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TOXIC
SUBSTANCES
AND
HUMAN RISK
PRINCIPLES OF DATA
INTERPRETATION

EDITED BY
ROBERT G. TARDIFF
AND
JOSEPH V. RODRICKS

Toxic Substances and Human Risk

Principles of Data Interpretation

Edited by

Robert G. Tardiff

and

Joseph V. Rodricks

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Toxic Substances and Human Risk

Principles of Data Interpretation

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SELF-ORGANIZING SYSTEMS

The Emergence of Order

Edited by F. Eugene Yates

TOXIC SUBSTANCES AND HUMAN RISK

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Contributors

Larry S. Andrews ARCO Chemical Co., Newtown Square, Pennsylvania 19073. *Present address:* Agriculture Research Division, American Cyanamid Co., Princeton, New Jersey 08540

Charles C. Brown National Cancer Institute, National Institutes of Health, Bethesda, Maryland 20892-4200

Stephen L. Brown Environ Corp., Washington, D.C. 20007

David Brusick Division of Molecular Toxicology, Hazelton Laboratories, Kensington, Maryland 20895

Edward J. Calabrese Division of Public Health, University of Massachusetts, Amherst, Massachusetts 01003

Gary P. Carlson Department of Pharmacology and Toxicology, School of Pharmacy and Pharmacal Science, Purdue University, West Lafayette, Indiana 47907

James E. Cone Division of Occupational Medicine, Medical Service, San Francisco General Hospital, San Francisco, California 94110

John Doull Department of Pharmacology, Toxicology, and Therapeutics, University of Kansas, College of Health Sciences, Kansas City, Kansas 66103

Kurt Enslein Health Designs Inc., Rochester, New York 14604

Ronald W. Estabrook Department of Biochemistry, Southwestern Medical School, University of Texas Health Science Center, Dallas, Texas 75235

- Edward R. Garrett** The Beehive, College of Pharmacy, J. Hillis Miller Health Center, University of Florida, Gainesville, Florida 32610-0494
- David W. Gaylor** Biometry, National Center for Toxicological Research, Jefferson, Arkansas 72079
- James R. Gillette** Laboratory of Chemical Pharmacology, National Heart, Lung, and Blood Institute, Bethesda, Maryland 20892
- Ronald W. Hart** National Center for Toxicological Research (HFT-1), Jefferson, Arkansas 72079
- Rolf Hartung** Toxicology Program, Department of Environmental and Industrial Health, University of Michigan, Ann Arbor, Michigan 48109
- David G. Hoel** Division of Biometry and Risk Assessment, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina 27709
- Philip J. Landrigan** Division of Environmental and Occupational Medicine, Mt. Sinai Medical Center, New York, New York 10029
- Stephen L. Longacre** Toxicology Department, Rohm & Haas Co., Spring House, Pennsylvania 19477
- Robert E. Menzer** Department of Entomology, University of Maryland, College Park, Maryland 20742-5575
- Gordon R. Reeve** Epidemiology, City of Houston Health Department, Houston, Texas 77030
- Joseph V. Rodricks** Environ Corp., Washington, D.C. 20007
- Robert Snyder** Rutgers University College of Pharmacy, Busch Campus, Piscataway, New Jersey 08854
- Robert G. Tardiff** Environ Corp., Washington, D.C. 20007
- James R. Withey** Environmental and Occupational Toxicology Division, Environmental Health Directorate, Ottawa, Ontario, Canada K1A 0L2
- Jeannee K. Yermakoff** Amoco Corporation, Environmental Affairs and Safety Department, Chicago, Illinois 60601

Preface

As society has become increasingly aware of the potential threats to human health due to exposures to toxic chemicals in the environment and the workplace and in consumer products, it has placed increased demands upon the still-fledgling science of toxicology. As is often the case when science is called upon to supply firm answers when pertinent information and fundamental knowledge are lacking, both the scientific and the social issues become confused and new tensions develop. One of the major purposes of this book is to focus on those aspects of the science of toxicology that pertain most to social issues—namely, analysis of risk for purposes of human health protection.

Although it is apparent that the discipline of toxicology is not yet prepared to provide firm answers to many questions concerning human risk, it is important that the rigorously derived information be used in the most objective and logical way to yield the closest approximation to the truth. This book is designed to supply as much guidance for such tasks as is permitted by the current state of our knowledge. Its emphasis is thus placed on *interpretation* of toxicity data (broadly defined) for assessing risks to human health. In this way, it differs from other basic toxicology texts, most of which emphasize methods for performing studies or describe various toxicological endpoints and classes of toxic agents.

After placing the science in its historical context, we have attained our objective by considering the various sources of evidence—from clinical, epidemiological, and laboratory data—that are used to identify toxic hazards and to infer their implications for human health. This volume also features a summary of principles pertaining to an often neglected but critical aspect of risk analysis—assessment of human exposures to toxic substances.

The chapters provide a judgmental context for synthesizing all information and methodologies that are used to analyze human risk. Risk analysis is depicted in its broadest sense, with the emphasis on its role in “safety” assessment. One of the underlying themes of this volume—that the science of toxicology serves only to assess risks and not to decide questions of risk toleration—surfaces in the final section, in the analysis of the traditional and neotraditional roles of toxicol-

ogy in standard settings and in the lessons of the past decade insofar as they have increased awareness of the limitations inherent in toxicology's contributions to public policy.

The book is designed especially for professional toxicologists, students of the science, scientists in regulatory agencies, and the regulated community.

Robert G. Tardiff
Joseph V. Rodricks

Washington, D.C.

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I

Historical Perspectives and General Concepts

Introduction

John Doull

Most regulators have long recognized the conceptual distinction between risk assessment and risk management and have utilized both concepts in establishing tolerances and standards for protecting human health. In 1983, these concepts were redefined and expanded by a National Research Council committee in a report entitled, *Risk Assessment in the Federal Government: Managing the Process* (National Research Council, 1983). In this report, risk assessment was considered to include some or all of the following four steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization. Risk management was defined as the process of weighing policy alternatives and selecting the most appropriate regulatory action, and integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision. More recently, a third concept has been added to the process: risk communication (Thomas, 1986). These developments have had a significant impact on the role of the toxicologist in the decision-making process and focused attention on the interactions among science, law, and regulation in the arena of safety assessment. It has been suggested, in fact, that a Risk Institute is needed to investigate the scientific and policy aspects of the total process and determine the appropriate contributions of all involved parties (Press, 1984).

Since toxicology and epidemiology have traditionally provided the scientific or factual basis for the evaluation and characterization of risk, it is useful to consider the evolution of the approach of these two disciplines to the protection of public health. In the subsequent chapters of this book, both the traditional and the current approaches of these disciplines are considered along with some of the current problems in creating the data base and interpreting both toxicological and epidemiological data.

JOHN DOULL • Department of Pharmacology, Toxicology, and Therapeutics, University of Kansas, College of Health Sciences, Kansas City, Kansas 66103.