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MANPOWER DEVELOPMENT AND TRAINING IN TOXICOLOGY AND CHEMICAL SAFETY

Report on a
Joint CEC/IPCS/WHO Workshop

Luxembourg
28 November - 2 December 1983

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This volume is an interim report meant to facilitate discussion and action. Comments are solicited and should be sent to the addresses given above.

EDITORS' NOTE

This document is the report of the International Workshop on Manpower Development and Training in Toxicology and Chemical Safety, held in Luxembourg, 28 November - 2 December 1983. It also takes into account the conclusions and recommendations of the Working Group on Occupational Profiles on Toxic Chemicals Control, held in Brussels, 15-19 December 1980, organized jointly by the WHO Regional Office for Europe and the Commission of the European Communities, with the support of the Government of Belgium and United Nations Development Programme.

Apart from selected working papers prepared to cover specific discussion topics at the Workshop and appended to this report, other papers were contributed by invited participants (Annex 10). These papers are available upon request from either the WHO Regional Office for Europe or from the Commission of the European Communities.

FOREWORD

There is probably no one in the world who is not affected, directly or indirectly, by the use of chemicals. If potentially hazardous chemicals are to be controlled in such a way as to protect human health while ensuring that the many benefits derived from the use of a wide range of chemical products are maintained, it is necessary to train adequate numbers of personnel in the necessary multidisciplinary skills. The long-range goal is to ensure that everyone - homemaker, factory worker, politician, medical doctor - receives information on toxicology and chemical safety appropriate and relevant to his/her work and life style.

The more immediate goal, that of training the various types of toxicologist needed, ranks high in the priority list of activities of the international organizations involved in the convening of this workshop.

The joint ILO/UNEP/WHO International Programme on Chemical Safety (IPCS) was established in 1980 on the basis of a series of decisions by the World Health Assembly. It includes among its principal objectives the promotion of training of the manpower needed for testing and evaluating the health effects of chemicals, and for regulatory and other control of chemical hazards. An important role in the development of the expertise needed for toxicological assessments and the preparation of training materials is played by the WHO Regional Office for Europe.

The Regional Office's work on curricula development and definition of tasks and educational objectives of toxicologists has formed part of the basis of this workshop. Efforts have also been directed towards recognizing the often special needs of the developing countries in regard to chemical safety and to adapting manpower training approaches, particular concerns of this workshop.

To fulfil its policies, the European Community requires the mutual recognition of toxicological testing results and a uniform approach in health risk evaluations of chemicals in its 10 Member States. In this regard, the contribution of the toxicologist is essential. Development of manpower in toxicology and training curricula form one of the elements of the European Community's proposal for an Action Programme on Toxicology for Health Protection now under consideration and of its medical research programme .

It is hoped that the output of this workshop will be useful in shaping national and international policies and programmes regarding the contribution of toxicology training to the globally important issue of toxic chemical control.

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INTRODUCTION

The vast number and array of chemicals that form an integral and essential part of industrialization necessitate extensive testing of their toxicity and evaluation of their potential hazard to human health and of the need for adequate prevention and control mechanisms. Knowledge of the toxic properties of chemicals and the mechanisms of their effects is also essential for providing appropriate detection and treatment. Toxicology is the scientific discipline which expanded from the above concerns when the process of fast and extensive industrialization indicated that economic benefits were accompanied by significant health hazards that included chemicals.

The process of industrialization has proceeded much more rapidly than the acceptance of chemical safety as a health priority. Consequently, this delay has brought about a dangerous lack of professional and auxiliary personnel trained in toxicology and chemical safety. This situation calls for increased capacities in manpower training in order to keep up with the growing demand to test, evaluate, monitor and control chemicals already on the market as well as those under development, and to diagnose and treat the adverse effects caused by exposure to these chemicals.

In the context of WHO's strategy for Health for All by the Year 2000 and the knowledge that exposure to chemical substances is still increasing in large parts of the world, manpower training in toxicology has been given high priority within both the UNDP-supported project "European Cooperation on Environmental Health Aspects of the Control of Chemicals" and the ILO/UNEP/WHO International Programme on Chemical Safety (IPCS). It was recognized that global policies and strategies for implementation of training programmes should be developed in order to guarantee a sufficient supply of adequately trained toxicological personnel at all levels and in all regions. A programme of action has been developed by the WHO Regional Office for Europe (WHO/EURO), as part of its global activity within IPCS.

A growing concern for chemical safety has also existed for a number of years among the Member States of the European Community with their extensive chemical industry, and regulations at the community level have been implemented in a number of cases. Similarly, a research programme to understand more fully the toxic effects of chemicals has been established. The need for adequately trained personnel is strongly felt in the European Community, and the Commission has been requested to implement a programme to develop manpower potential in toxicology.

To tackle these problems, the CEC and WHO/EURO have jointly organized several studies and consultations. Results of these activities were presented at the present Workshop with the aim of reviewing and discussing multiple aspects of manpower development and training in toxicology for chemical safety and reaching some practical conclusions and recommendations.

Various training programmes and courses in toxicology already exist, and further development of training programmes should benefit from their accumulated experience. With this goal in mind, the situation in Europe, based primarily on three surveys, was thoroughly reviewed. Professor J. Indulski presented the survey results from countries belonging to the Council for Mutual Economic Assistance, and Professor R. Lauwerys summarized surveys carried out in Member States of the European Communities and in ten other European countries. In addition, contributions on specific aspects of toxicology training in the United States and Japan were made by Dr C. Schönwalder and Dr Y. Kodama (on behalf of Dr. K. Tsuchiya), respectively.

Toxicology has evolved as a multidisciplinary field of science and is still in the stage of rapid development. Tasks in toxicology are multiple, and methodologies of various scientific fields are needed. The need for development and implementation of training programmes is determined by the existing demand for trained toxicologists. How many specialists in toxicology are needed? To help answer this question, fact-finding missions to three countries (Egypt, Netherlands and Poland) were conducted. The answers were not always straightforward, as definitions of a toxicologist and of his or her tasks varied. In general, a common view was evident: needs may vary according to the stage of a country's industrial development and its level of production, general and agricultural use of chemicals, and implemented control measures and legislation. To help provide guidance on needs assessment, a model approach prepared by Mr S. Kassel was presented. The model proved a useful tool for practical evaluation, and discussion concentrated on distinguishing between ideal and actual needs, taking into account employment opportunities.

In global terms, assessment of needs in developing countries is of particular concern. Participants from developing countries were given full opportunity to present their problems and to formulate recommendations.

The fundamental questions which participants of the meeting faced were:

(1) who is a toxicologist?

(2) for whom should a training programme be implemented; and

(3) what mechanisms should be sought to evaluate the needs and implement the programmes?

Since a fully satisfactory definition of toxicology could not be developed, a working definition of a toxicologist was adopted. A toxicologist was defined as a university graduate in a relevant branch of science or medicine, who has a general knowledge of the theory and practice of toxicology as the science dealing with adverse effects of chemicals to the health of living organisms and a specialist knowledge with practical experience in one or more areas of toxicology.

The lack of precision in such a definition is understandable when the multiplicity of tasks in toxicology is considered. Consequently, defining the subject area in toxicology training programmes is also difficult. Solution of this problem was sought in defining occupational profiles on the basis of identified tasks, which become the responsibility of an individual. Dr J.H. Duffus presented the occupational profiles for experimental toxicologists described in Manpower development for control of chemicals[1] (hereafter referred to as WHO/EURO Interim Document No. 2), and educational requirements.

In addition to a toxicologist, defined by the occupational profile as an experimental toxicologist, the Workshop found it necessary to distinguish two other basic types of toxicologists, namely, the clinical toxicologist and the analytical toxicologist.

Whereas there was no controversy regarding distinction of the clinical toxicologist, divergent views were expressed as to the definition of the analytical toxicologist as a separate category. The opinion was expressed that besides clinical and environmental analysis of toxic substances, numerous other tasks related to exposure assessment (including chemobiokinetics) must be taken into account for compiling an occupational profile for the analytical toxicologist.

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[1] Interim Document No. 2 in series Health Aspects of Chemical Safety, WHO Regional Office for Europe, 1981.

INTRODUCTION

Once occupational profiles are defined, appropriate training curricula can be developed for different categories of personnel. A target curriculum for those aspiring to attain complete knowledge of experimental toxicology has been described in WHO/EURO Interim Document No. 2 and was presented to the meeting by Dr J. Duffus. The task of the meeting was to evaluate this type of training approach based on a modular programme.

Having recognized three basic types of toxicologists, the meeting was faced with the task of developing training curricula for clinical and analytical toxicologists. Suggestions were made by Dr M. Geldmacher-von-Malinckrodt and Dr F. Conso.

Toxicology involves both fundamental and applied science. In formulating training programmes, attention should be paid to professions other than toxicologists which require at least some knowledge of toxicology. Prevention of chemical hazards, for example in industry, can be attained only if workers, managers and chemical safety officials are aware of such hazards. Not only occupational physicians but also general practitioners should be able to consider in their diagnosis the possible association of a disease with chemical exposure. Educational programmes are needed for increasing the awareness of chemical hazards and the competence of decision-makers. The meeting recognized a number of professions for which training curricula would require elements of toxicology and chemical safety. A matrix of programmes, from academic ones to short-term training courses and seminars, was developed and presented by Dr A. Berlin.

Career opportunity is one of the features which makes a scientific discipline a profession that attracts people. A relatively new discipline, such as toxicology, should have a well-defined career structure with recognized qualifications. A discussion of the mechanisms for possible recognition of qualifications was initiated by Professor J. Piotrowski and Dr L. Moustafa.

The task of providing advice and formulating guidelines for manpower development is both a challenge and an opportunity. The challenge is to respond adequately and in reasonable time to the need for qualified personnel. The opportunity is to develop and implement an educational programme, a cornerstone of chemical safety.

CURRENT TRAINING AND EMPLOYMENT IN TOXICOLOGY

Sources of Information

The current opportunities for studying toxicology have been assessed on the basis of questionnaire surveys carried out in 1982 and 1983 among European academic institutions and on the basis of specific reports from non-European countries. The surveys had two main objectives, the first being to draw up a list of existing toxicology training programmes and the second to ascertain to what extent students of other disciplines are made aware of toxic hazards. One survey was conducted in the 10 Member States of the European Community, and two similar surveys were carried out in the Member States of the Council for Mutual Economic Assistance (CMEA) and in several other countries within the European Region.

Three different approaches were used to estimate the current employment of persons who have been trained in toxicology during the last ten years: (a) a questionnaire survey conducted in Member State institutions in the European Community which offer a training programme in toxicology; (b) a fact-finding mission in three countries (Egypt, Netherlands, and Poland) and (c) specific reports from other countries.

Opportunities for Training in Toxicology

In Europe

Forty-six institutions offering a training in toxicology have been identified within the 10 Member States of the European Community. The programmes are usually offered at the postgraduate level. Their scope and content vary greatly. Some institutions offer training in specific areas of toxicology, such as analytical toxicology, forensic toxicology, and industrial toxicology. Approximately 20 institutions offer a postgraduate training programme in experimental toxicology of 1-year duration or more. Training in clinical toxicology exists only in three countries. Many of the institutions contacted (124 out of 188) provide some training on various aspects of chemical safety to graduate students in various disciplines, but the content and importance of the toxicology courses differ markedly from one institution to the other.

The survey carried out in 10 other countries within the European Region (Austria, Finland, Malta, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, and Yugoslavia) identified five training programmes in experimental toxicology and five programmes in specific toxicological fields. Among the 71 institutions contacted, 33 provide some training on various aspects of chemical safety to graduate students in several disciplines (medicine, veterinary medicine, pharmacy, biology and chemistry).

Several training programmes, all organized at the postgraduate level, have been identified in the Member States of CMEA: some programmes are mainly designed to train clinical toxicologists and require a medical degree, while others focus on the training of experimental or analytical toxicologists and are offered to graduates from schools of pharmacy, biology, chemistry, agronomy and veterinary medicine. At the undergraduate level, the majority of establishments of higher education also provide some toxicological information to students in many disciplines.

Selected non-European countries

In some countries, efforts have been made to familiarize tomorrow's general practitioners with current toxicological problems.

In Japan, toxicology lectures and laboratory work are included in many courses of the medical curriculum. Departments of preventive medicine and public health are responsible for teaching occupational and environmental toxicology to medical students (22-30 hours). To become a teacher or research worker with special interest in toxicology, medical graduates must obtain the degree of doctor of medical sciences offered by a department of preventive medicine or public health. In 1978, the University of Occupational and Environmental Health (UOEH) was established. At UOEH, a 3-month postgraduate course, compulsory for those graduating from the medical school, emphasizes occupational and environmental toxicology.

In some Latin American countries, extensive clinical toxicology courses have also been introduced in the medical curriculum and postgraduate training programmes have been developed. A detailed survey of these programmes is currently underway.

Research component in toxicology training

Some initiatives have been taken to stimulate toxicological research, which is also an important component of the training effort in toxicology. For example, in Europe, the Group of European Medical Research Councils has set up an advisory body which has generated several activities (e.g. collaborative research activities and European Science Foundation programme of grants in toxicology) to support young scientists doing toxicological research.

The pre- and post-doctoral training programmes set up in the United States by the National Institute of Environmental Health Sciences (NIEHS) have a strong research component in experimental toxicology of environmental chemicals.

Estimating Current Employment in Toxicology

Intercountry comparison

An attempt was made to compare the employment situation of toxicologists in three countries: Egypt, the Netherlands and Poland. Egypt represents a developing country importing chemicals, and the Netherlands and Poland represent countries with a developed chemical industry but with different socioeconomic systems. In Egypt, there is practically no demand for experimental toxicologists: at present, there are only 5-10 part-time "senior" toxicologists. At the level of analytical toxicologists, the limiting factor seems to be more job status and payment rather than lack of adequately trained people.

In the Netherlands, about 400 people are estimated to be active in the field of toxicology; of these, about 20-25 toxicologists would qualify as senior toxicologists, as defined in WHO/EURO Interim Document No. 2. However, vacancies for senior toxicologists in the Netherlands are scarce - and more scarce are senior toxicologists to fill these posts. This situation is not in line with the perceived needs. The major reason for this discrepancy seems to be scarcity of funds due to the economic recession.

In Poland, toxicologists are currently employed by research institutes, schools of pharmacy of medical academies, sanitary and environmental inspection institutes, occupational hygiene laboratories, and clinical toxicology units in hospitals. As there is no formal recognition of qualifications except for academic professionals and clinical toxicologists, the number of toxicologists can only be approximately estimated: senior toxicologists, 20-40 (including 5-10 clinical toxicologists); other toxicologists, 250-300 (including about 50-70 clinical toxicologists) and analysts employed in chemical safety 800-1000. All available posts for toxicologists are currently occupied, and the tendency is to upgrade their qualifications rather than to create new posts. The number of medical graduates involved in toxicology-related activities is currently considered too small.

Survey in European Community

A survey of the professional fates of about 500 recent graduates in toxicology in the Member States of the European Community revealed that the majority of individuals who have acquired training in experimental toxicology during the last 10 years are currently employed in universities and industries. Approximately 10% of those recently trained in experimental toxicology are employed in public administration and state laboratories. In Italy, about 60 recent graduates in clinical toxicology are employed in hospitals, medical universities and poison control centres.

Information from other countries

In Latin American countries, the number of currently employed toxicologists can be estimated as follows: 120 analytical toxicologists, 140 clinical toxicologists, 60 ecotoxicologists (subject area not covered by the Workshop), 20 experimental toxicologists, and a very limited number of persons involved in regulatory toxicology. The analytical toxicologists are occupied in forensic medicine departments, clinical chemistry departments, poison control centres, food control laboratories, environmental protection agencies, and research units in universities. The clinical toxicologists are employed in emergency and intensive care units in hospitals and in occupational health clinics or manage poison control centres. Experimental toxicologists are only employed by governmental laboratories.

In 1981, a survey was carried out in the United States to evaluate whether NIEHS's training programmes were meeting the needs of the employment sectors. This evaluation was designed to include: (a) an analysis of the current supply of and demand for environmental toxicologists; (b) a projection of future needs for environmental toxicologists; and (c) the contribution that NIEHS training support was making to the overall training effort in environmental toxicology in the United States. The survey was limited to those individuals involved in experimental toxicology of environmental agents at the research level. The employers of environmental toxicologists are the private, academic and government sectors. At the time of the survey, there appeared to be a shortage of manpower for research mainly in fields related to inhalation and reproduction.

Summary

A variety of systems already exist for training in toxicology. The most advanced are 4-year postgraduate courses in toxicology, producing scientists whose competence is mainly in experimental toxicology. Shorter courses also exist.

In most countries, certain positions within governmental agencies, industries, universities and hospitals require staff with advanced knowledge in toxicology. At present, those occupying these positions may not have received a formal training in toxicology: they have acquired their expertise through previous research activities in a closely related field and/or training on the job. The situation in many poison control centres illustrates this situation. Staff members of these centres frequently have not received a training in clinical toxicology but have acquired their expertise through their professional activities.

With the rapid development of toxicology, it appears more and more difficult for senior toxicologists in many organizations to acquire a sufficiently broad overview of their discipline without first receiving a formal training in toxicology.

ASSESSMENT OF NEED FOR TOXICOLOGISTS

Assessment of demand for trained experimental, clinical and analytical toxicologists is essential if the necessary manpower is to be available when required. To arrive at a reasonably accurate prediction of the number of senior experimental toxicologists required by toxic chemical control programmes in various countries, a model has been developed that attempts to show the basic relationships involved. While many activities undoubtedly have the potential for affecting the scope of toxic chemical control programmes and thus the number of senior toxicologists needed, four are of primary importance: development, production, general use, and agricultural use of toxic chemicals. For example, a country developing new chemicals may reasonably be expected to need more senior toxicologists than one which mainly manufactures chemicals; the latter, in turn, will need more such positions than a country that only uses chemicals.

From such considerations, a quantitative model can be derived for estimating total national requirements and hence the annual replacement rate necessary to maintain manpower in experimental toxicology at the appropriate level. This replacement rate is a measure of the number of graduates needed each year and should guide the development of courses to provide training for these graduates.

Comparing the results of the fact-finding mission undertaken in the Netherlands and the estimate obtained by applying the theoretical model suggests that the latter may be a useful starting point for predicting the need for senior experimental toxicologists. The model assumes a constant ratio between the number of senior experimental toxicologists and the general pool of experimental toxicologists but assigns no numerical value to this ratio. The Netherlands study suggested a tentative value for this ratio which would permit prediction of the total number of experimental toxicologists likely to be required by any country. Whether the assumption of a constant ratio and the estimated numerical value is correct needs to be tested. Such a test would form part of a further evaluation of the model and could be made in Italy and Ireland where some assessment of current need for experimental toxicologists has recently been carried out. This evaluation should take into account other criteria capable of affecting the demand for toxicologists including the diversity of chemicals being developed, produced, or used, and the level of control policy involving testing requirements, surveillance of use, etc.

A distinction must be made in practical terms between the "ideal" need of a country for toxicologists and the "effective" need or demand which depends on official recognition of the need for qualified toxicologists to implement chemical safety policies.

Although the need for clinical and analytical toxicologists is clearly recognized, no attempt has yet been made to assess the need and/or develop a model for this purpose in different countries. Such a model would have to be based on criteria different from those used to assess the need for experimental toxicologists. Examples of such criteria include demographic characteristics, structure of the health services, regulatory requirements, and the need for monitoring and exposure assessments. The need for expert clinical toxicologists also depends greatly on the awareness of general practitioner of the possible role of chemical exposure in human pathology. This observation stresses the importance of including clinical toxicology courses in the medical curriculum, not only for general practitioners but also for certain specialists.

NEED FOR TOXICOLOGY BACKGROUND IN OTHER PROFESSIONS

Depending on career development, several professions have to deal frequently with toxicological problems and need a background in toxicology.

Appropriate knowledge in toxicology is required for those involved with the regulation of chemicals, particularly administrators responsible for preparing regulations and organizing postregulatory control.

All university students studying subjects in which the manufacture, handling or disposal of chemicals (e.g. drugs, industrial chemicals or biocides) is an important aspect, or concerned with the consequences of chemical exposure on humans, animals, or the environment, should also acquire during their training an appreciation of toxicology as a basis for understanding the hazards of chemicals and the various elements of chemical safety. Development of appropriate levels of awareness of the risks associated with chemicals should be included in the undergraduate curriculum in medicine, veterinary science, pharmacy, agriculture, chemical engineering, and chemistry.

Members of health and safety committees in industry should also be trained in chemical safety. They should be given a knowledge of principles that is comprehensive and relevant. The aim of such training is to raise the competence of workers' representatives and management in identifying problems and using the expert skills of toxicologists.

The need for some toxicological knowledge by the general public to ensure safe use of chemicals was pointed out. This involves not only clear labelling, but also supply of information through education and the mass media. A top priority is to ensure that science and technology teachers at all levels of education are themselves taught the toxicological basis of chemical safety. This means inclusion of toxicology in all relevant degree curricula together with a continuing education programme for people already employed. The preparation of new readily available teaching materials for this programme is essential. In the context of making information available, a small but highly important group of professionals required to ensure current awareness of chemical hazards and needing a knowledge of toxicology are the documentalists and information specialists. Professional toxicologists should be prepared to be involved in dissemination of information and creation of awareness at all levels.

OCCUPATIONAL PROFILES

Experimental Toxicologist

WHO/EURO Interim Document No. 2 describes fully the derivation of the occupational profile for an experimental toxicologist, using an operational definition listing all the tasks that might conceivably form part of a toxicologist's responsibility. These tasks are subdivided into the following groups: experimental animal toxicology; experimental phytotoxicology; clinical toxicology; epidemiology; exposure evaluation; risk assessment; advice and consultation; and management and training. As an example, tasks related to experimental animal toxicology are given in Table 1. In constructing this list, the educational requirements for each task were also described in terms of areas of knowledge and levels of attainment. Two levels of attainment were defined: level I is the minimum required to perform the task adequately and level II that required for an evaluative and innovative role. It was clear that no one person could perform all the tasks listed. However, groups of tasks could be identified which would normally be the responsibility of an individual and these could be equated with known occupations: hence, such groups of tasks are referred to as occupational profiles.

A category 1 experimental toxicologist is a member of a toxicological team who is a specialist in one of the sciences that contribute to toxicology, has a general knowledge of toxicology, and is able to carry out tasks such as: application of chemicals, observation of effects, taking samples, macroscopic postmortem examinations, and preparation for histological examination.

A senior toxicologist (Category 2) is a person with wide experience in toxicology. He or she will necessarily have an expert knowledge in one or more of the specializations mentioned and familiarity with the broad field. He or she may be the leader of a toxicological team and may be involved in national and international consultancy, in heading national or international research projects, in decision-making in relation to toxicological problems at the governmental level, and in guiding future developments in the subject. He or she must be able to provide guidance in aspects of toxic chemicals control that may have public health implications, to plan and direct research, and, possibly, to organize training.

Profiles for the toxicological components of related occupations, such as sanitary engineers and food hygienists, were also prepared to illustrate the general applicability of the fundamental concepts.

Table 1 Tasks in toxic chemical control and the knowledge required for their performance[1]

Group 1. Tasks related to experimental animal toxicology

Task \ Area of knowledge	Chemistry (esp. analytical chem.)	Physics	Biology	Biochemistry	Physiology	Anatomy	Laboratory animal science	Laboratory plant science	Genetics	Microbiology	Molecular biology	Pathological anatomy	Histopathology	Haematology	Pathophysiology	Pathobiochemistry	Pharmacology	Oncology	Genotoxicology	Pathoembryology	Immunology	General toxicology	Clinical medicine	Veterinary medicine	Occupational medicine	Environmental health medicine	Epidemiology	Statistics	Law and regulations
1. Animal house cleaning							I																						
2. Animal feeding							I																						
3. Identification and characterization of test substances	II	I																				I							
4. Selection of test organisms			I				II		I	I												II							I
5. Application of chemicals to animals							I																						
6. Animal observation							I																						
7. Taking samples from animals						I	I																						
8. Veterinary laboratory analysis	I		I	I	I									I	I	I						I							
9. Animal house management and safety provision							II															I							I
10. Health care of animals							II																	II					

[1] The Roman numeral II designates expert knowledge, implying the ability to evaluate information and to innovate, based on considerable relevant experience. The Roman numeral I designates a lesser understanding.

Table 1 cont'd

Group 1 (contd)

Task \ Area of knowledge	Chemistry (esp. analytical chem.)	Physics	Biology	Biochemistry	Physiology	Anatomy	Laboratory animal science	Laboratory plant science	Genetics	Microbiology	Molecular biology	Pathological anatomy	Histopathology	Haematology	Pathophysiology	Pathobiochemistry	Pharmacology	Oncology	Genotoxicology	Pathoembryology	Immunology	General toxicology	Clinical medicine	Veterinary medicine	Occupational medicine	Environmental health medicine	Epidemiology	Statistics	Law and regulations
11. Macroscopic post-mortem examination of animals						I						I																	
12. Preparation for histological examination	I			I		I							I	I															
13. Pathological evaluation of post-mortem material from animals	I			I	II	II	I		I			II	II	II	II	I		II	I	II		II		II					
14. Studies on biotransformation of xenobiotics	I			I	I	I											I					I						I	
15. Determination of toxicokinetics	II			II	I	I									I	I	I					I						II	
16. Toxicometry	I			I	I	I	I					I		I	I	I	I	I	I	I		I						I	I
17. Determination of functional changes	I				I	I	I							I	I	I						I						I	
18. Determination of biochemical changes	I			I	I	I	I				I					I					I	I						I	
19. Diagnosis of abnormal findings in animals	I		I	I	I	I	I		I	I	I	I	I	I	I	I		I	I	I	I	II		II				I	
20. Determination of allergic and other hypersensitive effects	I			I	I	I	I				I	I	I	I	I	I					I	I						I	
21. Determination of effects on the immune system	I				I						I										I	I						I	

Table 1 cont'd

Group 1 (contd)

Task \ Area of knowledge	Chemistry (esp. analytical chem.)	Physics	Biology	Biochemistry	Physiology	Anatomy	Laboratory animal science	Laboratory plant science	Genetics	Microbiology	Molecular biology	Pathological anatomy	Histopathology	Haematology	Pathophysiology	Pathobiochemistry	Pharmacology	Oncology	Genotoxicology	Pathoembryology	Immunology	General toxicology	Clinical medicine	Veterinary medicine	Occupational medicine	Environmental health medicine	Epidemiology	Statistics	Law and regulations
22. Determination of irritation effects	I		I		I	I	I					I	I		I			.				I						I	
23. Determination of mutagenic properties	I		I	I	I	I			I	I	·I		I	I					I			I						I	
24. Determination of effects on reproduction	I		I	I	I	I	I		I		I	I	I		I	I			I	I		I						I	
25. Determination of embryotoxic and fetotoxic effects	I		I	I	I	I	I				I	I	I		I	I			I	I		I						I	
26. Determination of teratogenic effects	I		I	I	I	I	I		I		I	I	I		I	I			I	I		I						I	
27. Determination of carcinogenic effects	I		I	I	I	I	I				I	I	I	I	I	I		I	I			I						I	
28. Chronic toxicity tests	I		I	I	I	I	I		I	I	I	I	I	I	I	I	I	I	I	I	I	I		I				I	I
29. Laboratory management and safety provision	I	I	I	I	I		I			I	I											I							I
30. Development of methods	II	I	I	I	I	I	I		I	I	I	I	I	I	I	I	I	I	I	I	I	II						I	
31. Physico-chemical analysis	II	I	I	I																		I						I	
32. Diagnosis, treatment and investigation of intoxication	I		I	I	I	I								I	I	I	I					II		I					
33. Ensuring good laboratory practice	I	I	I	I	I	I	I			I				I								I						I	I

Most toxicologists enter toxicology by becoming members of a toxicological team after graduation as a specialist in one of the relevant sciences, medicine or veterinary medicine. In WHO/EURO Interim Document No. 2, the term "category 1 toxicologist" was applied to people at this stage and taken to cover the same people as they developed experience and knowledge to the point at which they were capable of team leadership and taking personal responsibility for full evaluation of toxicological data and the provision of expert advice. At this point, the term "senior toxicologist" or "category 2 toxicologist" might be applied.

Analytical Toxicologist

The occupational profile for an analytical toxicologist must still be developed. The main task of the analytical toxicologist is to carry out qualitative and quantitative analyses of toxic substances in biological and other relevant matrices appropriate to both clinical and experimental toxicology as well as to exposure evaluation. Furthermore, the analytical toxicologist must contribute to the elucidation of biotransformation and toxicokinetic mechanisms as well as to elaboration of structure-activity relationships and to the development of antidotes.

Clinical Toxicologist

An outline of an occupational profile for a clinical toxicologist discussed by the Workshop envisages someone with the ability to: carry out diagnosis and treatment of intoxications, evaluate the effects on human health of single or repeated exposures to a foreign substance, contribute to the evaluation of toxicological dossiers, compile such dossiers, participate in epidemiological studies, carry out clinical research, assist in preparing preventive measures, and to participate in teaching. It would seem that people of such wide accomplishment must inevitably be rare and that there is a requirement for more limited occupational profiles to describe the majority of clinical toxicologists who would specialize in one or two aspects of the subject and rely on other specialists for help where appropriate. The importance of such collaboration at all levels is again emphasized.

The growth of interest in preclinical, multifactorial and chronic effects of chemicals produces a particular demand for multidisciplinary study. To facilitate such studies in the near future, it may be necessary to establish postgraduate courses for practicing industrial physicians. Veterinary clinical toxicology has an important role in relating animal clinical observations to human clinical toxicology.

Conclusions

Clearly, much work remains to be done to describe occupational profiles for clinical toxicologists and analytical toxicologists in the same detail as has already been provided for experimental toxicologists in WHO/EURO Interim Document No. 2. The document provides an appropriate foundation for this, but it needs to be revised and extended to cover all three groups of toxicologists. Also, the opinion was expressed that more attention should be paid to the research component in each occupational profile.

TRAINING CURRICULA AND APPROACHES

Curriculum for the Experimental Toxicologist

WHO/EURO Interim Document No. 2 contains a target curriculum for the experimental toxicologist. Essentially, this curriculum is derived from the key group of tasks considered to constitute the occupational profile which distinguishes the experimental toxicologist from other scientists. From WHO/EURO Interim Document No. 2, the areas of knowledge required for these tasks can be identified and listed. Having done this, an educational curriculum to train personnel to carry out these tasks can be prepared simply by arranging the areas of knowledge as curriculum components in a logical learning sequence (Fig. 1). This produces the curriculum presented in Figure 2. It is called a target curriculum because it represents the target to be attained by any specialist in one of the disciplines related to toxicology who aspires to a complete grasp of the subject.

The course of study of the entrant to a toxicological team may be compared to the target curriculum to identify gaps in knowledge and experience. Once these gaps are identified, the entrant toxicologist can be guided to appropriate courses and personal study until the subject is fully mastered. The amount of extra study needed may be fairly small in the case of graduates in medicine, somewhat greater for graduates in pharmacology and biochemistry, and quite considerable for graduates in chemistry. To facilitate introduction of the target curriculum, most of the components have been described in WHO/EURO Interim Document No. 2. The components have been defined on a modular basis, with the basic module being the amount of material that can reasonably be taught in a one-week intensive course. Thus, the curriculum may be used to guide either full-time education or continuing professional education on a part-time basis.

Discussion drew attention to the need to emphasize the research component and ethical aspects. It was thought that more stress should be placed on the ability to think and to make the best use of relevant knowledge.

While the concept of the target curriculum seems readily applicable within the European context and has received favourable comment in the United States from the Environmental Health Sciences Review Committee of NIEHS, it will probably require amendment if it is to be applicable in developing countries. This would necessitate working groups of local experts meeting, probably on a regional basis, to prepare a strategy appropriate to local conditions.

Fig. 1 An approach for curriculum development

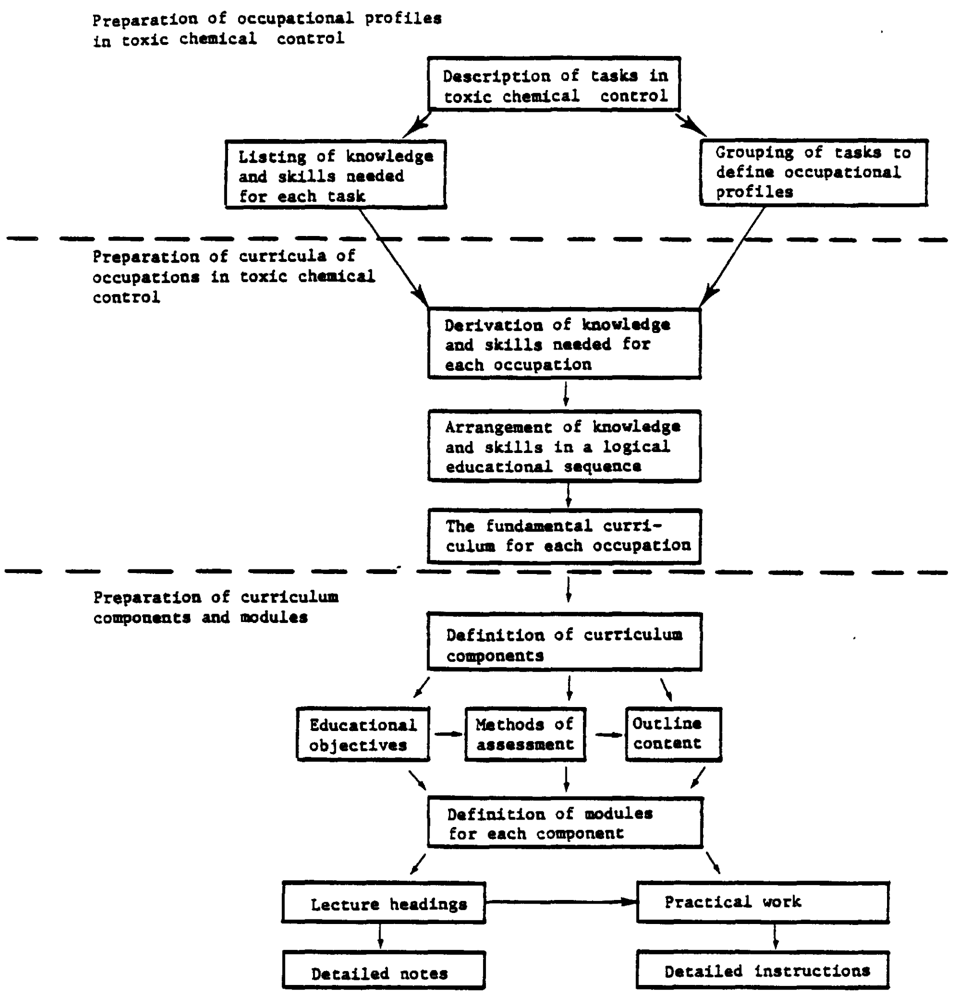
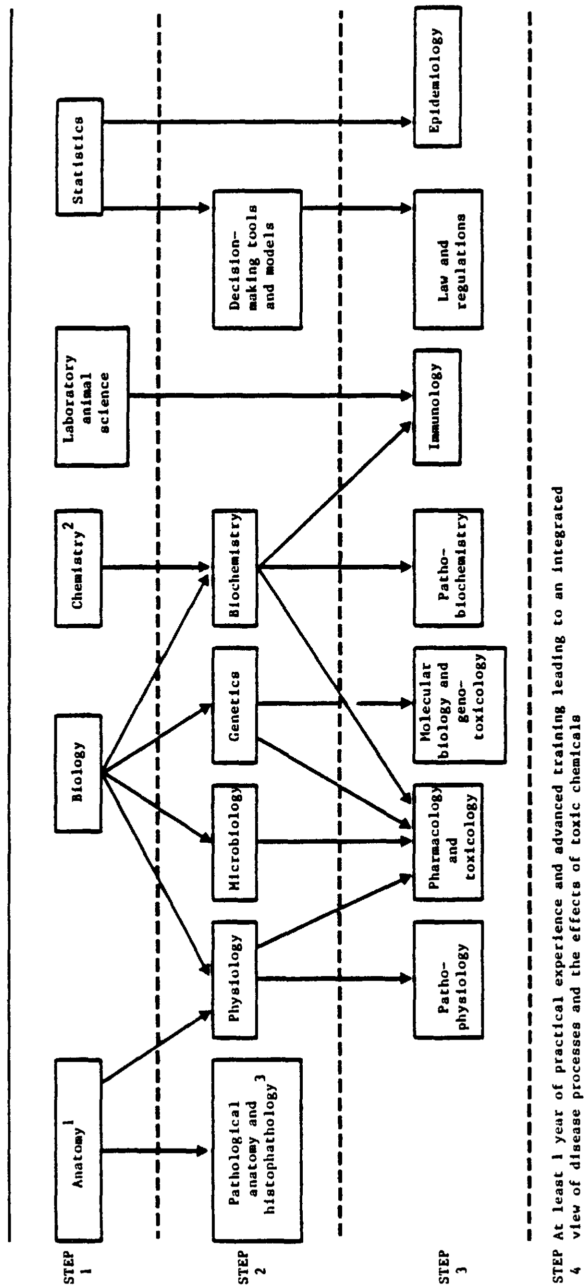


Fig. 2 Target curriculum for a category 1 toxicologist



[1] Including histology and embryology [2] Especially analytical chemistry [3] Including haematology and pathoembryology

TRAINING CURRICULA AND APPROACHES

There was a general but not universal view that an undergraduate curriculum in toxicology is unlikely to be satisfactory as no part of the subject could be studied in depth.

Curriculum for the Clinical Toxicologist

A two-stage curriculum for training clinical toxicologists was proposed. The first stage would be a normal comprehensive medical course. The second would be a thorough theoretical and practical training in clinical toxicology and related disciplines, such as occupational medicine, forensic medicine, and public health. The specific training in theoretical clinical toxicology could be based on a modular system, outlined below, while the practical part would include extended service in a clinical toxicology department and a shorter period in a poison control centre and in analytical laboratories. The trainee should have responsibility for diagnosing and treating intoxications, conducting clinical research, and contributing to publications, always under the supervision of a senior clinical toxicologist.

Five modules were suggested to cover theoretical aspects of clinical toxicology:

1. Studies of the circumstances in which human poisoning can occur, including epidemiology, concepts of monitoring, methods of detection of toxic agents, and case studies.

2. Examples of chemical products and their toxic effects on humans, analytical methods, methods of treatment and medicolegal aspects.

3. Toxic pathology by organ or system and the strategy for diagnosing causes, with a description of the clinical, anatomopathological and biological aspects of each disease and its pattern of development.

4. Treatment of human poisoning and evaluation of therapeutic agents, emergency actions at the individual, local, national and international levels.

5. Research methods in clinical toxicology, including ethical restrictions, aims of research, prognostic and therapeutic evaluation, evaluation of preventive measures, and detection of new toxic phenomena.

It was stressed again during the discussion that the various tasks associated with clinical toxicology (diagnosis and treatment of acute intoxication, expert advice to other clinical disciplines, outpatient clinics, information and prevention,and clinical research and training) would often be performed by different specialists and since these activities are complementary, they should be grouped ideally in one toxicological department of a large hospital.

The opinion was also expressed that general practitioners and medical specialists (internists, paediatricians) are not always sufficiently aware of the possible role of chemicals in human pathology. Therefore, there is a need to include a clinical toxicology course in the medical curriculum for general practitioners and several types of clinical specialist.

Curriculum for the Analytical Toxicologist

As with the other types of toxicologist, the curriculum for the analytical toxicologist must be derived from the occupational profile. Such a profile might include the abilities to: carry out qualitative and quantitative chemical analyses in any relevant matrix; interpret analytical results in a toxicological context; contribute to setting regulatory standards and provide guidance on health implications; evaluate adverse effects; and organize research and contribute to training. It therefore, follows that an analytical toxicologist will normally have a degree or equivalent in one of the chemical or pharmaceutical sciences, with a strong emphasis on analytical chemistry and a knowledge of the potential interferences to analyses present in complex matrices. In addition, further study will be necessary in relevant fields of medicine and biological science, especially general toxicology, toxicokinetics and toxicodynamics. Research experience, preferably while part of a toxicological team, would also be required.

Training and Educational Approaches in Toxicology and Chemical Safety

A frame for educational approaches in toxicology and chemical safety, as discussed and agreed, is summarized in Table 2, starting with the full-time formal academic training in toxicology and ending with short-term training in chemical safety.

It was stressed that in view of current efforts in a number of countries to improve structure and organization of the toxicology profession, there is a need to have maximum flexibility in such a frame. Furthermore, this approach does not include the extensive current practice of self-instruction combined with on-the-job training.

Table 2 Recommended framework for training approaches in toxicology and chemical safety

No.	Type	Purpose	Audience	Contents	Duration required	Remarks
1	Full academic training in toxicology	To produce professional toxicologists familiar with entire field	Professionals of various disciplines who aspire to become toxicology team leaders	Full-time degree programme or continuing academic education based on modules selected according to prior qualification of participants, and including training in research methods and a research project	Modular structure provides flexibility in programme planning and therefore in length of study required	Medical doctors following such a programme could qualify as clinical toxicologist
2	Supplementary academic training in toxicology	To provide members of toxicology team specialized in one area (e.g. mutagenicity, analysis) with sufficient familiarity of the entire field to facilitate effective interdisciplinary activity	Professionals of various disciplines who belong to a toxicology team or are about to join one	Continuing academic education programme, similar to above and to fill gaps in knowledge in fundamental subjects	Modular structure provides flexibility in programme and therefore in length of study required depending on qualification on entry	This training would enhance effectiveness of toxicologists as members of toxicological team. Analysts following such training would qualify as analytical toxicologists.
3	Seminars or workshops on selected topics in toxicology	To familiarize with specific areas or techniques of toxicology (e.g. neurotoxicology, mutagenicity) and evaluation methods	Primarily for scientists and professionals active in toxicology and related areas. In special cases appropriate for decision-makers (administrators)	Review of current knowledge and practice in clearly defined limited area	A few days to 2 weeks	
4	Intensive short-term course on principles of experimental toxicology	To expose to principles of toxicology, experimental methods and good laboratory practice	People with some scientific background who are becoming involved in toxicity testing and/ or interpretation of results but without formal training in toxicology	Review of fundamental background knowledge essential to toxicology, principles of toxicology testing methods and chemical safety	Several weeks' programme composed of three consecutive components: (a) preparatory (b) principles (c) applications	

Table 2 cont'd

5	Introduction to toxicology and chemical safety	To expose to the principles and methods used in toxicology and to provide an understanding of toxic effects and chemical safety procedures	Students, in academic programmes in chemistry, chemical engineering, agronomy, environmental engineering, medicine and other disciplines involving production, use of or exposure to chemicals	Review of toxicological principles, general methods of toxicology and their application to chemical safety	1 semester	Content is essentially a combination of courses 4 and 6 but in an academic setting
6	Short-term training on chemical safety procedures	To provide some understanding of toxicology and chemical safety to personnel working in related fields	People with chemical safety as only one component of their responsibilities (e.g. factory, food, and agricultural inspectors, management and trade union representatives, representatives of consumer groups and specialized press	Review of fundamentals of toxicology, exposure monitoring and assessment methods and design and implementation of safety procedures. Programme will depend on audience	1-3 weeks Programmes composed of two main consecutive components: - principles - applications (with especially-oriented examples)	

TRAINING CURRICULA AND APPROACHES

The need for international cooperation in implementing the proposals contained in this frame was recognized, with items 3, 4 and 6 being most amenable to such cooperation. Associated with this is the importance of making toxicological information available in local languages to disseminate it effectively. Funding to attend international meetings and courses may also be a problem. This will be especially true of courses lasting more than 1 or 2 weeks. In addition, the need to exchange toxicologists between research laboratories to both further their training and promote research has to be considered.

CAREERS IN TOXICOLOGY

Career Patterns

It must be recognized that the needs of society and the development of career patterns for toxicologists are closely interrelated. In particular, though there is an identifiable need for toxicologists to maintain and improve public health, continuing failure of society to perceive this requirement will inhibit the development of the profession. Hence, there must be an ongoing effort to inform the public of the necessity for vigilance in the use of chemicals and of the role of toxicologists in minimizing or preventing damage to health.

Three distinct areas of toxicology can be identified: experimental toxicology, clinical toxicology, and analytical or chemical toxicology. In each area, there is a need to attract good people and to stimulate basic as well as applied research. Three preconditions for the evolution of a career structure in toxicology have been suggested: (a) establishment of toxicology as an academic discipline by creation of chairs in appropriate faculties; (b) setting up of toxicological societies; and (c) the development of means of communication between toxicologists, for example, through journals, newsletters and meetings. The importance of legislation in generating a career structure should be re-emphasized, as well as the necessity to inform decision-makers to ensure that they react to perceived needs by making available the resources required to provide essential facilities. It was accepted that a career structure could be developed along the lines described by Lewis in Annex 6 and founded on properly defined educational curriculum.

A clear career pattern is needed to attract people to the study and application of toxicology. Such a career pattern must make clear the entrance requirements, the way by which professional status is attained, and the relation of renumeration to responsibility at different stages. Although in the past the term "toxicologist" has been applied loosely to people with different backgrounds and degrees of competence, recent and pending legislation and a growing awareness of the impact of chemicals on health have led to the demand for a clearer definition. An operational definition of the experimental toxicologist was formulated in WHO/EURO Interim Document No. 2, and this was used to develop the likely career pattern. Toxicology is seen as a second career, based on specialist study in one of the competent subject areas. Career development depends upon a widening of knowledge and experience to a point at which personal capacity for professional evaluation of toxicity data, formulation of responsible advice, and control of toxicological activities is recognized. The formalization of such recognition will vary from country to country.

There is a particular need to structure a career for clinical toxicologists. Clinical toxicology is the discipline which studies the harmful effects of chemicals on humans. It deals with the diagnosis and treatment of acute and chronic poisonings and their prevention. Research activities in this field involve detailed evaluation of cases of acute poisonings and epidemiological studies. A career structure for clinical toxicologists should be developed similar to that proposed for experimental toxicologists.

The career structure in clinical toxicology depends on an official recognition of the discipline by the supervisory governmental authorities and the creation of clinical toxicology departments. A department of clinical toxicology comprising an intensive care unit, outpatient clinic, analytical toxicology laboratory and an information centre should exist in large regional hospitals. Members of such a department would also act as consultants to other clinical departments. The head of the clinical toxicology department (team leader) should have the qualification of a clinical toxicologist (category 2). Limited career opportunities for clinical toxicologists (category 1 or 2) may also exist in industry and in various governmental and nongovernmental organizations (risk assessment).

Assessing the need for clinical toxicologists depends on the number of patients and the structure of national health services. The number of patients, in turn, depends upon the ability of the general practitioner to recognize chemically induced diseases.

The creation of more laboratories for clinical analysis to cope with the growing number of cases of acute and chronic poisonings will help to establish a career structure for analytical toxicologists. Career development in analytical toxicology will tend to follow responsibilities for applying sophisticated techniques and ensuring quality control. At the top level, there may be involvement in other areas of toxicology and further training may be necessary for this.

If people are to be motivated to pursue the extra study required to become competent as toxicologists at the highest level, adequate status and remuneration, in line with comparable professionals, must be available to them. There may be a need to develop a grading structure in order to describe the necessary experience and qualifications required for particular posts.

Recognition of Qualifications

Linked with career opportunities, formal recognition of qualifications in toxicology would be a valuable incentive for potential candidates, thus accelerating the development of well-trained manpower. Furthermore, restricting certain occupations and/or posts to those with formally recognized qualifications would be of great benefit for the development, implementation and acceptance of a chemical safety programme by increasing the level of professionalism. Recognition of three basic profiles of toxicologists was proposed: experimental toxicologists, clinical toxicologists and analytical toxicologists. A possible framework for the recognition of category 1 and 2 (team leader) toxicologists in each specialty was described. Competent work in toxicology is achieved mainly through the cooperative work of various specialists within a toxicological team. Recognition as a category 2 toxicologist should be reserved mainly for the team leader, i.e. the most experienced, evaluative toxicologist in the team.

It needs to be stressed, however, that recognition of toxicologists should be based not only on formal training, but also on experience gained in the field. A detailed description of the various organizations which certify toxicologists in North America was presented. In Canada, there are two ad hoc groups, organized by the Canadian Society of Pathology. In the United States, 10 boards, academies and associations have been organized to confer recognition of toxicologists by certification upon those members of the profession, who, voluntarily applying to be evaluated, succeed in demonstrating their competence to the body responsible for certification. At present, certification is voluntary: it is not a legal requirement.

In clinical toxicology, some formal system of recognition of qualifications is generally considered necessary, taking into account the needs of patients and differing health care systems. Without such recognition, it is unlikely that the separate clinical toxicology units needed will be established. It was thought undesirable to seek a national legal certification system or an internationally agreed system at the present time. It was suggested that the completion of the target curriculum in WHO/EURO Interim Document No. 2 might form a basis for recognition of qualifications, but until proper training is more widely available, approved experience in toxicology could be regarded as a reasonable substitute.

DEVELOPING COUNTRIES

Specific toxicological problems and situations related to chemical safety may vary from region to region. Likewise, the availability of both job posts and manpower and the demand for manpower may also be different in various regions. It was therefore considered important to give special attention to these topics. Discussion and specific recommendations were initiated by papers addressed to situations in Africa, India, South and Central America.

Tropical Africa

The prime toxicological problems are those relating to mycotoxins, poisonous plants, pesticides and inappropriate use of medicines. These problems are aggravated by the lack of trained personnel and financial support for their activities. Control and regulation of the use of chemicals are also made more difficult by the fact that they rely on toxicity assessments carried out in developed countries with climates and other environmental conditions quite different from those prevailing in tropical Africa. There is a need for toxicity testing which pays more attention to the prevailing conditions in tropical countries where chemicals may be used. Another major problem may be that of language, and attention must be paid to making important safety information available in local languages.

There is an immediate need to develop detoxification methods for toxin-contaminated foods. Analytical methods to detect toxins must be improved. Plant poisons and their use and abuse in traditional medicine need much more research. This essential work requires trained manpower, but even now there are unfilled posts for such people in West African countries. Manpower is also required to formulate and make available information on chemical safety for workers and the general public. In this regard, the international agencies should act to set up an African network for environmental chemistry to organize seminars, workshops and newsletters and to promote, as a matter of urgency, a manpower and research development programme.

India

In India, manpower availability for chemical safety, in relation to industrial growth and agricultural development, is a significant problem. Problems of chemical safety are increasing with industrialization and the updating of agricultural techniques accompanied by the increasing use of fertilizers and pesticides. The health impact of chemicals is made worse by malnutrition, undernutrition, and indigenous diseases. Comprehensive legislation, already in existence or in preparation, is not effective because of the lack of trained manpower. There is a clear need for personnel trained in toxicology to perform the following functions:

- construction of an inventory of toxic chemicals in relation to import, production and use, and a national register for potentially toxic chemicals;

- implementation of regulatory measures for licensing import, production, formulation, use, and disposal of chemicals;

- technological innovation to improve existing methods of preventing and controlling chemical pollution and to develop new and better methods;

- preparation of guideline documents and criteria for control of chemicals; and

- assessment of the health effects of chemical pollutants of air, water and food, and provision of advice on chemical safety to the public, the government and industrial and agricultural entrepreneurs.

The number of personnel at the Bachelor of Science level required in India might run to several thousands by the end of the century, with a proportionate number of higher-level scientists also being required.

South and Central America

Problems arise in the countries of this region from the transfer of technology from developed countries that causes rapid change in socioeconomic patterns rather than gradual pre-adaptation that would minimize the resulting difficulties. Excessive use of agrochemicals is causing particular concern. More analytical and clinical toxicologists are required to ensure safe use of pesticides. Epidemiological studies should be made to establish the extent of the health effects of chemical contamination.

In general, there is a shortage of toxicologists in South and Central America. Poison centres are being actively developed to provide both treatment and information, but this effort may be hindered by the lack of appropriately trained people.

In this connection, WHO/EURO Interim Document No. 2 might have a useful part to play in helping to establish suitable courses. However, it must be remembered that each country will need a programme tailored to its own particular requirements. The immediate need is for short courses for professionals now involved in controlling chemicals but with no adequate background in toxicology and chemical safety. There is also a need for postgraduate courses and for incorporation of toxicology in medical and veterinary training and in agronomy, engineering and chemistry degrees. The WHO/PAHO Pan-American Center for Human Ecology is working to facilitate the establishment of the courses needed and to make suitable educational material available in Spanish and Portuguese.

Conclusions

In general, there is a lack of awareness in the developing countries of the health problems associated with uncontrolled use of chemicals. Therefore, the top priority must be to ensure that the top decision-makers and government executives realize that this matter requires their urgent attention. This is a major role for IPCS. Decision-makers must also have expert advice, meaning that their advisers must be trained to the highest level. Even then, laws and regulations will require skilled monitoring for their enforcement, placing further demands on educational systems which may have difficulty in coping.

Chemically induced diseases are seen to be an increasing problem as the probability of living to an advanced age increases in the developing countries. Thus, the need for chemical safety programmes is likely to increase. Finance will be a problem, but it is likely that proposals for funding specific activities will receive sympathetic consideration from international agencies and sources of support such as the European Development Fund.

There is generally a severe lack of toxicologists in the developing countries. These countries have specific research needs in relation to their own natural products and conditions, and care must be taken to allow for these and other differences in developing local toxicological expertise. Clinicians must learn to diagnose poisoning, often against a background of malnutrition and infectious diseases. Perhaps the most urgent need is for local teachers with sufficient knowledge of toxicology to ensure general awareness of the importance of chemical safety and the means of ensuring it.

CONCLUSIONS AND RECOMMENDATIONS

General

1. A working definition of a toxicologist is a prerequisite for adequate communication on the subject and the following is recommended: a toxicologist is a university graduate in medicine or one of the branches of science relevant to toxicology who has a general knowledge of the theory and practice of toxicology and a specialist knowledge with practical experience in at least one area of toxicology.

Toxicology relies on methodologies developed in several branches of the basic sciences. Hence, competent work is achieved mainly through the cooperation of different specialists within a team. The concept of the toxicological team should therefore be further developed.

2. Toxicology is a relatively new discipline whose foundations are in an early stage of development. At present, further research is needed to make toxicology a more predictive science and to improve the resolution of practical clinical problems. Research is also an essential element in the training of toxicologists. Funding for research should be encouraged at the national and international levels.

3. Governments should be encouraged to create, as far as possible, the basic conditions for toxicology to develop as a discipline in its own right by establishing departments of toxicology in academic schools (i.e. medicine, pharmacy, veterinary medicine, agriculture and science). This would also constitute a step towards the institution of academic careers in toxicology. Wherever possible, the foundation of toxicological societies and professional/scientific journals at the national or regional level should be encouraged. The development of toxicology should also be accelerated through an exchange of information at the international level.

Furthermore, toxicology as a discipline should provide the necessary awareness of the toxic potential of chemicals at all levels of education in chemistry, chemical engineering and in pure and applied sciences in general. This can best be achieved by teachers of chemistry and biology, provided that their own training curriculum is amended in an appropriate way.

4. Toxicology as a discipline has a place in several occupational profiles, of which three seem to be essential. These profiles,

defined by both area of activity and type of qualifications required, are experimental, analytical and clinical toxicology. Clinical toxicology is open to medical graduates only. The two other fields are open also to graduates of veterinary medicine, natural sciences and chemistry. Specialists in any one of these fields could be engaged, within the limits of their competence, in a number of applied fields of toxicology, such as industrial, environmental, forensic, agricultural and regulatory toxicology and clinical diagnosis and treatment. The occupational profile and curriculum developed in WHO/EURO Interim Document No. 2 are considered appropriate, with some revisions for the training of experimental toxicologists. This approach could also be used as a model to develop target curricula for both analytical and clinical toxicologists.

5. Clinical toxicology is the discipline that studies the harmful effects of chemicals on humans. It deals with the diagnosis, treatment and prevention of acute and chronic poisonings. In most countries, it is not yet fully recognized as a medical specialty and efforts should be made to ensure that it is. In developing curricula for physicians who specialize in toxicology, emphasis should be placed on the need to diagnose chronic effects and on the use of preclinical effects for purposes of risk evaluation and prevention.

Training in toxicology and chemical safety should be included in the curricula of general practitioners and medical specialists, such as internists and paediatricians, who are not always sufficiently aware of the possible role of chemicals in human pathology. Sometimes, cases of chronic intoxication are not diagnosed and appropriate treatment is not provided, unhealthy situations are not always rapidly identified and preventive measures taken, and sound advice is not always given about the adverse effects of exposure to chemicals.

6. Current toxicological testing depends mainly on the use of laboratory animals. Human clinical and epidemiological studies are of special value for the detection of toxicity. The toxicology curriculum should include discussion of ethical codes dealing with animal welfare and research involving human subjects.

7. Precise information is not available regarding the qualifications required for professional activities in experimental, clinical and analytical toxicology. Surveys should be conducted in selected countries to establish the current qualifications required in the field of toxicology in government, industry, universities, etc., and to develop general criteria for these qualifications in the future; the development of these criteria at the international

level would help provide a common approach for risk management. If formal recognition of qualifications is adopted by a country, the self-trained professionals already working in the field, with long experience and of high standing, should be given due credit.

8. The theoretical model proposed for assessing manpower needs in toxicology, based on the production, use and degree of control of chemicals, was considered valuable and worth validating. The practical assessment of the need for toxicologists made in Italy and Ireland should be used to evaluate the adequacy of the model.

9. Career models of different degrees of sophistication were proposed in experimental, analytical and clinical toxicology. The assessment of the manpower needs model and the career models should be combined and developed into strategies for manpower development that are appropriate for national and regional needs.

10. It is not known to what extent additional training programmes in toxicology are currently needed. This should be estimated when the real demand for toxicologists has been assessed.

11. The poison control and clinical toxicology centres already active in a number of countries play an increasing role in informing physicians and the public of the risks of chemicals, and this should be developed further.

12. Safety and hygiene committee representatives have an important role to play in preventing occupational exposure to industrial chemicals; appropriate training programmes and short-term courses should be developed for them.

Workers, management representatives, occupational health personnel, safety engineers and labour inspectors are not always given proper training in the risks to health of exposure to and handling of toxic chemicals. An awareness of the need for such training is growing, as shown by specific requirements in recent European Community legislation. National and international authorities should ensure that all those responsible for health and safety at work receive adequate information about chemical risks.

13. The flow of communication and information between the toxicologist and consumer groups and the media has not always been adequately conducted, and appropriate educational programmes are needed to facilitate this exchange.

14. The proposed training approaches in toxicology and chemical safety may be used as a model in the manpower development programme. International organizations should organize or support

international seminars and workshops to facilitate the establishment of harmonized training approaches and provide training opportunities to candidates from countries lacking the necessary facilities.

15. To ensure that manpower development in toxicology proceeds as quickly and effectively as possible, with optimum use of all available resources and worldwide harmonization of approaches, the well-coordinated efforts of IPCS, CEC and other international bodies should be reinforced.

Of Special Relevance to Developing Countries

16. The successful control of infectious diseases in developing countries, combined with the increasing use of agricultural and industrial chemicals, has led to an increase in the death rate and in ill health resulting from both acute and chronic chemical poisoning. Nevertheless, most developing countries have inadequate facilities and personnel to deal with such problems, and substantial resources should be made available for manpower development in these countries.

17. Different degrees of industrialization and agricultural development exist within developing regions. It is therefore impossible to make general recommendations about manpower needs and training requirements that are applicable to all regions. A workshop should be organized as soon as possible in a developing country to assess these needs so that appropriate programmes and priorities can be planned.

18. It is likely that many instances of harm due to chemicals in developing countries are not brought to official attention because of a lack of public awareness of the hazards involved.

International organizations should try to increase awareness on the part of policy-makers and the public of the health problems posed by toxic chemicals, as this ignorance is one of the major reasons for the lack of trained manpower in the developing countries.

19. Training received in industrialized countries may not always be suitable to the socioeconomic framework of developing countries. Facilities and materials for education and training should be made available in the developing countries, addressed to local problems and written in the appropriate language.

20. Successful short courses on specific topics in toxicology, such as those held in Brazil and Egypt in 1983 with the support of IPCS and the individual governments, satisfy an immediate and urgent need to disseminate information. They should be continued, and extended to other countries as needed, with the support of appropriate international agencies and programmes.

21. A particular problem in developing countries that are dependent on agriculture is the use of pesticides by farm workers who are ignorant of their toxic properties and the safety procedures to be observed. An adequate supply of manpower is urgently required, trained in chemical safety, registration and regulatory control.

22. The idea of a day devoted to publicizing chemical safety and the impact of chemicals on human health and the environment should be launched.

Annex 1

ASSESSMENT OF NEED AND DEMAND FOR EVALUATIVE TOXICOLOGISTS

by

S. Kassel

Introduction

There is an urgent need to have a workable idea of the size of trained professional manpower required by toxic chemical control programmes in various countries in order to design and implement timely and adequate training efforts to produce the required manpower. The field of toxic chemical control is still in the early stage of development, with the provision of sufficient manpower capability for present and future needs being one of the primary tasks on the planning agenda.

However, the relatively recent origin of this field precludes the availability of statistical data that are common to more traditional fields faced with the task of quantitative assessment of manpower. The number of professional toxicologists that are needed to implement a given toxic chemical control programme is a function of a broad range of variables representing the scope and type of societal activities involving toxic chemicals. At this time, there appears to be no definitive list of the variables that significantly affect the number of required toxicologists and no proven formula that can relate that number to the quantitative expression of the variables. This lack of information can be redressed only by fact-finding missions to survey countries or regions that can be regarded as representative of the various chemical producer/user activities, followed by a detailed statistical analysis of the results.

This is the approach that must be taken to arrive at a reasonably accurate prediction of the necessary manpower numbers and the corresponding scope of the training programme. In the meantime, one can consider a rather broad and approximate outline of the problem and attempt to construct an abstract model showing the basic relationships involved. Its primary value would reside in assisting the field missions in their fact-finding tasks, as well as in providing a sense of the required scope to the manpower planning effort.

The Evaluative Toxicologist

In the construction of such a model, this assessment is limited to one kind of professional toxicologist, called the evaluative toxicologist for the immediate purpose of the present effort. This is understood to mean a relatively senior professional operating as a full-time toxicologist at least on the team-leader level, or in an advisory capacity. It is a person whose basic orientation is toxicology, rather than one of the specialized disciplines practiced in the routine operation of toxicological teams. The evaluative toxicologist is therefore a most important asset in any national comprehensive toxic chemical control effort.

The evaluative toxicologist is not the product of a standard academic training curriculum but represents the outcome of diverse career pathways that generally start with a traditional discipline, are supplemented by specialized training, and involve a period of training practice. Consequently, there can be no unique prescribed curriculum leading to the profession of evaluative toxicologist. Instead, the supply of evaluative toxicologists must be based on an adequate infrastructure of academic education in the several disciplines pertinent to toxicological activities, supplementary toxicological courses, and ongoing toxic chemical control operations providing the necessary practical training. The last requirement implies that areas commencing their toxic chemical control programmes now would have to import their evaluative toxicologists or train them abroad as long as adequate domestic control operations have not been established.

Criteria for Estimating Demand

The purpose of this paper is to develop a method for estimating the number of evaluative toxicologists required by the current levels of industrial production and/or consumption activity of a given country. Due to the lack of adequate statistical material at this time, the model developed here is essentially qualitative. It can be expressed in quantitative terms and modified to project expansion forecasts when numerical data become available.

The number of evaluative toxicologists required by the toxic chemical control programme is based on the demand generated by the employment spectrum of positions, qualified by local conditions that determine the level of toxic chemical control activity. The manpower numbers determined by the demand function are the basis for subsequent estimates of the necessary supply structure consisting of training facilities and programmes and employment opportunities.

The task of estimating the demand for evaluative toxicologists consists of two basic stages. First, we must determine where these professionals work and what do they do, before we undertake to count their number. Therefore, the first stage is necessarily qualitative and must precede the quantitative assessment. The qualitative assessment is also concerned with the kind of activity involving toxic chemicals pursued by the given country or region.

While there are undoubtedly many activities with the potential for affecting the scope of toxic chemical control programmes and thus the number of evaluative toxicologists needed, four are clearly of primary importance: development, production, general use, and agricultural use of toxic chemicals. Other criteria capable of affecting demand for evaluative toxicologists include the diversity of chemicals being developed, produced, or used, and the level of control policy involving, for example, testing requirements, evaluation, surveillance of use, and level of toxicovigilance. It is assumed here that the first four criteria should be sufficient in providing the basic indication of the scope of needed positions in the preliminary model.

The quantitative aspect of the criteria for the demand for evaluative toxicologists relates to the actual extent of the development, production, and use of toxic chemicals, as well as to the potentially pertinent indices that characterize the given country or region in terms of its economic, industrial, commercial, and agricultural activities and its demographic characteristics.

The separate consideration of the qualitative and quantitative aspects of the four criteria is significant: for example, the fact that new chemicals are being developed will by itself affect the distribution of evaluative toxicologists. However, the different quantitative levels of such development will have different effects on the number of positions for these toxicologists and must also be taken into account. In the present model, the discussion of the quantitative effects must necessarily be limited to their potential role in the model. The qualitative assessment will thus develop the basic structure of the assessment model. The quantitative assessment will then provide a method for expressing the structure in terms of numerical data.

Qualitative Model of Demand for Evaluative Toxicologists

The spectrum of locations where evaluative toxicologists can be found may be classified according to the organizations involved in toxic chemical control activities and according to the functions performed by these toxicologists. The organizations include government, industry, commerce, the university, health services, and other potential employers such as the armed forces and trade unions. In the framework of these locations, evaluative toxicologists are expected to perform a range of functions such as policy formulation, setting of standards, design and management of investigation, education in the field of toxicology, and toxicological research. Not all of these functions are expected to be performed within each organization involved in the toxic chemical control programme.

Table 1 shows the distribution of evaluative toxicologists by organization and function. Each location where a given function must be performed by evaluative toxicologists in a given organization or sector is marked by an X. The distribution of the X marks in Table 1 thus represents the full range of employment of evaluative toxicologists.[1]

The purpose of assessing demand is to assign a number of positions of evaluative toxicologists to each X location in Table 1, and then to add up all positions in all locations. The sum of all positions therefore represents the total number of evaluative toxicologists required for the given country or region. The number of positions at each location in Table 1 can range from less than one to several positions. Less than one position means that several functions are combined in one person, or that a toxicologist from one sector also serves in another sector, such as toxicologists from the university performing evaluative work for the government.

The four cardinal qualitative criteria noted above do not affect the number of positions at each location in the same way. Otherwise, the total number of locations in Table 1 could be simply multiplied by some appropriate coefficient associated with the development of new toxic chemicals, with the production of chemicals, or else with their use, as the case may be. There are four locations that appear invariant with respect to the qualitative criteria of development, production, or use of toxic chemicals: three are in the government sector, and one is in the sector of hospitals. The number of positions of evaluative toxicologists in government decision-centres at the level of policy formulation[2] and health risk evaluation is assumed invariant because these locations are at the top of the

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[1] Table 1 includes locations of evaluative toxicologists suggested by an expert opinion poll in the Netherlands (see Working Paper CEC/V/E/2/LUX/83/68/12; WHO/ICP/RCE 903(25)/12).

[2] Expert opinion of Netherlands poll does not consider policy formulation a function performed by toxicologists.

Table 1 Distribution of evaluative toxicologists by organization and function

	Organization								
	Government		Industry		Commerce		Universities	Hospitals	Other
Function	Intermediate agencies	Decision centres	Toxicology laboratories	Advisory services	Toxicology laboratories	Consultants			
Policy-making		X		X					
Standard setting	X								
Health risk evaluation	X	X		X		X	X	X	X
Dossier creation				X		X			X
Dossier evaluation	X	X		X			X		
Design and management of investigation			X		X				
Education			X		X		X	X	
Research							X		

toxic chemical control structure, can be expected to exist in any control programme, and may be considered relatively insulated from the routine workload generated by toxic chemical control activity. The location of standards setting in the intermediate agencies of the government is assumed invariant since that function is performed regardless of whether toxic chemicals are developed, produced, or used in the given country. Toxicological education in hospitals is assumed invariant for the same reason. It should be noted here that these locations are assumed invariant only with respect to the four primary qualitative criteria, but not with respect to he quantitative criteria (level of activity); the number of positions at these locations could be affected by high development or production levels.

It is also assumed that in countries that fell only into the user category, there will be no positions of evaluative toxicologists in the industrial sector, or positions related to the function of dossier creation. All the remaining locations of evaluative toxicologists are assumed sensitive to the criteria of development, production, and use of toxic chemicals.

Table 2 shows the distribution of the four qualitative criteria among the employment locations of evaluative toxicologists. Each location identified in Table 1 has been marked in Table 2 by letter symbols representing the possible number of evaluative toxicologist positions at that location, depending on the qualitative criterion. Thus, if the given country is a developer of new toxic chemicals, the particular location will have D positions; if the country is a producer or only a user of toxic chemicals, the location will have P or U/A positions, respectively. Invariant locations are marked Inv.

Of course, it is not possible to specify the actual number of positions at each location as a function of the designation, D, P, U, or A, in the qualitative model. As noted above, these designations should be further qualified in the quantitative model by suitable coefficients reflecting output levels and perhaps by additional criteria that can be developed when adequate statistical data become available.

Approach to the Quantitative Model

An illustrative approach to the quantitative prediction of demand for evaluative toxicologists can be derived from the qualitative model by postulating the following arbitrary, but not unreasonable, basic relationships.

A country developing new chemicals, a "D" country, can be expected to need more evaluative toxicologist positions than a country that mainly manufactures chemicals ("P" country); the latter, in turn, needs more of such positions than a country that only uses toxic chemicals ("U" or "A" country). For illustrative purposes, a developed industrial region of P type is assumed to require one position for each location in Table 2. It is further assumed that if P calls for one position, D is three times larger than P and U is three times smaller than P. Consequently, the value of 3 is assigned to each location marked D in Table 2, the value of 1 to locations marked P and Inv, and the value of 0.3 to locations marked U or A. In this approach, A has the same coefficient as U, but its distribution in Table 2 is more limited than that of U. Table 3 shows an illustrative distribution of the numbers of position by kind of chemical activity obtained replacing the symbols D, P, U and A in Table 2 by the values of 3, 1, 0.3, and 0.3, respectively.

The above example is based on the assumption that none of the functions listed in Table 2 is shared among the locations, and that all listed locations are necessary for the implementation of a toxic chemical control programme. In the development of the demand model, this example plays the role of a first approximation to the average demand baseline for four representative types of country.

The number of required evaluative toxicologists shown in Table 3 can be compared to the results of the expert opinion poll recently conducted by Jager and Tarkowski as part of a field survey of the Netherlands, Egypt and Poland (see Working Paper CEC/V/E/2/LUX/83/68/12;WHO/ICP/RCE 903(25)/12). In estimating the number of currently employed evaluative toxicologists in the Netherlands, the experts provided a range of answers from 20 to 35 positions; the average of the poll was 27 currently employed evaluative toxicologists.[1] According to the above report, the Netherlands is a mature producer of chemicals and pursues little development of new products. In our terminology, the Netherlands thus qualifies as a P country. Table 3 shows 24 evaluative toxicologists for type P. Therefore, the results of the expert opinion poll for the Netherlands are in good agreement with the approach to quantitative assessment reflected in Table 3.

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[1] All respondents also specified number of additional evaluative toxicologists needed; poll average was 17. However, they also stated "we do not need more, but better toxicologists ..", putting into question the additional needs.

Table 2. Distribution of evaluative toxicologists qualified by kind of chemical activity

Function	Organization: Government – Intermediate agencies	Government – Decision centres	Industry – Toxicological laboratories	Industry – Advisory services	Commerce – Toxicology laboratories	Commerce – Consultants	Universities	Hospitals	Other
Policy-making		Inv		D,P					
Standard setting	Inv								
Health risk evaluation	D,P,U,A	Inv		D,P		D,P,U	D,P	D,P	D,P,U,A
Dossier creation				D,P		D,P			D,P
Dossier evaluation	D,P,U,A,	D,P,U,A		D,P			D,P		
Design and management of investigation			D,P		D,P,U				
Education			D,P		D,P,U		D,P,U,A	Inv	
Research							D,P,U		

Inv = invariant number of positions
D = developers of new chemicals
P = producers of chemicals
U = users of chemicals
A = users of agrochemicals only

Table 3. Number of required evaluative toxicologists according to kind of toxic chemical activity

Kind of activity	Number of positions
Developers of new chemicals	64
Producers of chemicals	24
Users of chemicals	7
Users of agrochemicals	6

The actual number of evaluative toxicologists that are required by a given country may fall below or above the first-approximation baseline illustrated in Table 3, depending on the quantitative criteria of the level of development, production or use. The numerical values of these levels again are assumed to affect the number of positions of evaluative toxicologists in a manner depending on the location. Some locations in Table 2 will be affected by the quantitative criteria to a greater extent than others. Table 4 shows the sensitivity of the locations of evaluative toxicologists to the development and production output levels. The number of required positions at each location is indicated here as either moderately sensitive or highly sensitive to the output levels. It is apparent from Table 4 that differences in the output levels will mainly affect the number of positions of evaluative toxicologists in the industrial and commercial sectors.

Maintenance of the Required Manpower Level

The main purpose of estimating the demand for evaluative toxicologists is to predict the scope of the training system necessary to meet that demand. Evaluative toxicologists evolve from the ranks of professionals engaged in various areas of toxicological activity who, in turn, are recruited from graduates of several academic disciplines pertinent in varying degree to the field of toxicology. Consequently, the demand for evaluative toxicologists must ultimately be met by graduates in the pertinent disciplines.

The task of assessing the required training scope thus reduces itself to ensuring that the academic graduation rates in these disciplines are adequate to maintain the necessary replacement rate for evaluative toxicologists. This is the primary issue of the assessment model; various secondary issues, such as estimating the scope of supplementary specialized and on-the-job training facilities, depend on the resolution of the primary issue, i.e. the academic graduation rates required to match the toxicological replacement rate.

The correlation of graduation and replacement rates requires a body of statistical data that explicitly identifies the position of evaluative toxicologist, a concept that has only recently been defined. At this time, the only source of numerical data involving the concept of evaluative toxicologist is the report on the fact-finding missions to Poland and the Netherlands cited earlier. The statistical sample from the Netherlands mission is small, involving seven respondents. However, they represent a valid expert opinion and thus impart sufficient credibility to their data which also explicitly address the concept of evaluative toxicologist. The Netherlands data, therefore, are the basis of the following analysis of manpower supply.

The annual replacement rate of evaluative toxicologists (R_T) is the number of currently active practitioners of this profession (T) divided by their average professional life span (t_T):

$$R_T = T/t_T$$

Similarly, the annual replacement rate (R_Q) of all professionals (Q) active in the field of toxicology is expressed by:

$$R_Q = Q/t_Q$$

where t_Q = their average professional life span. Since evaluative toxicologists come mainly from the ranks of toxicological professionals, R_T is part of R_Q, i.e. the replacement rate of all toxicological professionals must be high enough to satisfy the replacement rate of evaluative toxicologists in addition to meeting the demands of the other areas of toxicological activities.

If $a = Q/T$, R_Q can be expressed in terms of the number of evaluative toxicologists as $R_Q = aT/t_Q$.

The required rate of academic graduations (R_G) should be somewhat higher than R_Q because of normal attrition rates. Assuming an

Table 4. Distribution of evaluative toxicologists according to level of development and production of toxic chemicals

Function	Organization: Government – Intermediate agencies	Government – Decision centres	Industry – Toxicology laboratories	Industry – Advisory services	Commerce – Toxicology laboratories	Commerce – Consultants	Universities	Hospitals	Other
Policy-making		M		H					
Standard setting	M								
Health risk evaluation	H	M		H		H	M	M	M
Dossier creation				H		H			
Dossier evaluation	H	M					M		
Design and management of investigation			H		H				
Education			H		H		M	M	
Research							H		

M = moderately sensitive to output levels H = highly sensitive to output levels attrition rate of 20%,

$$R_G = 1.2\ aT/t_Q$$

The determination of R_G is the objective of this analysis. R_G is the required annual rate of graduations from the several disciplines that serve as sources of toxicologists in general and of evaluative toxicologists, although less directly, in particular. To find R_G we must know the values of T, a, and t_Q.

For the first-approximation approach, the values of T are obtained from the example given in the preceding section. The values of a and t_Q are derived from the Jager and Tarkowski report and the data of the preceding section. The latter gave the value of T = 24 for a country of the type represented by the Netherlands. The Netherlands expert opinion poll estimated Q at 400, so that $a = Q/T \approx 17$. On the other hand, according to the report's Polish survey, Q ranges from 1000 to 1300 for Poland, and there may be from 40 to 50 fully fledged toxicologists, although it is not clear if they correspond to the concept of evaluative toxocologist. These figures yield the ratio of Q/T in the range from 20 to 30. Because of the definitional ambiguity involved, it is reasonable to accept a ratio closer to the figures from the Netherlands and set a = 20.

This means that for every evaluative toxicologist, there are 20 professionals with academic degrees active in the field of toxicology. Table 5 gives the required replacement rates and graduation rates computed with the aid of the above equations.

The values in Table 5 should be regarded as minimal for the following reasons. Better statistics may show that the Q/T ratio is higher than 20, as the Polish figures seem to indicate. The baseline figures for T given in Table 3 will be higher in larger industrial countries, when adjusted for actual development and production levels of chemicals. On the other hand, the professional life span of 40 years, an average for all toxicological personnel stated by the Netherlands expert opinion, seems quite high. Raising Q/T and T, and lowering t_Q will have the effect of increasing the values of all four variables in Table 5. However, it is unlikely that such adjustments will increase R_G by more than a factor of two for users and producers of chemicals of any size.

Table 5. Annual replacement rates for evaluative toxicologists and corresponding graduation rates for different kinds of chemical control activity

Kind of activity	T	R_T	R_Q	R_G
Developers of new chemicals	64	4	32	38
Chemical producers	24	2	12	14
Chemical users	7	0.5	3.5	4
Agrochemical users	6	0.5	3	4

T = number of evaluative toxicologists
R_T = replacement rate for evaluative toxicologists
R_Q = replacement rate for all toxicologists
R_G = graduation rate

Annex 2

CHANGING NEED FOR TOXICOLOGISTS IN ITALY RESULTING FROM EUROPEAN COMMUNITY LEGISLATION

by
P. Preziosi, A. Sampaolo[1] and V. Silano

Introduction

Toxicology develops at present along two closely interacting routes: (a) preventive toxicology and (b) antipoison and drug abuse therapy. To achieve success, both approaches require toxicologists with different types of specialization; namely, clinical toxicology, experimental toxicology and analytical toxicology. A medical doctor's degree is essential for a clinical toxicologist.

Preventive toxicology

The aim of preventive toxicology is risk assessment, the first step in risk-benefit analysis. Basic components of preventive toxicology are the production of experimental data to evaluate the effects of chemicals on human and environmental health and the assessment of expected or actual human and/or environmental exposure.

In Italy, investigations aimed at producing experimental data to evaluate the human and environmental health effects of chemicals (i.e. the main task of experimental toxicologists) are carried out by researchers with very different professional backgrounds. They include medical doctors, veterinarians, biologists, pharmacists and biochemists. Environmental monitoring and other investigations to evaluate or predict chemical exposure of workers, consumers, general population and environmental organisms through different routes including air, water, soil or food (i.e. the main task of analytical toxicologists) are mainly carried out by chemists and biologists.

Antipoison and drug abuse therapy and surveillance

In Italy, the treatment of acute intoxication caused by chemicals (i.e. the main task of clinical toxicologists) is usually carried out by anaesthesiologists at intensive care or antipoison centres. In this respect, it is interesting to stress that only in Florence

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is there a chair of toxicology with an associated clinical service; this chair is presently held by a university professor of toxicology with a pharmacological background. Subchronic and chronic intoxications are usually treated by the M.D. specialists for each system or organ affected in specific clinical departments. Occupational health physicians are involved in clinical problems related to intoxications occurring at the workplace.

EEC Legislation Imposing Requirements for Toxicological Investigations

Premarket testing of chemicals

Although thousands of natural and synthetic substances have been used for a long time, only relatively recently have regulations envisaged a premarket evaluation of risks for people and the environment, based on expected exposure levels and data from toxicity testing. Early international documents on toxicological testing of chemicals for the protection of public health are contained in several reports by WHO and joint FAO/WHO groups [1-4]. These documents mark the beginning of specific, concerted international action. Today, a number of international and intergovernmental organizations (e.g. WHO, OECD and EEC) are active in this important sector, drawing up recommendations and/or binding regulations for their Member States.

Most substances currently in use to which people and the environment may be exposed to a certain extent can be grouped in nine categories:

1. Cosmetics
2. Drugs
3. Feed additives
4. Flavourings
5. Food additives and colours
6. Food packaging materials
7. Industrial chemicals
8. Pesticides
9. Single-cell proteins

Requirements for toxicological and ecotoxicological premarket testing depend on two main factors: the intended use of the chemical and the historical period in which the requirements were drawn up. The premarket testing requirements of the Italian or EEC laws and those recommended by some international organizations for these groups of chemicals are given in Table 1. Recommendations to national authorities concerning the use of pesticides were published by the Council of Europe in 1981[6]. The Italian Pesticide Act was enforced in 1968 and is now being updated with the approval of further specific norms. The EEC Directive 78/631 on pesticides was adopted by Member States on 26 June 1978, but its implementation has been delayed while waiting for some annexes to be prepared. These annexes have now been defined, and implementation of the Directive is imminent.

Recommendations on premarket testing of drugs were published by WHO in 1975 [7]; the relevant Italian law on this topic is the Ministerial Decree dated 28 July 1977, which broadly follows EEC Directive 75/318. Alder et al. [8] have collated the pertinent drug toxicity regulations of various countries. A close look at the work indicates that the studies recommended in the various countries are very much alike. Recommendations on premarket testing of industrial chemicals were published by WHO in 1978 [9] and OECD in 1981 [10]. Directive 79/831 has been recently approved by the EEC and implemented in Italy (DPR 927, 2 November 1981).

The problem of toxicity testing of single-cell proteins to be used as animal feed was extensively dealt with in Italy during 1974-1979, and it has also been considered by the Protein Advisory Group of the UN system [11]. EEC Directive 83/228 has been recently issued on this matter. No legislative norms concerning toxicological premarket testing requirements have been approved until now in Italy or at EEC level with respect to food and feed additives, cosmetics and flavourings. Recommendations, however, have been enacted by FAO/WHO and EEC scientific committees (food additives, 1967 and 1980, respectively) [4,12], and the EEC Scientific Committee for Feed (feed additives, 1981) [13] and the Council of Europe (flavourings, 1974; cosmetics, 1978) [14,15].

Table 1 shows that several tests (e.g. acute and chronic toxicity studies and reproduction studies) are generally required for all the technical groups considered, whereas other types of investigation are required only for selected chemical groups. For instance, ecotoxicological testing is required only for pesticides, feed additives and industrial chemicals. Skin irritation and sensitization tests are not required for food additives and flavourings, but clearly from the standpoint of occupational hygiene, they are generally useful.

Lastly, specific requirements for mutagenicity tests are absent in a few cases (flavouring and food packaging materials) due to the fact that relevant recommendations were published some years ago.

<u>Human and environmental monitoring</u>

In addition to the above-mentioned EEC directives that impose requirements for some types of toxicological premarket testing,

Table 1. Premarket toxicological studies required for different groups of chemical at Italian (I), European Economic Community (EEC) or international (INTL) levels (After Macri & Silano [3])

Group of substances	Acute toxicity			Skin and eye irritation and skin sensitization			Subchronic toxicity			Chronic toxicity			Cancerogenesis			Mutagenesis			Metabolism			Effect on reproduction			Teratogenesis			Ecotoxicity		
	I	EEC	INTL	I	EEC	INTL	I	EEC	INTL	I	EEC	INTL	I	EEC	INTL	I	EEC	INTL	I	EEC	INTL	I	EEC	INTL	I	EEC	INTL	I	EEC	INTL
Cosmetics (R)	-	-	+	-	-	+	-	-	+	-	-	+	-	-	+	-	-	-	-	-	+	-	-	+	-	-	+	-	-	-
Drugs (LN/R)	+	+	+	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	-	-
Feed additives (R)	+	+	-	+	+	-	+	+	-	+	+	-	+	+	-	+	+	-	+	+	-	+	+	-	+	+	-	+	+	-
Flavourings (R)	-	-	+	-	-	-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	+	-	-	+	-	-	-
Food additives and colours (R)	+	-	+	-	-	-	+	-	+	+	-	+	+	-	+	+	-	-	+	-	-	+	-	-	+	-	-	-	-	-
Food packaging materials (LN/R)	-	+	+	-	-	+	-	+	+	-	+	+	-	-	+	-	-	+	-	-	+	-	-	+	-	-	+	-	-	-
Industrial chemicals (LN/R)	+	*	+	+	*	+	+	*	+	+	*	+	+	*	+	+	*	+	+	*	+	+	*	+	+	*	+	+	*	+
Pesticides (LN)	-	+	+	-	*	+	-	*	+	-	*	+	-	*	+	-	*	+	-	*	+	-	*	+	-	*	+	-	*	+
Single-cell proteins (LN/R)	+	+	+	-	-	-	+	+	+	+	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	-

LN = legislative norms
R = recommendations
\+ = required

\- = not required
* = requirement being developed

several other EEC directives or decisions contain provisions involving analytical investigations intended to monitor human exposure to chemicals. They deal with:

(a) Air quality (general environment)

- Council Decision 75/441/EEC (O.J. L 194, 25/7/1975)
- Council Directive 77/312/EEC (O.J. L 105, 28/4/1977)
- Council Decision 78/889/EEC (O.J. L 311, 4/11/1978)
- Council Directive 80/779/EEC (O.J. L 299, 30/8/1980)

(b) Air quality (at workplace)

- Council Directive 78/610/EEC (O.J. L 197, 22/7/1978)
- Council Directive 82/605/EEC (O.J. L 247, 23/8/1982)
- Council Directive 83/477/EEC (O.J. L 263, 24/9/1983)

(c) Water quality

- Council Decision 75/437 and 438/EEC (O.J. L 144, 25/7/1975)
- Council Directive 75/440/EEC (O.J. L 194, 25/7/1975)
- Council Directive 76/464/EEC (O.J. L 128, 18/5/1976)
- Council Decision 77/586/EEC (O.J. L 240, 19/9/1977)
- Council Decision 77/795/EEC (O.J. L 334, 24/12/1977)
- Council Decision 78/888/EEC (O.J. L 311, 4/11/1978)
- Council Directive 79/869/EEC (O.J. L 271, 29/10/1979)
- Council Directive 79/923/EEC (O.J. L 281, 30/10/1979)
- Council Directive 80/68/EEC (O.J. L 20, 26/1/1980)
- Council Decision 80/178/EEC (O.J. L 39, 15/2/1980)
- Council Directive 80/778/EEC (O.J. L 299, 30/8/1980)

(d) Specific chemicals and wastes

- Council Directive 76/403/EEC (O.J. L 108, 26/4/1976) (disposal of PCB and PCT)
- Council Directive 78/319/EEC (O.J. L 83, 31/3/1978) (toxic wastes)
- Council Directive 76/769/EEC (O.J. L 262, 27/9/1976) (limitations)
- Amendment I of Directive 76/769/EEC (O.J. L 197, 3/8/1979) (PCB)
- Amendment II of Directive 76/769/EEC (O.J. L 339, 1/12/1982) (PCT)
- Amendment III of Directive 76/769/EEC (O.J. L 350, 10/12/1982) (VCM)
- Amendment IV of Directive 76/769/EEC (O.J. L 147, 6/6/1983) (benzene)

Need for Toxicologists

In Italy, institutions and organizations that need toxicologists to discharge their responsibilities and carry out their duties are the National Health Service, contract toxicity testing facilities, universities, and other institutions. Estimations of new positions for toxicologists that could become available in Italy in the framework of the National Health Service during the next five years are shown in Table 2.

National Health Service

The National Health Service has both central and local structures.

(a) Central structures

This is composed of the Ministry of Health and its technical and scientific bodies: namely, the Istituto Superiore di Sanità (ISS) and Istituto Superiore per la Prevenzione e la Sicurezza del Lavoro (ISPSL) in Rome. Responsibilities of the central government include establishing framework legislation, recommending health standards and supporting research and international relations.

The National Health Service was established by the National Health Service Act in 1978 and is still in the process of being implemented. For instance, ISPSL, where several new positions for toxicologists are foreseen, has not been able to make these positions available yet. At ISS, a new department of toxicology has recently been established and about 20 positions for senior and junior toxicologists have become available; at present, these positions are being offered through national competitive examinations.

(b) Local (regional, provincial, municipal) structures

In Italy, there are 653 local health units which run about 90 regional hospitals and 6 antipoison centres. Regional responsibilities include local health and environmental management and development planning through regional legislation as well as coordination of local activities. Local health units are responsible for basic sanitation, education and safety, as well as for health services, and workplace inspection. Provinces generally have intermediate coordination tasks (e.g. as in local emergency situations).

Table 2. New positions for toxicologists (units) that should become available in Italy before 1988

National Health Service		Contract toxicity; testing facilities	Universities; other institutions	Total
Central bodies	Local bodies			
20-40	60-120	30-60	20-40	130-260

Contract toxicity testing facilities

A survey of the capabilities of Italian laboratories to test new chemicals in accordance with EEC Directive 79/831 has been recently carried out by ISS [16]. A questionnaire was sent to about 1500 university, governmental, government-controlled, private, regional and industrial organizations (chemical and pharmaceutical).

The form was divided into three parts. The first covered the name, address and other identification data of the laboratory. The second took into account its general characteristics, including the number of personnel, major fields of activity, main laboratory facilities, availability of computers, and library services. The third dealt with the types of test that can be performed, with explicit mention of all the physicochemical determinations (spectral characterization included), as well as the ecotoxicological and toxicological investigations listed in the Directive annexes. More than 150 forms were completed and returned. From the information collected, a large number of laboratories declared themselves capable of performing the more traditional and less time-consuming tests (Table 3), whereas response was poor for more complex and lengthy studies (e.g. long- or medium-term toxicity). Moreover, only a few laboratories identified themselves as able and willing to perform ecotoxicogical tests. Larger private centres for toxicological testing and research include the Life Science Research, Rome Toxicology Centre; and the Istituto di Ricerche Biomediche "A. Marxer" (RBM) at Ivrea).

It is not surprising therefore that an international advisory commission (IAC) consisting of leading chemists, ecotoxicologists, pharmacologists, toxicologists and legal experts, having taken into account among other things the considerable testing expenditure abroad by the Italian industry (approximately 5 million U.S. dollars annually), concluded that there is a real need to boost Italian toxicity testing by establishing a new and highly qualified institution capable of performing basic research, toxicity testing and related investigations. In the feasibility study for the Italian Toxicology Institute, the IAC estimated that at full working capacity, the total professional staff of the Institute should consist of about 60 scientists.

Universities and other institutions

In Italian universities there are 5 chairs of toxicology, 2 chairs of forensic toxicology, 41 chairs of pharmaceutical and toxicological chemistry and 40 chairs of forensic medicine. In addition, 24 institutes of occupational medicine have 34 chairs of occupational medicine and 15 chairs of industrial toxicology. The availability of new positions in this area is likely to develop slowly, with up to about 20% of the total present number in coming years.

The Italian National (Research) Council, although supporting a number of toxicologically oriented research studies and in particular the applied national project on toxicological risk, does not have a specific laboratory for toxicological research. However, numerous basic research projects relevant to toxicology are carried out in many of its laboratories.

The Istituto "Mario Negri" that is now starting a new branch at Chieti ("Mario Negri Sud") may offer some new positions for toxicologists during the next few years, as may the 5 scientific institutes for health care and therapy (Naples, Rome, Milan, Genova and Pisa) dealing with research on cancer under the supervision of the Ministry of Health (see Table 2).

Conclusions

The EEC legislation to protect human health and the quality of the environment has rapidly had effect, producing an increasing demand for toxicologists, particularly for those involved in preventive activities. In Italy, as a first response to this changing scene, a number of scientists with different academic background (e.g. medicine, biology, veterinary science, chemistry, and pharmacy) have become more interested in toxicology and have devoted themselves to toxicological occupations. This has permitted a partial response to

Table 3. Affirmative responses from laboratories in Italy concerning ability to perform certain tests (Taken from Binetti & Caroli [16])

Type of laboratory	University (N=71)		Governmental and Government-controlled (N=12)		Regional (N=17)		Industrial (N=48)		Private (N=8)		Total (N=156)	
Description	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Activity												
Physical chemistry	43	61	8	67	15	88	40	83	5	62	111	71
Microbiology	10	14	1	8	4	24	14	29	3	37	32	21
Ecotoxicology	13	18	0	0	5	29	3	6	2	25	23	15
Toxicology	18	25	2	17	8	47	11	23	2	25	41	26
Others	31	44	6	50	9	52	31	65	5	62	82	53
Availability of computers	48	68	10	83	5	29	31	65	5	62	99	63
Molecular weight determination	19	27	5	42	2	12	23	48	3	37	52	33
Chemical composition (%)	24	34	5	42	11	65	33	69	4	50	73	47
Spectral characterization	47	66	10	83	16	94	42	87	5	62	120	77
Melting point	25	35	4	33	13	76	38	79	4	50	84	54
Boiling point	12	17	1	8	7	41	31	65	3	37	54	35
Specific gravity	20	28	2	17	9	53	41	85	3	37	75	48
Vapor tension	3	4	0	0	1	6	13	27	0	0	17	11
Surface tension	9	13	2	17	2	12	14	29	1	12	28	18
Water solubility	12	17	1	8	4	24	31	65	3	37	51	33
Fat solubility	4	6	0	0	3	18	19	40	3	37	29	19
n-Octanol-water partition coefficient	8	11	1	8	2	12	17	35	3	37	31	20
Flash point	10	14	1	8	10	59	21	44	1	12	43	28
Flammability of gases, liquids, or solids	4	6	0	0	2	12	7	15	0	0	13	8
Autoflammability	1	1	0	0	1	6	4	8	1	12	7	4
Explosivity	1	1	0	0	0	0	6	12	1	12	8	5
Oxidizing properties	0	0	0	0	2	12	2	4	1	12	5	3
Aqueous dissociation constant	8	11	2	17	2	12	14	29	2	25	28	18

Table 3. cont'd

Type of laboratory	University (N=71)		Governmental and Government-controlled (N=12)		Regional (N=17)		Industrial (N=48)		Private (N=8)		Total (N=156)	
Description	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Exotoxicological tests, LC50												
Fish	8	11	1	8	6	35	6	12	1	12	22	14
Daphnia	2	3	1	8	0	0	3	6	0	0	6	4
Abiotic degradation												
Photolysis	2	3	0	0	0	0	7	15	2	25	11	7
Hydrolysis	1	1	0	0	0	0	7	15	1	12	9	6
Reduction-oxidation	1	1	0	0	0	0	5	10	1	12	7	4
pH	2	3	0	0	0	0	9	19	1	12	12	8
Temperature	2	3	0	0	0	0	12	25	1	12	15	10
Chemical stability	0	0	0	0	0	0	1	2	0	0	1	1
Others	0	0	1	8	0	0	9	19	1	12	11	7
Biotic degradation												
Fresh water (aerob.)	2	3	1	8	0	0	2	4	0	0	5	3
Fresh water (anaerob.)	2	3	0	0	0	0	0	0	0	0	2	1
Marine water	2	3	0	0	1	6	0	0	0	0	3	2
Soil	2	3	0	0	0	0	1	2	0	0	3	2
Sediment	2	3	0	0	0	0	2	4	0	0	4	3
BOD and COD determination	22	31	2	17	17	100	26	54	4	50	71	46
Long-term toxicity (no eff. level)	1	1	0	0	0	0	2	4	0	0	3	2
Algal growth inhibition	1	1	0	0	1	6	2	4	0	0	4	3
Long-term toxicity on superior plants	1	1	0	0	0	0	1	2	0	0	2	1
Long-term toxicity on earthworms	0	0	0	0	0	0	0	0	0	0	0	0
Bioaccumulation	2	3	0	0	0	0	2	4	1	12	5	3
Long-term biodegradation	1	1	0	0	0	0	2	4	0	0	3	2
Long-term toxicity on fishes	3	4	0	0	1	6	1	2	0	0	5	3
Acute toxicity on birds	2	3	0	0	0	0	1	2	0	0	3	2
Subacute toxicity on birds	2	3	0	0	0	0	0	0	0	0	2	1
Toxicity on other organisms	6	8	0	0	0	0	3	6	1	12	10	6

Table 3. cont'd

Type of laboratory / Description	University (N=71) No.	University (N=71) %	Governmental and Government-controlled (N=12) No.	Governmental and Government-controlled (N=12) %	Regional (N=17) No.	Regional (N=17) %	Industrial (N=48) No.	Industrial (N=48) %	Private (N=8) No.	Private (N=8) %	Total (N=156) No.	Total (N=156) %
Ab-, ad-, desorption studies	5	7	0	0	1	6	4	8	0	0	10	6
Acute toxicity on rat												
Oral LD50	13	18	1	8	0	0	15	31	3	37	32	21
Inhalation LC50	6	8	0	0	0	0	2	4	0	0	8	5
Dermal LD50	8	11	1	8	0	0	10	21	3	37	22	14
Dermal irritation, rabbit	7	10	1	8	0	0	15	31	2	25	25	16
Ocular irritation, rabbit	7	10	1	8	0	0	14	29	2	25	24	15
Sensitization, guinea pig	8	11	2	17	0	0	10	21	1	12	21	13
Subacute toxicity, rat (28 days)	10	14	1	8	0	0	11	23	3	37	25	16
Mutagenicity tests	14	20	1	8	2	12	6	12	3	37	26	17
Carcinogenicity tests	8	11	0	0	0	0	5	10	2	25	15	10
Teratogenicity tests	6	8	1	8	0	0	10	21	3	37	20	13
Reproduction tests	6	8	1	8	0	0	10	21	3	37	20	13
Subchronic toxity tests	8	11	1	8	0	0	9	19	4	50	22	14
Chronic toxicity tests	7	10	1	8	0	0	8	17	2	25	18	12
Toxicokinetic tests	5	7	1	8	0	0	8	17	2	25	16	10
Others	1	1	0	0	1	6	0	0	0	0	2	1

the new needs but has not helped achieve a common homogenous professional standard in toxicology in Italy. Therefore there is a need to develop adequate training programmes for those already working in the toxicological field in order to reduce gaps existing between scientists with different university backgrounds.

It is foreseen that the demand for toxicologists will further increase in the next few years and that a few hundred new toxicologists will be needed before 1988 (Table 2). The rate and extent of this increase will depend on legal and administrative factors controlling the inclusion of formal requirements for "toxicologists" as staff members of different organizations, including the National Health Service, contract toxicity testing facilities and research institutions, and the development of adequate specialization programmes for toxicologists with different postgraduate backgrounds. One of the key points to provide a career for toxicologists in Italy is the inclusion of formal requirements for toxicologists as staff members of the local health units and the establishment of specialized pharmacotoxicological services in regional hospitals in proportion to the number of beds and the size of the hospital. Some years ago, the Italian Superior Council of Health voted a resolution for the establishment of these specialized services (Appendix). In particular, the key issue is the legal recognition of the profession of toxicologist, possibly with different specializations (e.g. clinical, experimental and analytical), and of the curricula and postdoctoral training programmes leading to different specializations in toxicology.

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Appendix

Opinion of Italian Superior Council of Health (Session XXXVI, section III) on Need for Establishing Specialized Pharmacotoxicological Services in Italian Hospitals 26 January 1979

AGENDA

1. Revision of the list of health kindred disciplines (art. 67 DPR 27.3.1969, n. 130.

"Omissis"

Considering the following hospital activities belong amongst others to the pharmacotoxicological area:

- treatment of drug addicts (Law 685);
- pharmacological treatment in departments where new drugs are clinically evaluated;
- control of postmarket surveillance of adverse effects of drugs;
- monitoring of blood concentrations of drugs with the aim of checking on medicinal treatments (e.g. antiepileptics, digoxine);
- consultation on the use of drugs in pregnancy (e.g. psychotropes or antiepileptics, antihypertensives, diuretics) in relation to presumed teratogenesis and termination of pregnancy;
- participation in the drafting of therapeutic formulars in hospitals;
- collaboration with antipoison centres, intensive care and artificial kidney units; and
- relevant diagnostic procedures (e.g. neurotransmitters and metabolites, early toxic markers).

Is in favour

of the inclusion of Pharmacology and Toxicology among the disciplines for which examinations are planned reserving the right to specify titles, similarities and contents of these examinations

Is also in favour that

"Special Diagnosis and Treatment Services" should be set up for "pharmaco-toxicology" in hospitals in proportion to the size and number of beds. There does not appear to be any reason for toxicological or clinical pharmacological services with wards, since the work is mainly consultative and of specialized laboratory activities for these services.

Annex 3

TOXICOLOGY AND CHEMICAL SAFETY TRAINING OF WORKERS' REPRESENTATIVES IN HEALTH AND SAFETY COMMITTEES

by
J. Bustamante, P. Westerholm, R. Owen & E. Buringh[1]

Introduction

Throughout the world, the need for more information about the effects of man-made chemical products is becoming an increasingly serious problem. It is paradoxical that while national and international authorities are passing legislation to ensure a better awareness of the effects of new substances before they are placed on the market (e.g. the Toxic Substances Control Act in the United States and the Sixth Amendment to the Directive on the Classification, Packaging and Labelling of Dangerous Substances in the EEC), tens of thousands of substances are already on the market about which we have insufficient knowledge and which we cannot therefore adequately control.

Our interest in knowing about substances is therefore perhaps not the same as that of the manufacturer, who may be interested only in the industrial and commercial applications of the product, nor of the scientist, who prefers to isolate the toxicological data relating to a product from the human or social contexts in which the product is present or handled.

We speak of knowledge and control, because, as far as the trade unions are concerned, the knowledge that a chemical product is toxic or harmful entails an obligation to consider means of prevention to avoid the risk of adverse health effects from the product.[2]

[1] Address: FNV, Amsterdam, Netherlands.

[2] Our yardstick for assessing health effects is the improved version of the ILO definition of health drawn up in the Netherlands:

"...a nonstable state of the organism, the functioning of which, from the point of view of the worker himself and of health experts, is entirely satisfactory in relation to the physical and mental capacities corresponding to the sex and age of groups of workers who have not been exposed but who are otherwise comparable, in the light of the present state of medicine and the corresponding health care objectives, social attitudes and customs".

General Problems

There can be no disputing that workers' representatives, or workers themselves, need to be trained or informed on the main principles of chemical safety. However, it is not the aim to turn employees into toxicologists. In societies such as ours, the actions of individuals or groups of individuals depends to a very great extent on their access to information and their ability to interpret, clearly understand and utilize such information. It is essential to teach workers and workers' representatives the principles of toxicological risk assessment. Such assessment forms the basis for risk evaluations and decision-making regarding necessary action to reduce chemical hazards in the workplace. They are also needed in planning changes in industrial processes and production materials.

However, in discussing the training of workers' representatives, certain specific points, which can be both advantages and disadvantages, need to be considered.

First of all, it is important that the education or training provided for workers' representatives enables them to tackle specific practical problems at the workplace: it is not a question of training for training's sake. The aim should be to enable the representatives to deal with health hazards arising from working conditions and which require that some practical action be taken to eliminate them.

This fundamental point has certain implications. One of them is that workers' representatives taking part in toxicological training courses have such expectations; if their expectations are not fulfilled, the training may prove to have been in vain. The key word here is motivation; the target group accepts and digests the contents of the training or education to the extent that it feels they are of direct relevance.

Another motivating factor is the opportunity to put the knowledge acquired into practice. If there is opposition to the idea of using the knowledge to improve working conditions, motivation will probably diminish. This type of difficulty highlights the link which exists between the issue of toxicology training and the more basic question of the needs and democratic rights of the workers exposed to health hazards at the workplace.

Account must also be taken of the fact that workers often lack an adequate basic theoretical education. The approach must be as simplified, in terms both of the course objectives and the methods and teaching aids used. In other words, workers do not need to be taught the intricacies of toxicological science; they need to know how expert knowledge can be used for practical risk assessments. Time, or rather the lack of time, also needs to be taken into account. Most workers' representatives cannot obtain leave of absence for long periods, and this needs to be borne in mind when making up the curricula of training courses and setting priorities.

The aspects of toxicological training necessary for workers' representatives will thus be those which, within the limits already mentioned, enable them to ensure maximum protection against the chemical substances which workers are obliged to handle or which are present in the workplace air. At the same time, training in no way diminishes the responsibility held by the employer or the competent authorities for preventing chemical risks, this responsibility being a cornerstone of all preventive policy. Such preventive policy at local, national and international levels is essential as chemical products have gradually entered into widespread use in all sectors of the economy.

What Type of Training?

Recognition of different needs

First of all, a distinction can be made between work situations where the main feature is the handling of substances as raw materials or as intermediate or finished products, and other work situations where contact with such substances is more sporadic.

In both cases the role of the workers' representatives is to identify the potentially harmful products so that steps can be taken to control them. However, in the first case, the products will probably represent the main risk, whereas in the second case this could be accompanied by other, equally important or less important, risks. The risks caused by chemical hazards should be seen in perspective with other types of risks. For many groups of workers, other types of avoidable risks may be more important. This broad perspective should be kept in mind when setting up schemes for training workers. Toxicology training needs to be modulated to take account of the extent of the chemical risk.

Different levels of training may also need to be considered, depending on the amount of training time granted to the representatives, their basic training, and the nature of their responsibilities. Although most courses will be of short duration, based on an empirical approach to problems and designed to ensure easy assimilation of the facts, there could well be a need in some instances for more detailed, specialized courses or even university courses in industrial toxicology for certain types of workers' representatives.

At the risk of generalizing national, sectorial or even individual firms' practices, which, where they exist, are relatively diverse, we believe that basic toxicology training for representatives should comprise the following five components:

- effects of toxic substances;
- detection of risks;
- exposure limit values;
- regulations and agreements; and
- means of prevention and control.

This list is by no means comprehensive. As already stated, particular situations require specific training programmes.

Effects of toxic substances

The basic subjects to be covered in a toxicology training course are the types of adverse health effects which toxic products can produce, the different forms which they take, and the pathways via which they can penetrate the organism. However, in the case of courses for workers' representatives, the practical usefulness of the exercise will be increased if coverage is also given to cases of combined effects or synergy (relatively frequent) and the specific toxicity of particular substances handled in the workplaces in question. Obviously, health hazards related to long-term effects of exposure at low or moderate levels are important. Such exposures occur commonly at workplaces.

Unfortunately, the first problem is that the representative is often ignorant about the substance or substances used (i.e. about the name, composition or properties) and must rely on the labelling, when the product is labelled, or, in the best of cases, on explanatory notes provided by the manufacturer. Risk detection is therefore based on numerous factors, although in reality these can be reduced to three: information provided by the manufacturer or employer; pathology of colleagues; and monitoring the air at the workplace.

If the employer is cooperative, he will provide the worker with comprehensive instructions to ensure safe handling of the substance. But in some cases the product may have certain toxic properties of which the employer himself is not aware, or (as is true of most chemical products or compounds used in industry) the original tests may not have been sufficiently thorough to reveal, in addition to the product's noxiousness or physical dangers (e.g. inflammable, explosive, acidic), its carcinogenic, teratogenic or allergenic properties, or the likelihood of chronic toxicity. At the other end of the scale, an employer may expect his employees to work without any information whatsoever concerning the potential risks of the products they handle.

The training syllabus must take account of both types of situation and provide the representative with enough information to enable him to trace the risk path: in cases of health impairment, by establishing a link with the toxic properties of the substances handled or encountered; in cases where there is no information on the toxic properties of the product, by using the available data or the regulations in force to find an adequate source of information. In cases where the potential risks of gas, fumes or dust are known, workers' representatives need to know the real risk, which can be established by monitoring the air at the workplace, and they should therefore be taught measuring techniques and shown how to interpret the results.

Exposure limit values

This leads us to the problem of exposure limit values. At present, these tend much more often to represent socioeconomic compromises rather than medical criteria concerning the absence of health risks. Moreover, they exist for only about 500 substances, whereas there are tens of thousands of substances in use in industry. Consequently, the absence of a limit value does not necessarily mean that a substance is safe. Workers' representatives must be aware of these limitations, but, while bearing them in mind, they must know how to use the lists, endeavouring to reduce workers' exposure to a minimum. This applies to substances which are not carcinogenic. As regards carcinogenic substances and products, the union view is that there is no safe limit and that it is not therefore a question of only reducing exposure to such agents but of avoiding exposure altogether.

Regulations and agreements

The problem of limit values is closely linked to that of the regulations in force. Workers' representatives need to be made aware of these regulations as well as of the agreements existing between employers and unions. While this has nothing to do with toxicology per se, it is clearly an essential complement to the training of workers' representatives as it is of no use to them to be able to discover risk situations if they are unable to take steps to prevent or control them.

However, the workers' representatives are not the only ones concerned with observance of the regulations. The employer, the occupational physician and the chief safety officer have a duty to ensure that the standards are observed; if they do not do so, it is up to the workers' representatives to appeal to the competent authority. A knowledge of the regulations in force must therefore be accompanied by a knowledge of the procedures designed to ensure that they are observed.

Prevention and control

However, the prevention and control of risks go beyond legislation and constitute the main objective of the health and safety committees. This fifth element of training is rooted in the four previously mentioned. In the case of chemical products, the information on the nature of the product is the key to prevention.

When such information exists, various possibilities may be considered with a view to controlling the substance and avoiding the risk:

- replacement of the product by a less dangerous substance;
- isolation of work processes involving the product so as to avoid exposure of workers;
- ventilation, accompanied where appropriate by monitoring of the workplace and the wearing of personal protective equipment;
- restriction of access, or imposition of time limits; and
- as a last resort, the wearing of protective equipment.

However, if no such information exists, tests and studies should be carried out on the substance to establish the risks involved. In either case, the training received by the workers' representatives should enable them to make an appropriate choice and even, looking beyond the specific problems, to develop a preventive policy adapted to the needs of the workers they represent.

Particular Aspects

A whole range of related questions remain to be answered. They relate on the one hand to the diversity of situations existing in the various countries of Europe and on the other hand, to the occasionally conflicting interests which partially determine the response to this problem.

The title of this paper refers to workers' representatives in health and safety committees. However, such committees do not exist everywhere: the deciding factor is normally the size of the firm. Should toxicological training be given to workers' representatives in firms which are too small to have a health and safety committee? Our answer is yes, but we would add that this should only apply to small firms where a chemical risk exists, which can in fact frequently be the case.

Certain questions need to be answered in relation to the training itself. Since the courses are meant for workers' representatives, should they be organized by the unions, government or official institutions, or the employers? We make no attempt to hide our preference, which is for the unions wherever possible or,.failing that, for the unions in conjunction with government. However, there is a risk in this approach that the employer may place obstacles in the way of any training programme not under his control, particularly by refusing workers the necessary time off for the course.

The financing of such courses is another problem. However, it is worth mentioning that the firms will no doubt benefit economically from the early detection of risks which could later cost them dearly.

In conclusion, governments and international bodies are taking an increasing interest in these problems, perhaps because of the public health aspect which the prevention of chemical risks suggests to the general public, which is fairly sensitive to such questions. It is likely that everyone would gain from a coordinated approach, drawing on the experience of the countries which are most advanced in this field.

Annex 4

TRAINING IN TOXICOLOGY FOR DECISION-MAKERS AND ADMINISTRATORS

by
J.O. Järvisalo and J.H. Rantanen[1]

Introduction

Within any society, the management of risks caused by exposure to chemicals is a many-sided and continuous process. The assessment of risk, the compilation of regulations, and the establishment of control procedures to ensure that regulations are followed are important aspects of the management process [1-6].

Active participation in risk management requires that responsible personnel know not only about risk assessment itself but also about various facets of toxicology. The process of risk assessment clearly differs from procedures for postregulatory control. Consequently, it can also be assumed that the need for toxicological expertise and training varies in administrative posts related to societal risk management.

Agreements, recommendations and regulations to facilitate the control of chemical production and use are made on both national and international levels. It has become evident that administrators need pertinent toxicological knowledge to make such decisions and to carry out their normal work properly. However, this need has neither necessarily led to the active training of administrators in toxicology nor commonly to the creation of new posts for this purpose. Therefore, government agencies may not be competent to execute their tasks in the field of risk management. Individuals holding posts related to such tasks and those with practical work experience in the field of risk management constitute a very important group whose further education in the field of toxicology should be emphasized.

This paper briefly reviews the various aspects of societal risk management in order to identify the different posts and levels where training in toxicology is especially needed, keeping in mind the tasks and occupational profiles described in Interim Document 2.

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Although it is recognized that individuals or groups of individuals who are not administrators also participate in decision-making and control procedures related to risk management, this paper will not discuss their training needs.

Management of Risks caused by Chemical Exposure

In recent years, much attention has been paid to risk assessment of human exposure to chemicals [e.g. 1-6]. It has also been recognized that the proper use of data for risk management at the societal level inevitably assumes that administrators working at the authorities/agencies responsible for regulation and control should have considerable knowledge of toxicology in general and indepth knowledge of toxicology related to their own fields, be it occupational health, environmental health, food additives and contaminants, or pesticides.

Process of risk management

The process of risk management comprises four successive phases. Phase 1 is the identification or qualitative assessment of risk. The primary function of this phase is to link an exposure to one or more changes in human heath, and sometimes also to changes detected in experimental conditions. Phase 2, the estimation or quantification of risk, aims at estimating the level at which an exposure entails risk. Typically, it is based on as many analyses of quantitative exposure-effect and exposure-response relationships as possible. In phase 3, on risk evaluation, the health outcomes already detected are compared to other risks present in the particular society. Finally, in the risk regulation.phase, the societal response to risks, e.g. in the form of regulations, is considered. The aim of risk regulation is to find the level of risk acceptable to society and to determine other measures that may be taken to limit the societal effects of the exposure that entails risk.

The natural consequences of risk regulation is the need for control procedures. Control is either made voluntary or obligatory in risk regulations.

Phases 1, 2 and 3 are tasks limited to the scientific community, whereas phase 4 is not. Risk regulation contains a preparatory stage carried out by administrators and a final decision-making stage which is mainly a political issue. The control procedures of risk management are then determined and executed by the authorities/agencies formed for that purpose.

Differences in national approaches

Approaches to handling risk management vary from one country to another. A consensus system has been set up in the United Kingdom and the Nordic countries. In this system, administrative, industrial, scientific and labour organization representatives collaborate to reach a common, consensus-type of suggestion about the implementation of regulations. Essentially, such systems do not assume very comprehensive analyses of the available data; rather, the assumed level of risk is weighed against the assumed capability of the industry to deal with the demands created by the recognition of risk. The level to which the regulation is extended may well be a product of industrial or economic reality rather than well-defined acceptance of a particular risk level.

A very different way of handling the regulation phase of risk management prevails, e.g. in the Federal Republic of Germany, Japan and the United States. The approach assumes a more comprehensive analysis of the data and the production of well-founded estimates of risk. The level of risk accepted may be the endproduct of court action between the groups concerned e.g. industry versus government. An unfortunate feature of this procedure to establish regulations is that different authorities (e.g. occupational, environmental), propose suggestions independently of each other.

Tasks and Training of Administrators in Risk Management

Administratively, the management of chemical exposures in a society is the responsibility of several authorities/agencies. Such bodies typically exist for at least the following: occupational exposures; exposures through nutrition, drinking-water, medicine, and ambient air; effects of pollution on wildlife and the use of chemicals in agriculture and forestry (e.g. pesticides, fertilizers). As a result of these interests, factors considered relevant to risk assessment may differ considerably. Furthermore, the administrative bodies dealing with different types of exposure are not centralized with the consequence that approaches involving risk assessment of combined exposure through various routes are not common.

Three groups of administrative personnel participate in the issues of risk management in a society:

(a) government experts in the specific field of interest (administrative toxicologists) with specialized knowledge in toxicological problems;

(b) personnel preparing regulations, including chemists, pharmacists, hygienists and others who take part in the actual preparation of the regulations; and

(c) governmental or other personnel responsible for enforcement of the regulations.

Table 1 gives the suggested level of training for these groups.

a) Group 1 personnel

As mentioned above, the handling of risk regulation is distributed between various administrative authorities/agencies, each of which mainly prepares regulations concerning its own field of responsibility. Clearly, an agency should have sufficiently deep expertise in the branch of toxicology related to the regulatory activities of its sector, e.g. specific knowledge in nutrition and food toxicology when the use of food additives is regulated.

The minimal level of expertise that these regulatory bodies should have is indicated in the occupational profiles of WHO/EURO Interim Document No. 2 under the occupational profile for a toxicologist category 1. In addition, expertise as defined in WHO/EURO Interim Document No. 2 under the occupational profile for senior administrator in public health should be available within a particular regulatory authority.

Practical organization of the expertise in the regulatory agency depends very much on the country concerned. In small countries it may be possible for a single person to take care of such an activity, whereas in larger countries a group of toxicologists with varying levels of expertise and varying degrees of further specialization participate in the process.

However, the task of such administrative toxicologists is to take part in the actual risk assessment phase, and their pertinent knowledge in toxicology in their own field is needed to: (a) have full cooperation and understanding of the process of risk assessment in work groups with experts; and (b) transfer the essential aspects of the risk assessment phase to the people who prepare regulations from the juridical administrative point of view.

(b) Group 2 personnel

The other types of administrative personnel (item 2 of Table 1) who participate in the preparation of regulations on toxic chemicals include such occupational groups as chemists, nutritionists, biologists, pharmacists and hygienists. Their role in the

Table 1. Suggested level of training of administrators in risk management

Group[1]	Competence	Criteria for competence
(a)	Expertise in toxicology and e.g. public health	As defined for toxicologist category1[2] As defined for senior administrator in public health[2] Practical experience
(b)	Skills in toxicology	As defined for nontoxicologists[2] (course duration of 10-15 weeks)
(c)	Skills in toxicology	Depending on tasks, great variation (from expert training to short courses)

[1] Group (a) - administrative toxicologists in various fields; Group (b) - personnel preparing regulations; Group (c) - personnel involved in postregulatory control measures.

[2] See WHO/EURO Interim Document No. 2

preparation process may be considered an essential one. However, their need of training in toxicology is limited and has been described under the training of nontoxicologists involved in toxic chemicals control in WHO/EURO Interim Document No. 2. The training may be of the type described as an example of a short-term course in WHO/EURO Interim Document No. 2, or organized in the form of even shorter courses, a solution which may be preferable for people with difficulties in leaving their jobs for longer periods of time (see e.g. Survey of training programmes in toxicology and of toxicology courses in ten countries within the European region by R. Lauwerys given in Annex 10).

(c) Group 3 personnel

The third group of administrators requiring training in toxicology to be able to participate in societal risk management is rather large. It is formed of people in various occupations responsible for the control procedures of risk management. Depending on the amount of responsibility their work involves, they can be assumed to need different levels of training in toxicology.

The occupational titles concerned vary from officers of government agencies to inspectors of, e.g. workroom conditions or food products. Also involved are occupational health care personnel, chemists responsible for analysis of the chemicals concerned, and the technicians who actually perform the analyses. Many of these occupational profiles have also been specified in WHO/EURO Interim Document No. 2.

The need of such people for training in toxicology is typically related to their specific tasks. Such training may be arranged through the provision of task-oriented, short-term courses. On some occasions, however, as in the case of occupational health care personnel dealing with the health of workers exposed to toxic or potentially toxic chemicals, a thorough knowledge of toxicology will be necessary, ranging from the level of toxicologist category 1 to the level of knowledge obtained from the suggested short-term courses for nontoxicologists.

However, the level of knowledge required must in many cases be considered separately. This consideration should take into account the tasks of the person, his/her previous training, as well as career development in the field.

Encouragement of training for those already employed

In describing a field survey in the Netherlands, Kassel (see Annex 1) quotes Jager: "we do not need more toxicologists but better toxicologists". This statement is probably true for many Western countries. Most of them have reacted to the development of knowledge on the toxicity of chemicals and approaches to control their harmful effects through risk management by directing manpower to deal with such matters. However, the basic toxicological training of such people is often minimal or lacking, with the only expertise in the field gained from practical experience gathered during participation in the regulatory process.

The training of such people, primarily with the type of course described in Section 2 of WHO/EURO Interim Document No. 2, should be a matter of urgency. Because such people cannot be trained simultaneously, special stress should be given to toxicology courses short in duration but specifically oriented to problems related to their tasks.

The manpower in need of a higher level of toxicology training (administrative toxicologists, Table 1) in various administrative bodies and who take part in risk management in society is not very great in number. For example, Finland is a country with a total population of 4.8 million and a working population of 2.2 million. Risk management of exposure to toxic chemicals is distributed between six ministries (Social Affairs and Health, Trade and Industry, Internal Affairs, Agriculture and Forestry, Finance, and Environment), under which various agencies and administrators take part in the regulatory process and control procedures carried out on the basis of the regulations. However, the total need for trained toxicologists (category 1 or higher) probably does not exceed 55 persons. The allocation of such persons could be as follows: Ministry of Social Affairs and Health, 2; National Board of Health, 3; National Board of Labour Protection (both under the Ministry of Social Affairs and Health), 2; Ministry of Environment, 4-5; Food Administration and the Customs Laboratory under the Ministry of Trade and Industry and the Ministry of Finance, respectively, 4 and 5. About 20-25 administrative toxicologists would be needed in the provincial governments and about ten as environmental hygienists in the larger cities.

However, one special obstacle to filling administrative posts with people whose education is adequate in toxicology is that administration in Finland (and possibly in other countries, too) does not recognize such administrators as toxicologists. There is no accreditation for toxicologists, and such training is not mentioned among the qualifications for posts. To improve the situation, a change towards the recognition of toxicologists must be made so that properly educated people will be motivated to take administrative posts.

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Annex 5

CLINICAL TOXICOLOGY

by

F. Conso

Introduction

Toxicology is a multidisciplinary science involving the study of undesirable effects of chemical products and the evaluation of the risks of such effects arising. Initially based on observation of the interactions between chemical products and the human organism, it was essentially a medical discipline. Now it is also directed towards the acquisition of detailed information to enable the potential toxicity of a chemical product to be evaluated before any contact with humans and the environment. But whatever the level of sophistication of risk evaluation tests and of protective legislation, the medical surveillance of populations exposed to chemical products, whether at work, at home or in the general environment, remains an important aspect of toxicology and requires properly trained medical specialists.

The aim of this paper is to describe this specialist medical activity by concentrating on the following aspects of clinical toxicology: definition, work involved, job profile, needs, careers, training, and recognition of qualifications.

The problems arising from the toxicity of pharmaceutical products are not scheduled for discussion at this workshop. Nevertheless, they will be included in this report since they form a vital and integral facet of the work of clinical toxicologists.

Definition of Clinical Toxicology

Clinical toxicology is the medical discipline which studies the harmful effects of chemical products on humans. Its aim is to permit the diagnosis and treatment of acute or chronic poisoning in humans by using, *inter alia*, information provided by the other branches of toxicology, and to improve prevention in this field by collating observations and disseminating the resulting information. It is a comprehensive discipline, concentrating on the causal agent, a xenobiotic, rather than on the organ. Its justification lies in its specific methodological approach, aimed at establishing the effects of the toxic substance on the organism and its operating mechanisms, in its fulfilment of analytical requirements, and its role in treatment and prevention.

The terms of medical or human toxicology are often used in relation to clinical toxicology and analytical toxicology performed in hospital laboratories engaged in evaluating human exposure to chemical products by biological methods.

Work involved in Clinical Toxicology

Acute toxicology (single exposure)

(a) Diagnosis

Where massive acute poisoning occurs as a result of a suicide attempt or a domestic or industrial accident, the causal agent is often known. If it is not, a diagnosis can be made on the basis of various factors that can include the clinical symptoms, questioning of the victim's family and associates, and information obtained by the emergency services. In all cases the clinical diagnosis is verified by subsequent analysis.

In certain more difficult cases, where it is not apparent what toxic substance is involved or where the clinical aspects of the poisoning are unusual, it is necessary to conduct a more specific diagnosis. This involves an etiological study of all the foreign substances with which the victim comes into contact at home, at work or in other environments. A knowledge of the toxicity of new products is also required. The clinical toxicologist must be familiar with existing information networks and must know how to interpret critically the experimental toxicological data which he receives. This very specific line of research permits hypothetical diagnoses to be made; these can then be verified by analysis, and methods of treatment can be proposed.

When more than one person has been affected by a toxic substance, it is necessary to identify and record all the cases and establish the causal link between the pathology observed and the substance. In these cases, details of the different exposures to the substance need to be compiled (nature, intensity and duration) and epidemiological methods used.

(b) Treatment

Apart from certain antidotes, the methods of treatment for acute poisoning are not specific; they are those currently employed in intensive care units. In contrast, the indications take account of criteria of severity worked out on the basis of clinical research conducted by specialist departments. One example is paraquat poisoning, where the prognosis and treatment are based on clinical criteria (caustic lesions of the digestive tract), biological criteria (acid-base balance) and analysis (paraquat-in-blood level).

Indications for extrarenal dialysis also take account of the experimental and clinical criteria available for each toxic substance.

(c) Clinical research

It is not possible, for ethical reasons, to test nonmedicinal chemical substances on humans at the marketing stage. Chance cases of acute poisoning provide an opportunity to study the reactions of the product in humans, in particular from the point of view of kinetics, the various metabolites formed, and the biological impact of the substance. The course which the clinical and biological investigations should take can best be worked out through close collaboration between the clinical toxicologist and the experimental toxicologist; the latter knows the target organs - together with the limits for extrapolating from animals to humans, can propose analysis methods and can help in formulating decisions on methods of treatment. Inversely, the feedback of clinical information to the experimental toxicologist can provide ideas for additional research on operating mechanisms, for example, or for specific research on treatment (e.g. on administration of sulfhydryl radicals in cases of paracetamol poisoning). Further aims of clinical research in this area are to:

- describe new toxic syndromes by collating similar cases (as is done jointly by poison control centres);

- evaluate the relative danger of certain simple substances depending on the form in which they are presented: for example, caustic lesions caused by caustic soda solutions used for unblocking sinks; and

- establish prognosis criteria based on series of poisonings caused by similar products.

Chronic toxicology

This is concerned with the delayed harmful effects of xenobiotics in repeated contact with humans. In medical practice it can be separated into two parts: medicinal pathology, covering the undesirable effects of pharmaceutical substances; and chronic pathology in connection with repeated exposure to industrial or agricultural chemical substances at work, through use, or in the general environment. Both medicinal and chronic pathology involve three separate types of activity: (a) diagnosis and evaluation of the role of a chemical product in initiating or promoting chronic diseases; (b) treatment and prevention; and (c) clinical research, with the main emphasis on the epidemiological aspect.

Job Profile of the Clinical Toxicologist

Clinical toxicologist (category 1)

This is a medical doctor who, after basic clinical training, has had responsibility for diagnosis and treatment in postgraduate training in various medical specialties, and who has worked in an intensive care unit and is familiar with the various methods and indications encountered in such units. He must also have had specific training in the treatment of poison victims, including clinical diagnosis, interpretation of results of toxicological analyses, dialysis treatment and the use of antidotes and chelating agents. He must be familiar with the mechanisms, symptomatology and methods of treatment of immunoallergic reactions. He knows how to evaluate the effects on human health of single or repeated exposure to a foreign substance by dynamic exploration of the various parenchymes, by analysis of the biochemical and anatomopathological data and, if necessary, by postmortem examination.

As part of his theoretical training, the clinical toxicologist learns what happens to xenobiotics in the organism (resorption, kinetics, biotransformation, elimination and interaction) and can thus participate in multidisciplinary toxicological activities, e.g.:

- interpretation of levels of toxic substances in biological liquids and in different environments (e.g. water, air, food); and

- interpretation of data from toxicological dossiers in the fields of acute, medium-term or long-term toxicity, in particular experimental fetotoxicity, teratogenesis, mutagenesis and carcinogenesis.

With this training, supplemented where necessary by a knowledge of related disciplines (e.g. occupational medicine for industrial toxicology, forensic medicine for cases involving legal responsibility), he is able to:

- compile a comprehensive information dossier on the physicochemical characteristics of a substance, its biochemical actions under experimental conditions and in clinical practice, and possible methods of analysis; by pooling this information, he can improve the diagnosis, understanding and treatment of human poisoning;

- participate in epidemiological studies on the acute or chronic effects of medicinal products, industrial substances or pesticides, particularly in the fields of carcinogenesis or organ disease.

- carry out clinical research, either by toxicokinetic study of chance cases of human poisoning or by compiling data banks, which form the basis for monitoring programmes for drugs and toxic substances, through the systematic collection of clinical observations;

- assist in drawing up preventive measures in cooperation with the regulatory bodies; and

- participate in teaching the discipline.

Clinical toxicologist (category 2)

This is a senior doctor having, in addition to the above requirements, several years' experience and a thorough grounding in occupational medicine, forensic medicine and public health, with particular regard to clinical occupational disease, diseases caused by environmental pollutants and contaminants, statutory responsibilities and the application of laws and regulations, drug monitoring, and the monitoring of toxic substances.

He knows how to lead a clinical team and to organize medical research activities in the field of toxicology.

He is consulted by the national decision-making bodies and may be invited to assist international organizations in an expert capacity. He is responsible for training in the hospital department and the faculty of medicine and participates in the multidisciplinary teaching of toxicology at the university level. He must keep up with the latest developments in analytical and experimental toxicology.

Where are Clinical Toxicologists Needed?

In hospitals

As regards acute or sub-acute poisoning, the need for clinical and analytical evaluation and for access to bibliographical information suggests that these activities should be grouped together in the main regional hospitals, for example, in the form of a department of clinical toxicology. This department could comprise an intensive care unit and a hospitalization unit with an outpatient department; a toxicological analysis laboratory; and an information centre (poison control centre) serving both the hospital and the community. Clinical toxicology departments are warranted for populations of between 2 and 10 million.

A clinical toxicology department must be able to provide treatment or information on a 24-hour basis. To function smoothly it probably therefore requires 4-8 category 1 clinical toxicologists and 1-3 category 2 clinical toxicologists.

With chronic poisoning, diagnosis tends to be the main problem. This requires a complete evaluation of previous exposures to chemical substances (at work or at home) for certain patients admitted to internal medicine or specialist departments. A consultant in clinical toxicology, with additional experience in industrial toxicology, occupational medicine and environmental pathology, can perform this work in each major hospital group, coordinate the confirmations arrived at by analysis, and propose appropriate methods of treatment.

In industry

Clinical toxicologists specialized in industrial products are needed in the industrial toxicology departments of major undertakings, where they advise the occupational physicians. This activity is no longer confined to the chemical industry; it is becoming more widespread in the major production industries such as mining, automobiles and electricity.

They are also needed in the toxic control departments of those industries producing largely for the public. Monitoring of the marketed product and of the poisoning accidents to which it may give rise requires evaluation by a physician trained in clinical toxicology. These requirements exist in the chemical (pesticides in particular), the agri-foodstuffs, and the cosmetics industries.

Finally, clinical toxicologists are required in the drug control departments of the pharmaceutical industry set up to monitor drugs put on the market and to collate examples of iatrogenic disease notified by consumers and prescribing doctors..

The level of qualifications required for work in industry depends on the type of role. A high qualification (level 2) is necessary for toxicologists employed as advisers to occupational physicians. In an industrial toxic control department, initial recruitment may be at the first level of qualification, with subsequent progression towards a higher qualification. Toxicologists working in industry must retain their specific clinical background by maintaining close contacts with the clinical toxicology centres at the main hospitals in their region.

In other organizations

Under this category are included governments, governmental agencies, consumer organizations and trade unions.

The clinical toxicologist, whose knowledge extends towards analytical and experimental toxicology, may, like toxicologist specializing in chemical analysis or experimentation, reach the level of "evaluative toxicologist" (see Kassel, Annex 1) and be required to participate in the drawing up of standards, the evaluation of the health risks of toxic substances, and the formulation of research guidelines.

Figure 1 shows in diagrammatic form the various institutions which need clinical toxicologists, and the levels of qualification required in each case.

What are the Career Possibilities?

In hospitals

Career development in each country should be the same as for other medical hospital staff. Recognition of the discipline should enable specific toxicology treatment units to be set up and ensure an independent career structure. However, the reality in most countries is entirely different: clinical toxicology units are in fact run by intensive care specialists, clinical pharmacologists and specialists in occupational or forensic medicine, who already have a career in their original discipline.

Therefore, the career of clinical toxicologist necessarily depends on official recognition of the discipline by the supervisory governmental authorities (Ministry of Health and Ministry of Education). If recognition is achieved, a career plan for clinical toxicologist in teaching hospitals can be proposed (Fig.2, adapted from the model produced by Lewis, Annex 6).

Poison control centres in certain countries (Belgium and Switzerland) offer full-time or part-time doctors' contracts which fall outside the framework of the service regulations for normal hospital doctors.

Outside hospitals

Career structures could be set up in institutions which employ clinical toxicologists. Such structures exist at present for occupational physicians and medical consultants.

Training of Clinical Toxicologists

There is at present no perfectly structured training course in clinical toxicology. However, an ideal training course comprising two successive stages could be proposed, based on the circumstances prevailing in certain industrialized countries and the requirements of the job: initial stage (comprehensive medical course) and training stage consisting of both nonspecific and specific parts. The specific training would be slanted towards the clinical sciences, with obligatory training in resuscitation and theoretical and practical training in other disciplines (e.g. nephrology, neurology, immunoallergy). Also included would be training in, for example, occupational medicine, forensic medicine and public health. Specific training in toxicology would be both theoretical and practical. The theoretical part would be based on a modular system, possibly also involving other biological disciplines; the practical part would comprise an obligatory period of service in a clinical toxicology department, a period in a poison control centre, and a period in an analysis laboratory.

The total duration of the course, following the initial medical course, would be 4 years. The length of the individual stages could be varied to comply with existing national training systems for specialists.

Three principles should be observed during the clinical toxicologist's training period. The trainee should:

(a) be given responsibility for diagnosis and treatment;

(b) conduct personal clinical research and participate in publications; and

(c) be under constant supervision by an accredited clinical toxicologist.

The Appendix gives an example of a theoretical training programme as part of the specific training of clinical toxicologists.

Fig. 1 Needs for clinical toxicologists

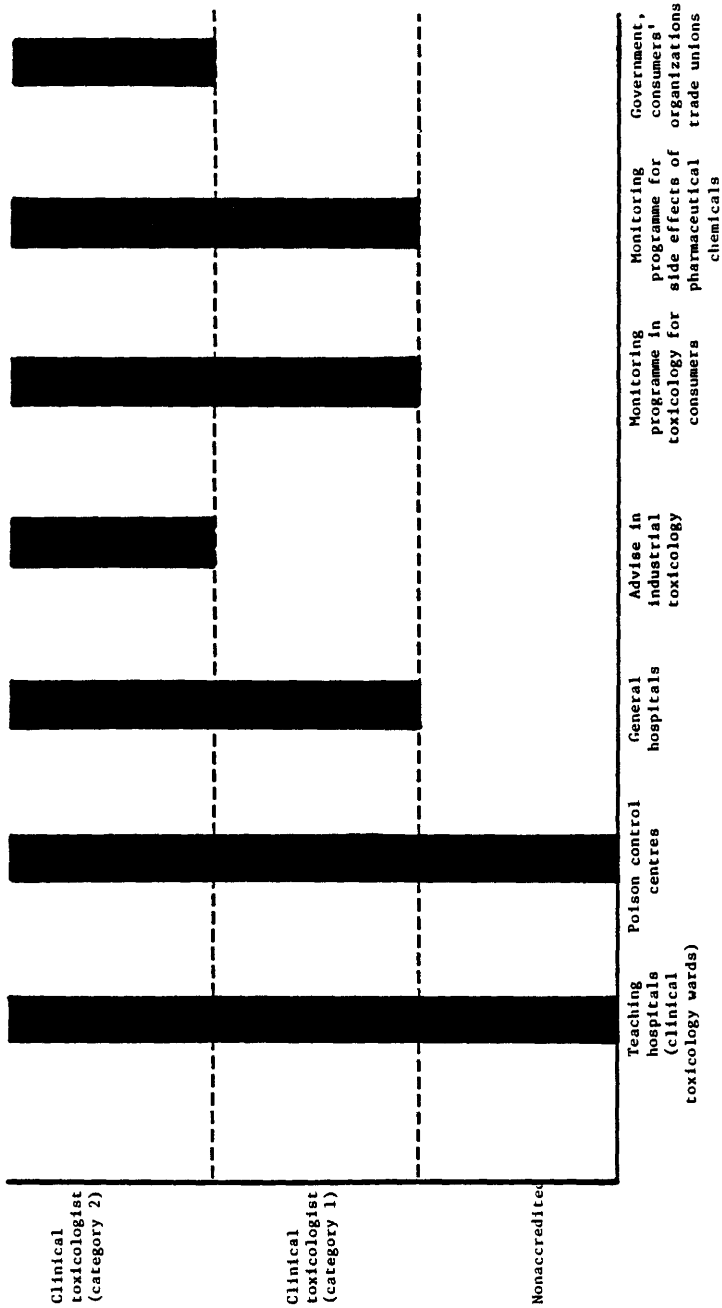
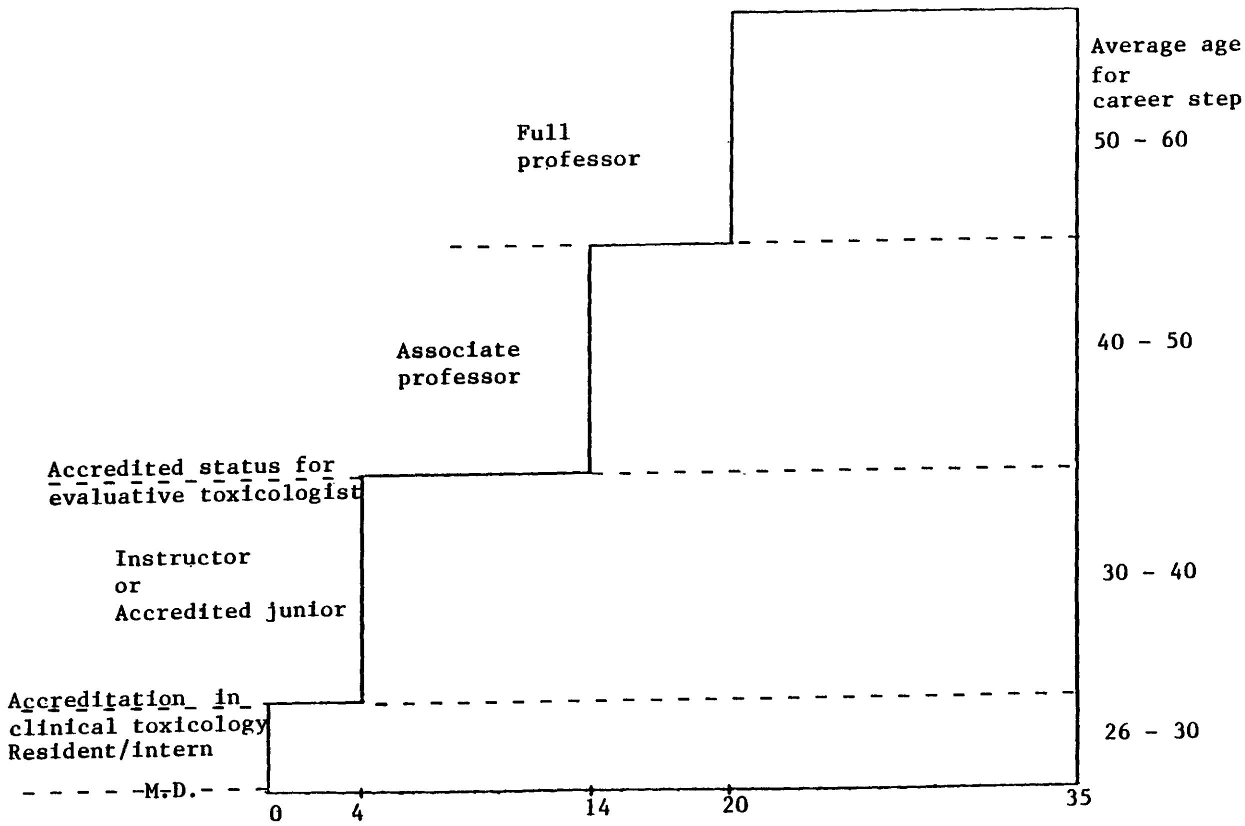


Fig. 2 Career pattern in clinical toxicology



Recognition of Qualifications

Qualification in clinical toxicology should be recognized on the same basis as the qualifications for other medical specialities in each country. This already happens in the United States, where there is the American Board of Medical Toxicology (approximately 60 graduates, including a number not resident in the US) and in Poland, where qualification as a clinical toxicologist is based on three years' clinical work, including six months in an acute poison treatment centre, as well as theoretical training in the discipline.

Mutual recognition of training in clinical toxicology by the Member States of the European Community would be desirable.

Conclusions

1. Clinical toxicology forms a real part of hospital work.

2. Clinical toxicology is based essentially on medical care structures, since its main objectives are the diagnosis and treatment of acute and chronic poisoning in humans.

3. The specific requirements in terms of documentation and means of analysis suggest the need for regional centres.

4. Clinical toxicology must be recognized in its own right in hospitals and universities in order to ensure a career development structure.

5. Training is based on the system used for other medical disciplines and should equip the future clinical toxicologist to take responsibility for diagnosis and treatment.

6. There are career outlets outside the hospital context, in particular in industry, where the monitoring of toxic substances is expanding.

Appendix

Theoretical Training of Clinical Toxicologists

Numerous aspects of this training programme, common to all branches of toxicology, are detailed in the basic curriculum for toxicologists proposed in WHO/EURO Interim Document No. 2. The authors state that in order to become a clinical toxicologist, it is necessary to have additional training in the fields of prevention, diagnosis and treatment of poisoning. A detailed training programme is therefore required for clinical toxicology, whereas the other branches of toxicology will require a more general approach based on particularly illustrative examples. The clinical toxicology programme could be presented in modular form (as detailed below). In terms of hours of training, it represents the most important part of the theoretical training programme, which also includes:

- a thorough grounding in chemistry;
- study of the methodologies used in nonspecific fields, (statistics, epidemiology, methodology of prevention, and methodology of decision-making);
- study of general toxicology (analytical toxicology/analytical physicochemistry and experimental toxicology); and
- study of legislation and regulations concerning the safety of chemical products and the protection of workers and consumers.

The contents of these various topics are detailed in WHO/EURO Interim Document No. 2, (pp. 47-74).

The detailed training programme in clinical toxicology given below covers all the elements necessary for the diagnosis, treatment and prevention of poisoning in humans.

Module 1: Studies of circumstances in which human poisoning can occur

Poisoning epidemics. Examples of collective poisoning by food contamination, environmental contamination or cosmetics. Methods employed for collating cases and determining the causal agent.

Concept of monitoring of toxic substances.

Deliberate poisoning (suicidal or criminal). Statistics and case studies. Addiction: drugs, alcohol, tobacco. Dependence, habituation, withdrawal.

Poisoning in industrial or rural environments. Concept of skin and eye protection. Large-scale mass poisoning following accidents; long-term poisoning. Occupational health monitoring.

Poisoning through exposure in the home (cosmetics, medicinal products).

Statistics and case studies.

Chronic contamination by atmospheric or food pollutants. Indirect toxicity.

Methods of detection.

Module 2: Examples of toxic products and their effects on humans

This course covers all the chemical products which are in everyday use or are highly toxic. In each case the following aspects are treated: physicochemical characteristics of the product, detection by analysis, mechanisms of its biological effect and experimental concepts of toxicity.

Acute and chronic toxicity in humans. Treatment of poisoning. Prevention. Medico-legal aspects.

Rules and regulations.

Medicinal products: psychotropes, cardiotropes (digitalis preparations, quinidine, beta blockers), analgesics (salicylates, paracetamol), opiates.

Industrial products: metals (lead, mercury, cadmium, arsenic, chromium, nickel), organic solvents (benzene solvents, chlorinated or fluorocarbon solvents, carbon disulfide, alcohols, ketones), various organic compounds, epoxy derivatives, aromatic amines, caustic gases (chlorine, ammonia, phosgene), polycyclic aromatic hydrocarbons, nitrosamines, dioxin.

Pesticides: organophosphorus and organochlorine derivatives, carbamates. Nitrophenol-derived herbicides, paraquat, methyl bromide, etc.

Domestic products: carbon monoxide, corrosive products, detergents, glycols.

Poisonous vegetable products (roots, leaves, berries), poisonous mushrooms.

Poisonous animals (hymenoptera e.g. wasps, snakes, scorpions, spiders, fish).

Atmospheric pollutants: SO_2, NO_x, ozone, formaldehyde.

Food pollutants: mycotoxins, products transmitted from packaging, etc.

Module 3: Toxic pathology by organ or by system. Strategy for diagnosing causes

This module covers the effects produced by short-term or long-term chemical poisoning in each major medical discipline. The clinical, anatomopathological and biological aspects of each disease are described, as is the pattern of development. Great stress is placed on the importance of the diagnosis procedure to identify the causal agent.

Neurological pathology: comas, convulsions, encephalopathic diseases, behavioural problems, polyneuritis, polyradiculoneuritis.

Respiratory pathology: interstitial pulmonary disease.

Immunoallergic bronchial pathology, etc.

Hepatic pathology: toxic hepatitis caused by direct poisoning or immunoallergy, chronic ailments: occlusive arterial disease, peliosis, hepatic adenomas, etc.

Renal pathology: acute or chronic disease of the renal tubules. Diseases of the glomeruli caused by poisoning or immunoallergy.

Cardiovascular and muscular pathology.

Pathology of the digestive tract: pancreatitis, colic necrosis.

Skin pathology: chloracne, contact dermatitis.

Pathology of the reproductive system: fertility disorders, embryotoxicity, fetotoxicity, teratogenesis.

Pathology of the metabolism: porphyria, breakdown in oxidative phosphorylation reactions.

Cancers and chemical products.

Immunotoxicity.

Genetic anomalies in humans: detection and interpretation.

Module 4: Treatment of human poisoning

Emergency action in the case of isolated acute poisoning: principle of removing the victim from the toxic atmosphere. National and international plans for dealing with cases of mass poisoning. Methods of immediate treatment available. Assistance from poison control centres.

The place of treatment of symptoms in emergency toxicology.

Methods of decontaminating the skin, eyes, and digestive and respiratory systems.

Dialysis methods: description - renal and extrarenal dialysis, indications for and limits of these methods.

Neutralizers, antidotes and antagonists (examples, indications).

Chelating agents: principles of chelation, examples of chelating agents, indications and limits, immunoallergic chelation - specific antibodies.

Evaluation of therapeutic agents in human toxicology: limitations on animal experimentation in this field, concept of criteria of severity.

Module 5: Clinical toxicology research

Ethical restrictions on studies involving human subjects.

Aims of research: determination of the kinetic and metabolic characteristics of the toxic substance in humans; description of pathology; prognostic evaluation; therapeutic research; evaluation of preventive measures; detection of new toxic phenomena.

Methods:

- study of cases of large-scale poisoning (kinetics, metabolism, therapeutic research);
- study of series of cases for the purpose of describing the toxic disease and identifying the criteria for prognosis;
- epidemiological approach for the purpose of evaluating quantitative or qualitative changes in poisoning after the introduction of preventive measures; and
- introduction of warning systems in various types of institution to ensure early detection of new toxic phenomena (clinical toxicology departments, poison control centres).

Annex 6

A CAREER IN TOXICOLOGY

by

K. Lewis

Introduction

This paper provides a framework in which career opportunities for toxicologists can be identified and recognized. It discusses a methodology for determining the present and future opportunities for toxicologists and examines the sources of new entrants to the profession and discusses how they can acquire competence. The paper builds on the developments which have already taken place within the WHO European Regional Office programme for manpower development in toxic chemical control.

Recognition is taken of the development of a target curriculum of educational and experience standards for professional accreditation, as an evaluative toxicologist, the development of knowledge criteria and provision of occupational profiles for toxicologists and related professions (see WHO/EURO Interim Document No. 2).

The need for career development is examined and an attempt made to identify the organizations with which the profession may be concerned. It also illustrates the possible opportunities which may be available for toxicologists in both nonmedical and medical organizations. The ways in which future toxicologists can be recruited and an example of how toxicologists may progress to the top of their chosen career is given. The identification of various grades of toxicologist is examined, and the need for recognition of the toxicological profession is discussed.

The recommendations contained herein identify the details which need to be compiled to enable what can only be described in this paper as a framework, to be developed into a profile of the toxicological profession.

Background

In recent years, concern over the adverse effects of toxic chemicals on humans has grown to the extent that international legislation has been deemed necessary to control the development, testing, manufacture, transportation and disposal of such chemicals. For the toxicologist this development has brought recognition of a more formal "profession" with agreement on educational standards, on the tasks which a qualified toxicologist must be competent in performing, and the evaluation of the level and breadth of knowledge required by the toxicologist to ensure competence.

A toxicologist has to apply expert knowledge to the study of the adverse effects of chemicals on living organisms, and assess the probability of their occurrence. Traditionally, toxicology was almost exclusively concerned with the interactions of chemicals with human or other mammalian systems, and was considered primarily a branch of medical science. It has today developed into a complex multidisciplinary field which has expanded into new areas and assumed new dimensions of importance due mainly to increasing international concern for safeguarding human health and the environment against the effects of toxic substances.

The present-day requirements of the toxicologist mean that gaining the educational standards required and acquiring the knowledge and experience necessary to achieve competence takes considerable effort involving postgraduate study and practical experience. A number of people already working in the field of toxicology may not possess such qualifications or have not attained the breadth of experience required to meet the total demands of this new toxicological profession. Unless career opportunities are available and are seen to be attainable, such individuals will not be encouraged to seek the additional qualifications and experience necessary. Similarly, unless the profession offers attractive prospects for job satisfaction and remuneration, potential senior toxicologists (referred to in this paper as evaluative toxicologists) will not be tempted to undertake the necessary undergraduate and postgraduate study.

The generic term "toxicologist" has been widely and variously used in different countries and societies, depending on historical development and local circumstances. The term has been applied to graduates, for example, in medicine, veterinary medicine, biological sciences, chemistry and pharmacy, and to diverse functions ranging from routine chemical analyses to evaluative, interpretive and advisory functions at the highest levels.

WHO/EURO Interim Document No. 2 contains two major components on which a comprehensive and integrated manpower training strategy can be developed. The first of these components describes the parameters of the profession in terms of occupational profiles. The second component details training and experience requirements based on the occupational profiles which scientific and medical graduates require to ensure the educational competence of an analytical, experimental or clinical toxicologist (category 1). Further development to the status of an evaluative toxicologist (category 2) is achieved through the gaining of wider experience.

Education and Experience Requirements

Since the awareness of the need for evaluation and control of toxic chemicals has only recently emerged, there is very little precedent and experience on which to develop a manpower training strategy rationally designed to produce personnel with the proper skills and attitudes where they are needed at an affordable cost. At present, toxicologists come from many different backgrounds. Some become toxicologists after formal academic specialist training while others become toxicologists through a more or less structured apprenticeship. It is necessary to examine the various disciplines from which future toxicologists will be recruited to ensure that the different levels of education and experience required for individuals to achieve recognition as a toxicologist are included within the career structure.

The following areas of knowledge contribute to the education of a category 1 toxicologist: chemistry (especially analytical chemistry), biology, biochemistry, physiology, anatomy, laboratory animal science, genetics, microbiology, molecular biology, laws and regulations, pathological anatomy, histopathology, haematology, pathophysiology, pathobiochemistry, pharmacology, oncology, genotoxicology, pathoembryology, immunology, general toxicology, veterinary medicine and statistics.

The target curriculum set out in WHO/EURO Interim Document No. 2 indicates the additional study required by various scientific and medical graduates, including a minimum of 1 year of practical experience as a member of a toxicological team, before the graduate could be considered as attaining the competence of a category 1 toxicologist.

The curriculum is to be regarded as the minimum which can be considered adequate for a category 1 toxicologist to be recognized as competent to assess the full range of toxicological data. Further training in many of the component areas may well be desirable, and postgraduate courses for continuing advanced education must be developed.

A further period of wide experience is then necessary before the toxicologist would be recognized as a category 2 toxicologist.

The broad spectrum of knowledge and experience required of a toxicologist automatically identifies the primary source of future toxicologists in that they will be graduates who have acquired a first degree in medicine, veterinary medicine or one of the natural science. For a new entrant to the profession, such education and experience patterns are set out in Figure 1.

A second source of potential recruits to the toxicological profession are those people with lesser educational qualifications who are employed in assisting toxicologists as, for example, laboratory technicians, and who are prepared to and are capable of undertaking in full the further training necessary.

Third, in the future there may be the undergraduate who elects to take a first degree in toxicology, where such degrees are available. It is anticipated that such a person would need to spend a short period employed as an assistant before becoming a full member of a toxicological team.

The differing educational and experience requirements of each of the above groups, and indeed of the various disciplines in the first group, means that the completion of the target curriculum for a category 1 toxicologist and the length of experience necessary to become a category 2 evaluative toxicologist will differ depending on the candidate's academic background and professional history.

Identifying Career Structures

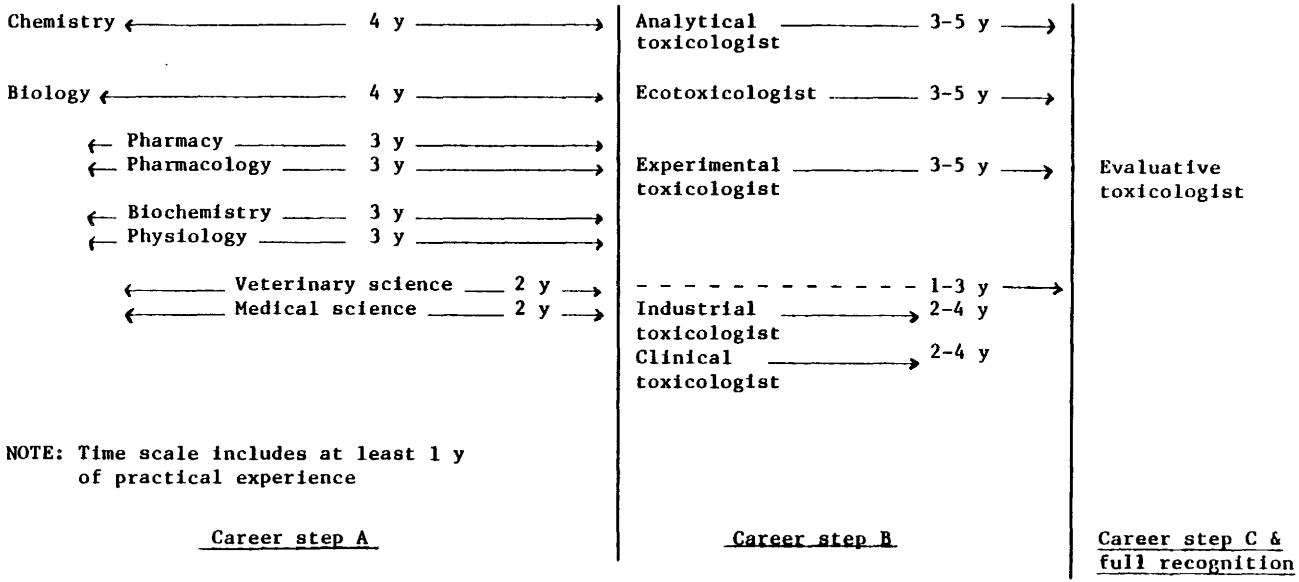
In identifying and structuring careers for toxicologists, the full spectrum of possible opportunities and the various requirements for toxicological advice need to be quantified for each area in which opportunities exist. This means classifying the different types of organization in which the toxicologist could be employed and analysing the requirements of each organization or country according to its needs.

The identification of career prospects and opportunities is not only to encourage entry into the profession but also to aid the identification of a professional toxicological profile, such as:

- providing a clearly defined route for promotion (career ladders) to enable individual toxicologists to appreciate the efforts required and the rewards available;

- providing motivation to achieve promotion by identifying the rewards available both in terms of job satisfaction and remuneration, which will provide an incentive to individual toxicologists to seek recognition and progress thereafter;

Fig. 1 Sources of toxicologists: education and experience requirements for new entrants



- equating remuneration with increased responsibility to encourage toxicologists to continue to accept increased responsibilities and contribute to the advancement of the profession;

- providing professional status to ensure toxicologists are treated and compared fairly in relation to other related professions; and

- assisting in the planning, administration and management of the activity to ease the task of those responsible for the planning and management of professional resources within the toxicological function.

One of the difficulties in attracting recruits to the profession is that currently and for the immediate future, toxicology will be seen as a "secondary" career which may be of interest to graduates who have or are in the process of establishing themselves in their "primary" profession. It may be seen as a logical extension to their first career choice, and if so, they will pursue new goals, or it may be viewed as an adjunct to their main career where they could gain ancillary experience while pursuing their original aim.

The possible future establishment of an undergraduate degree in toxicology, leading to wider postgraduate training to fulfill the requirements of the target curriculum, would encourage undergraduates to choose toxicology as their main career.

There are two principal ways of providing a satisfying career path which are relevant to the toxicological profession: the "management-type" career, and the "specialist-type" career. The two approaches are not mutually exclusive. Throughout one's career, it is possible to specialize in a subject area while holding management responsibility, although at some point the individual will be recognized more for his management or specialist skills.

Individuals will achieve job satisfaction in differing ways, and therefore the opportunity of being able to choose a specific career path is highly desirable. The choice of career path should not restrict reward; toxicologists will normally be remunerated for their contribution to the organization rather than whether they become a specialist or manager.

Figure 2 identifies the functional steps in a toxicological career ladder, the skills required at each of those steps, and the relationship between the management- and specialist-type careers. Depending on the individual organization structure, a number of the functions shown in Figure 2 may be combined within one job title (post) or the job content (post description) subdivided into several posts. However, this does not detract from the need to provide these principle functions and to accommodate them within a career ladder.

The difference between job titles and job content, which together define the job profile, and the descriptions contained in the already established occupational profiles is that occupational profiles form a list of various tasks that toxicologists must be competent in performing. The job profile is a selection of those particular tasks required under a specific job title and this will vary considerably depending on the organization's needs.

It is necessary to determine at which functional step the post holder should be recognized as an evaluative toxicologist: this may differ between organizations and countries, depending on individual requirements. A post which includes responsibility for professional standards, and consequently a professional decision-making responsibility, should be held by a person who is qualified by both education and experience and hence professionally recognized. It is suggested, therefore, that this would occur at the evaluation level shown in Figure 2, i.e. step C on the career ladder.

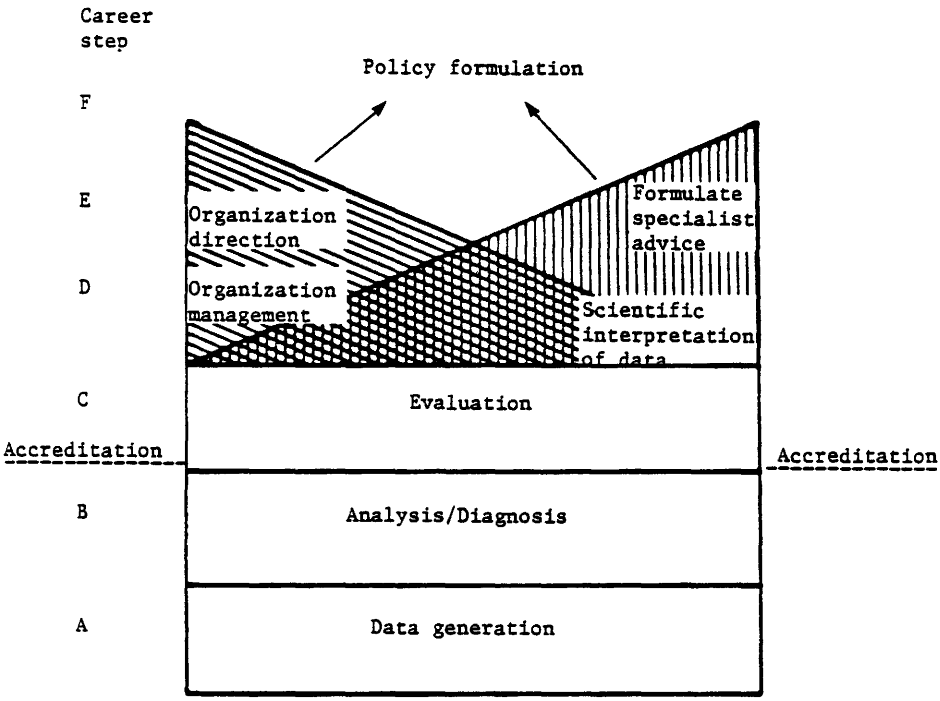
This post is identified as the lowest step on the career ladder for the category 2 evaluative toxicologist. Promotion is possible through willingness to accept wider managerial responsibilities for those wishing to follow a management-oriented career or by acquiring considerable experience in a specialized facet of toxicology.

Employment Patterns and Career Structures

Employment patterns

The introduction of current and proposed legislation regulating the control of new toxic chemicals provides opportunities for toxicologists in a wide spectrum of differing organizations. It is felt that the major employer of toxicologists will be the chemical manufacturing industry, but many other organizations will require such services and will provide career opportunities at one or more levels: for example, private manufacturing industry (other than chemical manufacturing); public manufacturing industry (other than chemical manufacturing); public utilities and services, health and medical services, including hospitals and poison centres; commercial advisory consulting companies; trade advisory associations; trade unions; national government; research

Fig. 2 Career ladder



Note: Career step A refers to those initially without the experience and educational requirements to start studying for target curriculum establishments; armed forces; universities; and governmental laboratory services. The list is not exhaustive but serves to demonstrate the diverse types of organization in which an evaluative toxicologist could be employed, although not all these types of organization will be found in individual countries.

Table 1 in Annex 1 (p.47), however, illustrates the currently perceived needs for evaluative toxicologists in various functions. It can be seen that by developing a matrix of opportunities provided by organization type/function, a full range of career paths can be identified as available to the potential evaluative toxicologist. This will provide job satisfaction for both those who wish to generalize in a management-oriented career and for those who choose to specialize.

Advancement opportunities offered by the individual types of organization will vary considerably. While potential employment opportunities may exist in many different areas, the need for toxicological expertise is, at present, often not recognized. Thus, the real manpower need and the consequent career opportunities available cannot be accurately determined.

Career opportunities

Not all types of organization will provide the range of opportunities for a full career structure. Most will require only the services of a toxicologist at certain functional or specialist levels while others, such as the chemical manufacturing industry, will be able to offer a full range of career prospects. The precise needs and size of the organization will determine the requirements.

Similarly, the needs of individual countries will differ. The number of toxicologists required will be affected in some manner by the following factors:

- size and type of economic activity;
- level of toxic chemical control;
- size of chemical industry;
- development of agriculture; and
- particular spectrum of activity comprising toxic chemical control.

The above list can be extended by many more specialized factors, each of which is capable of influencing the number of toxicologists and evaluative toxicologists needed. Consequently, the career opportunities afforded by the employment patterns shown in Table 1 in Annex 1 will differ considerably in individual countries, depending primarily on whether the country is a large developer, a manufacturer, or a significant user of chemicals. The function and tasks performed currently by toxicologists also vary widely, from advisory functions at the highest levels of decision-making to the performance of routine analytical tasks.

Toxicology is an interdisciplinary science, and work in any of its branches is usually performed by a team. Such a team must be directed by an experienced toxicologist, who may also participate in the tasks carried out by the team. Toxicologists have been subdivided into two categories. Category 1 comprises those who have come into the field as graduates in appropriate disciplines and are learning, by experience or by attending courses, the knowledge and skills appropriate to the toxicological tasks which are their responsibility. This category includes all toxicologists other than those at the highest level (category 2 evaluative toxicologists) who are widely experienced and are contributing actively to the process of decision-making.

It is recognized that clinical toxicology, a specific subsection of toxicology, requires a degree in medicine. Although the clinical toxicologist can follow similar career paths as the nonmedical toxicologist, there are specific career opportunities available only to such specialists and these should be distinguished from those followed by the more generalist toxicologist. It is desirable, therefore, that the opportunities both within medical and nonmedical organizations be clearly defined and career ladders within each type of organization identified and recognized.

Currently, there is no reliable information as to the number of posts available at each function level or, indeed, any specific knowledge of the requirements of different organizations. Therefore, the following illustrations should only be interpreted as a broad hypothesis.

Figure 3 indicates career opportunities available to all toxicologists, while Figure 4 illustrates the additional specialist opportunities available to clinical toxicologists. These figures give examples of possible opportunities offered by both nonmedical and medical organizations in the various classifications shown in Table 1 in Annex 1, indicating how the needs of various organizations dictate whether full or restricted career opportunities can be provided. Figures 3 and 4 also illustrate possible career opportunities for toxicologists wishing to move between organizations of differing character.

Although these examples should only be considered illustrative, fact-finding missions have been made to Egypt, the Netherlands and

Poland to study the requirement for evaluative toxicologists in these countries and examine the training and career opportunities available (see Working Paper CEC/V/E/LUX/83/68/12, WHO/ICP/RCE 903(25)/12). The evidence collected has been extrapolated and compared with the employment distribution of evaluative toxicologists shown in Figure 2 to indicate the career levels available in each country. The opportunities which exist, although different in each circumstance, do provide meaningful career opportunities for the aspiring evaluative toxicologist, in line with those examples shown in Figures 3 and 4.

Career Profiles

In compiling the occupational profiles in WHO/EURO Interim Document No. 2, the primary aim was to define the tasks which might be combined as the responsibility of one person in a given occupation. While the tasks should have international validity, it was recognized that the occupations as defined might not apply precisely to all countries. However, it is believed that similar occupations could usually be found. However, where it is stated in the occupational profiles that ability to carry out a task is required, it does not follow that anyone in the particular occupation must necessarily perform the task in person: it is possible that the person may simply have the responsibility for seeing that the task in done.

Category 1 toxicologists can be currently considered in the following subject groupings:

- Clinical toxicologists - Industrial toxicologists (occupational health and consumer monitoring)	Those toxicologists with a medical degree
- Experimental toxicologists - Analytical toxicologists - Ecotoxicologists	Those toxicologists with a science degree

The exact area and function in which the category 1 toxicologist works usually determines which of the above classifications is appropriate. The main role of the evaluative toxicologist (category 2) is the interpretation of the results of toxicity testing in

Fig. 3 Possible career opportunities

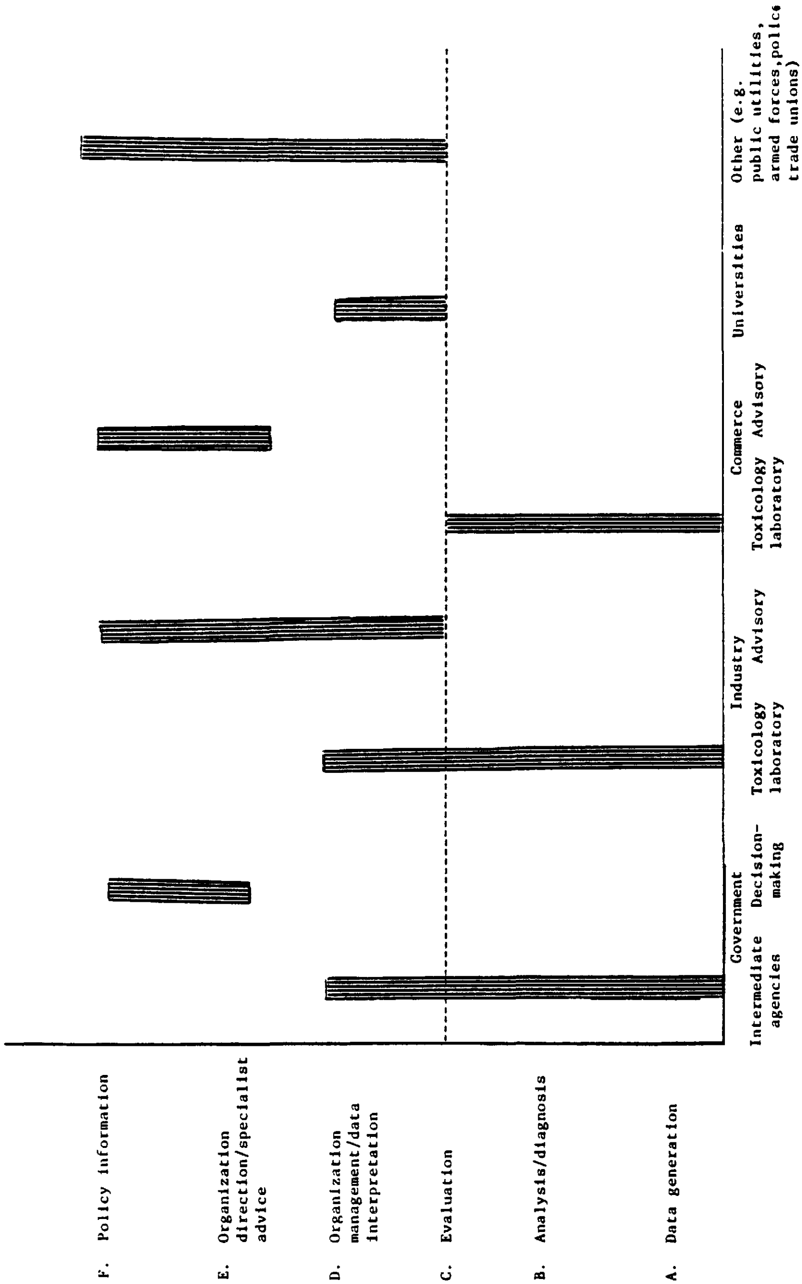
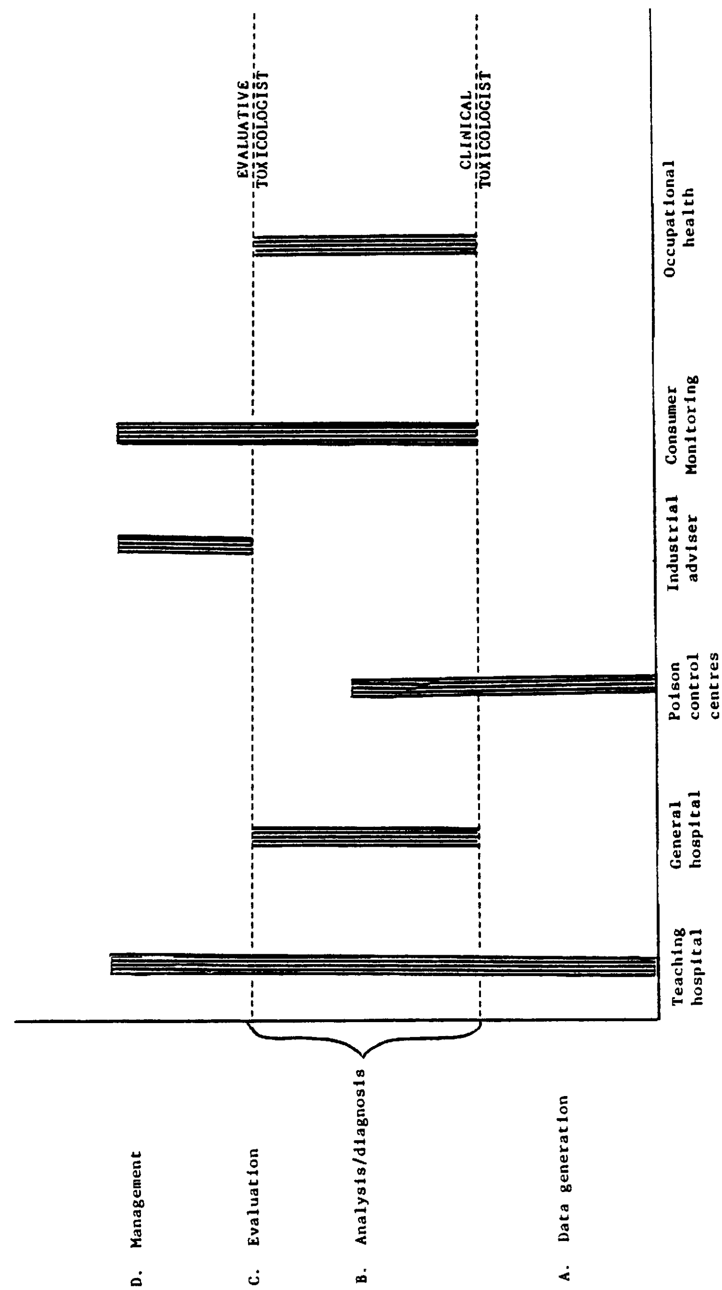


Fig. 4 Specialist career opportunities for medical graduates



relation to results from epidemiological studies and the evaluation of likely hazards to human health.

The above occupational descriptions have been compared to the career structures illustrated. As a consequence, Table 1 identifies the functional steps in a toxicological career ladder, the skills required at each of the steps, and the relationship between the management- and specialist-type careers. It describes the basic components of a career path model and also illustrates the education/experience requirements for all functional levels and identifies this with each step on the career ladder. The levels of responsibility and capabilities expected of toxicologists at each career step are also indicated.

The toxicologist wishing to pursue a purely specialist type of career would not necessarily have a span of control above that of a "team leader" position in managerial terms, (step C in Table 1). However, by the indepth knowledge acquired in a particular subsection of toxicology, he would take on the role of interpreter and aspire to become a specialist adviser without limiting career prospects. It is more than likely that promotion would best be found by this person in non-industrial organizations, such as a research establishment, or in academics.

In addition to the basic components of the career path model, Figure 5 gives an indication to the nonmedical new entrants to the profession of the expected age at which toxicologists could achieve promotion. It also provides a guide to expected remuneration (in percentages) at each career step, depending on the discipline and background of the individual.

While the career of those medical graduates wishing to become evaluative toxicologists can be considered in the same context as that shown in the basic components of the career path model (Table 1), additional specialist opportunities are available in toxicology which are determined as part of the medical profession (Figure 6). Recognition of the clinical toxicologist is already well established, and this determines career progression in hospitals, poison centres and the medical aspects of industrial toxicology (e.g. occupational health). In view of this, the career pathways and career profile of the medical graduate (Fig. 7) is somewhat different to that of his nonmedical counterpart.

Career profiles will vary, depending eventually on the requirements of individual countries. Such models need to be constructed on a country-by-country basis to be useful to the individual toxicologists in planning their careers and to act as a guideline to countries and organizations in enabling them to plan and administer their toxicological requirements and services efficiently.

Recognition of Toxicological Profession and Accreditation of Toxicologists

International legislation for toxic chemical control has highlighted a requirement for the testing and evaluation of the harmful effects of potentially toxic chemicals by competent toxicologists. This in itself requires a definition of "competence".

The generalist nature of modern toxicology and the many disciplines which contribute to the subject have made the formal recognition of toxicology as a profession in its own right essential to ensure competent performance and to achieve international confidence in evaluation and advice on toxicological problems. Thus, there are two principal reasons for establishing an accreditation system in relation to toxicology. First, legislative and economic imperatives demand accreditation of toxicologists to ensure competence. Second, there is a need to identify clearly the profession of toxicology and those fully qualified to pursue it. This implies some mark of status for those who satisfy stipulated educational requirements.

The evaluative toxicologist must be capable of taking responsibility for professional standards, evaluating data from wide-ranging and differing functions, and formulating advice which may have far-reaching consequences. Such a person must be recognized as having attained a high educational standard and gained sufficient experience to offer an unbiased evaluation.

In the well-established professions of, for example, accountancy or law, the designations of accountant and lawyer imply a person possessing certain skills and capabilities acquired by education, training and experience, and therefore able to give unbiased advice in a well-defined range of functions. This is not the situation in toxicology, where current requirements cross a number of traditionally recognized professional boundaries. It is therefore necessary to define the parameters of the profession and to identify the skills required of the professional toxicologist.

The evaluative toxicologist is therefore qualified by education, training and experience to be capable of accumulating, interpreting and evaluating scientific data to determine human health risks, either directly or environmentally, and to advise on preventive and curative measures. Any function which demands responsibility for setting these professional standards and as such has a professional

Table 1 Basic components of a career path model

Career step	Career ladder		
F		Policy formulation	
E	Organization direction	OR	Formulate specialist advice
D	Organization management	OR	Scientific interpretation of data
C	Accreditation	Evaluation	
B		Analysis/diagnosis	
A		Data generation	

Knowledge, experience and qualifications	Responsibilities and capabilities
As below with 7-9 y experience at stage E. Comprehensive knowledge of business strategy and awareness of national and international development, policies and legislation in toxicological field.	Total responsibility for toxicological policy of organization.
As below with 5-7 y experience at stage D. Knowledge of business strategy and awareness of national and international development, policies and legislation in toxicological field.	Responsible for total management and direction of toxicological research establishment or toxicological division of large industrial manufacturing company or capable of initiating and directing fundamental research relating to toxicological problems and helping to formulate policy.
As below with 3-5 y experience at stage C, with comprehensive knowledge of management systems and procedures. Full knowledge of national and international legislative requirements.	Responsible for general management of toxicological department including all aspects of research, statutory testing documentation and administration or capable of planning research to solve practical problems in toxicology.
As below with 3-5 y experience at stage B and having achieved accredited status. Knowledge of pertinent legislative requirements essential. Basic knowledge of management procedures and systems.	Supervise work of single toxicological team and coordination and evaluation of results. Capable of intrepreting evaluation of results and giving general advice based on such interpretation.
First-degree specialist graduate in medicine, veterinary science or general science, and studying for target curriculum.	Responsible for undertaking toxico logical testing and research under supervision.
This step refers to those entrants initially without necessary educational and experience requirements to begin studying for target curriculum.	

Fig. 5 Career profile for nonmedical graduates

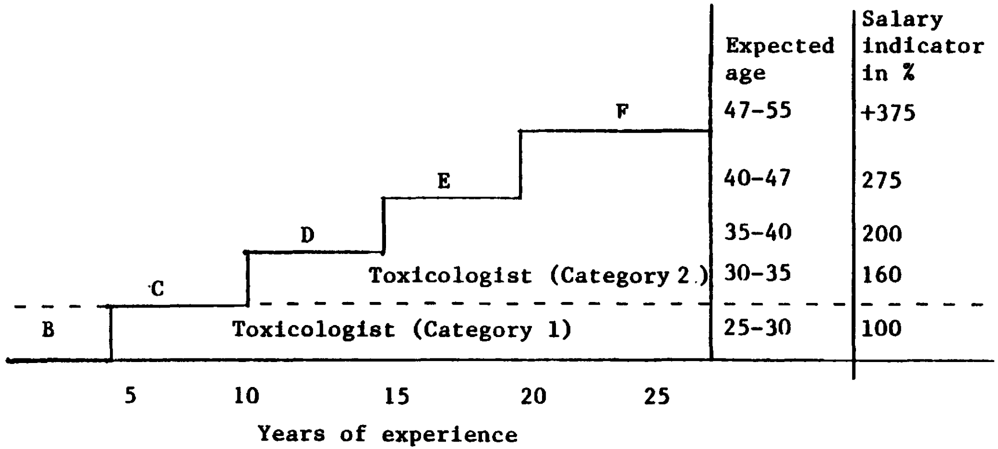


Fig. 6 Specialist opportunities in toxicology

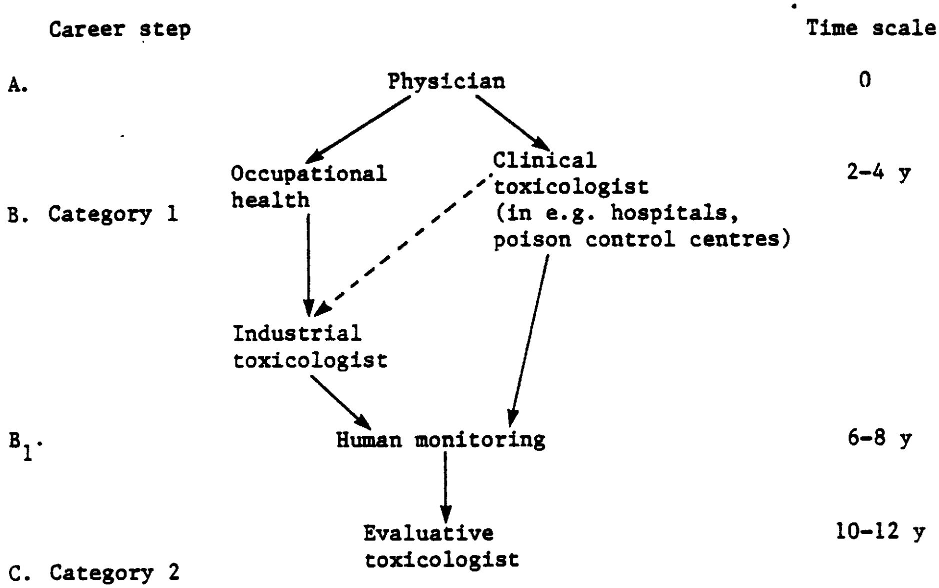
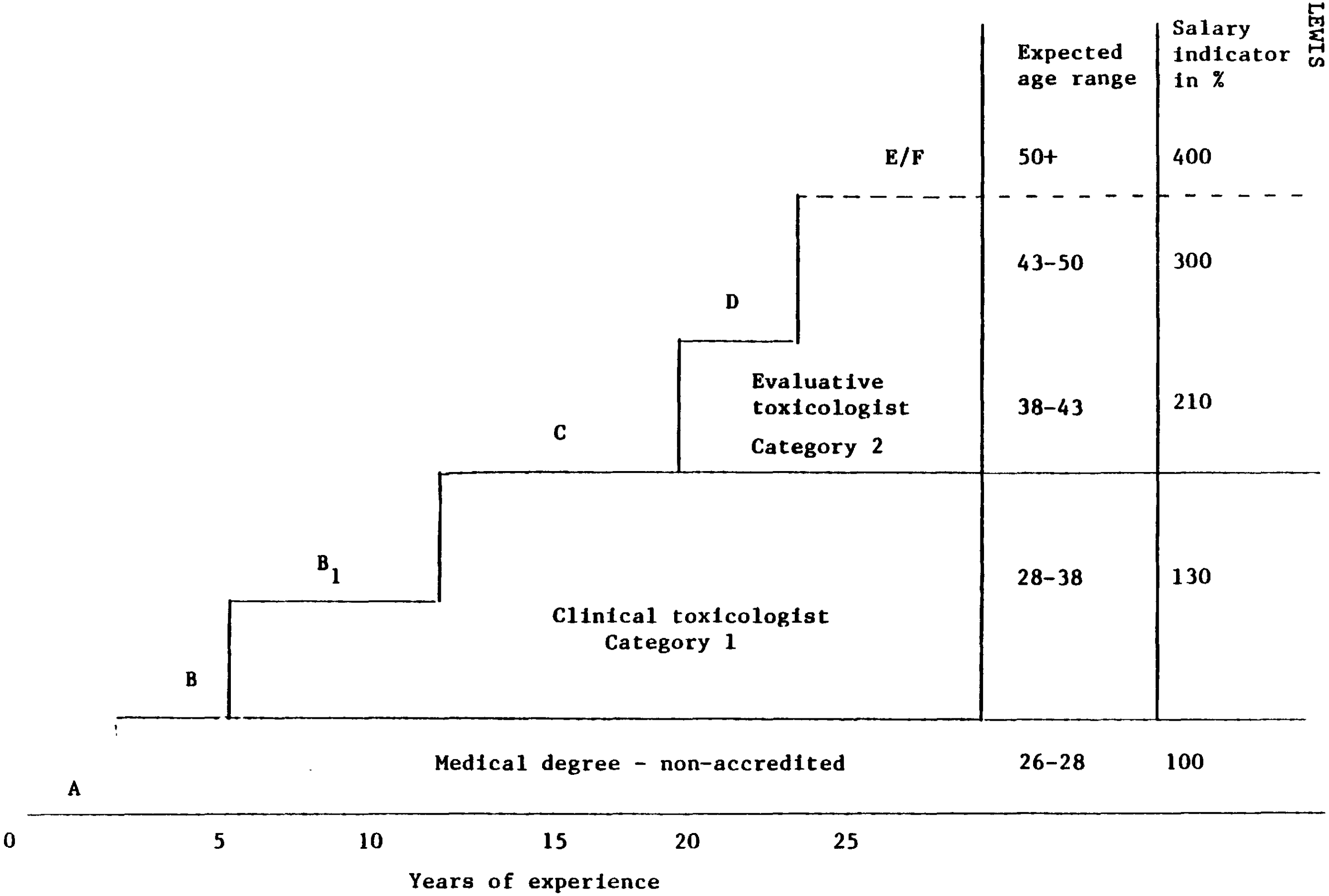


Fig. 7 Career profile for medical graduate



decision-making responsibility, should be undertaken by a person qualified by both education and experience who is professionally recognized as fulfilling the above definition.

The need for accreditation of toxicologists is necessary therefore to:

- give a guarantee of performance and minimize bias in evaluation;
- provide international recognition, ensuring equivalent evaluations;
- recognize a minimum qualification for professional recruitment; and
- inspire confidence in professional advice.

The main criteria for accreditation must be proficiency in the total subject area. A degree in one of the main components, such as medicine, veterinary medicine, pharmacology, biochemistry, physiology, biological science or chemistry, must be the first criterion. The second criterion may be a postgraduate degree or other formal recognition of achievement which could include significant experience in the subject, to the satisfaction of a responsible institution. The combination of a medical degree with postgraduate training in the components of the toxicology programme not covered by the medical degree should lead to the recognition of qualification as a clinical toxicologist. Satisfaction of the two criteria stated should not only ensure that the substance of the curriculum (as set out in WHO/EURO Interim Document No. 2) has been learned but also that the quality of understanding and ability of the candidate for accreditation has been assessed and found to be adequate.

Once facilities for training in the component subjects of the curriculum for toxicologists have been fully developed, the mechanism for recognition of qualifications for accreditation should be straightforward. As the basis for recognizing qualifications is educational, the responsibility would fall most naturally on universities or similar institutions of higher education, with registration and accreditation being provided by selected institutions recognized as being competent to judge in such matters.

Currently and within the immediate future, the need for both category 1 and 2 toxicologists will rapidly increase due mainly to legislative requirements. At the same time, many individuals already working within the subject area may qualify for recognition as accredited toxicologists on the basis of wide experience, while others may need varying amounts of supplementary study.

As the formal training required by the curriculum will not be fully available in the short term, such candidates for accreditation could be awarded a certificate of attainment in toxicology on the basis of submitting a curriculum vitae and if necessary taking an examination under the auspices of the selected institutions mentioned previously. Certification would be based on a satisfactory comparison with the curriculum for either a category 1 or category 2 toxicologist and be awarded accordingly.

A similar procedure may also be necessary to meet the urgent needs of less-developed countries where the immediate requirement may be for someone with less experience than the evaluative toxicologist.

In all cases it should be stressed that accreditation should be awarded on favourable assessment of the individual's academic and experience attainments and comparison with the target curriculum.

Summary

This paper deals with the recognition, assessment of needs, and potential careers of "full-time" toxicologists, that is, those working exclusively in the subject area. There are many other occupations which require a knowledge of toxic chemical control in varying degrees; these have not been considered.

The following recommendations are therefore pertinent to the development of a profile for the toxicological profession.

1. The assessment of manpower requirements to meet the demands on full-time toxicological expertise from current and impending legislation should be properly planned to ensure efficient manpower development in relation to available training resources.

2. Governments, professional bodies and universities should consider it a matter of high priority to recognize toxicology as a profession in its own right.

3. The urgent needs of developing countries to establish a reservoir of trained and experienced personnel in toxicological matters should be further examined in relation to local circumstances.

4. The target curriculum of training lays the foundation for the development of a career in toxicology. It does not provide for the additional training requirements of those toxicologists who wish to follow a management-oriented career; these will need to be identified. Due to the rate of increasing knowledge

within toxicology, regular updating courses will be necessary for all toxicologists to maintain a knowledge of the latest developments within the profession.

5. It should be determined how toxicologists will compare with other similar professions in terms of status and remuneration, in line with the needs of the individual countries and available professional resources.

6. There may be a need to develop a grading structure to describe the necessary experience and qualifications required for particular posts in differing organizations and countries. The concept of a category 1 and category 2 toxicologist recognizes that grading is necessary. However, it may need to be further refined to cope with the complexities of differing requirements.

The educational and experience requirements for an evaluative toxicologist inevitably mean that a large number of candidates will at some stage choose a career in a related area where a knowledge of toxicology is required. Because of this, the number of accredited evaluative toxicologists is likely to be less than those needed, thus ensuring good career prospects for those prepared to fulfill the requirements for a category 2 toxicologist.

The various approaches outlined in this paper will enable the clear definition of the parameters of the toxicological profession, identification of the spectrum of opportunities available to those entering the profession, definition of the various levels of competency expected of the profession, and identification of the additional areas of training necessary to meet those requirements. Furthermore, they will generate comprehensive information to allow individual organizations and countries to develop a system of training and manpower planning that ensures the right number of toxicologists, trained to the recognized level, available in the correct place, when required, to ensure that the obligations to provide adequate control over toxic substances are adequately met.

Annex 7

NEED AND CRITERIA FOR RECOGNITION OF QUALIFICATIONS IN TOXICOLOGY

by

J.K. Piotrowski

Introduction

Developing skills and understanding in toxicology is a long and painful process based on practice, self education and involvement in research activities. Formal recognition of the necessary qualifications will be a valuable incentive for potential candidates, thus accelerating the development of well-trained manpower in toxicology.

At the user's end, the qualifications of the toxicologist are of great importance: decisions concerning health protection or economics which are based on the judgements made by toxicologists have far-reaching consequences. For those responsible for the management of toxic substances, it would be desirable that the judgements be made only by professionals of high quality. Therefore, some restriction in the availability of certain occupations and/or posts, based on formal recognition of qualifications, would be of mutual benefit.

Care must be taken, however, that the systems to be developed are not too demanding: gaining recognition of one's qualifications may be difficult but must be feasible for those already working in the field as well as those to be recruited.

Basic Profiles of Toxicologists

Most professionals engaged in toxicological activities belong to one of three professional profiles. Experimental toxicologists engage in toxicity evaluation on animals. Their basic education is usually in medicine, veterinary medicine, pharmacology (where it exists), pharmacy, biology or biochemistry. Phytotoxicologists represent a special branch within this group. Clinical toxicologists engage in the diagnosis and treatment of intoxications, preventive activities in industry, and epidemiological work on exposed populations. Their basic (compulsory) education is in medicine, with some postgraduate specialization in internal medicine prior to engagement in toxicology. Chemical toxicologists deal with exposure monitoring and evaluation as well as risk assessment and experimental research on absorption, metabolism, toxicokinetics, biochemical effects and interactions. Their basic education is usually in chemistry, pharmacy or biochemistry.

The qualifications of professionals in these profiles depend on two components: (a) competence in the basic field (e.g. biology, medicine, chemistry) and (b) type and intensity of experience in toxicology, postgraduate training and self education as well as intellectual interaction with other members of the toxicological team. Assuming that both components are rated highly enough, the candidate may apply for formal recognition of qualifications in toxicology. However, the qualifications must be considered jointly with the basic academic training in order to assess competence in a given type of toxicological activity. Thus, it would be reasonable to give some indication of the profile (as above) in the certificate, e.g. toxicologist, grade 1 (in clinical toxicology).

Need for Formal Recognition of Qualifications

Activities in toxicology are, as a rule, performed in teams where the critical role is played by the team leader. It would be desirable, therefore, that the team leaders receive recognition of their qualifications in toxicology prior to designation to a given post. These highly experienced professionals represent grade 2 qualifications.

As an example, in the concepts developed by the Polish Toxicological Society, recognition of grade 2 qualifications would be required in the future for all posts of heads of toxicological laboratories (e.g. sanitary stations at the district level, departments of forensic medicine, poisoning centres, major industrial enterprises, and regional dispensaries for occupational diseases) and also for senior lecturers (assistant professor and above) in the teaching units of toxicology and senior staff members of research laboratories in toxicology.

Apart from the team leaders of laboratories, who represent the profile for analytical or experimental toxicologist, a number of grade 2 specialists will be required as leaders of clinical teams (poisoning centres, dispensaries, epidemiology groups) and as individual consultants. The requirements of grade 2 qualifications in toxicology should also be extended to all technical members of policy-making and standard-setting bodies.

From the above it is seen that restrictions in employment should be limited to critical posts where grade 2 qualifications are required. In the system of manpower development, the role of grade 1 specialists would be limited to staff functions. Alternatively, restrictions (or indications) could be extended to the second-in-command (deputies at all restricted posts) where grade 1 would be satisfactory.

Criteria for Recognition of Qualifications

Recognition represents the final step of the entire training process and must be discussed in relation to the training system.

My personal opinion is that the training system should not attempt to create at the Master of Science level and above an excessively rigid uniform model of a toxicologist. In practice, it is important that the specialists are expert in some aspect within their field of competence and, at the same time, are capable of understanding and interpreting the more general facts and data. In addition, the curricula should have flexibility. Figure 1 shows some possibilities for grade 1 specialists in analytical and experimental toxicology and Figure 2 for grade 1 clinical toxicologists. The two basic alternatives are "technical" or "academic". For the former, an examination by an appropriately selected "Board of Specialists" should yield a certificate of grade 1 toxicologist. For those who choose the academic career in toxicology, a Doctor of Philosophy should be approved as equivalent to grade 1 specialization.

The same two alternatives can be left for the grade 2 curriculum (Fig. 3). A grade 1 specialist (non-academic) would be expected to acquired experience in more than one narrow field of toxicology, pass additional training and self education, enter some research activity and, finally, gain recognition by the seniors of the discipline. No formal examination would be needed. The alternative curriculum, for a scientist, would require more research, possibly not limited to one area, teaching and other activities inherent in academic careers. The recognition of the achievements and rank among the scientists takes the form of either a second scientific degree (e.g. Doctor of Science) or appointment to a senior post in academic toxicology (e.g. professor, docent). Whatever criterion is accepted, it should be recognized as equivalent to the grade 2 specialization in toxicology.

The criteria for recognition in either group should be matched with the demand. For instance, the academic rank at which qualifications are recognized as equivalent to grade 2 in toxicology could be set at the level at which the number of available scientists is equal to half the number of specialists required for the whole country (i.e. professors only; professors and readers; professors, readers and senior lecturers?). Once the basic numbers have been agreed upon, admission of non-academics to grade 2 could be based on more or less rigid criteria with regard to kind and duration of practice, training, extent of research experience, etc.

As an example, in Poland the system could be started with the narrow group of scientists having a degree above the Ph.D. (habilitation) in toxicology (docents and professors) and those appointed to the posts of heads of departments of toxicological chemistry. This number, about 15 in Poland, could be set as being half the number of required grade 2 toxicologists. A board of seniors, selected from among these professors, could further approve qualifications of the next 15 professionals from the non-academic institutions engaged in toxicology. After the approval of the non-academics, the board of seniors could be restructured for the next term.

The board of seniors would play the critical role in the whole system. It would have to be aware of the actual demand for toxicologists in all areas of activity and adjust the criteria for recognition accordingly. In selecting members of the board of seniors, the society of toxicology (where such exists) could be given authority.

Criteria for the recognition of grade 1 in toxicology could be less rigid. A reasonable ratio of numbers in grades 1:2 starts probably with 5:1, but a higher ratio, say 10:1, does no harm. Therefore, the approval process could be decentralized so as to cope with the numbers required in the system. In selecting members of the boards of specialists, as well as in policy decisions, the board of seniors could be given authority.

The compatibility of various national systems could be taken care of by the European Society of Toxicology acting jointly with the International Programme on Chemical Safety.

Fig. 1 Curricula for grade 1 experimental and analytical toxicologist

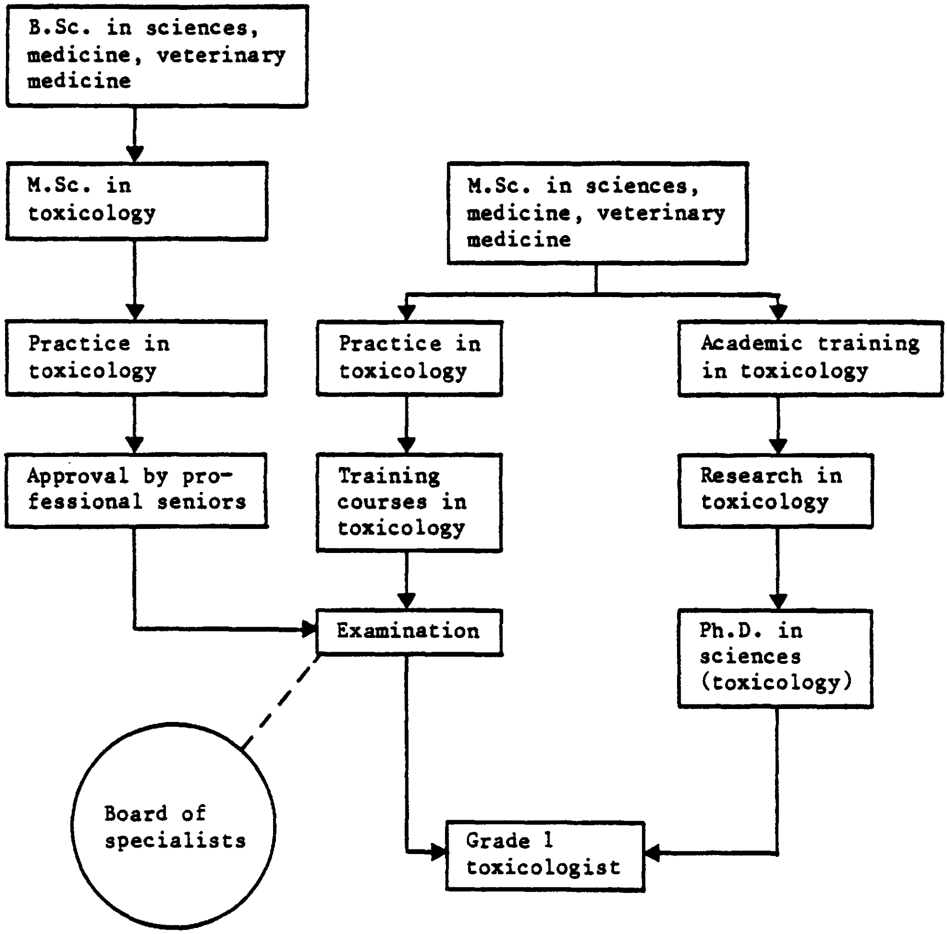


Fig. 2. Curricula for grade 1 clinical toxicologist

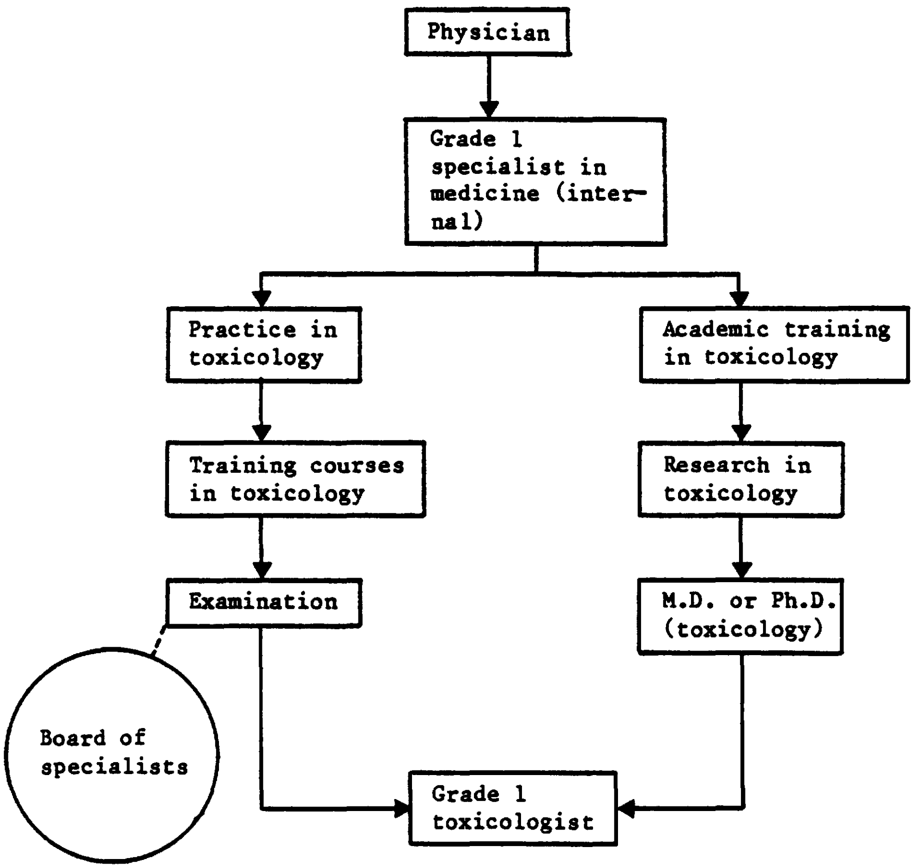
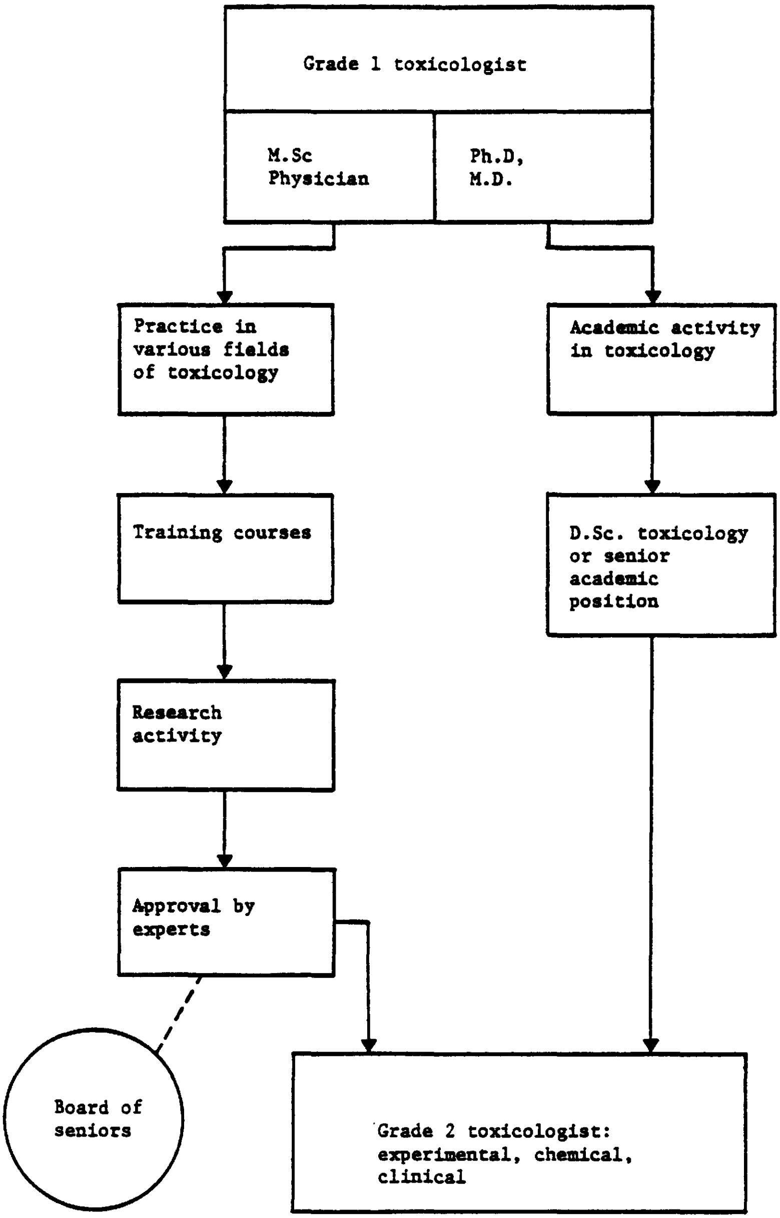


Fig. 3. Curricula for grade 2 toxicologist



Annex 8

SPECIFIC TOXICOLOGICAL PROBLEMS AND TRAINING NEEDS OF TROPICAL AFRICAN COUNTRIES

by

E. A. Bababunmi

Introduction

Africa is second only to Asia (the largest continent) in size and is the most compact of all the continents. It has an area of approximately 11.7 million square miles. Seventy-five per cent of the African land mass falls within the intertropical zone, as do most of the developing countries of the world. Africa's population is estimated to be about five hundred million. African countries situated in tropical or semitropical climes are among the least developed in the world. Among the thirty poorest nations in the world, twenty are in Africa. Disasters such as droughts and floods often intensify the malnutrition and general unhealthy conditions of the populations in tropical Africa.

The International Programme on Chemical Safety (IPCS) has previously enumerated in detail several problems which arise from the use of, and exposure to, chemicals in developing countries such as those in tropical Africa. Facts indicate that large populations living in developing countries are at risk in a way similar to the populations subject to risk in the industrialized and developed nations.

Specific Toxicological Problems of Tropical Africa

McLean et al. [1] summarized the specific toxicological problems of tropical Africa as follows:

1. Various drugs used to treat infectious and parasitic diseases are toxic.

2. Toxic plants are used as food crops and toxic fungal contaminants are present in food crops.

3. The need for pesticides for public health and protection of crops and products is far greater in tropical than in temperate climates.

4. Local industry is often conducted in small workshops (e.g. lead battery makers) with no knowledge of toxic hazards to workers or environment, and mining operations are often too large to be easily disciplined.

5. There is massive dependence on the import of industrial and consumer products, for which the original toxicity assessment has been made by people with no knowledge of local conditions.

6. Hazardous materials and hazardous or polluting industries are being exported from powerful industrial countries, where the processes are coming under public criticism, to less-developed countries. There, government officers are less able to resist the usual combination of rich local and richer foreign firms, trade unions are weaker, and truly expert advice on potential risks and benefits hard to obtain.

7. Malnutrition and genetic variation in tropical populations may make toxicity data gathered elsewhere inappropriate.

8. The low level of public education on questions of toxicity is frequently combined with problems of language barriers and literacy, making it difficult to get proper use of medicines and pesticides.

9. There is a shortage of human and financial resources to set up a system of education and public control of hazardous substances.

Problems in mycotoxicology

The Joint FAO/UNEP Conference on Mycotoxins, held in Nairobi, Kenya, 19-27 September 1977 concluded that there are eight major tasks in the field of mycotoxicology:

- surveys to establish the incidence and sites of occurrence of mycotoxins;

- design of sampling plans that will provide representative samples of lots of contaminated commodities;

- development of measures that can be applied to prevent the occurrence of mycotoxins in human food and animal feed;

- development of new or improved processes for decontamination of commodities by removal of contaminated grain;

- development of chemical or solvent extraction methods for detoxication of contaminated products, particularly for mycotoxins other than aflatoxin;

- investigation of the adverse effects of feeds contaminated with mycotoxins on animal health and productivity and wholesomeness of animal products;

- mycotoxins in the food supply as related to human health; and

- development of improved analytical methodology and detection methods.

Problems in phytotoxicology

Two major tasks of phytotoxicology have been identified by an expert group of toxicologists at the 1979 International Symposium on Toxicology in the Tropics: cyanogenesis in foodstuffs in tropical Africa, and the presence of toxic chemicals in medicinal plants of Africa.

(a) Cyanogenetic glycosides

Several plant species of African origin and of agricultural importance exhibit the phenomenon of cyanogenesis whereby prussic acid (HCN) is liberated when plant tissue is damaged. Cyanogenesis has a very broad phylogenetic distribution. Nartey [2] reported that it occurs in well over 1000 plant species, representing some 80 families and 300 genera. Many of these cyanophoric plants play important economic and nutritional roles in tropical Africa. The plant species of Manihot, Phaseolus, Sorghum, Arachis, Pennisitum, Zea, Colacasia, Alocasia, Acacia, Bambusa, Macrosamia and Encephalartos, all of which are incorporated in human diet and animal feed, contain varying levels of cyanogenic compounds and free HCN. An adult, in regions where cassava forms the staple diet, consumes as much as 750 g of this food item daily, a quantity capable of generating 35 mg of HCN. This value is known to be approximately equal to half the lethal dose of HCN. Correlations exist between dietary cyanogen contaminants and diseases such as tropical ataxic neuropathy, goiter, cretinism and mental retardation.

(b) Herbal residues

There is evidence to suggest that various health problems, including some forms of cancer, have their origin in the presence of toxic chemicals in herbal medicines. The use of traditional remedies for several disease states is very common in African countries, and the active components of many of these concoctions are not known. Pyrrolizidine alkaloids may be ingested in contaminated grains or in herbal teas or medicines. It is possible that ingestion of pyrrolizidine alkaloids is a contributing factor to the high incidence of liver cancer in certain parts of Africa. Africa has over 300 species of Crotalaria plant, all of which examined so far contain pyrrolizidine alkaloids.

(c) Endogenous food toxins

Endogenous food toxicity is widespread indeed in tropical Africa. Some toxins present in tropical foods are hypoglycin, dioscorine, sapotoxin, cycasin, mushroom toxin, capsaicin, halogeton toxin and fluorooleic acid.

Urgent Training Needs

Apart from peculiar problems, the task of the African toxicologist in his home country are similar to those in developed countries.

Existing manpower and training institutions

It is quite noticeable that institutional frameworks for environmental toxicology in Black Africa are limited. The major constraint is acute lack of manpower.

In the best and the most advanced of African countries, certainly not more than 3% of the total number of scientists employed in any research institute (medical, agricultural or industrial) have advanced or comprehensive training in the principles and methodologies of toxicology. The bulk of the scientists and technicians in these institutes are traditionally, by training, chemists, biochemists, pathologists and microbiologists.

During a recent familiarization visit of mine to a federally owned agricultural research institute in Nigeria, the assistant director (for research and planning) indicated that only one out of every four available and established posts for toxicologists is filled. Indeed, toxicologists are hard to come by in almost all of the medical, veterinary, agricultural and industrial research institutes in Nigeria and in other West African countries for that matter. The one and only Food and Drugs Training Institute of Nigeria's Federal Ministry of Health conducts short-term training courses from time to time for civil servants who are food inspectors. These occasional workshops and seminars are held in collaboration with the Food and Agriculture Organization of the United Nations and also under the auspices of the United States Bilateral Technical Cooperation. There are no effective or clearly defined institutions which are responsible for research and training in clinical toxicology in African countries such as Nigeria, Ghana and Kenya. This, in fact, applies to virtually all countries of East and West Africa. There are, of course, a few well-trained clinical pharmacologists, neurologists and pathologists, who normally are based in the medical schools and in teaching hospitals such as those in Korle-Bu (Ghana), Nairobi (Kenya) and Ibadan (Nigeria). These medical scientists attempt occasionally to assess clinically the problems of the toxicity of locally important life-saving drugs.

Multinational drug corporations which are incorporated in most countries of tropical Africa are, by and large, marketing companies. Toxicological research and training are therefore the responsibility and function of the parent company which normally has its headquarters based in the technologically advanced and industrialized countries.

Analytical chemistry and epidemiology

There are urgent training needs for the development of scientific personnel (particularly analytical chemists and epidemiologists) who will tackle the following problems.

1. Evaluation of the total extent and of the control of cyanide poisoning attributable to foodstuffs containing cyanogenic glycosides is needed.

2. Because naturally occurring toxic substances could be of particular significance for human health in tropical Africa, these substances should be characterized and their toxic potential evaluated. More basic epidemiological data are required as well as information on food spoilage and contamination.

3. Pesticides are essential for use in agriculture and public health, but proper formulations, packaging, labelling and analytical control are needed for safe and effective use. Surveys are required to ascertain the levels of pesticide in foodstuffs, and a monitoring programme should be established.

4. While local industries, such as gari production (prepared from manioc), packaging of pesticides, and chemical industries are being developed, attention should be directed to the introduction of safe practices to protect workers from known health hazards.

5. Central to all these proposals is the communication problem concerning the dissemination of appropriate information. There is a need to inform health personnel, managers in industry, agriculturalists and the general public about the the nature and hazards of chemical substances - both naturally occurring and synthetic - and to help them develop safe practices.

Role of international agencies

To assist African countries, the following projects by international agencies, such as CEC and WHO, could facilitate several national efforts in Africa in the urgent training of scientific personnel in the areas of general and tropical toxicology:

- establish firm relationships with existing indigenous scientific institutions (or organizations) in African countries;

- contact and establish close links with national and pan-African scientific associations such as the Pan-African Environmental Mutagen Society;

- focus attention on the peculiar toxicological problems of Africa at international conferences; and

- focus the attention of international agencies on priorities among the problems of tropical toxicology. For instance, UNESCO has recently created the African Regional Network for Environmental Chemistry (ARNEC). ARNEC has two subregional networks: one for West Africa (with the Department of Chemistry, University of Ibadan, Nigeria, as its coordinating centre) and the Department of Chemistry, University of Nairobi, and the other for East and South Africa (with Kenya as the coordinating centre). A major objective of the network is "to organize workshops and seminars among participating institutions and to disseminate scientific information on research activities and the results of these by means of publications such as newsletters to help to increase general awareness of the chemistry of the environment". An expansion of this project and possible participation of other international agencies should be encouraged.

Conclusions

1. There is an acute shortage of skilled manpower who can tackle effectively the peculiar (and general) problems of toxicology in tropical Africa.

2. There is a need to promote throughout tropical Africa and the world an awareness of the significance of toxicology to the health of tropical Africans.

3. Multinational corporations based in Africa should support national and international strategies for the development of toxicologists and support staff in such ways as:

   - systematic manpower training policies;

   - recruitment policies;

   - manpower replacement policies;

   - career expectation of toxicologists (this has to be attractive for the institution or national body to attract and retain the best human resources), and

   - investment in tropical research and development.

4. The ultimate role of international agencies in assisting Africa in the urgent training of toxicologists is threefold:

   - effective coordination of activities;

   - long-term planning; and

   - increase of funding support specifically for the development and training of toxicologists.

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Annex 9

CURRENT MANPOWER AVAILABILITY FOR CHEMICAL SAFETY IN INDIA IN RELATION TO INDUSTRIAL GROWTH AND AGRICULTURAL DEVELOPMENT

by

C.R. Krishna Murti

Introduction

One of the major side effects of the development process is the introduction of large numbers of chemicals in countries which had not formerly been exposed to them. The meaning of the word "xenobiotics" cannot be more appropriate than in the situation being faced in the developing countries where the living environment and the biosphere reserves associated with it have to cope with new chemical species. While a large number of these chemicals are a boon to people eager to improve the quality of their lives, a substantial number have been recognized as potentially toxic. Their safety to the people who handle them during their production and use, to the general population exposed either voluntarily or involuntarily to them, and to the life-support ecosystems is therefore of great concern to developing countries.

Safety evaluation of chemicals is a growing, multidisciplinary enterprise, and toxicology is an important scientific component of this activity. Besides playing a major role in safety evaluation, toxicologists are also called upon to assume decision-taking or decision-guiding responsibilities by governmental agencies and industry. The public is likely to become more and more aware of the impact of chemicals and for it to influence national policies on chemicals in a meaningful way, there is need for enlightenment derived from scientific knowledge of both the beneficial and the harmful effects of certain chemicals.

This paper attempts to present an overview of the current manpower availability for chemical safety in India where developmental programmes envisaging intense industrial activity and updating of agriculture are being implemented on an unprecedented scale. Admittedly, India may not truly represent all developing countries, but the experience gained in India in the control of toxic chemicals may be relevant to the situation which many of them will soon face. It is also likely to be useful in exposing toxicologists of the developed countries to the challenge of unravelling the mode of toxicity in some special circumstances. Some aspects of research and development requirements, and hence trained toxicologists, were discussed earlier in notes outlining the relevance of the International Programme of Chemical Safety (IPCS) to India [1].

Industrialization as Part of Development Strategy

Industrialization has been accepted by many developing countries as part of the strategy to transform their tradition-bound feudal societies into economically self-sufficient welfare states. In the five-year period of 1970-1975 the growth rate of industrial activity in developing countries was substantial, although their combined contributions to the global output of manufactured goods was only 7%. This figure is expected to rise to 17.5% or even 25% [2,3]. Of the total industrial output of the developing countries in the 1970s, Latin America accounted for 50%, Asia and the Middle East together for 23%, and Africa for 13%. The forecast for 2000 AD indicates a shift, with the possibility of Asia and the Middle East outstripping Latin America. The trend towards industrialization is evident for 38 countries for which statistics are available, and at least ten of these can be ranked as industrialized according to the UNIDO criterion [4], by which the proportion of the gross domestic product generated by manufacturing industries has to be more than 30%.

The pattern of industrialization of developing countries shows wide differences, but certain common features can be recognized.

1. Industrial activity seems to concentrate in existing urban settlements and to add significantly to overcrowding, shortage of water and housing, and inadequate hygiene and sewage disposal.

2. Industrial activity has stimulated the expansion of the unorganized sector of the economy (40-70% of the urban labour force) in addition to strengthening the organized sector.

3. Industrial activity has attracted foreign investments through "transnationals", often bringing hazard-prone technology not permitted in developed countries.

4. Industrial activity has permeated into regions with low base-levels of pollution.

5. Exploitation of mineral resources and construction of huge iron and steel complexes or super thermal power stations have increased alien settlements in ecosystems, including virgin forests, which had traditionally sustained tribal communities, leading to some social tension.

Updating of Agrotechniques as Part of Development Strategy

Developing countries with a traditional agricultural base are committed to updating their agrotechniques. The four major inputs advocated for increasing agricultural productivity are improved seed, irrigation, chemical fertilizers, and pest control chemicals, and all these have varied impact on the environment [5].

Another important feature of the developing world is that, besides supporting a high density of population, most of the countries identified as food deficient are also those where the ravages of insect vector-borne epidemics remain to be controlled. Programmes to control vector-borne diseases in the public health sector and warlike measures adopted to eliminate pests in the agricultural sector, both by extensive use of chemical pesticides, operate in absolute isolation of each other [6,7].

Today, the indiscriminate use of pesticides is recognized as one of the top ten chemical pollution problems of global concern [8]. Although many developing countries have legislation to control the use of insecticides, the fact remains that massive agricultural use of chlorinated pesticides and organophosphates for vector control has resulted in the emergence of insecticide resistance in disease vectors [9,10] and extensive contamination of food and crops with residues of nonbiodegradable pesticides [6].

The rapidly increasing use of chemical fertilizers has also resulted in several ecotoxicological problems. The most prominent among these are the effects of runoff, leading to eutrophication of aquifers and resulting in overgrowth of weeds and the consequent compulsion to use chemicals to control them.

Chemical Pollution versus Development

Most of the developmental activities undertaken by the developing countries have a potential to produce chemical pollution with varying degrees of human health effects as well as impact on the life-supporting ecosystems. Such pollution is almost unavoidable, and developing countries have to learn to cope with it.

But pollution can be controlled. The requisite technology and expertise have therefore to be developed by innovative research and manpower training programmes [11,12]. The impact of chemical pollution on human health, with special reference to developing countries, has been dealt with elsewhere [13]. For discussion here, suffice it to say that the problems posed by chemical pollution have begun to surface and they cannot be ignored any longer, however overwhelming their magnitude might be.

The chemical industry

The growth of the chemical industry is a good index of development as well as an indicator of the potential for chemical pollution. In India, the chemical industry registered a very significant growth rate in the period 1950-1980. On one side there are the high-volume basic inorganics, including processed minerals, alkalines and acids and various metals used in industry, construction and defence. On the other side, there are the low-volume, capital-intensive and obsolescence-prone fine chemicals and pharmaceuticals and pest control chemicals. In brief, the contribution of the chemical industry to the gross national product is about 7% - a figure comparable to that of the United States although the turnover and the value is only one tenth or fifteenth of the corresponding figure for the latter.

The development of the chemical industry in India in the context of toxic chemical control has been dealt with more extensively in an earlier paper [12]. With the rapid growth of such industries as plastic and synthetic fibres, pharmaceuticals including units producing veterinary medicines, textile dying and printing, leather-tanning and food-processing, estimates for organic intermediates have been substantially upscaled in recent years. This suggests the necessity to update earlier estimates of pollution loads as well.

Legislation for Toxic Chemical Control

Lok Sabha, the Indian Parliament, adopted in 1981 a comprehensive Air Pollution Act which went into the Statute Book in early 1982. The regulatory provisions under the Act have been worked out, and the Central Board for Prevention and Control of Water Pollution has been vested with the responsibility of implementing the Air Pollution Act in addition to the provisions under the Water Pollution Prevention and Control Act. Besides this national agency, each state has constituted its own pollution control boards.

Under a directive from the Cabinet Secretariat, the Scientific Advisory Committee to the Cabinet has initiated steps to regulate the entry, manufacture and disposal of toxic chemicals and hazardous microorganisms. A working group constituted by the Department of Environment at the request of the Government has prepared a priority list of chemicals for which threshold limit values are to be established to protect industrial workers.

Laws which already exist in relation to hazardous chemicals are the Drugs and Cosmetics Act, the Food Adulteration Prevention and Control Act, the Insecticide Act, and the Factory Act. The directives to the above acts have included requirements for quality control, inspection and disposal of toxic chemicals. Thus, the Water Pollution Prevention Act envisages setting up a battery of monitoring stations along the major rivers, lakes and tanks from which water is drawn for drinking purposes. The quality of water has to be tested and certified to conform to water quality standards set up by the Indian Standards Organization or other statutory bodies entrusted with the task of laying down standards. Directive III of the Insecticide Act describes all the tests to be conducted on a pesticide before a license can be issued for its manufacture and distribution. The Drugs and Cosmetics Act enjoins upon manufacturers the responsibility of submitting complete reports after testing, at various phases, the biological properties of the chemical proposed to be used for therapeutic purposes. Under the Food Products Regulation procedures and the "AGMARK" system, it is compulsory to "stamp" processed food products after appropriate sampling and testing.

India is a sustaining participant of the Codex Alimentarius programme set up jointly by FAO and WHO and the Food Contaminant Review and Residue Panels of FAO. With the possibility of extensive contamination by mycotoxins due to faulty storage methods in the postharvest phase, or residues of pesticides and seed treatment chemicals used in preharvest technology, there has been growing concern about the assessment of health effects and the need for prevention. Admissable daily intakes for many such pollutants are being established to meet the special requirements of vulnerable populations.

Manpower Requirements for Toxic Chemical Control in India

The following activities will require an ever-increasing number of trained toxicologists:

- construction of an inventory of toxic chemicals in relation to import, production and use as well as a national register for potentially toxic chemicals;

- implementing regulatory procedures to be completed for licensing the import, production, formulation, use and disposal of toxic chemicals;

- technological innovations to adapt existing methods for prevention and control of chemical pollution;

- research and development leading to newer technologies for prevention and control of chemical pollution;
- preparation of guideline documents and criteria for control of chemicals to which humans are exposed, both voluntarily and involuntarily; and
- assessment of the health effects of chemical pollutants of air, water and food, and furnishing advice based on scientific knowledge of the safety of chemicals to the public, the government, and industrial and agricultural entrepreneurs.

There are few institutions or agencies in India which undertake the development of manpower for the above activities. By and large the available manpower has emerged from the transformation of chemists, biochemists, pharmacologists, veterinary pathologists, and public health engineers confronted with the problems. The postgraduate diploma in public health and industrial health offered by the All-India Institute of Public Health and Hygiene, or postgraduate departments of social and preventive medicine of some medical colleges or the integrated Master's Degree in Environmental Sciences offered by some universities do include toxicology in their syllabi. Madras University has, however, begun on an experimental basis a two-year Master of Science in Industrial and Environmental Toxicology, drawing the faculty members from the Post-Graduate Institute of Basic Medical Sciences, the Veterinary College, the Forensic Science Laboratory, the Centre for Environmental Studies, and other institutions in the city.

Estimation of need

A tentative estimate has been made of trained manpower at the level of Master of Science to undertake various tasks in the hierarchy of the management of toxic chemicals. Since any university course has to generate an employment potential to gain credibility, the programme presently offered by Madras University is oriented towards research and development in academic institutions and industry. The number of technicians needed at the Bachelor of Science level of toxicology for routine jobs of inspection, analysis in the field, and monitoring stations may run to several thousand by the end of this century. A proportionate number of scientists at the Master of Science level will be required for undertaking higher tasks and responsibilities.

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Annex 10

WORKING PAPERS AND BACKGROUND MATERIAL

Working Papers

CEC/V/E/2/LUX/83/68/6 WHO/ICP/RCE 903(25)/6	Review and analysis of training programmes in toxicology and of toxicology courses in selected European countries, summary, by J. Indulski (English)(see background paper)
CEC/V/E/2/LUX/83/68/7 WHO/ICP/RCE 903(25)/7	Review and analysis of training programmes in toxicology and of toxicology courses in Member States of the European Community, by R. Lauwerys (English)
CEC/V/E/2/LUX/83/68/8 WHO/ICP/RCE 903(25)/8	Survey of toxicology programmes and manpower in environmental toxicology in the USA, by C. Schonwalder (English) (see background paper)
CEC/V/E/2/LUX/83/68/9 WHO/ICP/RCE 903(25)/9	Toxicology in medical training in Japan, by K. Tsuchiya (English)
CEC/V/E/2/LUX/83/68/10 WHO/ICP/RCE 903(25)/10	Toxicology and chemical safety training of workers' representatives representatives in health and safety committees, by J. Bustamente, P. Westerholm, R. Owen & E. Buringh (English, French)
CEC/V/E/2/LUX/83/68/11 WHO/ICP/RCE 903(25)/11	Survey of the professional fate of recent graduates in toxicology, by R. Lauwerys (English)
CEC/V/E/2/LUX/83/68/12 WHO/ICP/RCE 903(25)/12	Findings of surveys in Egypt, Netherlands and Poland of existing manpower needs in toxicology, by K. W. Jager & S. Tarkowski (English)
CEC/V/E/2/LUX/83/68/13 WHO/ICP/RCE 903(25)/13	Changing needs for toxicologists in Italy resulting from European Community legislation, by P. Preziosi, A. Sampaolo & V. Silano (English)
CEC/V/E/2/LUX/83/68/14 WHO/ICP/RCE 903(25)/14	Specific toxicological problems in tropical African countries and training needs, by E. A. Bababunmi (English)

CEC/V/E/2/LUX/83/68/15 WHO/ICP/RCE 903(25)/15	Current manpower availablility for chemical safety in India in relation to industrial growth and agricultural development, by C. R. Krishna Murti (English)
CEC/V/E/2/LUX/83/68/16 WHO/ICP/RCE 903(25)/16	Requirements for training in clinical toxicology, as experienced by poison control centres, and the role which the latter may play in training, by M. Govaerts & N. Lery (English, French)
CEC/V/E/2/LUX/83/68/17 WHO/ICP/RCE 903(25)/17	The training of poison control centre staff in medical clinical toxicology: a view from the United States, by F. & F. Oehme (English)
CEC/V/E/2/LUX/83/68/18 WHO/ICP/RCE 903(25)/18	A career in toxicology, by K. Lewis (English)
CEC/V/E/2/LUX/83/68/19 WHO/ICP/RCE 903(25)/19	Assessment of needs and demand for trained toxicologists, by S. Kassel (English)
CEC/V/E/2/LUX/83/68/20 WHO/ICP/RCE 903(25)/20	Training requirements in toxicology in Bulgaria, by M. Spassovski (English, German)
CEC/V/E/2/LUX/83/68/21 WHO/ICP/RCE 903(25)/21	Training in toxicology for decision-makers and administrators, by J. O. Jarvisalo & J. H. Rantenen (English)
CEC/V/E/2/LUX/83/68/22 WHO/ICP/RCE 903(25)/22	Needs and criteria for recognition of qualifications in toxicology, by J. K. Piotrowski (English)
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There is probably no one in the world who is not affected, directly or indirectly, by the use of chemicals. If potentially hazardous chemicals are to be controlled in such a way as to protect human health while ensuring that the many benefits derived from the use of a wide range of chemical products are maintained, it is necessary to train adequate numbers of personnel in the necessary multidisciplinary skills. The long-range goal is to ensure that everyone – homemaker, factory worker, politician, medical doctor – receives information on toxicology and chemical safety appropriate and relevant to his/her work and life style.

The more immediate goal, that of training the various types of toxicologists needed, ranks high in the priority list of activities of the international organizations involved in the convening of this workshop.

To fulfil its policies, the European Community requires the mutual recognition of toxicological testing results and a uniform approach in health risk evaluations of chemicals in its 10 Member States. In this regard, the contribution of the toxicologist is essential. Development of manpower in toxicology and training curricula form one of the elements of the European Community's proposal for an action programme on toxicology for health protection now under consideration and of its medical research programme.

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