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NOTE

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This volume does not constitute a formal publication. It is an interim report meant to facilitate discussion and action and has not received such detailed editorial revision as other WHO publications. It may be re-issued in an expanded and revised version when the remaining programme components are completed and when comments on the ideas expressed in this volume have been received. Comments are solicited and should be sent to the Director, Promotion of Environmental Health, at the address given above.

FOREWORD

Life is a risky business. To try to eliminate all risks would be futile because any such attempt would certainly bring society and its individuals to a complete standstill. We have always lived with risk and seem destined to continue living with it in the foreseeable future - now we must learn to manage it.

The risk management process can be conceived as consisting of the following components: hazard identification, risk estimation, risk assessment, determination of propensity for risk acceptance, analysis of benefits, disbenefits and alternatives. These components lead to public decisions which are more or less rational, subject to a great variety of pressures exercised, on the one hand, by interest groups and, on the other, by public opinion, preconceptions and fears.

Hazard is defined as a set of circumstances with a potential for causing harm. In the context of chemical control, hazard identification depends upon qualitative and quantitative information on the toxicity of chemicals acting either singly or in groups. This information is derived from a variety of chemical, toxicological, clinical and epidemiological data.

The two main approaches to the evaluation of health effects are epidemiology and laboratory experimentation. The experimental approach involves the use of animal models for estimation of effects on humans. One of the major difficulties in this approach is the number of extrapolations that are inherent in the process, such as extrapolation from animals to humans or from large doses and high levels over a short time to low doses over prolonged periods. The epidemiological approach studies effects on humans and thus obviates the necessity for extrapolating from one species to another. Nevertheless, in drawing conclusions from epidemiological evidence, some important and difficult extrapolations have to be made, e.g. from occupational exposure to community exposure or to multiple exposure. The difficulties in design, evaluation and interpretation of epidemiological studies are well known and need not be enumerated here.

When attempting to use the results of these investigations for the purpose of risk assessment and the subsequent decision-making, the various explicit or implicit assumptions and uncertainties which are inherent in the extrapolation process are important to keep in mind.

Having defined the hazards to the best of our ability, we are faced with an equally difficult task of defining risk estimation, which, for the purpose of this document, we shall define as estimating the extent of harm and the probability of its occurrence. In the context of chemical control, this approach will usually mean prediction of additional incidence of various diseases, disabilities or defects caused by exposure to predicted levels of the chemical in question, acting either singly or in combination with other chemicals which are likely to affect given individuals or population groups.

Up to this stage of the process, we are dealing with data (imperfect as they may be), extrapolations (admittedly difficult) and predictions based on the best available evidence. The next step of the process involves value judgements. In trying to assess the risk, we are in essence attempting to answer the question: how significant or important are the expected effects? This question raises, of course, a host of other equally difficult questions. Important for whom? According to what criteria? From whose point of view? Who is to judge? The argument has been raised that these considerations should not be included in the risk assessment process because these types of question cannot be answered "rationally". However, the decision-makers must answer these questions either explicitly, by formulating formal decision criteria, or implicitly, by making decisions based on intuition or on their assessment of the balance between the various private and public pressure groups.

The decision-making process must also consider the public propensity for taking various kinds of risk, which varies widely from society to society and from individual to individual depending on a host of cultural, socioeconomic and psychological factors, as well as on the type and nature of the risk in question. Risk predictions are made in terms of statistical probabilities, which most people find difficult to visualize and understand. We seemingly face a situation in which there is an almost total lack of

meaningful communication on this subject between the scientists who generate the information, the public for whose benefit it is supposedly generated, and the decision-makers who must make far-reaching decisions based on imperfect, incomprehensible and frequently scant information, while at the same time trying to respond to the pressures and demands from, on the one hand, an insufficiently informed public and, on the other, frequently biased interest groups. Meaningful public participation in this decision-making process requires a conscious effort to improve communication between the scientific community, industry, the public and the decision-makers.

In an effort to improve such communication, the WHO Regional Office for Europe sponsored the Seminar on Evaluation and Risk Assessment of Chemicals, organized by the Institute of Occupational Medicine in Lodz, Poland, in collaboration with the Institute of Occupational Health in Helsinki, Finland, and the Institute of Radiological Health in Belgrade, Yugoslavia. As the name implies, the Seminar was centred on the process of risk assessment based on the available toxicological and epidemiological evidence and taking into account the benefits, disbenefits and implied costs of the possible control actions. It was attended by senior scientists and decision-makers concerned with control of chemicals. In addition to discussing the risk assessment process, the Seminar included a number of case studies illustrating the extent to which risk assessment was taken into consideration in the subsequent decision-making.

This volume contains the papers delivered at the Seminar, grouped roughly according to the components of the risk management process as defined above. As will be seen from the proceedings, the Seminar was only partially successful in illuminating the various components of risk assessment and their interaction. Some aspects have been discussed in considerable detail, others have been touched upon, while still others escaped the attention of the participants.

Nevertheless, the discussions have hopefully succeeded in throwing some additional light on this complicated and important subject. This volume, therefore, is offered, in full knowledge of its imperfections, as an attempt to stimulate additional research and debate.

FOREWORD

The WHO Regional Office for Europe, in cooperation with other interested organizations and institutions, intends to organize additional consultations and meetings on the various aspects of risk assessment in chemical control in the near future. These activities will result in a publication on this subject, which will include the contents of this volume in a suitably modified form.

A. Gilad

CONTENTS

OPENING REMARKS

by
J.A. Indulski

The development of industrialized civilization has been marked with the expansion of the chemical industry. Chemistry has penetrated all areas of human life and has been an important factor in shaping our lifestyles. However, the expansion of chemistry has also generated great concern about the detrimental effects of chemicals on human health and the environment. As has been assessed by the World Health Organization, some four million chemicals have been isolated from natural products or synthesized. About 60 000 are used in daily life as industrial chemicals, fuels, pesticides, drugs, food additives and different chemical consumer products. Many of these chemicals appear in the working environment or in water, food and soil as pollutants resulting from the wastes of production and consumption. The number of chemicals in use is increasing rapidly; according to the aforementioned source, 200-1000 new chemicals are put on the market every year.

The recent accidental exposures of epidemic proportions in several countries due to industrial accidents or the release of toxic chemicals into the environment in products or as waste are still vivid in our memories. They emphasize the great need for efficient preventive activities and for appropriate systems to control human exposures to chemicals. Consideration must be given to dangers to the general population and to special high-risk groups as a result of occupation or place of residence.

The Institute of Occupational Medicine in Lodz has put great emphasis on recognizing and controlling exposure of workers to chemical pollutants, and its scientific effort is, in great part, devoted to industrial toxicology. This emphasis on industrial toxicology and the Institute's substantial contribution to the recognition and evaluation of toxic hazards in the still extensively developing Polish industry are due to the former director, Professor Jerzy Nofer.

Chemical pollution is, however, a global problem, and coping with it properly requires good and efficient international collaboration based on internationally

Chemical pollution is, however, a global problem, and coping with it properly requires good and efficient international collaboration based on internationally accepted programmes. I think that I will express the feelings of all of us gathered here when I say how much the efforts, programmes and actions in this particular field initiated and carried out by the World Health Organization have been appreciated all over the world. I cordially welcome Professor M. El-Batawi, Head of the Occupational Health Office at WHO headquarters in Geneva, Dr J. Parizek from the Environmental Health Division at WHO headquarters in Geneva, and Dr M. Draper from the WHO Regional Office for Europe in Copenhagen. Our Institute has benefited greatly from the collaboration with WHO. As an institute of occupational health, we have particularly collaborated with the WHO Occupational Health Office. Many programmes formulated by this office have been successfully incorporated in the occupational practice in our country, and I express many sincere thanks to Professor El-Batawi for such fruitful cooperation.

Industrial toxicology has also been an area for our close cooperation with the WHO Regional Office for Europe. In the period 1973-1977, the Institute, in close collaboration with WHO, implemented a toxicology programme sponsored by the United Nations Development Programme. The success of this project was largely due to excellent guidance by Professor Sven Forssman, a WHO technical adviser to that project.

The new International Programme on Chemical Safety launched by WHO has gained international support, and Poland plans to participate actively in it. The first step of our active participation is the organization of this seminar. We are greatly honoured to have this excellent chance to meet you at this Institute. I am privileged and greatly pleased to welcome such distinguished lecturers from abroad, who will share their wisdom and knowledge with us. The opening ceremony is also honoured by the presence of our distinguished guests: Dr Cwirko, Director of the Department of Occupational Health of the Ministry of Health and Social Welfare; His Magnificence Professor Kotelko, Chancellor, Medical Academy of Lodz; Professor Rafalski, Vice-Chancellor, Medical Academy of Lodz, Member of Parliament and Chairman of the Parliamentary Commission of Health; Professor Rozniecki, Vice-Chancellor, Medical Academy of Lodz; Professor Groszkowski, Dean of the

OPENING REMARKS

Pharmaceutical Faculty, Medical Academy of Lodz; Mr Nosko, Head of the Department of Science of the Party Committee in Lodz; Dr Matczak, Head of the Health Department of Lodz; Professor Lasotowa, Vice-Dean of the Pharmaceutical Faculty, Medical Academy of Lodz; and Professor Chmielnicka, Department of Toxicological Chemistry, Medical Academy of Lodz.

During this week, we hope that everyone will take the opportunity to learn not only from the lectures but also from one another during discussions. In this way we may better understand our problems and arrive at a solution for them.