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Paustenbach

Human and Ecological Risk Assessment

Theory and Practice

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Theory and Practice

Edited by

Dennis J. Paustenbach

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FOREWORD

EIGHT LESSONS FROM THE REAL WORLD OF RISK ASSESSMENT

"Life is about risk, and it ends badly," Senator Daniel Patrick Moynihan once observed wryly in response to my testimony as U.S. Environmental Protection Agency (EPA) Administrator about risk assessment and the regulatory process. The always thoughtful, often provocative New York senator intended by his observation to remind me to keep things in perspective, not to be defensive about failing to ensure zero risk in environmental regulations. The function of risk assessment, Moynihan believed, is not to drive risks to zero, which would rarely be possible, but to illuminate choices, costs, and priorities. The first discovery in applying risk assessment to the real world is that zero risk is not a prudent objective of policy. Moynihan understood that. But the position is not obvious.

A regulator wishes to provide maximum protection when formulating a new rule. But the very enterprise of honestly assessing, even to the point of quantifying, risks is a confession of limited expectations. Someone still may become ill or even die. Better that the rule protect life and do so unqualifiedly. That, in fact, was the thinking behind the Delaney rule, which prohibited even trace elements in processed foods of substances that had been found, in any quantity, to cause cancer in test animals. As testing became more refined it became more impractical to ensure that no single molecule of such chemicals be present in processed foods. And although Delaney did not apply to fresh fruits and vegetables, moves to eliminate infinitesimally small amounts of carcinogenic chemicals sometimes threatened to raise the costs or reduce the availability of an important source of nutritious foods. In instances where risks can be entirely eliminated, through substituting a different process or chemical for an offending product, the regulator's task is simple. But decisions that reach the EPA Administrator are rarely straightforward and typically involve tradeoffs. "Zero risk" is not ordinarily an option in regulating any more than in other areas of life.

The first of the eight lessons that I learned as administrator was that different federal agencies can come to very different conclusions about risk. It frankly was the biggest and most disturbing of my experiences with risk assessment to learn that the U.S. Food and Drug Administration's regulation of dioxin in the early 1990s was an order of magnitude less conservative than EPA's dioxin standard. The difference had huge economic consequences: if the EPA standard was applied, compliance costs would be billions of dollars more than if

the FDA standard were used. When I asked the EPA Science Advisory Board to advise me on which agency's approach was sound, they concluded that both standards had been reached using scientifically accepted methodologies for extrapolating from test animals, one using a method based on the body weight of the rats, the other based on the skin surface of the animals. I found this advice highly disappointing and frustrating. The temptation, if both risk assessments were scientifically valid, was to choose the FDA approach since it entailed the least cost to the economy.

After receiving the scientists' inconclusive judgment about EPA's dioxin standard, and also reading other papers raising serious doubts about our understanding of dioxin, I ordered a full-scale scientific review of dioxin. That review was designed to involve the best governmental and nongovernmental expertise on all aspects of dioxin, and to be fully transparent, peer-reviewed at every stage of the review. It was intended to serve as a model, for all government agencies confronted by expensive and controversial scientific problems and particularly for EPA, which has sometimes been criticized for not opening up its scientific reviews to outside involvement or to public view. That review, only recently completed and released, now stands as perhaps the most extensive and thorough, and longest running, risk assessment ever undertaken. The original impetus for it was my discovery that scientists considered two risk assessment techniques technically valid even though they resulted in widely divergent conclusions. So my second lesson is that differing methodologies result in different conclusions about risk even among experts and in my view make a powerful case for harmonizing protocols in order to retain the confidence of the decisionmakers and the public.

A third lesson, also driven home to me by my encounter with dioxin regulation, was the need to look beyond a simple toxic endpoint such as cancer. One criticism of EPA's early approach to dioxin and other chemicals concerned the agency's focus on cancer in its toxicological characterization. Historically, EPA has given a high priority to cancer in the design of regulations. Some American scientists and many Europeans have criticized what they see as an excessive preoccupation with cancer, in EPA as in the broader society in this country, to the neglect of neurological, fetal, endocrinological, and other impacts. The dioxin study was intended to respond to this criticism by analyzing a broad suite of possible effects on human health.

A regulator must, in fact, balance and weigh various types of risk and illness when making policy. The by-products of chlorination of drinking water expose the public to a lifetime cancer death risk estimated to be one in a hundred thousand, a risk greater than the one-in-a-million range EPA generally prefers. EPA and the broader society accept such a risk because of the much larger offsetting risk posed by cholera, typhus, and various intestinal disorders chlorination protects against. The task for the regulator is to balance the risks and benefits. As assumptions and risk ranges become more transparent, the regulator's decisionmaking process can seem coolly cerebral, calculating body counts by the numbers. The temptation is to fudge the numbers and not acknowledge the tradeoff

that is implicit in a selection of lesser evils. My fourth lesson from my experience is that tradeoffs are unavoidable and that evolving technology and growing transparency will illuminate them more starkly, heightening further the importance of keeping the public's confidence in EPA and other regulatory bodies.

Differing characterizations of risk and varied methodologies for risk assessment are not only found among different agencies. Even within EPA itself, programs take different approaches to risk. In some instances this is inevitable. When regulating for air pollution or pesticide levels in food, for example, the affected public is the entire population. When regulating for Superfund, however, a much smaller population that resides near abandoned hazardous waste dumps is affected. Thus the pesticides' program is concerned with average individual risk, based on assumptions derived from U.S. Agriculture Department studies of how much of different foods Americans actually eat. In contrast, assessments of waste sites might focus on the maximally exposed individual (MEI).

The air program, in setting standards for hazardous air pollutants, bases its decisions on two populations: on aggregate population risk and on maximum individual risk. We used this approach in setting the standard for benzene in 1991, when we set a standard designed to result in no greater than a six-in-ten-thousand risk to the very small percentage of the population that works daily with benzene in coke by-product recovery plants, on benzene storage vessels and the like, and one-in-a-million average lifetime risk to more than 95% of the population. (The Clean Air Act amendments of 1990 required major and expensive changes to coke ovens to make them much safer. I do emphasize that the exposure assumptions are very conservative.) The fifth lesson is that the nature of a problem, its situational reality, the degree to which it affects the larger population or whether it has a more selective impact on certain subsets of the public, justify tailoring the methodology and risk characterization to the specific problem.

A word about exposure assumptions. In 1990, the FDA, implementing a new analytical procedure, was able to detect much smaller concentrations of contaminants than under its previous system. As a result, FDA found residues of the fungicide Procymidon in French, Italian, and a small amount of Spanish wines. Procymidon was widely used in Europe to protect grapes against the fungus botrytis. Botrytis is desirable to concentrate flavor in sauternes, but it's a serious problem for most grape growers. Procymidon had been issued a tolerance or maximum permissible residue level in Europe and Japan, but the manufacturer had never applied for one in the United States, and as long as FDA was not detecting it, there was no concern.

Once we became aware of the presence of an unregistered chemical in imported wine, I ordered a ban on further shipments. The ban caused wine to accumulate in the warehouses and on the docks of European ports. The European Union's (EU's) commissioner for agriculture indicated that more than $400 million of EU exports were being excluded, and there were dark fears that my move was driven by trade and not environmental considerations. Noises were even made about retaliation against U.S. agriculture exports.

EPA pesticides' and toxics' staff determined that based on limited testing that had been done and made public, Procymidon in very large doses had caused cancer in test animals, but that the levels represented in imported wines posed a negligible risk. As soon as we concluded that any risk was negligible, we looked for a means consistent with our laws to allow preexisting stocks of wine to come in.

In the meantime I was visited by the French ambassador who was incredulous that the United States would exclude a half billion dollars' worth of trade when the decision-maker himself and his expert staff considered the threat negligible. The French believe more in a politics of consequence than of process.

The Italian ambassador also paid me a call. He, too, was uncomprehending. "If it's not a risk, why not let it in?" he said. And then he asked about the data from test animals. I told him about the male rats fed high doses of Procymidon who had developed cancer of the testicles. "Of the testicles," he cried. "Italian wine! Nothing could be worse." I had the impression that like a lot of American risk experts he thought we were overdoing it on cancer, but the reproductive organs, that was something much more serious, that got his attention.

Ultimately, we set an interim tolerance for already treated grapes based on available data, and banned imports of all future Procymidon-containing wine pending the full range of tests required to earn registration in the United States. During one meeting with staff on the matter, I ascertained that our initial exposure assumption was based on a consumption over several decades of two liters per day of wine containing Procymidon. I said surely that's unreasonable, no one drinks two liters a day. And one of my staff members quietly replied, "Yes they do; my father does."

There truly is a maximum exposed individual. One may ask fairly whether it is the function of regulators to fashion policies protective of such consumption practices if the cost to the rest of society—to grape growers and wine makers and wine buyers and drinkers—is consequently much higher.

Notice here just how conservative the EPA staff's initial approach was. The two liters containing Procymidon would have had to have come from the 20% of French wine containing Procymidon or the 10% of Italian wine so affected. Letting a little light in on the exposure assumption revealed how unrealistic it was. Nevertheless, the lesson here is that a hugely consequential decision had to be made with partial data. My sixth lession is that much if not most decisionmaking about risk will be tentative and uncertain, valid to the degree it is founded on current science but vulnerable to revision in the light of new research.

Superfund has relied on different exposure assumptions from other EPA programs, though it conducts its risk assessments similarly. The risks it addresses are worst-case, hypothetical present and future risks to the maximum exposed individual, i.e., one who each day consumes two liters of water contaminated by hazardous waste. The program at one time aimed to achieve a risk range in its clean-ups adequate to protect the child who regularly ate 10,000 milligrams of dirt.

And it formerly assumed that all sites, once cleaned up, would be used for residential development, even though many lie within industrial zones. Some of these assumptions have driven clean-up costs to stratospheric levels and, together with liabilities associated with Superfund sites, have resulted in inner-city sites suitable for redevelopment remaining derelict and unproductive. The consequence, in New Jersey and other areas, has been to impose a drag on urban redevelopment in the inner city, and to push new industry to locate in pristine, outlying sites. My seventh lesson is that the resulting loss of property tax revenues, industry, and jobs in many older urbanized areas is itself a kind of pathology our environmental laws should consider, particularly as we have become more sensitive to issues of environmental justice for people of color. Fortunately, during the 1990s, more realistic assumptions about future uses, and consequent changes in cleanup standards, came to be accepted.

An important role of the regulator is to communicate clearly about risks. I once was presented data indicating an unacceptable high residue of the pesticide EBDC in many fruits and vegetables. EBDC at high doses had induced carcinogenic tumors in test animals. I ordered a ban on further applications of this widely used chemical. Scientific staff who briefed me on the available data told me they strongly suspected that further analysis would show that by the time fresh fruits and vegetables passed through supermarkets and reached people's tables there would be negligible or even nondetectable residues of the pesticide. When I conducted the press conference announcing a ban on application of EBDC for more than 40 food products I also said that, if further research indicated that the carcinogenic risk was negligible I would remove the ban. Over the following year additional testing was done and it was reassuring, as EPA scientists had predicted. However, when I then proposed to follow through and remove the ban the same scientists were incredulous. "The press will murder you," one said; "you've admitted that EBDC is a known carcinogen." I went ahead and announced removal of the ban, informing the press that I had promised to follow the science. I invited the press to treat the issue seriously and reminded them that their hyping of an earlier pesticide scare, Alar, had resulted in mothers calling EPA in tears because they had fed their children fresh apples. Press reaction was, in fact, straightforward in reporting on the scientific basis for the decision. Thus, the eighth lesson I learned is that consistent communication about risks, always relying on the science, can go a long way toward warding off public health scares and in shaping a careful and responsible journalistic take on a complex, potentially alarming, problem.

This, then, is the real world of risk assessment. To a regulator it requires a balancing of goods and bads, tradeoffs of apples and oranges. And it rests fundamentally upon sound science, upon samples, tests, studies, comparisons, experimentation. Before there can be specific numerical probabilities of illnesses or deaths for a decisionmaker to ponder, there must have been careful research. Scientific method undergirds the entire regulatory system. This book is an important contribution to the evolving science of risk assessment upon which so much of the integrity and effectiveness of environmental policy rests.

When Dr. Paustenbach's previous text was published in 1989, it filled an important void in the environmental sciences. Before that time, risk assessments were usually conducted by regulatory agencies or those within the regulated community (and their consultants) and were of varying quality. Most of these assessments lacked transparency, that is, few persons knew exactly how the calculations were performed and the basis for the exposure factors and other assumptions. Further, only a few assessments had been published in peer-reviewed journals before 1990 and this tended to inhibit the maturation of the scientific aspects of risk assessment. Thus, his textbook of case studies became a foundation against which others could assess the thoroughness of their work.

This new text comes at a time when the field has passed through its infancy and is now a generally well-respected approach for objectively evaluating environmental issues. Many well-known and respected authors have contributed to this text and have described methods that they have used to evaluate complex environmental questions. Appropriately, an emphasis has been placed on presenting analyses that address topics ranging from risks due to contaminated groundwater, occupational hazards, radionuclide emissions to the community, consumer products, and a variety of risks to wildlife. The overall quality of the text, with the emphasis on providing transparency in the calculations, the quantitative description of uncertainty in the risk estimates, and the importance of proper risk characterization should help ensure that better quality risk assessments are conducted in the coming years. Students and practitioners will benefit significantly from the work of Dr. Paustenbach and his colleagues.

WILLIAM K. REILLY

William K. Reilly is chairman of the Board of the World Wildlife Fund, and was Administrator of the U.S. Environmental Protection Agency under President George H. W. Bush. He headed the U.S. Delegation to the Rio Conference on Environment and Development in 1992.

FOREWORD TO THE FIRST EDITION

Having twice served as Administrator of the Environmental Protection Agency, first in the early 1970s and, most recently, in the mid-1980s, I am convinced that significant differences exist between those two periods of time. In the early 1970s our overriding concern was the gross pollution of our air and our water; this was pollution that we could smell, see, and feel, and that had a significant effect on the environment in which we lived or played. In the mid- to late-1970s, our focus changed and we became more concerned about toxic pollutants—those that affect our health. Cancer and its causes became significant factors in how we feel about environmental contaminants. The concern over cancer coupled with our ability to detect vanishingly small amounts of contaminants dramatically increased the reach and costs of present-day environmental regulations.

The difference in our perception of environmental threats has led us to different approaches in dealing with those threats. It seemed to me in the early 1970s that money alone would solve most of our pollution problems. It soon became obvious that there would never be enough money and that there would always be new environmental problems to solve. The challenge was how to make intelligent judgments about the health risks posed by the myriad of pollutants of concern and which to address first.

When I went back to EPA in 1983, one of my primary goals was to introduce into the EPA decision-making process the concepts of risk assessment and risk management, and to ensure that everybody understood that there was a clear and necessary distinction between the two concepts.

Risk assessment is the scientific evaluation of the human health impacts posed by a particular substance or mixture of substances. Risk management involves a whole host of factors, such as technological feasibility, cost, and public reaction; factors that must be purged from the risk assessment process to the extent possible.

We also tried at the EPA in the mid-1980s to bring some commonality to the risk assessment process for substances that were dealt with by other agencies of the federal government such as the Occupational Safety and Health Administration, the Food and Drug Administration, and the Consumer Product Safety Commission. Our effort in this regard has been modestly successful. It is fair to say that, as a result of the dedication and determination of many in the federal government in recent years, the quantitative approach to analyzing environ-

mental problems, which is the essence of risk assessment, has become generally accepted.

As is clearly demonstrated in this text, many of the ideas which we proposed in 1983 have been implemented in recent assessments. Unlike earlier attempts, scientists have become more comfortable with describing the uncertainties in the assessment process. They also feel more comfortable about stating that sufficient scientific data are not available to reach a firm conclusion.

It is also apparent from the assessments presented in this text that we are more skilled at estimating human exposure and more willing to acknowledge the uncertainties in our estimates of the possible risks associated with exposure to carcinogens and developmental toxicants. Perhaps the most important breakthrough is that the final decision, the risk management judgment, is no longer confused with the scientific evaluation of the data. This change is important and hopefully permanent.

An area where I felt scientists and risk assessors, in particular, could do a better job was in the communication of risk. We need to describe the hazards posed by suspect substances as clearly as possible, tell people what the known or suspected health problems are, admit our uncertainties, and help the public understand the risk in a larger context. There are a number of examples in this text which do a good job of showing how to present these issues in a comprehensible form.

Scientists should be willing to take a larger role in explaining risks and the risk assessment process to the public. Unfortunately, due to the great pressures on regulatory agencies, the regulated community, and the consultants who serve each of them, scientists have rarely had the opportunity to reduce these often voluminous assessments into papers suitable for publication. Indeed, only a handful of risk assessments addressing specific contaminated sites or chemicals have been published.

For many reasons, Dr. Paustenbach's text is an important and timely contribution to the fields of environmental and occupational health. The breadth of our environmental concerns is clearly illustrated by the diversity of issues discussed here.

He and his colleagues are to be congratulated for having prepared a reference text which presents a large number of rather complex evaluations. This text can serve as an important reference point against which risk assessments of the coming years can be compared. It is my hope that future evaluations will be much improved as a result of the information presented here.

WILLIAM D. RUCKELSHAUS

Former Administrator
United States Environmental Protection Agency
June 1, 1988

PREFACE

Since World War II, most persons living in industrialized nations have enjoyed an amazing improvement in their quality of life and standard of living. For example, mortality at childbirth is no longer considered to be a serious risk, to either the mother or the child. Specific diseases, such as cholera, whopping cough, polio, malaria, diphtheria, measles, and mumps, are now relatively insignificant or have been virtually eliminated in the United States and most other developed countries. Life expectancy continues to increase with each decade and a greater percentage of Americans report that they look forward to living into their seventies, eighties, and beyond. Increased longevity is largely a result of numerous technological advances that have resulted from the synthesis of more than 100,000 different chemicals. Many of these chemicals are pesticides and herbicides which make it possible to feed the world's growing population, as well as life-extending pharmaceuticals.

However, while the existence of such chemicals has improved the quality of life, the improper handling and disposal of many chemicals from about 1900 to 1970 resulted in significant degradation of the environment. It was determined that the presence of industrial chemicals in our food, groundwater, soil, sediment, and ambient air posed some yet-to-be-fully-understood human and ecological hazards. Public concern about these chemicals in the early 1960s, coupled with Rachel Carson's 1962 book entitled *Silent Spring*, essentially launched the first wave of environmentalism in the United States. Since then, virtually everything about the way we handle chemicals—from basic research, through manufacture, to ultimate disposal—has changed. From about 1970–1985 alone, nearly two dozen major pieces of federal legislation and thousands of regulations were promulgated in the United States in an effort to control how chemicals were manufactured, used, distributed, and disposed. However, in spite of implementation of better controls, clean-ups, lesser emissions, and these regulations, the majority of Americans continue to perceive chemicals in the environment to be among the greatest health risks that they face.

During this same 10–15 year period, our analytical methodologies became much more sensitive. Thus, we began to find chemicals in our food, air and water which has previously gone undetected. By 1980, we were able to measure chemical concentration levels in the parts per billion (ppb) and parts per trillion (ppt) range in most environmental media. Due to these incredible technological advancements in analytical chemistry, it was no longer informative to tell the public that "a certain chemical has been detected in a particular media and that

at some dose in some animal test that chemical produced some adverse effect." It was obvious that merely detecting even the most acutely toxic substance did not mean that it would pose a significant health hazard. Instead, an approach for making decisions about the significance of environmental sampling results and toxicity data was needed. Thus, the practice of risk assessment drew broad support. Over time, the relatively primitive approaches of the 1970s that were used to characterize risk soon evolved into the current practice of risk assessment. It took only a few years for risk assessments to be considered the primary scientific tool for combining the information from animal toxicity studies, dose–response data, and exposure studies to predict risks to humans and aquatic/avian species. By the mid-1980s, risk assessments were a consideration in virtually all decisionmaking.

Over the past 25 years, the practice of risk assessment has evolved considerably. Initially, the scientific community was quite excited over the possibility of quantitatively predicting risks to humans. Significant sums of money were spent to reduce exposures to certain chemicals when the predicted lifetime cancer risk to an individual exceeded some arbitrary risk criterion, such as 1 in 100,000 or 1 in 1,000,000. Thousands of lawsuits were also filed alleging harm from possible exposure to extremely low concentrations of various substances. Our confidence to precisely predict cancer risks and characterize certain non-cancer hazards, however, eventually eroded as we learned that biology and ecology just aren't that simple. By the late 1980s, it was clear that there were perhaps as many as eight different general modes or mechanisms through which chemicals could cause cancer and that each probably required a different mathematical approach for predicting risk at low doses (something yet to be adequately understood). Scientists learned that not only were toxicity and exposure aspects important, but the persistence of the chemical in humans and the environment also needed to be understood. Thus, the focus on pharmacokinetics and environmental fate/transport. By the 1990s, it became even more clear that our emphasis on cancer effects may have been well intended, but perhaps the non-cancer risks (developmental toxicity, reproductive impairment, endocrine effects, etc.) were even more important than once thought and the cancer risks due to environmental contaminants were relatively inconsequential.

Although the field of risk assessment had matured by the early 1990s, it was often not a transparent process. For example, not all of the bases for exposure calculations were described, the various results from low-dose extrapolation models were not always presented (with confidence limits), the studies which constituted the hazard identification were not always critically evaluated (with weight given to the better studies), the risk characterizations were often one sided or not clearly presented, and the uncertainty in the results was rarely quantitatively described. In large measure, the quality of the assessments stagnated in the 1980s because few, if any, were published in the peer-reviewed literature and there was no compendium or text where persons could see how these assessments were or should be conducted. It was this state of affairs that convinced me that it was time to assemble and share many of the better risk assessments of the period;

an effort that came to fruition in the form of the first edition of this book. I believe that the success of that text, which sold more than 5,000 copies, illustrated that scientists were anxious to learn how to conduct high-quality assessments, and there was an interest in having greater transparency in the process. Hopefully, the significant improvement in the quality of risk assessments conducted over the past ten years is, in part, due to the case studies that were presented in that text.

The practice of risk assessment has significantly improved over the past decade for many reasons. First, more than 200 risk assessments have been published in the peer-reviewed literature. These include comprehensive articles on stationary or mobile sources as well as articles that deal with predicting risks due to exposure to single and multiple chemicals at low doses. Second, at least five peer-reviewed journals now focus on the topic of risk assessment: *Risk Analysis, Regulatory Toxicology and Pharmacology, Journal of Toxicology and Environmental Health, Human and Ecological Risk Assessment*, and *Journal of Environmental Toxicology and Chemistry*. More than a dozen other major journals also occasionally publish articles that focus on some aspect of risk assessment. Third, at least five professional societies place a strong emphasis on risk assessment: Society for Risk Analysis (SRA), International Society for Exposure Assessment (ISEA), International Society for Regulatory Toxicology and Pharmacology (ISRTP), Society of Toxicology (SOT), and Society of Environmental Toxicology and Chemistry (SETAC). Fourth, the U.S. Environmental Protection Agency (EPA) has done an outstanding job at producing documents that have helped standardize and elevate the overall practice of risk assessment by publishing nearly 5,000 pages of general reference and guidance documents. Other nations have also developed a number of publications that have helped bring uniformity to the risk assessment process on an international level.

The purpose of this text, which presents both theory and practice, is to provide the scientific community with an up-to-date single source of information about how to conduct human and ecological risk assessments. The diversity of subjects addressed and the specific cases were intended to share with the reader many of the changes and improvements in the practice of risk assessment that have occurred over the past decade.

The chapters of this book are presented in such a way that the text can be used in graduate level courses, or can serve as a daily reference for practitioners. The first section addresses the basic components of a human health assessment: hazard identification, dose–response assessment, exposure assessment, and risk characterization. The second section deals with the same components, but as they relate to ecological risk assessment. In short, the first six chapters represent the theory portion of the book.

Most of the remaining sections present various case studies that address some of the common environmental and occupational health challenges that scientists have faced over the past 10–15 years. Because it is expected that these same problems (contaminated food, soil, air, water, sediment, and consumer products) will require our attention for at least another 20 years, I believe these case

studies will be most helpful to those scientists tasked with characterizing the associated risks. As in the first text, cases involving chemical hazards and exposure to radionuclides are included.

The number of chapters devoted to ecological issues is greater than in the prior text because, in my view, the focus of most of the major risk assessments in the coming years will be driven by hazards to wildlife or contamination of domestic animals and fish that are consumed by humans. Although this field is still evolving, it has made tremendous advances over the past decade and this will undoubtedly continue throughout the next decade. I expect many of the lessons learned in conducting assessments of human health hazards to continue to be experienced by scientists and regulatory agencies in the ecological arena. Due to the myriad of mistakes made and dead ends pursued over the past 20 years on the human health side, it is my expectation that the learning curve in ecological risk assessment should be far less costly.

As before, a section which addresses risk communication and some aspects of risk management is included. Unlike the previous text, a section on evolving issues has been added. Although perhaps surprising, during the early to mid-1990s, it was unclear to me that there were going to be a sufficient number of new and challenging topics to warrant bringing better scientists to the environmental field. I was also concerned that risk assessors had already developed techniques for addressing nearly any question one could raise about human health hazards. At the time, it seemed that most of the exciting improvements were going to be in the field of ecological assessment. However, the introduction of human health concerns about endocrine disruptors, the threat to children's health, chemical mixtures, persistent organic pollutants (POPs), genetically modified foods, subtle non-carcinogenic effects and genomics has convinced me that there is at least another decade of exciting challenges facing risk assessors.

Because risk assessments have definitely earned their place in the decision-making process, it seemed reasonable to add chapters on life-cycle analyses and cost–benefit analysis. After presenting more than 1000 pages illustrating the way to conduct high quality assessments and having illustrated their usefulness and importance, it only made sense to close the text with a discussion of the precautionary principle. For the past five years, it has been speculated by many scientists and regulatory agencies that a scholarly application of the precautionary principle could bring an end to risk assessment and, as such, it seemed an appropriate thought-provoking topic for closing the text.

Risk assessments offer an opportunity for the public to develop an understanding of the critical issues associated with the presence of industrial (and pharmaceutical) chemicals in our environment. It has been, and continues to be, my belief that if emotionalism and subjective claims carry more weight than a thorough and objective analysis, mankind will almost surely compromise its ability to achieve all of the goals of which it is capable. A number of scientists and political scientists have warned us of the hazards of such an approach (see the book *The Demon-Haunted World* by Carl Sagan). If we wish to maintain a standard of living close to that to which we have become accustomed in the de-

veloped countries, we need to evaluate the various controllable risks in a uniform and scientifically defensible manner. Such evaluations should help ensure that significant hazards are controlled while insignificant ones are placed much lower in our priorities.

The contributors to this text are among the premier persons in the field. Approximately 60 contributors were drawn from more than a dozen scientific disciplines. They have been responsible for conducting a significant fraction of the important assessments in the United States. Some have helped formulate both domestic and international environmental policies and regulations. It has been an honor to work with them over the three years needed to bring the text to completion. Their qualifications are exceptional and their understanding of the field is validated by the quality of their contributions. I thank each scientist who participated.

Even though I have carefully read and critiqued every chapter, I am unable to endorse uniformly each of the methods used or opinions expressed by the various authors. Since these authors are experts in their respective specialties, it would be presumptuous to have insisted that all of them approach their analysis in exactly the same manner that I might have chosen.

I would especially like to thank my various administrative assistants of the past 4 years for their enthusiasm and support. Specifically, I thank Suzanne Milani for initially saying that "there is at least one more book left in you" and who helped me launch the effort. She was followed by an incredibly disciplined and supportive colleague, Bev Wicker. Lastly, I very much appreciate the support of my current assistant, Neha Patani, who was able to pull together the loose ends and help bring the project to closure.

I also wish to express a special thanks to Bob Esposito of John Wiley & Sons. He is a true professional who values his authors.

It is my hope that you will learn as much from this text as I did in assembling it.

DENNIS J. PAUSTENBACH

Woodside, California

CONTRIBUTORS

BRUCE N. AMES, Department of Molecular and Cell Biology, University of California-Berkeley, Berkeley, California 94720

DEBORAH BENNETT, Harvard School of Public Health, 401 Park Drive, Room 404L, P.O. Box 15677, Boston, Massachusetts 02215

RANJIT BHARVIRKAR, Department of Civil Engineering, North Carolina State University, Raleigh, North Carolina 27695-7908

J. N. BLANCATO, National Exposure Research Laboratory, U.S. EPA, Las Vegas, Nevada 89119

MARGARET A. BRANTON, ARCADIS, 301 East Ocean Boulevard, Suite 1530, Long Beach, California 90802

LARRY BREWER, Springborn Laboratories, Inc., 790 Main Street, Wareham, Massachusetts 02571

TIMOTHY CARROTHERS, Pharsight Corporation, 800 W. El Camino Real, Mountain View, California 94040

GAIL CHARNLEY, HealthRisk Strategies, 826 A Street SE, Washington, DC, 20003

VALERIE A. CRAVEN, Exponent, Inc., 631 First Street, Suite 200, Santa Rosa, California 95404-4716

C. C. DARY, National Exposure Research Laboratory, U.S. EPA, Las Vegas, Nevada 89119

WILLIAM DESVOUSGES, Triangle Economic Research, 2775 Meridian Parkway, Durham, North Carolina 27713

E. DONALD ELLIOTT, Yale Law School, New Haven, Connecticut 06520

SHIH SHING FENG, Applied Biosystems, Inc., 850 Lincoln Centre Drive, Foster City, California 94404

BRENT FINLEY, Exponent, Inc., 631 First Street, Suite 200, Santa Rosa, California 65404

SUSAN M. FLACK, ENSR International, 1544 North Street, Suite 110, Boulder, Colorado 80304

H. CHRISTOPHER FREY, Department of Civil Engineering, North Carolina State University, Raleigh, North Carolina 27695-7908

GEORGE FRIES, Independent Consultant, 2205 Bucknell Terrace, Silver Spring, Maryland 20902

LOIS SWIRSKY-GOLD, Carcinogenic Potency Project, Lawrence Berkeley Laboratory, One Cyclotron Road, Mail Stop: Barker Hall, Berkeley, California 94720

MICHAEL GOODMAN, Exponent, Inc., 310 Montgomery Street, Alexandria, Virginia 22314

JOHN D. GRAHAM, Center for Risk Analysis, Harvard School of Public Health, Boston, Massachusetts 02115

KIRK J. GRIBBEN, Alcoa, Inc., Alcoa Technical Center, 100 Technical Drive, Alcoa Center, Pennsylvania 15069-0001

THOMAS E. GUARDINO, ECONorthwest, Eugene, Oregon 97401

MARK HARRIS, Harris Environmental Risk Management, 1900 Bluffview Court, Flower Mound, Texas 75022

SEAN M. HAYS, Exponent, Inc., 4940 Pearl East Circle, Suite 300, Boulder, Colorado 80301

MIRANDA HENNING, ARCADIS, 24 Preble Street, Suite 100, Portland, Maine 04101

W. E. KASTENBERG, Nuclear Engineering Department, University of California-Berkeley, 4103 Etcheverry, Berkeley, California 94720-1730

BRENT KERGER, HSRI, Inc., 2976 Wellington Circle West, Tallahassee, Florida 32309

JIM KNAAK, University at Buffalo, Department of Pharmacology and Toxicology, 7 Earldom Way, Getzville, New York 14068

LESTER LAVE, Carnegie-Mellon University, GSIA (Tech and Frew St.), Carnegie-Mellon University, Pittsburgh, Pennsylvania 15213

NANCY LA VERDA, Exponent Health Group, 310 Montgomery Street, Alexandria, Virginia 22314

HON WING LEUNG, Independent Consultant, 15 Deer Park Road, Danbury, Connecticut 06811-2717

GEORG LEUBECK, Fred Hutchinson Cancer Research Center, 1100 Fairview Avenue, Seattle, Washington 98109-1024

HEATHER MACLEAN, University of Toronto, Toronto, Ontario, Canada, M51A1

H. SCOTT MATTHEWS, Carnegie-Mellon University, GSIA (Tech and Frew St.), Carnegie-Mellon University, Pittsburgh, Pennsylvania 15213

KRISTY E. MATTHEWS, Triangle Economic Research, 2775 Meridian Parkway, Durham, North Carolina 27713

MONTE A. MAYES, Dow Agro Sciences, 9330 Zionsville Road, Indianapolis, Indiana 46268

T. E. MCKONE, University of California-Berkeley, 140 Warren Hall, #7360, Berkeley, California 94720-7360

HARRY L. MCQUILLEN, U.S. Fish and Wildlife Service, 2800 Cottage Way, Room W-2605 Sacramento, California 95825

SURESH MOOLGAVKAR, Fred Hutchinson Cancer Research Center, 1100 Fairview Avenue, Seattle, Washington 98109-1024

WARNER NORTH, NorthWorks, Inc., 1002 Misty Lane, Belmont, California 94002-3651

ROB PASTOROK, Exponent, Inc., 15375 SE 30th Place, Suite 250, Bellevue, Washington 98007

G. T. PATTERSON, Department of Pesticide Regulation, State of California, Sacramento, California 95814

DENNIS PAUSTENBACH, Exponent, Inc., 149 Commonwealth Drive, Menlo Park, California 94025

BARBARA PETERSEN, Novigen Sciences, Inc., 1730 Rhode Island Ave., NW, Suite 1100, Washington, DC, 20036

PAUL S. PRICE, The LifeLine Group, 129 Oakhurst Road, Cape Elizabeth, Maine 04107

DEBORAH PROCTOR, Exponent, Inc., 320 Goddard Way, Suite 200, Irvine, California 92671

DAVID RABBE, Chemical Land Holdings, Inc., Two Tower Center Boulevard, 10th Floor, East Brunswick, New Jersey 08816

DOUGLAS P. REAGAN, URS Greiner Woodward Clyde, Stanford Place 3, 4582 South Ulster Street, Denver, Colorado 80237

WILLIAM REILLY, Aqua International Partners, L.P., San Francisco, California 94104

FRANK SELKER, Decision Management Associates, LLC, Portland, Oregon 97201

ANNE SERGEANT, U.S. EPA, Office of Research and Development, National Center for Environmental Assessment, 1200 Pennsylvania Avenue, NW, Washington, DC, 20460

JANE SEXTON, Exponent, Inc., 15375 SE 30th Place, Suite 250, Bellevue, Washington 98007

PATRICK SHEEHAN, Exponent, Inc., 1970 Broadway, Suite 250, Oakland, California 94612

WALTER SHIELDS, Exponent, Inc., 15375 SE 30th Place, Suite 250, Bellevue, Washington 98007

THOMAS H. SLOAN, Department of Molecular and Cell Biology, University of California-Berkeley, Berkeley, California 94720

PAUL SLOVIC, Decision Research, 1201 Oak Street, Eugene, Oregon 97401

JESSICA GLICKEN TURNLEY, Galisteo Consulting Group, Inc., 2403 San Mateo Boulevard NE, Suite W-12, Albuquerque, New Mexico 87110

JOHN WARMERDAM, Exponent, Inc., 1970 Broadway, Suite 250, Oakland, California 94612

NADINE M. WEINBERG, ARCADIS, 24 Preble Street, Suite 100, Portland, Maine 04101

TOMAS WIDNER, ENSR International, 1420 Harbor Bay Parkway, Suite 120, Alameda, California 94502

JONATHAN B. WIENER, Center for Environmental Solutions, Duke University, Box 90360, Durham, North Carolina 27708

PAMELA WILLIAMS, Exponent, Inc., 4940 Pearl East Circle, Suite 300, Boulder, Colorado 80301

NATALIE D. WILSON, N.D. Wilson & Associates, LLC, 12948 Victoria Avenue, Huntington Woods, Michigan 48070