1 Introduction, General Conclusions, and Recommendations*

1.1 INTRODUCTION

In 1982, the Scientific Group on Methodologies for the Safety Evaluation of Chemicals (SGOMSEC) undertook an in-depth review of the methods for estimating the risk of chemical injury. In its report, the Group emphasised that the prediction of harm to human health and to non-human biota requires a reliable assessment of exposure (Vouk *et al.*, 1985). The purpose of the present study was to examine the adequacy of existing methods for the quantitative estimation of exposure of human beings, non-human biota and of ecosystems.

The choice of the topic of exposure assessment reflects in part the rapid advances in this field and the realisation that identification and quantification of exposure can be of prime importance in the prevention of adverse consequences to human health or to ecological systems caused by chemical and physical agents.

Numerous approaches and methods have been proposed to estimate exposure to chemicals. These estimates find many uses: as a basis for regulatory decisions, to provide an early warning of pollution trends that may later result in damage to human health, populations, communities or ecosystems, and to serve to identify populations or individuals at high risk.

In this publication, the methodological issues of exposure assessment are discussed in a Joint Report, expressing the combined view of the Workshop participants. The publication also contains 21 individual contributed papers prepared by the participants prior to the meeting which were used as background information for the deliberations and which subsequently have been subjected to peer review.

Three distinct, but related, approaches to exposure assessment are discussed in this Report:

(1) methods based on environmental monitoring data to estimate exposure levels in air, water, soil or food, followed by integration of the dose for chemicals occurring in more than one medium;

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* This section was prepared by G. Butler, B. Goldstein, P. Bourdeau, N. Nelson and R.G. Tardiff.

(2) methods based on modeling the transfer of chemicals and their degradation products through the biosphere from source to target organism; and

(3) methods based on analysis of tissues and excreta, and the detection of biological lesions.

These different approaches to exposure assessment have been developed by specialists in widely different fields: analytical chemistry, mathematics and statistics, and biomedicine. A purpose of the meeting was to bring together these disciplines to achieve a better understanding of the concepts and linkages between the major approaches.

Participants were requested to focus on the validity and application of existing techniques, to review the potential applicability of newer and developing methodologies, and to discuss approaches to analyze and interpret data as a means of predicting exposure to chemicals. No matter how reliable the estimates of exposure may be, there remains the important task of deciding the meaning of the data in terms of impact on society and on ecosystems.

At the outset, it became evident that there was a need to develop a common understanding of the term "exposure". As a working definition, the working groups initially adopted the general concept developed in an earlier SGOMSEC Workshop (Vouk *et al.*, 1985). Under this concept, the term "exposure" can be applied at any level of biological organisation ranging from subcellular structures to entire ecosystems. Inherent in this concept, however, is the need to define precisely the target or receptor under consideration. The definition of exposure was further elaborated and refined during the course of the meeting, especially by the working group on Exposure Measurements (see Chapter 2).

A number of conclusions and recommendations of a general nature were developed during the study. These are given below. Conclusions and recommendations relating to the three approaches discussed in the Report are given at the end of each relevant section of this Report.

The last section of this document describes the state-of-the-art of selected analytical methods and instruments for measuring concentrations in environmental media that may contribute to human or non-human exposure to pollutants. Particular attention is devoted to instrumentation and methods for measuring air exposures.

1.2 GENERAL CONCLUSIONS

(1) The importance of accurately assessing exposure to environmental toxicants is becoming increasingly evident. Protection of human health and the general environment from the adverse consequences of chemical and physical agents depends upon understanding exposure. Fortunately, the

methodology necessary to assess exposure is evolving rapidly to meet this challenge. This evolution is occurring across a broad range of scientific disciplines pertinent to exposure assessment. Modern computers allow the construction of models and the analysis of pollutant movements across compartments that are pertinent to understanding the kinetics of the transport, the alteration of chemical and physical agents in the general environment, and the determination of toxicokinetics occurring within the human body or within an ecosystem. The continuing explosive rate of development of analytical techniques permits the direct determination of chemicals in environmental media and in biological systems at concentrations that are orders of magnitude less than those measurable just a decade or two ago. Parallel rapid advances in biological sciences, including the development of biotechnological techniques, are enabling the analysis of seemingly minuscule changes in biological systems produced by xenobiotics, and are opening the possibility that calibration of these changes with external exposure and internal effects can markedly improve our ability to assess the risks of chemicals.

(2) A problem central to all approaches to exposure assessment is the need for validation. Model validation is an expensive and difficult process, particularly when field studies are used to compare model prediction with performance of the real system. Careful validation and quality assurance of analytical techniques used for measuring pollutants in air, water, food, and soil, including personal monitoring approaches, is an absolute necessity. Similar attention to accuracy, precision, sensitivity, and the other attributes of a fully validated technique is necessary for biological monitoring techniques. A particularly crucial aspect of validation of biological endpoints in humans, animals or ecosystems is the need for understanding the implications of the endpoint. The extent to which a biological change can be related to exposure, or considered an adverse effect, requires careful calibration and an understanding of the basic biological processes underlying the observed change. Unfortunately, the highly public nature and, often, the urgency of exposure measurements lead to the tendency to rush into use new models and analytical techniques before they have been properly validated.

(3) Estimation of human exposure needs to be made across media. Unfortunately, the focus of national and international regulatory activity has been for the most part on a single medium. This has led to a compartmentalisation of control efforts which has driven research activities. Thus separate organisations support research limited to air, water, food, or soil. However, chemical contaminants usually are present in more than one medium, both because of their inherent physicochemical properties and because of the diverse exposure pathways associated with human activities. More focus on the assessment of multimedia exposure is necessary to understand and prevent adverse effects.

(4) Regulatory efforts also tend to focus on individual agents rather than on the mixtures of chemicals that often constitute the exposure environment. One of the greatest challenges facing exposure assessment is the development of methodology to assess exposure to mixtures of chemicals.

(5) Modeling the impact of environmental chemicals in a single medium or in multiple media requires an understanding of human activity patterns. Individual activity patterns are a major determinant of the extent of human exposure. As we move in and out of different microcosms, and as we vary respiratory rates, food and water consumption, work and personal habits, the extent of individual exposure may be altered dramatically. Many of the simplifying assumptions made in the past (e.g. 2 liters of drinking water daily; inhalation of all ambient pollutants outside of one's door for 70 years lifetime) have been of value in approaching the problem of estimating human exposure. However, they are no longer compatible with the advanced exposure assessment techniques available today. Understanding human activity patterns in geographical and temporal relation to exposure sources and, particularly, understanding the activity patterns of susceptible individuals in a population will maximise the use of recent advances in the methodology of exposure assessment. Further, the goal of preventing the adverse effects of environmental agents requires the ability to interdict exposure.

(6) The major focus in the field of exposure assessment has been on the development of methods pertinent to human exposure. The overall concepts and procedures are generalisable to ecosystems and are already in use by ecologists. Further dissemination and application of exposure assessment methodology to non-human species and to ecosystems would be of considerable value.

1.3 GENERAL RECOMMENDATIONS

(1) The broad range of methodology available for the assessment of exposure cuts across many scientific disciplines. For optimum use of advances in preventing the adverse effects of environmental agents, communication among these disciplines and communication with those who have the authority to control environmental agents are imperative. This includes an emphasis on developing "user friendly" approaches.

(2) Validation of all techniques used in exposure assessment must be an inherent part of the process. Scientists developing or using exposure methodology must insist that techniques be fully validated and that support be made available for all aspects of data validation, ranging from understanding the implications of the approach to standard quality assurance. Where possible, multi-laboratory comparative approaches should be fostered.

(3) Exposure assessment methodology needs to focus on more than

one medium, as many potentially hazardous chemical and physical agents are present in multiple media.

(4) Supplemental exposure assessment methodology needs to be developed to meet the challenge of simultaneous multiple chemical exposures.

(5) Data on human activity patterns pertinent to exposure assessment are greatly needed. These should include field studies to better understand the micro-environments that people visit and the activities they perform.

(6) Major efforts are needed to apply to ecosystems the concepts and methods developed for human exposure assessment.

(7) The training of additional scientists is needed to advance the field of exposure assessment.

1.4 REFERENCE

Vouk, V.B., Butler, G.C., Hoel, D.G., and Peakall, D.B. (Eds.) (1985) *Methods for Estimating Risk of Chemical Injury: Human and Non-Human Biota and Ecosystems*. John Wiley & Sons, Chichester.