

Foreword

“Risk assessment is easy. You can learn it in two steps.... Each step takes 10 years.” This quote, attributed to Arnold Lehman of the U.S. Food and Drug Agency in the early 1950’s, epitomizes the way many of us risk assessment scientists learned our trade. That is, the very slow accumulation of knowledge wrought not only from the daily practice of one of risk assessment’s many disciplines, but also from the rubbing of shoulders with other disciplines to develop a judgment or decision for a particular chemical or situation. The interactions among the many disciplines, such as toxicology, epidemiology, and mathematics, more often resembled a logic problem or perhaps a Chinese puzzle. It was seldom that pulling on only one aspect of the problem, or depending on only one discipline among several, yielded the best decision. It was the integration of many aspects and disciplines that often yielded the best solutions. Those of us fortunate enough to have a good mentor or two, perhaps took these two steps a little more quickly. But even after 30 years in the field, I learn new things each week, and do not for one moment think it is different with any of my colleagues.

Periodic attempts at expediting this learning process have been made through the publication of books, and the development of numerous risk assessment guidelines by federal agencies of many countries or international groups, such as the International Programme on Chemical Safety (IPCS). These guidelines have in particular codified best practices. Unfortunately, these books and guidelines were written more for the practicing risk assessment scientist, not the novice.

Quite simply, a need exists for basic level and accessible educative materials in risk assessment field, and, thus, the motivation for this book. What you will find here is a focus on graduate level education, but with plenty of substance for post-doctoral students and experts from other fields that are beginners in risk assessment. The overall emphasis of this book is on balancing the theory of risk assessment with its practice. In fact, one needs to have a fundamental grasp of the overall theory of risk assessment, and be grounded in one of its many disciplines, in order to make a good practitioner.

Written by expert risk assessment scientists, who nevertheless are still learning themselves, this book will encompass the traditional areas of hazard identification—both toxicology and epidemiology evaluation, dose-response assessment, exposure

assessment, risk characterization, and mixtures assessment. However, this book also delves into emerging areas, such as data from genomic arrays, the European Union REACH, global harmonization of risk assessment approaches, training boot camps, and case studies.

In nearly all cases, risk assessment decisions and judgments will need to be made in the face of uncertainty, whether it be with individual data, extrapolation to a more relevant, and usually lower, exposures, or with the use of the results of one animal specie as a surrogate for the anticipated results in another specie. In many of these cases, the uncertainties are large and the resulting risk assessment values would perhaps be more appropriately associated by a range, rather than a single value. In fact, the idea of using a range in risk assessment values to represent the underlying biological variability has currency in recent U.S. National Academy of Science findings. But this idea really is not new. In fact, “It is the mark of an instructed mind to rest satisfied with the degree of precision which the nature of the subject permits and not to seek an exactness where only an approximation of the truth is possible.” Aristotle

Sincerely,



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Editors' Preface

We are equally passionate about the subject of risk assessment and enjoyed working together to design, propose and edit a book to convey our ideas for a simple reason—no one to date has published a book targeting individuals that want to learn about risk assessment, but have no experience in it. While there are several expert level books, they aren't for beginners.

Sol noticed when he was starting to study risk assessment, that there weren't any books like this. He used materials from publications, and several professional societies to get educated. Jose participated in several workshops on risk assessment, but did not find a basic book to complement his training. Jose also noticed that educational activities at a national meeting were not focusing on graduate students or post-doctoral trainees but rather expert practitioners. He thought there was a great opportunity to provide risk assessment education, thus Jose decided to conduct a skills survey and developed a panel presented at Society of Toxicology.

After that, Springer approached us with the idea of a book. The journey from idea to publication has taken us approximately two years, and every bit of the effort has been worth it. Sol and Jose have spent several Mondays and Fridays on conference calls, reviewing and discussing the components of the book to make sure introductory concepts are present in each chapter. The goal is by no means to be comprehensive, but rather to function as a bridge and connect readers that we presume to have a toxicology preparation, with the practical aspects of risk assessment.

Each chapter is composed of four parts that include: an abstract, learning objectives, main body and a short summary. We recommended reading the chapters in the order presented as each chapter creates a foundation for the following chapter. Learning a new topic should cover two basic questions. The first question is what? This book breaks down the “what” of risk assessment in building block chapters. The second question is how? This book also shows “how” through several examples within text, as well as case studies to practice at the end.

We are excited about this contribution to the scientific and professional community, we hope that you find it a useful resource, whether you are using it in a class, or you are learning risk assessment on your own.

We welcome your feedback on the book, to help us improve future editions, please contact us at smbobst@yahoo.com or joseanibaltorres@gmail.com.

Best Regards,

A handwritten signature in black ink, reading "Sol Bobst". The signature is fluid and cursive, with a long horizontal stroke extending from the end.

Sol Bobst, Ph.D., DABT.

A handwritten signature in black ink, reading "José A. Torres". The signature is cursive and elegant, with a large, sweeping initial "J".

José A. Torres, M.S., Ph.D.

Toxicological Risk Assessment for Beginners

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