the Government is entitled to charge for a service that directly benefits private individuals or entities. The idea of charging user fees for the regulatory review of drugs has been debated for many years on the grounds that industry is not the only direct beneficiary of a premarketing review; the public also stands to benefit from drugs being introduced into the market. In 1992, Congress passed groundbreaking legislation, the Prescription Drug User Fee Act (P.L. 102-57), requiring drug manufacturers to pay user fees for FDA's review of their product applications. Under the provisions of the act, FDA uses a portion of the funds it collects to improve the drug approval process.

Similarly, Congress could enact new legislation to allow EPA to collect user fees from individual manufacturers for reviewing industry-submitted information about pesticides and toxic substances. Although a sizable portion of EPA's regulatory activities involves industry-wide standard-setting, the agency also reviews the applications of individual manufacturers. Manufacturers or importers of new pesticides and new chemicals, in general, are required to obtain premarketing registration or submit premanufacturing notices, respectively. Fee levels would have to be set to approximate the costs of such reviews. Whether the fees would be sufficient to warrant creating and administering a user fee program would need analysis.

INCREASING FEDERAL APPROPRIATIONS

As another approach, Congress could appropriate more money for health risk research. Research is the source of new methods for improving the accuracy of risk assessment and new ways of preventing, treating, or remediating risks that have already been identified. The desired outcome of this area of research is to enable society to make informed decisions about which risks to reduce and which to tolerate.

Yet despite the advantages of increased resources, nondirected increases in funding can present problems. Chief among them is that little evidence exists to suggest that Federal agencies, if given more money, would direct the funds toward research of the highest national priority. In fact, existing priority-setting mechanisms may allocate resources ineffectively and inefficiently to agency programs. As a result, enhanced resources alone may not provide a commensurate improvement in the process of risk assessment because the most critical areas of research maybe neglected. In any case, substantial increases in appropriations are not likely.

ISSUE 2: How can Congress foster research on risk assessment methodology?

As defined in this report, methodological research is aimed at improving the methods for assessing risks to human health. Specific examples of such research include efforts to improve

the extrapolations from laboratory results to predictions of human effects; to explore new approaches to extrapolating results obtained at high doses in animals and at high exposure levels in workers to estimates of effects at low ‘ ‘environmental’ exposures; and to improve estimates of risks and methods for analyzing uncertainties.

OTA’s emphasis on methodological research does not imply that other research is not important to risk assessment. Rather, it recognizes that other kinds of risk assessment research have already benefited from substantial attention and support. For instance, research in chemical-specific data development for identifying toxicants has long been emphasized in Federal programs and undoubtedly that emphasis will continue. Today, however, methodological research seems to offer the best opportunity to move the field of risk assessment-forward. Yet it receives little attention and funding.

Optimism about methodological research springs from several sources, but two are especially important. The rapid advances in basic biological and biomedical research provide a wealth of information that further research may incorporate into health risk assessments and tools for toxicological research. In addition, generic methodological research provides results that can be applied to large numbers of chemicals. That kind of broad scope is particularly attractive given the enormous backlog of chemicals for which little or no information about risk is available and for which resolving questions about toxicity through traditional testing methods are impractical. Furthermore, new chemicals are being developed, many to replace older chemicals. Methodological research offers the possibility of developing methods for screening to prevent introducing new risks.

Option A: Continue with present policies.

A major conclusion of this study is that relatively meager resources are devoted to such research. In particular, of the $600 million that OTA estimates the Federal Government spent on health risk assessment research in fiscal year 1993, only $65 million (11 percent of the total) went toward improving risk assessment methodology. Some progress is likely under present policies, but the pace will be slow.

While methodological research holds the prospects for improving the accuracy of risk assessments, the controversies on health-risk based decisions are not entirely about the accuracy of risk assessments. They are about different viewpoints. There is not now and there may never be a consensus among those who hold the two major conflicting views in this area: the one, that human health is paramount and that costs and forgone benefits should not be weighed against it, and the other, that some threats to health are sufficiently small that they can be tolerated and that controlling them costs too much. The general conflict between the two perspectives may be intractable, but conflicting interpretations of toxicity data from scientists supporting either view help to fuel the discord. Research into specific areas of uncertainty can help to reduce some of this conflict.

Moreover, under present policies, any augmenting of the resources allocated to methodological research will involve shifting funds from other programs, a move that could cause new controversy. For instance, if the shift were made at the expense of toxicity testing in support of the identification of toxicants, it could be viewed as reducing research in an area of historical Federal emphasis and promoting research that is perceived by some as being the industry’s responsibility.

Still, there are arguments for such shifts. Continuing with present research policies will exacerbate problems in setting standards and undercut the confidence of the public in the standards (and government) because of questions raised about risk assessment results. While industry and taxpayers pay billions of dollars in control and cleanup costs, everyone is left uncertain about how much safety has been

purchased or how much risk has been left unaddressed.

Option B: Promote or mandate more interagency coordination of methodological research.

It is all too frequent a complaint that Federal research programs need to be better coordinated. But some areas of research labor under a greater disadvantage than others when coordination is lacking. Health risk assessment research and especially methodological research, which draws from diverse scientific disciplines, are such areas.

The linkage to regulatory decisions is a distinctive feature of health risk assessment research and a further reason for coordination. Many of these decisions pose problems common across agencies that can be addressed by targeted research. Such targeted research could be potentially better handled in a coordinated manner.

Improving the coordination of research efforts, both within and across agencies, has been seen as important to improving risk assessment for more than a decade. And some efforts have been undertaken. At the national level, the National Toxicology Program was created in 1978 to coordinate Federal programs in toxicological testing. At the program level, EPA's Research to Improve Health Risk Assessment program coordinates research by providing funds to offices within EPA's Office of Research and Development to address problems that cut across research disciplines and issues in improving health risk assessments.

Yet despite those and other efforts, research programs are separated by more than the barriers of organization and location existing among and between agencies, programs, and disciplines. Power struggles over budgetary and bureaucratic turf are common, according to many agency scientists and managers interviewed by OTA. In addition, fragmentation within and across agencies has impeded effective communication, created unnecessary duplication, and stymied research progress toward overarching goals.

Some coordination can occur as a result of leadership at different levels of management—within, between, and among agencies and within programs and laboratories. Perhaps perversely, dwindling resources may provide momentum to these voluntary efforts as program and laboratory managers have no choice but to enter into collaborative efforts to complete research that previously they might have accomplished alone.

A major drawback to taking no action to promote or mandate more interagency coordination is the opportunities that may be lost for large-scale integration of programs. More comprehensive efforts at coordination can lead to synergistic advances in research and more efficient uses of resources-provided that strong leadership is exercised to prevent agencies from transforming coordination efforts into mere paper exercises.

To coordinate research on health risk assessment methodology research, Congress could promote central coordination or establish a lead agency.

PROMOTING CENTRAL COORDINATION

Congress could mandate that research on risk assessment methodology be coordinated centrally through the Executive Office of the President (EOP) to enhance its visibility and promote better communication. Because Federal agencies spend only about $65 million for research on health risk assessment methodology, coordinating such a program would require only modest resources. In fact, the Federal Government's investment in this type of research is so small that some might argue that coordination is unnecessary. The other side of that argument holds that scarce resources deserve the greatest of care.

One possible mechanism has been established: the Federal Coordinating Council on Science, Engineering, and Technology (FCCSET), which is chaired by the President's Science Adviser, is a cabinet-level interagency group charged with coordinating the Federal Government's activities in science and technology.

FCCSET in 1991 and 1992 had some focus on health risk assessment research: its Subcommittee on Risk Assessment of the Committee on Life Sciences began effort to identify future health risk assessment research needs. Although this activity was not aimed at coordinating research projects, the activities of the subcommittee were a first step in creating an inventory of ongoing research activities, which could be useful in future coordinating efforts. A research inventory would have allowed FCCSET members to identify redundant research, areas of little or no activity, and research efforts that could be usefully integrated across agencies. However, this project apparently has been put quietly to rest with the transition to the Clinton Administration.

Even with an active effort, there are limits to the effectiveness of FCCSET or an organization like it. First, FCCSET members were typically policymakers so highly placed in each Federal agency that they were unfamiliar with the technical aspects of research, which impaired their credibility among researchers. Second, the FCCSET staff was quite small; often one staff member was assigned to more than one committee, leaving the bulk of the staff work to agency personnel. Unless FCCSET (or a like organization) were given more staff, it will lack the capacity to coordinate government-wide research efforts. Third, any FCCSET-like activity, however worthy the cause, will inevitably raise the specter among researchers of political tampering, because of the committee's proximity to the President.

ESTABLISHING A LEAD AGENCY

A lead agency could be assigned responsibility for developing and maintaining an inventory of ongoing projects; spearheading cross-agency planning of research to meet the most pressing needs of risk assessors; encouraging collaborative research across Federal agencies and possibly with industry and academia; and offering centralized resources, technical assistance, and public information.

A lead agency to coordinate research offers several advantages. It can draw on its own experience, staff, and resources—although additional resources would be needed for its increased responsibilities. No legislative changes would be necessary if it were located in an existing department or an agency. Also, the creation of a Department of Environmental Protection could provide an administrative location for a lead agency. A lead agency also has an operational investment in the success of efforts at coordination because of its own responsibilities for research or risk management (or both). In addition, using a lead agency instead of the EOP for coordination can ameliorate concerns about the politicization of research.

Yet such an undertaking as coordinating all research on health risk assessment methods may drain the resources of a lead agency. A further problem is the resentment such a designation—and the additional resources to be provided-may foster among other agencies. That outcome could conceivably undermine the very purpose of the action.

Were Congress to proceed with this option, a key factor in selecting a lead research agency would be whether to choose a research or a regulatory body. A regulatory agency would help to ensure greater relevance in selecting research directions aimed at meeting the immediate needs of regulation. A research agency, in contrast, would help to ensure proximity to scientific advances, but its link to regulation would be more remote.

Option C: Establish a risk assessment research agency.

Congress could establish a small agency to administer funds for health risk assessment methodology research. A small but highly visible source of funding for research on health risk assessment methods could focus Federal efforts, draw attention to the promise of the research, attract qualified investigators, provide a forum for review and guidance of the research from all

interested parties, and, if it were structured appropriately, include built-in mechanisms for judging its success. Such a Risk Assessment Research Agency (RARA) could review applications for research funds from inside and outside the Federal Government, evaluating them in the light of whether they would improve risk assessment. Funding for RARA could be secured by tapping the resources of Federal research agencies, which would raise problems, or by new appropriations, also problematic.

Any tap on a Federal agency, however, is likely to encounter stiff resistance. It is to be expected that each of the agencies that currently funds risk assessment research will be reluctant to part with its funds. Somewhat counterbalancing that tendency will be the knowledge that money spent by RARA will be directed at risk assessment methodology. Managers in other agencies who support such research may favor its being performed by the new agency, since, as this report documents, it is currently being done on the margins at the agencies. By contributing agency funds and individual guidance, they will earn credit for successes and dilute responsibility for approaches or programs that do not work.

To ensure that each agency currently involved in risk assessment is treated fairly, RARA could be governed by aboard of directors consisting of the head of each agency that contributes to it. The board could designate an executive officer to oversee the day-to-day operation of RARA and later decide between a permanent executive (the model for most grants and contracts officers at the National Institutes of Health and EPA) and a rotating executive who would serve a fixed 1- or 2-year term (as is done in some programs at the National Science Foundation). RARA would also benefit from a board of nonfederal expert advisers on the direction of its research and panels of experts to review proposals that it is considering funding.

RARA could be located administratively in any Federal organization that supports health risk assessment research, but at least two reasons can be advanced for placing it within the National Institute of Environmental Health Sciences (NIEHS). NIEHS has more than a decade of experience hosting the National Toxicology Program, which pools the resources of a number of agencies to address cooperatively government-wide needs for toxicological research and testing. Moreover, NIEHS has mechanisms in place to administer grants, and it would need few additional resources to administer the RARA programs. An argument can also be developed to support EPA's housing such a program based on that agencys experience in its Research to Improve Health Risk Assessment program and its administration and funding of competitive cooperative agreements. Establishing RARA within a new organization, such as the proposed Department of Environmental Protection or the National Institute of the Environment, would allow the program to develop in an environment without pre-established barriers.

Regardless of where RARA is placed, it may be criticized as duplicating or being unresponsive to the functions of existing agencies. An active board of directors, with an interest in the coordination of research as well as the concerns of their own agencies, could dampen such criticisms.

One of the most significant aspects of RARA is that it would provide a mechanism for evaluation if it commanded all (or a major part) of the funds allocated for risk assessment methodology research. The agency could be established with a sunset provision that required a thorough review of its activities at the end of some set period. Eight years might be appropriate. Two years could be used to establish RARA, solicit proposals, and make the first funding decisions. Most grants would be made for 3 years, provided that the agency's funding pattern parallels other Federal research activities. With 3-year grants, the scientists who received the earliest grants would be able to apply for continuation grants during the 8-year period.

During those years, the board of directors, in consultation with researchers, policymakers, and

users of risk assessment results, could be required to set forth the objectives of the methodological research supported by RARA. The primary criterion for success might be whether RARA-supported research had made a perceptible difference in risk assessment policies. At the end of the 8 years, RARA's board of directors, along with other agency managers and appropriate congressional committees, would evaluate the agency's success. Its future would depend on the outcome of the evaluation.

ISSUE 3: Should Congress mandate more targeted research to improve risk assessment ?

In broad terms, targeted research is designed to solve a specific problem or meet an objective set in advance by an agency or by congressional imperative. In the context of this report, research can be targeted to areas likely to have the greatest impact on policy and decisionmaking. Targeted research is a tool that can be used to link research to the decisionmaking process,

Targeted research on health risks is especially appropriate for regulatory agencies that use risk assessment to develop standards, guidelines, and regulations. It is also appropriate for agencies like DOD and DOE that have research capability as well as an operational investment in the outcome of research-in the form of cleanup programs designed to reduce risk.

Targeted research is especially useful for filling gaps in the data required for specific risk assessments and, more generically, for developing new methods of performing risk assessment. It should not be confused with "mandated" or ''manager-directed' research, in which the scope and methods of a research project are dictated in advance by the managers of an agency. Such projects are less likely to undergo peer review and be awarded competitively. Pertinent examples of targeted research programs are EPA's Research to Improve Health Risk Assessment program and methodological programs at FDA's National Center for Toxicological Research (NCTR).

Frequently people think of targeted research as synonymous with applied research, but targeted research can be either basic or applied, as long as its goal is to meet an agency's established objective. The Human Genome Project of the National Institutes of Health/Department of Energy is an example of targeted research that is basic in orientation. As defined by OTA in this report, targeted research is linked to a specific goal; thus, terms such as "directed," "identified," or "prioritized" research are also appropriate. Any of those terms expands the concept of targeted research beyond the narrow connotation of applied research.

The most familiar method for Federal agencies to target research is Requests for Proposals issued to the scientific community to solicit research intended to address a specific problem. Scientists inside or outside the agency prepare competitive applications detailing how they would study the problem. After a process involving peer review and ranking of the proposals, funds are awarded to scientists whose applications appear most likely or best suited to yield an answer.

Option A: Continue with present policies.

More targeted research may not be necessary. Programs at EPA and FDA's NCTR are already moving in the direction of more targeted research. In addition, establishing more targeted research programs may discourage highly productive researchers, who would rather pursue projects of their own design and interest. Another advantage of no congressional action at this time is that increased targeting may be perceived as leading to lower-quality science. (One way of overcoming such a perception is by using a properly designed procedure for competitive awards.) A final advantage to inaction is that the efficacy of programs of targeted research-in health risk assessment specifically-has not been evaluated. It may be too soon to assess the achievements of EPA's prototype for that kind of research, the RIHRA program. RIHRA was established in 1988 to support targeted, long-term research to

reduce uncertainties in risk assessment. Such programs take at least 5 years-and usually longer—to mature.

Option B: Mandate programs of targeted research at some Federal agencies.

Congress could mandate more programs of targeted health risk assessment research at Federal agencies with responsibilities for risk management. In its mandate, Congress could stipulate broad objectives (e.g., ''improve risk assessment methodology' yet permit agencies enough flexibility to set and revise their own discrete goals to meet those objectives.

An example of possible targeted risk research comes from an OTA study that stated that DOE cleanup of contaminated nuclear sites is proceeding haphazardly, without an adequate understanding of the risks to human health. A program of targeted research in health risk assessment at DOE might improve the process. It could focus on those substances and combinations of substances at cleanup sites, such as complex mixtures of solvents and radioactive materials to which people are likely to be exposed. Furthermore, by redirecting some resources from remediation to research, strategies for cleaning up the sites could be underpinned by research results based on the conditions for a particular site, such as soil, geography, climate, and the number and types of exposure conditions. These efforts could direct DOE's remediation efforts to those areas of highest priority and set levels for remediation that are appropriate for that site.

Option C: Support setting research priorities based on risk.

Congress could support risk-based priority-setting for health risk assessment research as a less prescriptive way of encouraging agencies to establish their own programs of targeted studies.

In the simplest terms, risk-based priorities constitute a "worst-first" strategy: priorities for research are established on the basis of the degree of risk that a substance or situation represents. The degree of risk, in turn, is determined by risk assessment. In recent years, this kind of prioritization has received endorsements from several sources. For example, EPA managers, responding to concerns that EPA's agenda is set more by public and political perceptions than by expert-based judgment about risks, issued a landmark report in 1987 that ranked and compared environmental problems on the basis of the managers' risk estimates. The report's message was that EPA should set priorities for its programs-and its resources-according to the ranking of risks. EPA's Science Advisory Board reviewed and endorsed the report and in so doing expanded the concept of risk-based priorities for research. Two other advisory committees of nationally recognized scientists have also recommended risk-based research priorities. Such a priority for research does not dictate priorities for regulation, which are set inconsideration of many other factors in addition to the level of risk.

Not everyone endorses setting research priorities on the basis of risk. Those who object cite several arguments, for example:

- risk assessment itself is so fraught with uncertainties that it should not be used to set directions for research programs;
- agencies will use risk-based priorities to ignore environmental problems that are of concern to the public or to ignore environmental problems that have few data on which to base risk assessments;
- rankings of environmental problems tend to be problem-specific and fail to recognize the need for research that can cut across many risk assessment issues and affect many problem-specific needs; and
- using risk to set priorities will skew research in the direction of existing problems rather than anticipating those that may crop up over the long term.

Supporters of using risk-based research priorities acknowledge that the approach has problems,

but they contend that it ensures a role for science in a process that historically has been dominated by political and budgetary concerns. Supporters also point out that the vast majority of EPA's research is driven by legislative mandates and would not be affected.

Similarly, Congress could support a "value-of-information" approach to resource allocation that bases priorities for research on whether its results can improve risk management. Most research aims for a greater degree of scientific certainty. In contrast, a value-of-information approach gives higher priority to research based on utility for risk management, channeling resources to research that will have the most impact on decisionmaking. That kind of decision framework "point[s] decisionmakers towards the most valuable improvements in information, enabling them to better evaluate the ever changing tradeoff between more analysis and more action. This type of analysis could be appropriately conducted in the Center for Research Policy discussed in issue 1, option B, under Central Coordination.

ISSUE 4: How can Congress promote research linkages and technology transfer among the Federal Government, universities, and industry?

In times of limited, even declining Federal budgets, research linkages among the Federal Government, industry, and universities are critical for advancing health risk assessment research. These linkages could be important for at least three reasons: they infuse more resources into the field; they bring together researchers with different backgrounds, expertise, and interests; and they increase the trust between the public and private sectors. Congress could consider ways to promote research collaborations. Not all areas of health risk assessment research lend themselves to industry linkages because of inherent conflicts of interest, but many areas would benefit from Federal collaborations with researchers from academia and industry.

One way to foster such linkages and provide incentives for industry involvement is through the commercialization of products developed by health risk assessment research. In addition, product development and commercialization could provide incentives for the private sector to invest even more in this research, given the enhanced prospects for commercial success.

In addition to the growing demands for research in the United States, the other industrialized countries are increasingly interested in using these risk assessment methods for making their regulatory decisions. As quantitative risk assessment (QRA) methodologies were being developed by the United States in the 1980s, the international use of QRA was limited or nonexistent. That pattern, however, may be changing. The overwhelming need, for example, for environmental cleanup in the former communist countries in Central and Eastern Europe has spurred interest in U.S. risk assessment methodologies. In particular, the potential usefulness of QRA in setting priorities for those massive cleanup efforts has prompted ever greater demands from those countries for environmental health information.

As the world leader in health risk assessment research [see app. A of the full report], the United States can set the pace in research and product development:

- equipment and supplies for toxicological testing;
- equipment and supplies for monitoring exposure, both in the environment and inside the body; and
- computer software for estimating risks and their associated uncertainties and for providing options for decisionmaking.

Other types of products, which are beyond the scope of this report, include pollution prevention devices and technologies for environmental remediation.

Specifically, Congress can act to encourage the academic foundation of research and set the stage

for commercializing products invented by Federal scientists or university scientists who receive Federal support. In particular, Congress could develop programs at the Department of Commerce for transferring technologies that arise from health risk assessment research. The National Institute for Standards and Technology could play an important role in such transfers.

Option A: Continue with present policies.

If Congress takes no action, opportunities may be lost for cultivating U.S. preeminence in health risk assessment research and assisting in the commercialization of products. That market is not limited to the U. S., and it is likely to expand as Central and Eastern Europe begins to confront decades of environmental contamination. Those market pressures will probably lead to commercialization regardless of Federal support of such efforts.

Domestically, the need for information about the toxicity of the new chemicals added annually to U.S. chemical registers increasingly outpaces the ability of researchers to produce it. Furthermore, new methods are needed to provide decisionmakers with sufficient data on large numbers of chemicals for regulatory decisions. Those new methods will come from new investigators entering the field. Congressional support could enhance opportunities for collaboration that might otherwise be lost as declining resources and incentives discourage researchers from conducting health risk assessment research.

Option B: Establish academic centers for health risk assessment research.

Congress could establish academic centers that support health risk assessment research and training. It could also supplement the existing support for center grants funded by the National Institute of Environmental Health Sciences and the National Institute for Occupational Safety and Health. To stimulate support for research by industry, the grant awards for centers could be contingent on attracting matching levels of industry support. (The element of matching support is an essential feature of National Science Foundation center grants to universities in other areas of scientific and technological research.)

Even though academic centers are more likely to concentrate on research at the beginning of the ''pipeline' of commercialization, industry might well be interested in investing in research at this early stage, provided that the Federal Government offers encouragement through such mechanisms as tax incentives. Industry also has a stake in ensuring that training of environmental health professionals continues at academic centers, especially since some analysts predict a shortage of trained professionals in the field.

Option C: Promote technology transfer of innovations from health risk assessment research.

Congress could build on existing legislation and take steps to encourage the transfer of ideas and innovative technologies derived from health risk assessment research-for example, improved toxicological tests and technologies for exposure monitoring.

Legislation enacted over the past decade promotes the commercialization of research by permitting Federal grantee institutions, contractors, and laboratories to retain the rights to inventions they develop with Federal funding.[7] Scientists at those institutions can collect a portion of the royalties attached to the inventions; in addition, the legislation authorizes Federal agencies to enter into research efforts with the private sector through cooperative research and development agreements (CRADAs). Such agreements can be in place early in the research process—well before an invention has been developed.

The United States is currently the world leader in the kind of research discussed in this report, but

[7] The Bayh-Dole Act of 1980 (P.L. %517) and the Federal Technology Transfer Act of 1986 (P.L. 99-502) set out these principles.

it may be flittering away opportunities to transfer the technology to the private sector. The burgeoning national and international demand for these products offers a promising prospect for commercial ventures. But even more relevant to this report are the research opportunities that might be created if more resources were infused into the field. Some of the steps Congress could take to expand Federal efforts to transfer technology from health risk assessment research to the private sector include the following:

- Educational efforts----Congress could encourage Federal agencies to be more vigorous in educating their scientists about the personal financial advantages of patenting inventions. Agencies can also be encouraged to market their scientists' inventions more aggressively to private investors. The National Institutes of Health, for example, maintains an online database, available to the private sector at no charge, that lists by research topic inventions developed by Federal scientists. Similar initiatives could be fostered in other agencies.
- Grants or contracts to universities--Research grants and contracts to universities can be targeted toward the development of health risk assessment technology. They could also be structured to require matching industry funds for commercializing research products.
- Government programs for technology transfer----congress could create or strengthen programs at EPA and the Department of Commerce to promote the transfer of technology developed by health risk assessment research to industry. EPA's Office of Science, Planning and Regulatory Support administers the agency's responsibilities for the Federal Technology Transfer Act of 1986 and tries to find additional users for the agency's research products. The primary role of the Commerce Department is to develop and promote new inventions and technologies, and it could be directed to establish a program to promote the products of health risk research. The internal research programs of the department are conducted within the National Institute for Standards and Technology, which would appear to be the logical location for such a program.

Option D: Encourage industry support of health risk assessment research.

Chemical industry organizations, like the American Industrial Health Council, have long called for increasing the use of research results in decisionmaking. Their rationale is that these results would support enlightened regulatory policies. With such a tangible investment in the outcome of research, industry is ripe for encouragement to expand its commitment to health risk assessment research. Congress could seek ways to increase industry's investment in research through tax credits, joint sponsorship of projects, or regulatory incentives.

INCENTIVES FOR RESEARCH INVESTMENT OR PUBLIC-PRIVATE PARTNERSHIPS

There are two existing models of partnerships in industry-sponsored research in health risk assessment: industry consortia and private-public partnerships. The Chemical Industry Institute of Toxicology represents a consortium of industries that sponsors toxicological research. In contrast, a model of public-private partnership is the Health Effects Institute, a nonprofit research organization created by Congress in 1980. Its $6-million budget, which is jointly supported by EPA and automobile manufacturers, is directed toward determining the effects of auto emissions on health. In both cases, the designers of these programs devoted extensive efforts to ensuring high-quality, unbiased research and avoiding possible conflicts of interest. Such efforts are vital considering that even the perception of a conflict of interest can doom research results to obscurity.

Conflict of interest in public-private collaborations can be averted by judiciously selecting the

research projects to be conducted and by carefully reviewing the results of the research, perhaps by using an external review board. At least two areas of research are less likely to provoke controversy because public and private interests converge: research to prevent or reduce risks, and research on methods of toxicological testing aimed at developing cheaper, more cost-effective means of hazard identification.

REGULATORY INCENTIVES

Regulation can also encourage industry-sponsored research. Existing regulations can be revised and new regulations formulated to include incentives-rather than requirements-for scientific innovation. FDA, for example, responded to the plight of patients with acquired immunodeficiency syndrome (AIDS) by developing regulations that urged manufacturers to establish a drug's efficacy by faster means through new, clinical ''surrogate endpoints. ' Those endpoints replaced the standard clinical endpoint-mortality-and are used to predict more quickly whether a drug is actually working. This kind of regulation is purposefully intended to encourage innovation in clinical research.

Congress could foster industry-sponsored research by mandating or encouraging Federal regulatory agencies to review existing regulations more frequently than they now do and to update them with the latest scientific and technological advances. But health advocates may argue that because that approach merely sets forth a process and does not require regulatory changes, and because most regulations are oriented toward protecting health, a review of that kind could create a climate favoring less protection, which would force the advocates to defend the status quo. In contrast, industry may favor more frequent reviews and updating, given its opinion that, in general, most risk-related regulations are too burdensome and often obsolete scientifically. Another difficulty with this approach is that experts usually disagree about whether and when the science is ready to be incorporated into regulations. Debates over the strength of the science, however, can sometimes be a smoke screen for insoluble differences in regulatory philosophy.

A further obstacle to government-industry partnerships has been the protection of industry's proprietary information. Industry-government collaborations are unlikely unless industry is guaranteed that there will be no punitive reprisals or loss of control over proprietary material.

Option E: Provide incentives for collaborative research.

Congress could provide or designate discretionary funds to agencies to promote multidisciplinary collaborative research. The agencies could award the funds competitively, through a process of peer review, to investigators who are collaborating within or across agencies, with academia, or with industry. Funding could be administered through existing mechanisms; however, criteria would have to be developed for what constitutes collaborative research, because the intent of this option is to stimulate new collaborations that might not have otherwise occurred. Its advantages are that health risk assessment research would become broader and more responsive to diverse needs. Its disadvantage is the length of time required for establishing interdisciplinary communication.

ISSUES IN LINKING RESEARCH TO DECISIONMAKING (RADON AS A CASE STUDY)

The original request for this analysis asked for an examination of risk assessment research and not for a study of any particular issue in risk assessment. A subsequent request, however, specifically asked OTA to analyze an ' 'inconsistency' in EPA's approaches to reducing exposures to "indoor' radon, under the provisions of the Indoor Radon Abatement Act and the Safe Drinking Water Act. The request also asked OTA to provide policy options for developing a con-

sistent approach to reducing risks from indoor radon.

Radon is a radioactive gas. It originates from minerals in the Earth, and it has increased cancer rates in miners exposed to high levels. Typically, concentrations of radon are higher inside buildings than they are outdoors because the building partially "traps" the gas, making indoor radon the greater risk.

Radon in water poses a risk, in part because a fraction of waterborne radon volatilizes into indoor air, and, in part, because of ingestion of waterborne radon. EPA has proposed regulating radon in water based on its responsibilities under the Safe Drinking Water Act and the risks it associates with inhalation of airborne radon that comes from water and risks from ingesting water that contains radon. The proposed regulation is opposed by many utilities that provide drinking water. They claim that EPA has overestimated the number of cases of cancer that can be expected from radon in water and that the regulation will cost more than EPA estimates. The resulting controversy over the expected benefits and costs of the regulation resulted in Congress's directing EPA to revisit its estimates of benefits and costs and to submit the revised estimates to EPA's Science Advisory Board for review. That review concluded that the estimate of neither benefits nor costs is certain, and EPA has not yet released its report (November, 1993).

The indoor radon issue is a case study of the interplay between risk assessment and risk management. It is discussed here in two parts. The first part examines the opportunities to derive a more certain estimate of the risks from indoor radon; the second presents options for addressing the inconsistency in Federal approaches to reducing exposures to indoor radon.

RADON EPIDEMIOLOGY AND RISK FROM RADON IN WATER

Extrapolating from the results of animal tests to estimate the risks to humans complicates most risk assessments. It does not complicate the issue of risk from radon, however, because information about radon comes from studies of exposed humans. Nevertheless, no direct information exists to associate exposure to indoor radon with the risk of cancer. Instead, information has been culled from studies of miners. Miners in the past were exposed to radiation levels well above those experienced in most dwellings and, indeed, well above the levels experienced in today's regulated mines and other nuclear workplaces. Moreover, the miners were exposed to other toxic substances in the workplace, and almost all of them smoked. (Smokers are much more likely than nonsmokers to develop lung cancer as a result of radon exposure.)

Estimating the risk posed by radon in homes, therefore, involves an extrapolation from the effects seen at high levels of exposure and under mining conditions to estimates of the cancer rates that may be associated with the lower levels of radiation encountered in homes. Although some of the specifics differ, radon is typical of all assessments that depend on using risk data from high exposures in the workplace as the basis for estimating environmental risks. The options that follow focus on epidemiologic studies that might better inform estimates of risk from radon. In addition to those, it is possible that laboratory studies of the mechanisms of carcinogenesis and of the chemistry and molecular biology of repairing radiation-caused damage will be instrumental in Confirming or altering risk estimates.

There is no requirement for direct evidence of risk to justify environmental regulations. In fact, for many regulated chemicals, the evidence of cancer risks comes from animal toxicity testings. The projected risks for some of these chemicals are so small (risks of 10^{-6} to 10^{-5}, which are equivalent to between 3 and 30 excess cancer deaths per year in the United States), that no epidemiologic study can detect them. The risks of lung cancer deaths from indoor radon, however, are sufficiently large-EPA calculates them as between 7,000 and 30,000 deaths annually, with upwards of 90 percent of those deaths

occurring among smokers—that they might be verified, falsified, or sharpened by epidemiologic study. Studies to date do not answer the question of whether the risk estimate is correct, but ongoing or future studies may provide an answer. Such information could improve public health decisions regarding exposures to radon and provide researchers with invaluable experience through an investigation designed to test the accuracy of a risk assessment.

ISSUE 5: Can epidemiologic studies confirm, reject, or sharpen the estimates of the risk posed by indoor radon?

According to EPA and DOE, scientists around the world are conducting some 18 epidemiologic studies to determine quantitative relationships between exposure to different levels of indoor radon and rates of cancer. The studies share certain characteristics: all involve locating people with lung cancer or the records of people who have died from lung cancer and comparing their exposures to radon and other risk factors with the exposures of people who do not and have not had lung cancer. The frost group of people are called "cases," the second, "controls"; the studies are called ''case-control studies. ' Ideally, exposures to indoor radon are determined by measuring the levels of radon in all of the houses in which each case and control lived. (In practice, houses sometimes have been torn down or are no longer available for such measurements.)

The studies can differ from one another in a number of ways. Some studies question both cases and controls (or their surviving next of kin) about diet. All of them include questions about smoking, and some may obtain more complete information than others about radon exposure. Such differences complicate the interpretation of all of the studies taken together. For example, studies that do not ask about diet cannot supply information about that issue, and the rigor with which questions about smoking habits are asked provides more or less certain information about that risk factor. Such difficulties in comparison and interpretation can be at least partly overcome by the technique of meta-analysis.

Option A: Accept the results of a meta-analysis as sufficient to answer questions about the level or risk posed by exposures to indoor radon.

Some of the 18 epidemiologic studies of indoor radon noted above have been completed, and the results are mixed. Some show no association between levels of indoor radon and rates of cancer, and some show a trend in increasing rates with increasing exposure. All of the studies are hampered by their small size-a few hundred or fewer cases and controls—and all of them have limited power to detect increases in cancer that would be expected if the currently accepted method of extrapolating from the results of the miner studies is accurate. Combining the results of all studies in a meta-analysis will increase the statistical power of the analyses and may be able to inform scientists and policyrnakers about the level of risk posed by exposure to radon in homes.

Both DOE and EPA are considering meta-analyses that will begin when the ongoing studies have been completed and published. DOE has designated two university researchers as coordinators for the review, one in the United States for analysis of North American studies and one in England for analysis of European studies. The ongoing studies are expected to be completed in 1994; allowing 12 months for the analyses would mean that results from the meta-analysis should be available in 1995. (It may be more realistic, given how schedules slip, to expect the results of the meta-analysis in 1996.) Completion of the meta-analysis will not mark the end of the flow of new information about radon, however, and new information will be factored into other meta-analyses as it becomes available. For instance, two case-control studies, one in Iowa and one in Missouri, are expected to be quite informative but will not be completed before the end of 1997.

When the DOE or EPA meta-analysis is complete, the scientists involved will probably have satisfied themselves that the evidence supports one of three conclusions about the risks from indoor radon: 1) the studies of indoor radon and cancer justify no change in the estimates of the range of risks and the best estimate of risk based on the miner studies; 2) the studies justify changes in the estimates; or 3) the studies, for whatever reasons, do not provide sufficient information to decide between conclusions 1 and 2.

Reaching conclusion 1 or 3 would support EPA's continuing use of the current risk estimate, based on the miner data, in risk management decisions. Conclusion 2 would probably lead to consideration of a new risk estimate, and risk management decisions are certain to be influenced by such a change. Whatever conclusion is reached, Congress or a department or agency in the executive branch might consider an additional study to examine the question of how much lung cancer is associated with exposure to indoor radon.

Option B: Convene a planning group to consider a study to answer questions about risks from exposure to indoor radon.

Based on extrapolations from the studies of miners, EPA's best estimate is that residential exposure to radon is associated with about 14,000 deaths (with a range of between 7,000 and 30,000 deaths) from lung cancer annually. These estimates are sufficiently large that the risks, if they are realized, might be detectable in an epidemiologic study. One scientific justification for a large-scale study of the effects of exposure to indoor radon is that it offers the chance to test a risk assessment estimate-in this case, the estimate of risk from indoor radon that is based on the miner studies.

In 1981, OTA proposed a large-scale study of lung cancer to provide definitive answers about quantitative relationships between smoking patterns and lung cancer, as well as information about occupational and other exposures and lung cancer. To those still-valid justifications can be added the opportunity to learn about quantitative relationships between indoor radon and lung cancer.

Lung cancer is the most frequent cause of death from cancer in the United States. Congress could directly mandate that a committee be established to plan a large-scale study of lung cancer in the United States, or it could direct a department or agency of the executive branch, to establish such a committee. The committee could be housed in an executive branch organization, at the National Academy of Sciences, in a university or consortium of universities, or at OTA. Its functions would be to decide whether any study can provide a definitive answer to the question of how much risk is associated with indoor radon and, if it is possible, to design such a study. If an organization such as the Risk Assessment Research Agency (described in issue 2) or the Center of Research Policy (described in issue 1) were established, it would be appropriate to assign it the task of deciding whether a large-scale study of indoor radon should be undertaken.

A committee such as that just described offers several advantages. Its deliberations would be highly visible. It would call attention to the process of designing the study and invite the participation of everyone with a stake in its design; that inclusiveness would promote efforts to make the study as comprehensive as possible. If the study were comprehensive, it might provide substantial data not only about radon but also about smoking, occupational exposures, dietary habits, and perhaps other risk and protective factors. The committee could decide whether to collect and store lung tissue from subjects in the study to provide material for biochemical and molecular analysis, both with current techniques and with techniques yet to be developed.

Yet the chances of agreeing that such a study is possible and that it could provide definitive answers are probably rather small. Obtaining accurate measures of past exposure to radon is fundamental to the success of such a study, as is

obtaining accurate information about past or present smoking, exposure to environmental tobacco smoke, workplace exposures, and eating habits. The planners may well conclude that no study can obtain that information with sufficient accuracy to provide definitive answers. That decision would not be without value: the evaluation methods used by the committee would find further employment in the Government's consideration of requests for epidemiologic studies to investigate other environmental hazards.

If the planning committee decides that no feasible study could be designed to answer questions about indoor radon, Congress and the country might have to accept that radon reduction activities would continue to be based on risks estimated from the studies of miners. It is also possible that the costs of a study like the one described above or the time necessary to complete it would make the effortless than worthwhile, and Congress could decide not to fund it.

Finally, Congress could decide that the study was feasible and worthwhile and could allocate funding for its conduct. If that decision were made, policy makers would have to decide on a regulatory course for the time necessary to conduct the study. In particular, a decision would have to be made about whether to impose a moratorium on regulating radon until the study was finished.

Planning such a study could involve one or two staff members for perhaps 2 years and the cost of three meetings of the committee. It would also include evaluation and review of all documents and their publication. The total cost of the planning phase would be between $250,000 and $750,000.

Whatever the results of the epidemiologic effort, any result that does not support the current risk estimate is likely to cause few difficulties for scientists but substantial problems for regulatory agencies. Although scientists may have to modify their conclusions as new results are produced, the nature of their data-dependent work makes such revisions relatively commonplace. In contrast, EPA might have to adjust its regulations, which is a more difficult task. If the new studies show that the risk estimate on which the regulations are based is low, tighter regulations can be drafted in keeping with the new information. If the current risk estimate is found to be high, the regulations could be relaxed, but relaxing regulations has proved to be difficult in the past. Moreover, the expenses borne under the prior regulation would not be recoverable.

ISSUE 6: Can there be a consistent approach to reducing radon exposures?

The request that OTA examine questions relating to indoor radon was prompted by EPA's proposal to regulate the level of radon in water to 300 pCi/L under provisions of the Safe Drinking Water Act. According to EPA, that concentration in water will contribute 0.03 pCi/L radon to air because of the volatilization of radon from water. (The ratio of radon in water to radon in air that originates from the water source is about 10,000 to 1.) The request to OTA noted that the regulatory goal, 0.03 pCi/L, is lower than the concentration of radon in outdoor air, which varies between 0.1 and 0.5 pCi/L; in addition, it is more than a hundred times lower than EPA's ''action level" for indoor radon, which is currently 4 pCi/L. The request asked OTA to examine the inconsistency' between and among the levels and provide options for a more consistent approach to reducing risks from radon (see box l-A).

The apparent inconsistency arises because different laws apply to radon in different media. Under the SDWA, EPA sets goals for the maximum contaminant levels of toxic substances in water. For carcinogens, those goals are zero because of the policy position that exposure to any level of a carcinogen poses some risk. When zero is not attainable, EPA generally sets the maximum contaminant level (MCL) to allow the cancer risk from the substance in drinking water to range between 10^{-4} and 10^{-4}. Although EPA's

proposed MCL for radon in water, 300 pCi/L, was established because EPA concluded that the technology was available to achieve this standard, it is nevertheless associated with a risk of 2 X 10^{-4}, which is near the desired range.

The goal of the Indoor Radon Abatement Act (IRAA) is to reduce exposures to indoor radon to the same levels seen in outdoor air. Currently, EPA's action level of 4 pCi/L radon in air is greater than that goal, and it is based, at least in part, on practical considerations, As former EPA Assistant Administrator L.S. Wilcher noted:

> While the 4 pCi/L target risk for radon in indoor air represents a higher level of risk [than the risk associated with the proposed MCL for radon in water], it is the lowest risk level which the Agency considers to be technologically feasible for all homes.

The inconsistency takes on practical significance when the observer considers the contribution that radon in water makes to total exposure to radon. The proposed regulation of radon in water would reduce the concentration of radon in air that comes from water to 0.03 pCi/L and leave most of the exposure to indoor radon unaddressed. Indeed, EPA's Science Advisory Board said in 1992, ''Frankly, radon in drinking water is a very small contributor to radon risk except in rare cases, and the Committee suggests that the Agency focus its efforts on primary rather than secondary sources of risk. '

Formally, three approaches are available to address the inconsistency: 1) reduce exposure to radon from air that enters the house to the level of radon expected from the volatilization of radon from water under the EPA's proposed regulation; 2) relax the proposed regulation on exposures from waterborne radon so that exposures from water and air are reduced to some comparable level; or 3) work toward a politically acceptable compromise between reductions in waterborne and airborne radon.

The first approach is impossible. EPA's proposed regulation would reduce the concentration of radon in air that comes from water to 0.03 pCi/L. The 'background' concentration of radon in outdoor air is approximately 10 times higher than EPA's regulatory limit for radon in water. Therefore, the infiltration of outdoor air into a house produces a 10-fold higher concentration than EPA would allow from water. As is recognized by IRAA, it is impossible to reduce indoor concentrations below outdoor concentrations.

Under the second approach, the proposed regulation of waterborne radon could be put aside and new regulations brought forward so that the contribution from waterborne radon to inside radon is no greater than the contribution from outside air or no greater than some fraction of the contribution from outside air. This second approach is discussed in the options below. Its advantages include eliminating the inconsistency and reducing the costs of the water regulation; its primary disadvantage is that it would lessen the reduction in exposure to radon that would be achieved under SDWA regulation.

Acknowledging the tradeoff in the second approach leads to the third. Resolution of the inconsistency, should it be reached, would surely be a political act, perhaps involving Congress, EPA, other agencies, both Federal and non-Federal, and private sector organizations.

OTA offers the following three options that address the inconsistency identified in the request.

Option A: Accept the inconsistency and let the Environmental Protection Agency deal with exposures to radon under existing laws.

The inconsistency does not prevent actions to reduce exposure to radon. In responding to congressional inquiries, EPA points out that its approach to regulating radon parallels its approach to other waterborne carcinogens. In addition, the agency actively encourages citizens to test houses and other buildings for radon gas and to take action if the levels of radon in air are greater than 4 pCi/L. Should Congress do nothing

further about regulating radon, EPA will probably continue along this course.

Under its responsibilities for the SDWA, EPA estimates that about 41,000 water suppliers now produce and distribute water that would exceed the proposed regulatory standard. EPA specifies aeration as the best available technology to reduce concentrations of radon in those systems to the proposed regulatory limit, and it has estimated the benefits and costs of that course of action.

As a result of the so-called Chafee-Lautenberg Amendment (Section 591 of the Housing and Urban Development, Veterans Administration, and Independent Agencies Appropriations Bill of 1992), EPA completed a multimedia risk assessment for radon in July 1993. The same amendment imposed a moratorium, which expired on October 1, 1993, on EPA's proposed regulation. [Congress has extended the moratorium to October 1, 1994.] The amendment was prompted by the inconsistency of approaches to reducing exposure to radon and the costs of the proposed regulation. As Senator Chaffee said during consideration of the amendment:

> The dispute here is about the relative risk of radon in drinking water. And since the Federal Government does not require that any steps be taken to correct the principal source of the risk, namely the gas that comes from the soil, the drinking water suppliers, quite rightfully, wonder why they should be required to clean up drinking water at a great expense.

The results from the congressionally mandated 1993 multimedia risk assessment were very nearly the same as those that EPA presented in its proposed regulation in 1991. According to EPA, the regulation will save about 80 lives annually. Some organizations, such as the Natural Resources Defense Council (NRDC) and Friends of the Earth (FOE) have stated that an MCL of 300 pCi/L is too high and that it (and the attendant risk) can be reduced further. Some water suppliers, pointing to the costs of the measure, also object to the proposed MCL. In its draft regulation, EPA estimated that each averted cancer death would cost about $2.3 million. On one side of the argument, some water utilities estimate costs of between $65 million to **$89** million for each averted cancer death and between $443 million and $592 million for each averted cancer death in nonsmokers. Arguing on the other side, NRDC and FOE assert that a lower MCL would require regulation of more water suppliers with further reductions in radon exposures and in cancer risks at little additional cost.

The costs of regulating radon in water can be compared with the costs of childhood immunizations, a public health measure that has greatly increased in cost in recent years and produced calls for reducing the profits of pharmaceutical companies. The costs of childhood immunizations have increased from between $7 and $23 in 1982 to between $129 and $244 in 1992. The annual cost of regulating radon in water—estimated by EPA to be about $50 per family served by average-sized water supply systems and $120 per family served by small systems-ranges between a fifth to a little less than half the one-time cost of immunization. The estimate by the Association of California's Water Agencies of $340 per family per year for the radon-in-water regulation exceeds the one-time cost of immunization.

The continuing annual family cost—between $50 and $340-of the radon-in-water regulation (which will affect about 1 percent of the total exposure to radon) can also be compared with EPA's estimate of the cost of actions to reduce the amount of radon entering homes directly from the soil. Direct entry of radon from soil contributes, on average, 99 percent of the radon in indoor air. The one-time cost of bringing indoor radon concentrations down to 4 pCi/L or lower ranges from $500 to $2,500 per house, with an average of $1,200 and average operating expenses of $68.

Whatever the actual costs would be, it is likely that NRDC and FOE are correct in stating that reducing concentrations to levels below the MCL is possible and could be realized if the regulation

were made final. Given the capital and operating costs of reaching the proposed MCL and the possibility that the MCL would be changed as technology improves, many water suppliers will probably design their systems to reduce concentrations to a level well below the currently proposed MCL. Moreover, NRDC and FOE cite experts who state that the only additional cost, after aeration systems are installed, of lowering radon concentrations in water is the cost of electricity. The review by EPA's Science Advisory Board of the agency's 1993 multimedia risk assessment suggested that EPA should consider using granulated activated charcoal as an alternative for radon removal in some water systems. The costs of that course of action have not been estimated.

The option discussed here, allowing EPA to continue along the course it has plotted, will not address the inconsistency in the legislation, but it could nevertheless be presented to the public as the chosen option. The inconsistency is built into the current system; it does not make the system unworkable.

Option B: Use the reauthorization of the Indoor Radon Abatement Act to direct EPA to integrate all routes of exposure in considering acctivities to reduce exposure to radon.

The multimedia risk assessment demonstrates again that only a small part of the risk posed by radon comes from waterborne radon. It does not offer guidance for what is to be done as a result of that demonstration.

If Congress decides that the multimedia risk assessment or other considerations suggest a new approach to reducing radon exposures, it can use the reauthorization of the IRAA as a vehicle. However, while Congress is working out the details of an integrated approach to reducing exposures to radon, it would probably have to advise EPA about regulating radon in water.

If Congress anticipates that an integrated approach to reducing exposure to radon would produce a different level for radon in water than the level proposed under the Safe Drinking Water Act, it could direct EPA to continue the moratorium on the proposed regulation. Or, as an alternative to having no regulation of radon in water while EPA works out an integrated program of exposure reduction under the IRAA, Congress could require EPA to set a standard for water, taking into consideration other radon exposures. For instance, radon in water could be regulated so that it contributes no more radon to indoor air than is present in outdoor air. (As an approximation, the Science Advisory Board suggests that the regulatory level for radon in water under this approach be set between 1,000 and 3,000 pCi/L rather than at 300 pCi/L as in the current proposal.) Such an approach would serve at least three purposes: it would reduce the greatest risks from radon in water; it would provide valuable experience to EPA, utilities, and engineering and consulting firms in designing mechanisms to reduce concentrations of radon in water; and it would allow for adjusting those levels after the integrated exposure reduction program is completed under the IRAA. Moreover, results from ongoing or future epidemiologic studies may alter EPA's risk estimates. The period allowed for EPA to develop an integrated radon exposure program under the IRAA would permit the incorporation of new scientific information.

A congressional decision to delay the proposed regulation of radon in water has drawbacks as well. It will allow more exposure than would be permitted if regulation proceeded under the SDWA. As a result, some of the exposures that would have been averted under the SDWA would remain. A decision to delay the regulation would also insinuate Congress into EPA's regulatory program and interfere with the functioning and autonomy of that agency.

Option C: Include radon in a comprehensive law for regulating indoor air.

Some indoor air pollutants, such as radon, arise from soil and water. Others come from utilities, as

when natural gas is used for cooking and heating; from cooking itself; from building materials such as asbestos; from formaldehyde in carpeting; from commercial chemicals; and from biological sources-animal dander, insect parts, molds, and mildews. Over the years, legislators have considered enacting an indoor air pollution law to address these complicated exposures. Such legislation, combined with Congress's directing EPA not to regulate radon in water under the SDWA, could resolve the inconsistency in current approaches and give EPA the authority to approach indoor radon in a unified, multimedia way. Treating the risks presented by indoor air in a concerted fashion would probably lead to greater reductions in overall exposures than would be achieved under current laws. In general, the solutions to indoor air problems caused by different substances are all likely to follow similar paths, such as improving ventilation and filtration, among others. A single piece of legislation might facilitate considering the risks as a whole rather than piecemeal.

Given the time it takes to enact legislation, implement new programs, and draft regulations, a few years might pass before radon in water is regulated under a new, comprehensive law. To deal with that possibility, Congress could direct EPA to formulate interim regulations, as in option B, to limit radon in water to levels that contribute no more to total exposure than does outdoor air.

EPA administers 12 laws. That multitude of mandates and responsibilities reflects the twists and turns of increased concern about the environment over the years and Congress's intense interest in the agency's functioning. The suggestion of a new law directed at indoor pollutants does not mean that the number of laws would be increased by one. Rather, it could lead to subsuming the IRAA under the new law and keeping the number of laws constant.