Environmental Toxicology & Risk Assessment

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Foreword

The First Symposium on Environmental Toxicology and Risk Assessment was held 14–16 April 1991 in Atlantic City, New Jersey. ASTM Committee E-47 on Biological Effects and Environmental Fate sponsored the symposium. Wayne G. Landis (Western Washington University), Jane S. Hughes (Malcolm Pirnie, Inc.), and Michael A. Lewis (Battelle Columbus Laboratories) were the symposium chairmen. They also served as editors of this publication.

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Overview

In the five years since I (WGL) first chaired an ASTM symposium, much has changed in the field of environmental toxicology. This book is one example. In the series that spawned this volume, this book would have been the fifteenth volume of the series in Aquatic Toxicology and Hazard (and sometimes risk) Assessment. ASTM Committee E47 celebrated the accomplishment of 10 years of symposia in 1986 by having a review session summarizing the last ten years in aquatic toxicology. We expanded the symposium in 1991 to include both aquatic and terrestrial, plants and animals, and to formalize the importance of environmental risk assessment. As this overview of the 1991 Environmental Toxicology and Risk Assessment symposium volume is being written, the 1992 meeting has already been held and the 1993 meeting is in the planning stages. The editors of this volume, Wayne Landis, Mike Lewis and Jane Hughes, have participated in previous ASTM symposia and were privileged to chair the 1991 meeting and edit this volume. In the following paragraphs we will try to summarize this volume and place a perspective on its contribution in the development of environmental toxicology.

A major theme in this volume is on ecological risk assessment. The first section "Ecological Risk Assessment under TSCA" deals almost exclusively with the monumental task of performing risk assessments for thousands of compounds submitted for the Premanufacture Notification process (PMN). This section is important because it is one of the first thorough reviews of the ecological risk assessment as practiced by the Office of Toxic Substances. These risk assessments include industrial chemicals and genetically engineered organisms slated for fermentation or small scale release. Clements et al. reviews the use of structure activity relationships in the evaluation of new chemicals. Separate papers by Zeeman and Gilford and Nabholz and Miller review the ecological risk assessment process as it relates to the Toxic Substances Control Act (TSCA). Sayre and Kough review the ecological risk assessment process as it pertains to genetically engineered microorganisms, a sometimes controversial and emotion-laden issue.

As crucial as it is to obtain accurate toxicological data for a single species, there is an increasing realization that information describing the impacts of xenobiotics on the population and community levels of biological organization is equally important. This issue is discussed in the next section "Evaluating Ecological Impacts at the Population and Community Levels." New methods of evaluating populations and developmental aberrations in response to toxicant stressors was presented in papers by Emlen and followed by Graham and Freeman. Microcosms and their utility in evaluating impacts of degradative microorganisms, sediments and metals were reviewed by a series of papers by Graham and Freeman, Landis et al. and Pratt et al. Ram and Gillett concluded the session with a report on the use of an aquatic/terrestrial food web model for the assessment of the risk associated with the classical environmental contaminant, polychlorinated biphenyls.

Biomarkers or physiological indicators of stress has been an enduring topic in the field of environmental toxicology. Morphological and molecular methodologies are reviewed in this section. The morphological changes due to pH in Zygnemataceaen algae is presented by Clayton and Hoshaw. This is followed by a report by Babich and Borenfreund on the applications of the neutral red cytoxicity assay for use with aquatic organisms. Using the chromosomal puffing of *Chironomus* as an indicator of induction of proteins for detoxification and therefore an indication of toxicant impact is reported by Bentivega and Cooper. Dyer et al. report on the use of stress proteins and their use in the evaluation of water quality.

Because ASTM is a standards writing organization, among the most important aspects of the annual ASTM environmental toxicology meeting is the presentation and evaluation of new methods. The last two sections of this volume save this goal and tradition. The evaluation of contaminant hazards and impacts in the marine environment has become as important as issues of sediment toxicity, effluent toxicity from pulp and paper manufacturing, and releases of petroleum and refined petroleum products. An entire section is devoted to Marine Toxicity Test Methods to reflect this emphasis and several excellent review papers are included.

Echinoderm biomonitoring methods are reviewed by Bay to lead off the Marine Toxicity Test Methods section. Hunt and Anderson discuss how toxicity testing with mollusks has evolved from a research program to a normal and routine exercise. Marine plant toxicity testing is reviewed by Thursby et al. In addition to methods, the application of these methods to hazard and risk assessment is covered. The evaluation of potential water column toxicity due to sediment contamination is reviewed by Burgess et al. Management options as pertaining to risk for the deposition of contaminated sediments is reviewed by Peddicord.

Methods development forms a crucial part of environmental toxicology, one that is sometimes overlooked as relatively unimportant and routine. Nothing could be further from the truth. New methods in toxicity testing and evaluation are often the critical factor in the confirmation of new theories and in the acquisition of new data that confirm or refute the predictions of a risk assessment. A proposed methodology for the use of freshwater mollusks is presented by Johnson et al. Another discussion dealing with the variability of toxicity testing and the search for a reference toxicant, in this case copper and hexavalent chromium, can be found in Jop et al. Mysid shrimp have become a popular toxicity testing tool in recent years and Kahn et al. provide an interesting comparison of the toxicity of ambient waters to these organisms. Finally, Newsome et al. present a quantitative structure activity relationship study of the toxicity of amines to freshwater fish, thereby contributing to the literature estimating environmental toxicity from structure.

Overall, the papers in this volume are typical of those in the many ASTM symposia volumes that have been published during the last 15 years in that they represent a blending of regulatory concerns, basic research, risk and hazard assessment, and methods development. During the five year period from 1986 to 1991, important developments in the field of environmental toxicology occurred, especially the recognition that risk assessment is a useful paradigm by which it is possible to ask important questions. Just after the 1991 ASTM Environmental Toxicology and Risk Assessment Meeting, the United States Environmental Protection Agency sponsored a four day workshop to review the agencies risk assessment framework. The results of that workshop along with the revised ecological risk assessment framework have just been published.[1] The significance of the standards setting process that ASTM E47 contributes to is no more evident than in this document. The importance of having standard evaluation schemes for toxicity and exposure determinations and for monitoring of the accuracy of the risk assessment will be crucial to the further implementation of risk assessment in the regulatory process. Much of the development of these methods has been the subject of the 14 preceding Aquatic Toxicology and Risk Assessment volumes and this new edition.

[1] Framework for Ecological Risk Assessment, Risk Assessment Forum, U.S. Environmental Protection Agency, EPA/630/R-92/001, February 1992.

One of the most important realizations that we the editors have come to is that the change in the name of the annual ASTM symposium from Aquatic Toxicology and Risk Assessment to Environmental Toxicology and Risk Assessment reflects the maturation of the science. Researchers working with virtually any system in the field of environmental toxicology are asking the same basic questions: what is the mode of action?, what is the fate of this compound?, how does laboratory data reflect the field situation?, how important are the impacts of a toxicant on population and community level interactions?, how clean is clean enough?, how do we predict the long term effects? Within the framework of a risk assessment it should be easier to separate the important questions from those less crucial. In addition, similar questions of experimental design and intrinsic experimental variability exist regardless of the environment or species studied.

The next 15 years of ASTM environmental toxicology symposia should prove as interesting as the previous 15. How about some predictions. By the year 2006 risk assessment will be as integrated into the framework of how we think of environmental toxicology as the building blocks of DNA are to molecular biology. Estimation of chemical fate and toxicity by quantitative structure activity relationships using detailed molecular models of interactions and similarities will have replaced the models simply based on octanol/water partition coefficients. Ecosystems will undergo evaluations using multivariate means of visualizing interactions and looking at the differences in stressed versus unstressed systems. Such evaluations may replace conventional endpoints. Indexes such as the index of Biological Integrity will have long been replaced by more sophisticated means of evaluating large and complex systems.

Investigation of molecular interactions of toxicant versus site of action will be routine, both by molecular modeling and routine biochemical analysis. Research will probably still be driven by regulation, but the regulations will reflect the scientific reality. Finally, in fifteen years the three of us will be regarded, (I hope) as part of the old guard of environmental toxicology with young and perhaps irreverent scientists challenging our paradigms and pushing back the frontier.

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Ecological Risk Assessment Under TSCA

Maurice Zeeman[1] *and James Gilford*[1]

Ecological Hazard Evaluation and Risk Assessment Under EPA's Toxic Substances Control Act (TSCA): An Introduction

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REFERENCE: Zeeman, M. and Gilford, J., "**Ecological Hazard Evaluation and Risk Assessment Under EPA's Toxic Substances Control Act (TSCA): An Introduction,**" *Environmental Toxicology and Risk Assessment, ASTM STP 1179,* Wayne G. Landis, Jane S. Hughes, and Michael A. Lewis, Eds., American Society for Testing and Materials, Philadelphia, 1993, pp. 7–21.

ABSTRACT: Ecological hazard and risk assessment methods have been developed by the U.S. EPA to systematically evaluate new chemicals, existing chemicals, and genetically engineered microorganisms (GEMs) regulated by the Office of Toxic Substances (OTS) under the Toxic Substances Control Act (TSCA). About 70 000 existing chemicals are already on the TSCA Inventory, with thousands of new chemicals being assessed each year for their eventual manufacture and placement on this inventory. New chemicals have little or no ecological test data to evaluate. This lead to the development and regular use by OTS of Quantitative Structure Activity Relationships (QSARs) to evaluate the potential hazards of new chemicals to aquatic organisms. The estimates of hazard for existing chemicals and GEMs are mostly based upon test data supplied by industry. Over the last decade, OTS has identified several test endpoints of ecological concern, developed a scheme for the tier-testing of chemicals, provided guidelines on the methods for performing such tests, and evaluated and/or developed ecological data used in the assessment of thousands of chemicals. Estimates of aquatic and terrestrial hazards are compared with the concentrations of substances expected in the environment and an evaluation of the potential risk made. Ecological risk methods vary from the simple comparison of the potential hazards with the estimated exposure (that is, the quotient method) to simulation modeling.

KEY WORDS: Toxic Substances Control Act, ecological risk assessment, new chemicals, existing chemicals, GEMs, SAR, QSAR, quotient method, ecological endpoints, tier-testing scheme, ecotoxicity test guidelines, ecological risk-assessment guidelines

In September of 1990, William K. Reilly, the Administrator of the U.S. Environmental Protection Agency (U.S. EPA) received a report from the EPA's Science Advisory Board (SAB) on the appropriate priorities and strategies that the EPA should undertake in the future (EPA 1990a). The first two recommendations of the SAB were that the EPA should: 1) target its effort for the greatest risk reduction, and 2) attach as much importance to reducing ecological risk as human health risk.

Ecological risk assessment has played a secondary role to human health concerns ever since the agency was established in 1970. Nevertheless, there are portions of the EPA where a long-standing committment to the concept of ecological risk assessment has not only been embraced, but has actually been actively implemented (Rodier 1987; Walker 1990a; Nabholz 1991).

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[1] Branch Chief and former Branch Chief (retired), respectively, Environmental Effects Branch, Health and Environmental Review Division, Office of Toxic Substances, United States Environmental Protection Agency, Washington, D.C.

Background

The Toxic Substances Control Act of 1976 (TSCA) provided the EPA with the authority to require development of adequate data for assessing the risk to human health and the natural environment from industrial chemicals identified as having risk potential. Within EPA, the Office of Toxic Substances (OTS) is responsible for implementing TSCA.

The Health and Environmental Review Division (HERD) of OTS provides the expert scientific and technical evaluation of hazard of industrial chemicals and genetically engineered microorganisms (GEMS), and determines the type and adequacy of data needed to identify and assess their possible adverse effects. The scientific and technical staff implementing those aspects of TSCA concerned with adverse ecological effects of industrial chemicals and GEMs is located in the Environmental Effects Branch (EEB) of HERD. Over the last decade, this group has provided significant direction to and rationale for how ecological risk assessment activities can be accomplished within the confines of TSCA (Rodier 1987; Walker 1990a).

To assure that adequate data are developed to assess the possible adverse ecological effects of industrial chemicals, as mandated by TSCA, the EEB has established procedures and guidelines for developing data that are appropriate and adequate for assessing ecological hazard and risk. An analogous approach is currently under active development for GEMs subject to regulation under TSCA (Harrass and Sayre 1989; Sayre 1990; Sayre and Kough this volume).

For industrial chemicals, the OTS approach to ecological risk assessment (Fig. 1) is analogous to the risk assessment paradigm of the National Academy of Sciences (1983). To establish this approach required the development of: 1) appropriate ecological endpoints, 2) a tier-testing scheme for estimating impacts on such endpoints, 3) ecotoxicological testing guidelines, 4) models and techniques for estimating ecotoxicity from chemical structure (SARs, QSARs), 5) hazard assessment factors for establishing chemical concentrations of environmental concern, and 6) risk assessment methodologies that characterize the risks by incorporating the hazard (ecotoxicity) and exposure data (Rodier 1990; Nabholz 1991; Rodier and Mauriello this volume). In sum, these methods should

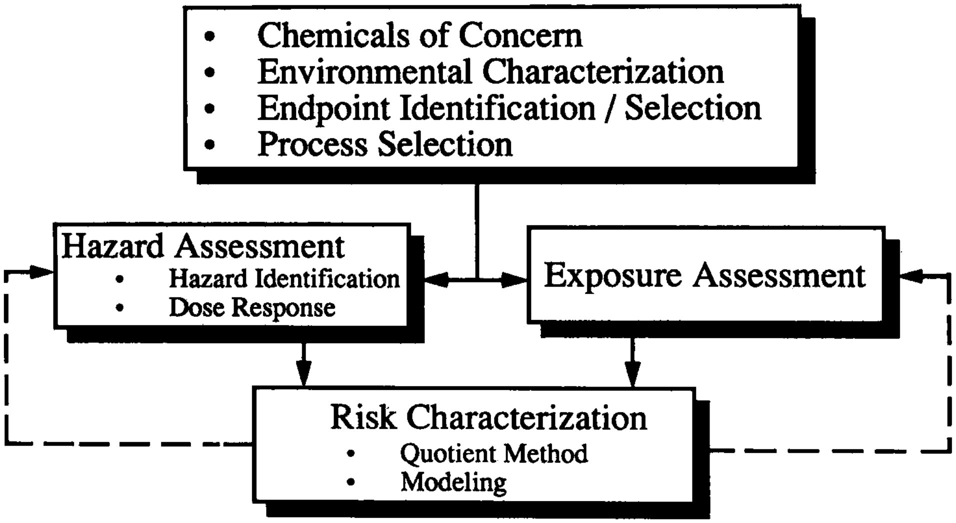

FIG. 1—*OTS ecological risk assessment process.*

allow for an estimation of the impact of adverse effects of chemicals (and with recent suitable modifications, of GEMs) on ecological systems, such as on plant and animal populations (ecological endpoints).

Developing the Ecological Risk Assessment Process

Ecological Endpoints

Ecological endpoints are those adverse effects on the environment of sufficient importance to warrant regulatory action under TSCA (for example, fish toxicity). Ecological endpoints are a basic consideration in determining the kind and amount of ecotoxicological data needed to evaluate the potential hazard and risk posed by a chemical or GEM. Recognizing this need, the EEB set out to identify adverse ecological effects that would serve as endpoints of regulatory concern and also to determine the kind and amount of data needed to assess the probabilities of such effects occurring (Clements 1983).

To determine these regulatory endpoints, existing U.S. environmental legislation was examined to determine what ecological endpoints have been perceived by the U.S. Congress to be of sufficient societal or economic importance to be protected by legislation. The review of U.S. legislation focused on the policy aspects of the 268 laws examined. The intent of 20 of the respective Acts was determined to provide protection for natural resources valued by society for economic or other reasons. The specific natural environmental resources identified in the various Acts were such things as wildlife, wilderness, agricultural lands, and air, land, and water. These resources were to be protected from reduction, degradation, or loss in quality, quantity, or utility.

In an activity complementary to the above, an extensive search of the existing scientific literature on toxic chemicals was conducted to identify occurrences of adverse environmental effects in the field that resulted in some form of regulatory action (Van Voris et al. 1979). The literature search revealed nine cases of adverse environmental effects under field conditions, in which toxic chemical contaminants reduced, or led to a loss of, quality, quantity, or utility of valued resources. It was concluded that the adverse effects caused by the chemicals involved (kepone, DDT, PCBs, mirex, carbaryl, endrin, and phosphamidon) were the result of: (a) undesirable changes in the rates of population growth, mortality, or reproduction; or (b) through bioaccumulation of the chemical within a food chain to a level hazardous to other organisms in the environment.

Consequently *mortality, growth and development,* and *reproduction,* and their potential impacts at the population level were selected as critical features to be considered when assessing the ecological risk posed by industrial chemicals. These endpoints have been used, and are being used currently, as the primary focus in OTS in assessing the potential risk of industrial chemicals causing adverse environmental effects of regulatory significance. A study conducted by the Oak Ridge National Laboratory for the EPA's Office of Research and Development's Synfuel Project also identified the same ecological endpoints as being of primary concern in assessing risk to the environment (Barnthouse et al. 1982).

Tier-Testing Scheme and Surrogate Species

Having identified critical ecological endpoints that can be measured, OTS then set out to determine the kind and amount of testing needed to develop sufficient data to measure the potential hazard of a chemical and assess its risk to the environment. That effort resulted in the development of a testing scheme (Fig. 2) that identifies the kind and amount of ecotoxicological testing required for ecological risk assessments (EPA 1983a, 1983b; Smrchek et al. this volume).

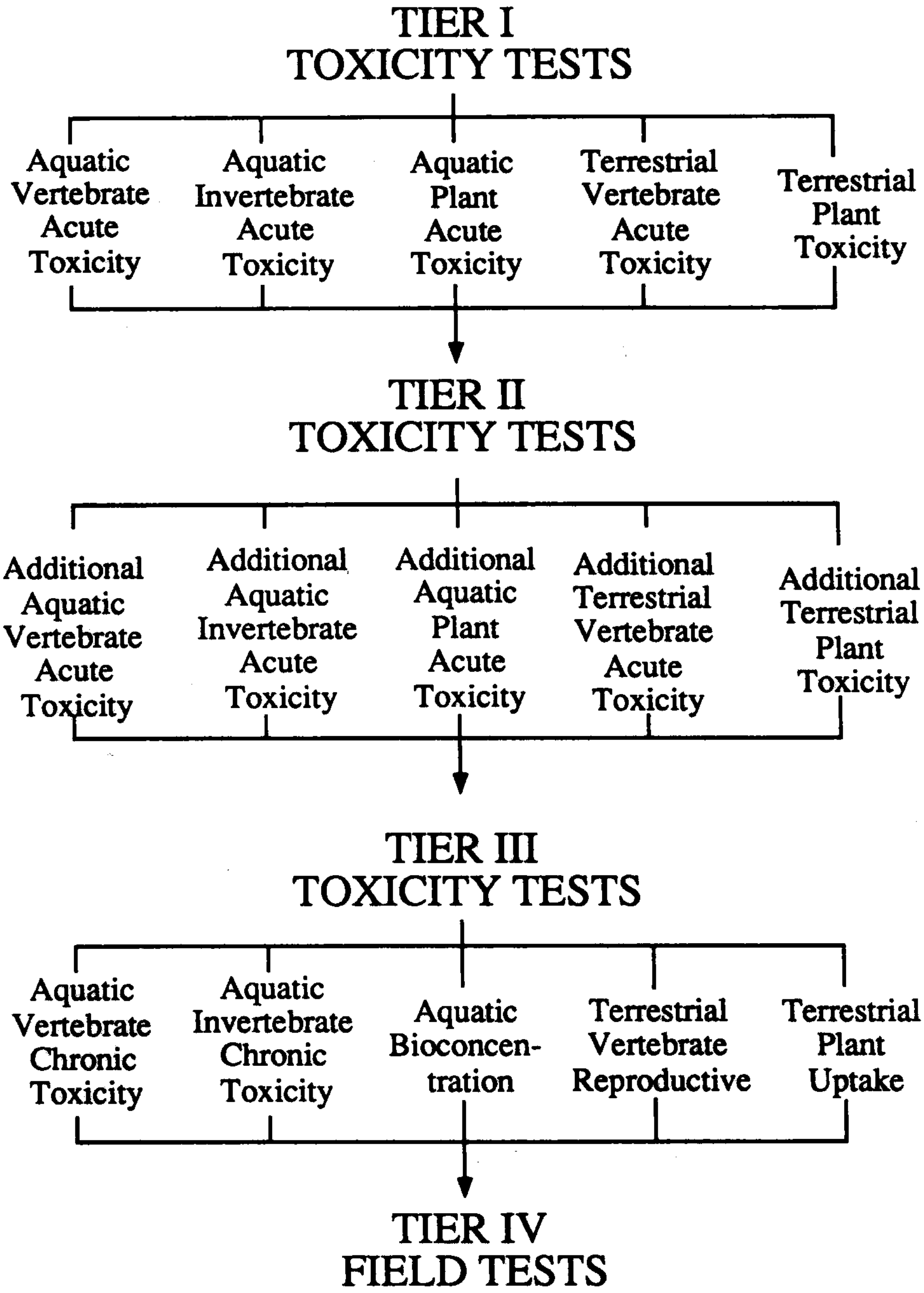

FIG. 2—*Ecological testing scheme.*