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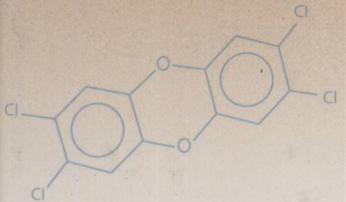

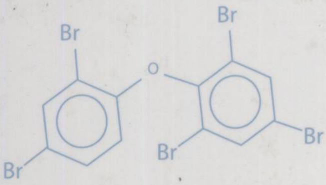

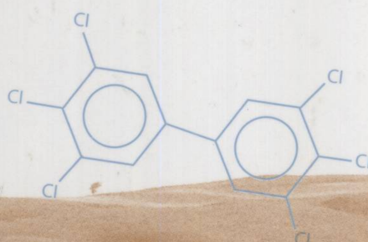

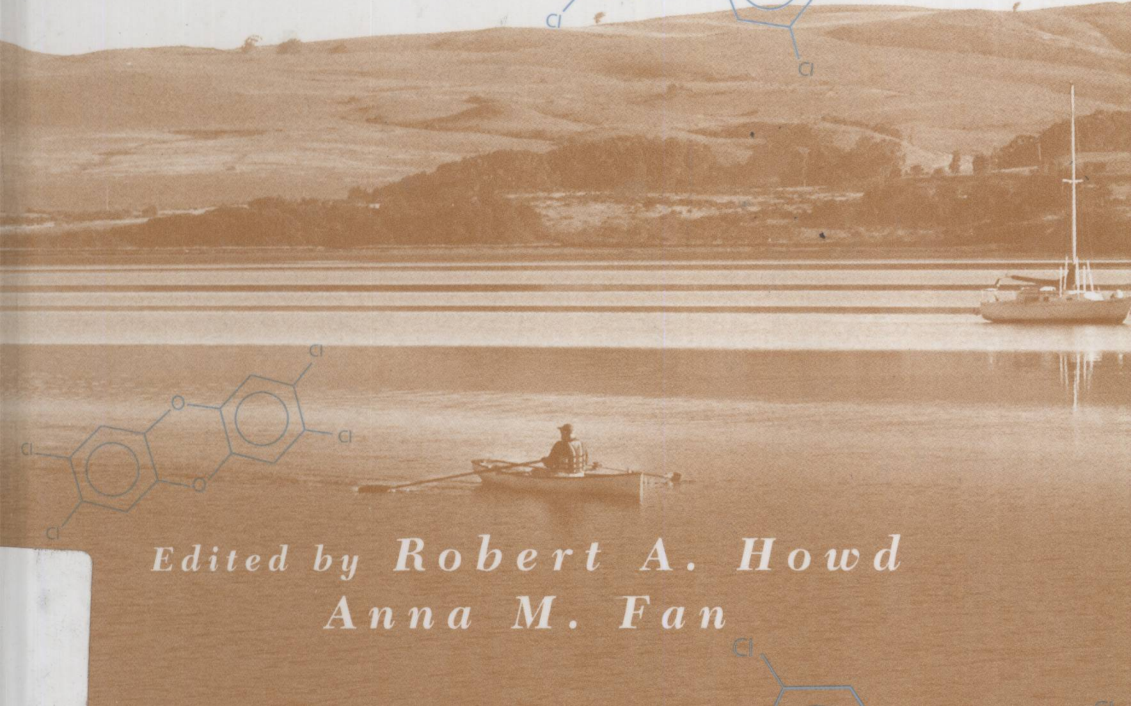

Edited by **Robert A. Howd**
Anna M. Fan

RISK ASSESSMENT FOR CHEMICALS IN DRINKING WATER

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FOREWORD

People have a right to expect that the water they drink, the food they eat, the air they breathe, and the environments where they live and work promote the highest possible level of health. They rely on their health agencies to identify hazards in these environments and to prevent avoidable exposures that are inconsistent with this objective.

Public health systems work best when they prevent hazardous exposures without waiting for epidemiologic studies to measure the adverse effects. This is possible through consideration of experimental studies and models that can identify health risks before they can be observed in humans. This means, however, that risk assessment models often cannot be validated by direct observation, as can models in other fields such as demographics, economics, or weather.

Accordingly, the methods of risk assessment are as important as the results of any one risk assessment. Continuous examination is necessary to ensure that risk assessment methods reflect current scientific understanding and benefit from new experimental systems and models. At the same time, public health agencies are facing new demands, for example, to evaluate the cumulative effects of multiple hazards on susceptible populations and life stages. Risk assessors are meeting this challenge by developing methods that go beyond single-chemical, general-population scenarios to address more complex, but also more realistic, situations.

This volume, which examines current risk assessment methods for chemicals in drinking water, should facilitate understanding and improvement of these methods. It includes perspectives from scientists who are grappling with contemporary risk issues at the California EPA, Health Canada, and the U.S. EPA's program, regional, and research organizations.

The existence of vigorous, independent risk assessment programs in many countries and also in state agencies is essential to the public health infrastructure. These programs can be viewed as laboratories where innovations in risk assessment methods are developed, implemented, and tested. The best of these ideas receive wider discussion en route to refinement and adoption by other state, national, and international agencies. Such innovation and examination ensures that risk assessment methods continue to reflect emerging scientific understanding and to meet the needs of health agencies worldwide.

The California risk assessors who have edited this book have a unique and valuable perspective in that California has committed to an independent risk assessment of all regulated chemicals in drinking water. In an effort to share their knowledge gained through years of experience in drinking water risk assessment, they have assembled a stellar list of co-authors to address critical regulatory and risk assessment issues. Although not every important subject can be covered in depth in a single volume, this book represents an important compilation of observations and documentation of risk assessment methods, plus a useful guide to the rest of that voluminous literature.

VINCENT JAMES COGLIANO

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PREFACE

Risk assessment for chemicals in drinking water has much in common with risk assessment for other purposes, together with some elements that are unique. This book is intended to cover both aspects, to provide an integrated source of information on the current principles and practices. It is based on many years of experience in the practice of risk assessment, by the editors and the authors. The perspective taken is that of public health protection, as practiced by federal and state governments, mainly within the United States. The most important source of risk assessment guidance available is the United States Environmental Protection Agency (U.S. EPA). However, information relevant to risk assessment of chemicals in drinking water is scattered across dozens if not hundreds of publications, some not readily available, spanning over the last twenty years. For this book we have attempted to assemble and summarize this information to provide a more comprehensible and up-to-date resource.

In taking on the task, we have also attempted to capture current thinking on major risk assessment issues, uncertainties, and ongoing controversies. We acknowledge that our perspectives do not encompass the entire spectrum of toxicology and risk assessment opinion and practices, and we stand by the use of health-protective assumptions in risk assessment. That is a basic requirement for a public health agency. Our intent in pointing out the uncertainties and controversies is to address the health protectiveness of current practice as well as to indicate areas where current practice might be improved by obtaining information to more adequately address or reduce these uncertainties.

However, when the uncertainties in risk assessment of chemicals in drinking water are acknowledged, risk assessors may face certain criticisms. The general public dislikes being told about uncertainty in protecting their health; the purveyors of drinking water who want to assure the public that their water is safe to drink are not receptive to hearing about how much we do not know; the chemical producers or users often tend to think that the uncertainties about chemical hazards are being vastly overstated. In some cases, there are also community organizations that believe the chemical risks are being understated. The lack of complete or adequate information and the need for methodology development to parallel the generation of new data leave room for future resolution of currently existing scientific issues and conflicts. The responsibility of risk assessors for public health purposes is to examine carefully all the available information, describe and interpret it fairly, and conduct risk assessments that are sufficiently health protective.

Most of the risk assessment experience of the editors has been with the state of California. Our department, the Office of Environmental Health Hazard Assessment (OEHHA) in the California Environmental Protection Agency (Cal/EPA), is the principal risk assessment group for California and has been developing guidance on acceptable levels of chemicals in drinking water for about twenty years. The current system was created with the formation of Cal/EPA in 1991, which incorporated the then-existing risk assessment responsibilities from the Department of Health Services. The program was further strengthened with the passage of the California Safe Drinking Water Act in 1996 (HSC 116350-116415). In California, OEHHA provides the risk assessment for chemicals in drinking water, while the responsibility for regulation of chemicals resides in the Division of Drinking Water and Environmental Management of the Department of Public Health. This is consistent with the guidance in the classic reference, *Risk Assessment in the Federal Government: Managing the Process* (National Research Council, 1983), which recommended separation of risk assessment and risk management. The federal government and many states have a similar system whereby the risk assessment and regulatory functions are kept at arm's length. The U.S. EPA practice is explained in detail in Chapters 1 and 2.

Although microbiological hazards are a major factor in providing safe and potable drinking water, this discussion focuses on the chemicals that may be found as drinking water contaminants. This is largely because microbiological contaminants are addressed in different ways, with different risk assessment methods, and often, by separate governmental agencies or departments. The exclusion is not meant to imply that microbial contaminants are any less important. In fact, development of safe drinking water supplies was initiated and sustained by the need to protect against microbial contamination. That this has led to secondary problems with chemical contaminants formed in the disinfection process is a fact of life for chemical risk assessors, and should not be taken as a source of conflict between those whose task is to manage microbial contamination and those whose focus is on the chemical contaminants. The editors hope that this book may be of interest and use to both groups.

The discussions of risk assessment practices in this book describe the present state of the field and are also intended to reveal directions in which it might be improved. The current practices are under continuous reevaluation and critique. However, advances in risk assessment practices do not occur through the efforts of any central committee, nor by a single systematically organized process, but rather through an avenue of open discussion and input for developing a reasonable level of consensus. Any thoughtful scientist can undertake the initial steps, by pointing out an issue and proposing how it might logically be addressed. This book is intended to support this larger interest group, because the larger the audience of concerned citizens, the more rapidly the issues can be identified and addressed. A majority of senior professionals currently involved in the practice of risk assessment have developed the specialty during their careers. Because the work involves multiple disciplines, they have a special appreciation for how a diversity of backgrounds has enriched the present practice of risk assessment, and wish to see this process continue.

The basic issue is that risk management is best carried out by regulatory agencies, while risk assessment should be driven by science. However, science considerations are often intertwined with the social and economic aspects, and thus may be caught up in the political process. Perhaps this is more likely to occur at the national level, where the results of a decision will have a greater impact, as compared to the state or regional levels. This may lead to situations in which a state is in a better position to address important issues than those who are nominally the national leaders. This is an underlying theme in some of the chapters, but not necessarily made explicit in them.

The California Office of Environmental Health Hazard Assessment has the largest state organization for risk assessment and therefore has been in a unique position to provide an independent viewpoint for risk assessment, with the resources necessary to provide the scientific support for it. The drinking water program at OEHHA has the legislative mandate to provide independent reviews of all regulated chemicals in drinking water. The state law specifies that California standards (maximum contaminant levels) can be equal to or lower than the federal standards. In addition, California can develop regulations for chemicals not regulated at the federal level. In several cases OEHHA risk assessments for emerging chemicals have been finalized earlier than those of U.S. EPA, and California regulations were subsequently developed earlier than national standards. This has not necessarily put us at odds with U.S. EPA scientists, with whom we are likely to be in agreement, but rather, we have occasionally been the standard bearers for new concepts. In some cases California has been first to implement risk assessment practices first described and endorsed by U.S. EPA.

This perspective of the entrenched outsider—the loyal opposition, if you will—was a major factor leading the editors to develop this book. While often finding ourselves not totally hand in hand with the progress at the national level, we press forward, sometimes with the support and encouragement of U.S. EPA staff, sometimes not. This book might be considered to be a showcase for these efforts as a whole. That is, we present here, with the assistance of several U.S. EPA authors and other leaders in risk assessment practice, an overview of the field both as we see it and as we would like it to become—through the combined efforts of those who wish it to be carried forward. Our overall goal is to promote and encourage the science of risk assessment, particularly for exposure to drinking water contaminants.

The book first covers the major concepts and considerations of risk assessment, including how the present practice has evolved and is evolving. We wish to highlight major ongoing efforts, such as the influence of a better understanding of toxicological mechanism on risk assessment, the improved cross-species extrapolation that can be achieved by considering the basic physiological processes of the test species compared to humans, and the sources of variations in toxicological responsiveness. For the latter consideration, major efforts are being put into documentation of changes associated with the different human life stages, from the fetus to the elderly and frail population. Eventually, these present efforts will revolutionize risk assessments, and we can only hope to capture a snapshot of these efforts in passing.

The chapters on risk assessment practices are followed by descriptions of risk assessments of specific chemicals, which are used to illustrate a theme or problem. These chapters illustrate some of the interesting problems of risk assessment, and it should not be inferred that risk of all, or even a majority of the regulated chemicals, is controversial or poses some quandary to the risk assessors (or risk managers). In fact, almost the opposite is true. Most chemical risk assessments are rather straightforward. Needless to say, those are not discussed in detail here. But with the issues and discussions presented, we hope that something else shines through in this lengthy tome—that risk assessment can be intellectually stimulating, and even fun. Most of us like our jobs and enjoy the challenges provided by this risk assessment profession. We hope this is noticeable.

The two final chapters of the book more explicitly describe risk assessment needs and propose directions for the future. You will learn about some frustrations, but also about goals and dreams. Despite our immersion in the day-to-day problems of deadlines, data interpretations, and bureaucracy, it is important to step back once in a while and look around at where we are—or should be—going. This book has provided us the opportunity to do that, for which we are grateful.

Robert A. Howd
Anna M. Fan

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1

INTRODUCTION TO DRINKING WATER RISK ASSESSMENT

ROBERT A. HOWD
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The need for a clean and safe drinking water supply for centers of population has been recognized for over 2000 years. The early Romans recognized that human activities and effluent were a major source of water pollution, and that providing water from relatively unpopulated areas was a solution to the problem. In 312 B.C. the Romans under Appius Claudius began development of an aqueduct system to deliver water taken from the Tiber River upstream of the city, thus improving the quality and quantity of their water supply (Okun, 2003). It has been said that the availability of a good water supply through their extensive aqueduct system enabled the rise of Rome as a center of civilization—and it has also been speculated that the use of lead for water pipes helped lead to its downfall, through slow poisoning of the population. This has been disputed, with evidence that terra-cotta was a preferred piping material, resulting in better-tasting drinking water. Thus, the maintenance of drinking water quality has been a major quest throughout the development of modern civilization.

However, it was not until the efforts of John Snow in 1854, analyzing a cholera epidemic in London, that specific diseases were shown to be associated with drinking waters that looked and tasted clean. For those who may not have heard the story, John Snow, a London doctor, noticed that many of the people who died of cholera in that summer's epidemic had a common factor; they all obtained their drinking water through the Broad Street well. He had the pump handle removed and the epidemic faded away. For this analysis and his subsequent publications,

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John Snow is credited as being the father of epidemiology. An excellent summary of these events is available at the Web site of the University of California–Los Angeles, at http://www.ph.ucla.edu/epi/snow.html.

If the slow progress of development of safe drinking water supplies from early Roman times until the mid-nineteenth century seems strange to us today, we should recall that the "germ theory" of disease wasn't elucidated by Louis Pasteur until two decades later, in the late 1870s. Recognition that bacteria were major causes of diseases, that these bacteria could be distributed in drinking water, and that removing the bacteria would protect the population from important diseases such as cholera and typhoid eventually followed.

In the United States, water quality was at first maintained in exactly the same way as in ancient Rome, primarily by transporting clean water through pipes and canals from sparsely populated regions. The need and purpose were exactly the same: to protect the drinking water supply from sewage contamination. However, transporting water over large distances is expensive, and obtaining water from nearby rivers and streams was seen by many municipalities as a preferred option. Filtration through sand was instituted in the late nineteenth century to clarify the water and decrease the bacterial contamination. This step decreased the incidence of cholera, but it soon became obvious that this was not adequate. The incidence of waterborne illnesses such as cholera and typhoid was observed to correlate with the source of the drinking water supply in major American cities, even after filtration was instituted (Okun, 2003; Pontius, 2003). Removal of bacteria by chemical disinfection began to be evaluated.

Chlorination of drinking water for bacteriological control was begun in the United States in 1908 (in Boonton, New Jersey), although it had been studied extensively before that time in both Europe and the United States (Baker, 1948). The treatment was quickly demonstrated to make a tremendous difference in disease transmission. The discoveries leading to the technique are considered to be one of the greatest public health breakthroughs of all time, preventing millions of illnesses and deaths.

DEVELOPMENT OF DRINKING WATER REGULATIONS

The first regulations for drinking water purity were primarily for bacteriological control, beginning with the U.S. Public Health Standards of 1914. These first standards applied only to water used in interstate commerce. However, eventually all 50 states adopted comparable standards for their public water supply systems (U.S. EPA, 1999). Drinking water standards for chemicals were introduced in the U.S. Public Health Standards amendments in 1925, which included standards for lead, copper, and zinc. A few more metals were added in the amendments of 1942. By 1962, the 28 constituents or properties listed in Table 1 were regulated by the U.S. Public Health Service (U.S. DHEW, 1969).

Information on the potential health effects of contaminants in drinking water, particularly those derived from the developing chemical industries, accumulated