

EUROTOX's view regarding the ROLE and TRAINING of certified European registered toxicologists (ERT)

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Abstract

Toxicology's evolution from a traditional science of poisons to an extensive discipline has introduced complications and ambiguity in the definition of a scientific area of qualification and training. The need to define toxicology and to identify and standardise the roles and the profiles of practising toxicologists in order to certify the professional credibility of toxicologists has been recognised by national registries and certifying boards across the USA, Europe and Asia.

Established in 1994, the EUROTOX Model (www.eurotox.com) has promoted the harmonisation of educational differences, practical experiences and common visions and requirements for the accreditation of toxicologists in Europe. Such harmonisation should be seen as an indispensable step towards the mutual recognition of registered toxicologists at a global level and to promote the development of shared educational and training programmes on a regional basis.

A description of typical professional roles for toxicologists with required educational background, training and experience are presented in this paper and serve as the basis for the ERT templates, a self-evaluation tool for individuals seeking ERT recognition. © 2006 Elsevier Ireland Ltd. All rights reserved.

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1. Introduction

Efforts to ensure the safe use of chemicals are presently the main concern of toxicology. Toxicology is a scientific area that has profoundly changed its fields of knowledge and application to take account of scientific progress, and to meet the needs of society. In many respects the rapid development of the chemical and pharmaceutical industries during the 20th century provided a giant step in the progress and quality of life, but not without consequences. Today, there is an increase

of awareness of the negative impact of chemicals (synthetic and natural-origin) to human and animal health, as well as, the environment. As a result, toxicology has evolved from the traditional science of poisons into an extensive discipline that seeks to identify, estimate and control the benefits and adverse effects of chemicals in order to preserve the health and the environment from undesired effects. This conceptual evolution has led toxicology to occupy a key role in the complex scenario of public safety and to obtain an important function in the decision-making process where science has to interact with, and occasionally confront technical, political and societal visions.

The tasks toxicology has been called to accomplish have major implications with regards to how its scientific scope has evolved and is evolving. Toxicology

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Table 1
Status of the ERT register (2006)

Societies in EUROTOX	30
Societies with a register	12
Registered toxicologists	1178
Registered toxicologists vs. EUROTOX members	7000 (16.8%)
Registered toxicologists vs. societies with a register	5127 (22.9%)

is continuously adapting its field of knowledge and application in response to new issues and concerns, not only through the recognition of new disciplines or professional entities, but often also through the creation of alliances with existing scientific authorities. As a result, toxicology has become a lively area of debate with an engaging combination of eclectic and specialist professionals. In addition, the several branches and connections in different disciplines and the numerous alliances with traditional disciplines gathered under the umbrella of toxicology, have introduced some complication and ambiguity. Of particular concern is the definition of a scientific area of qualification and training, since the subject has undetermined and shifting borders.

In this scenario, the need to define toxicology as a diverse science and to identify and standardise the roles and the profiles of practising toxicologists has been widely recognised. This situation has led to a desire to harmonise and possibly certify the professional credibility of toxicologists through the establishment of national registries and certifying boards across the USA, Europe and Asia.

National registries were promoted in Europe during the 1980s and 1990s, whose admittance criteria embraced and harmonised the educational differences, practical experiences and common visions and requirements according to the EUROTOX¹ Model, which was formulated in 1994 by merging three founding registries.

The European register of toxicologists has been in existence for over 10 years and is a listing of individuals accepted by each registry and compliant with the original EUROTOX Model (<http://www.eurotox.com>). As shown in Table 1, today nearly 1200 toxicologists are currently recognised as European registered toxicologist (ERT). Table 2 shows the distribution of ERT registration by country.

¹ Aiming to foster toxicology, both scientifically and educationally throughout Europe, EUROTOX is the Federation of European Toxicologist and European Societies of Toxicology which together accounts for approximately 7000 members from around Europe. In addition, it counts nearly 500 individual members from more than 50 countries.

Table 2
ERT registration by country (2006)

Austria	17
The Netherlands	274
Finland	43
France	131
Germany	152
Ireland	5
Italy	29
Norway	62
Poland	In process
Spain	36
Switzerland	145
Turkey	In process
UK	281

Even though a high degree of harmonisation presently exists, significant work remains to further align the national registries and reviewing panels to identify as much as possible, the requirements and characteristics for the accreditation of toxicologists in Europe. Such harmonisation should be seen as an indispensable step towards the mutual recognition of registered toxicologists at a global level and to promote the development of shared educational and training programmes on a regional basis.

A review of the required educational background, needed training and experience, and the description of typical professional roles for toxicologists are presented in this paper.

2. Educational background and training requirements

In contrast to other professional roles the educational basis of a toxicologist can start from a heterogeneous group of scientific disciplines. This heterogeneity complicates the definition of the basic scientific background, and the theoretical and practical training requirements. Nevertheless, this is an indispensable step in the description of the practising toxicologist in Europe. The ERT Model requires a relevant scientific educational background to a higher level (graduate) combined with extensive and extended (at least 5 years) of supervised training in the main disciplines of toxicology in recognised centres. Consequently, the basic academic requirements are a common denominator used by national registries affiliated to EUROTOX during the evaluation of applicants seeking recognition.

The basic educational background requires a university degree (honours, 3 years) in a biomedical subject such as toxicology, biology, medicine, veteri-

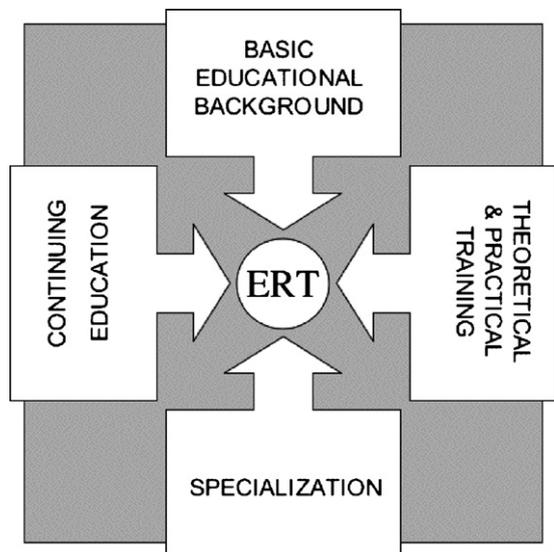


Fig. 1. Summary of ERT requirements.

nary or pharmaceutical sciences. Other disciplines such as chemistry, chemical engineering or agronomy are also mentioned in some national schemes. The ERT approach is to consider as appropriate a university degree in disciplines with a relevant link to toxicology, including biomedical sciences, biology, pharmaceutical sciences, medicine, veterinary, food and environmental sciences, pharmacology, toxicology chemistry and agronomy. From this heterogeneous intake, however, great importance is attached to the post-graduate training, which must focus on topics specifically related to toxicology. Specific topics that must be addressed to achieve adequate theoretical and practical training to obtain the ERT recognition are presented below and summarised in Fig. 1.

- The foundation subjects including introduction to analytical, mechanistic and organ-specific toxicology, experiment design, biometry and statistics.
- Animal and human studies; *in vitro* cytological studies; understanding of carcinogenesis; current ecotoxicological concerns; principles of biomonitoring; epidemiology; genetic and reproductive toxicology; metabolism and kinetics of xenobiotics; molecular and mechanistic toxicology approaches; clinical toxicology; occupational toxicology; sensitisation and allergy; immuno and radiation toxicology; clinical, gross and histo-pathology.
- Regulatory toxicology and information technology.
- Risk assessment, techniques in the field, case studies and outcomes.

Continuing education in toxicology, considered a pre requisite necessary for registration and re-registration purposes, can be achieved through the following activities:

- Attendance of meetings, symposia, and refresher courses;
- Attendance of short courses, specialty meetings, workshops, and seminars;
- Regular consultation of texts and literature sources;
- Performance of risk assessment or regulatory activity.

In addition to the proposed theoretical training, the achievement of appropriate practical training and experience is seen as indispensable. It is recognised that the way that such training is achieved can vary depending on the specific activity of the candidate. Toxicologists working in the field of research will most likely acquire an intensive experience being based in a single department, while individuals working in regulatory bodies or private institutions are expected to acquire a general training. Despite these differences, the acquisition of practical skills in different subjects is expected for a minimum of 5 years. Within this period, a practical awareness concerning the following topics is expected to have been achieved, with in-depth knowledge in at least two of them:

- Post-mortem methods and gross pathology; microscopic identification of the major organs; microscopic recognition of the major pathological processes; foetal and neonatal examination for malformations.
- Making observations and records of signs in animals and humans; *in vivo* monitoring; biomonitoring; biomarkers.
- Basic principles of cell culture microbiological methods, including applied methodology such as the Ames Test; recognition of basic chromosomal aberrations; blood film analysis; subcellular fractionation techniques.
- Standard analytical methods: e.g. spectrophotometry, gas chromatography, mass spectrometry, and high performance liquid chromatography.
- Analytical techniques: protein determination, enzyme activity, Western blotting, and radiochemistry.
- Data retrieval, data derivation computer assisted technologies, data bases, data banks, and data acquisition.
- Determination of pharmacokinetic parameters.

3. Professional roles

In order to qualify for the ERT title, candidates have to demonstrate their active professional participation in

the field of toxicology. Despite the difficulties of defining the general role of a toxicologist because of the existence of different scientific backgrounds and broad areas of application, toxicologists can be divided, according to their field of activity, as follows:

- Education;
- Basic and applied research;
- Risk assessment;
- Regulation.

Depending on their scientific interests and the area of application, toxicologists can be regarded as occupying their different professional roles within four major fields:

- Academia (education, basic research);
- Industry (applied research, risk assessment);
- Advisory (ecotoxicology, clinical toxicology, forensic toxicology);
- Regulation.

3.1. Academia

Universities or other public non-governmental institutions employ a substantial number of toxicologists. In the academic institutions, toxicologists are involved in two main activities: basic research and education. As in other scientific disciplines involved in the field of life sciences, basic research plays a fundamental role in the acquisition of knowledge and in the development of new experimental techniques. Among the research activities, the following are listed:

- Study of the mechanism of action of toxicants in biological systems;
- Understanding the biochemical and physiological alterations caused by a toxic event;
- Development of analytical techniques and experimental models, including in the field of reduction, refinement and replacement of the use of animals.

In addition to research, activities such as teaching and training represent important tasks of toxicologists in the academic world. Often, the recognised expertise and specialisation allow academic toxicologists to be called upon as advisors by private institutions or governmental agencies.

3.2. Industry

The chemical industry is involved in the production of a large array of goods such as detergents, medicines,

food additives and cosmetics that frequently come in contact with humans. The role of the industrial toxicologists is to contribute to the development of safe products and to evaluate the acceptability of the risk when a new product has to be introduced in the market. Industrial toxicologists deal with every aspect that concerns the hazard identification and the risk evaluation of chemical products, intermediates and possible contaminants. Specifically, they are responsible for:

- The collection and the interpretation of toxicological information for the hazard evaluation of chemicals, by means of bibliographical searches or the performance of toxicological testing;
- The assessment of risk for workers, the general population and environments exposed to chemicals;
- The scientific support needed to register new substances under national and international schemes.

Depending on the size of the company, the commercial toxicologist may be more or less specialised. For instance, large companies typically employ a team of industrial toxicologists specialised in different topics and have internal toxicology laboratories where experimental work is carried out both for basic and applied research, while medium or small companies employ fewer toxicologists whose task is to develop a general background since these companies typically outsource the experimental activities to toxicologists in contract laboratories. Depending on the degree of specialisation, industrial toxicologists must develop knowledge in multiple scientific disciplines and possess strong communication skills to interact both internally and externally with experts such as engineers, chemists, occupational physicians, regulatory bodies and academic experts, many of whom have very different backgrounds.

3.3. Advisory

3.3.1. Ecotoxicology

By analogy with classical (human-orientated) toxicology, ecotoxicology is presently perceived as a self-sufficient scientific discipline orientated to health and survival of the world and its associated systems (i.e. marine biosphere, etc.). This subject has rapidly acquired importance as it responds to society's concerns about the quality and the protection of the environment, as we know it. Ecotoxicologists are scientists specialised in the study of toxic effects of chemicals on the environment. Professional spheres of ecotoxicologists are mainly associated to research centres involved in the protection of the environment (universities or private or

public institutions). In addition, large companies such as chemical, agro-chemical or pharmaceutical companies, particularly concerned with environmental matters, employ ecotoxicologists for activities of monitoring and environmental risk assessment. Additional to the study of the adverse effects of chemicals on organisms, and due to the complexity of the ecosystems, ecotoxicologists are involved in a series of different activities, which may include:

- Study of the environmental fate of pollutants and their possible bioaccumulation in the food chain;
- Chemical, biological, microbiological and toxicological analysis for quality control;
- Analytical monitoring of the ecosystems (flora, fauna, environmental compartments);
- Study of sub-lethal effects occurring in flora and fauna following long-term exposure to pollutants (changes in populations, genetic changes, physiological adaptations);
- Development of biotechnologies for remediation applications;
- Development of theoretical predictive models for the description of environmental fate of pollutants.

Depending on the specific research field, the scientific background of ecotoxicologists has to cover a large spectrum of disciplines ranging from biology, ecology and microbiology to environmental chemistry, biochemistry and analytical chemistry.

3.3.2. Clinical toxicology

Clinical toxicologists are physicians specialised in the knowledge of adverse effects to humans caused by chemicals (typically medicines and abusive substances) in the treatment of poisoning from such chemicals. The prevention and the management of emergency cases where a poisoning event has occurred are the main activity and task of the clinical toxicologist. Clinical toxicologists are generally employed in specialised structures like hospitals and anti-poison centres where they undertake:

- Identification of the cause–effect relationship in cases of poisoning;
- Treatment of patients accidentally or voluntarily poisoned, identifying the cause and applying the adequate therapy;
- Interpretation of the analytical results obtained from poisoned subjects;
- Exchange of information on the management of poisoned patients via a poison information service;

- Assessment and development of new methodologies, therapies for treatment or new methods of diagnosis for chemical poisoning;
- Follow-up and surveillance of cases for the identification and the evaluation of possible sequels.

Today clinical toxicologists are particularly involved in the evaluation of possible effects of chemicals in the workplace and the environment, in particular in cases of pre-existing pathologies that could complicate or confound the correlation with the exposure to the chemicals themselves.

3.3.3. Forensic toxicology

Forensic toxicologists deal mainly with medico-legal issues where the use of chemicals, drugs or poisons are implicated. The forensic toxicologist is responsible for the isolation, identification and quantification of foreign substances in biological matrices in the context of legal cases where a fatality or damage is related to the assumption of chemical substances themselves. These cases may range from simple determination of abusive substances to cases of accidents attributable to involuntary or deliberate use of toxic substances or to undesired side effects of drugs. A deep knowledge of analytical chemistry techniques is thus a fundamental qualification expected for forensic toxicologists.

Besides the quantitative determination of foreign chemicals, the forensic toxicologist is nowadays called to answer specific questions, like when and how the chemicals entered the body or whether and to what extent the clinical picture could be related to the measured levels. In order to do this, in addition to training and experience in analytical chemistry, biochemistry, physiology, pharmacology and pathology knowledge is necessary.

3.4. Regulation

Regulatory toxicology is the branch of toxicology that provides scientific support to national and international regulatory bodies responsible for the protection of human health and the environment. Before new chemicals are released to the public sector they must be safely screened for potentially harmful effects. Industrial toxicologists, using model systems that provide predictions of what might happen in people, do this screening. Appropriate animal toxicity testing is a mandatory legal requirement for many chemical categories to provide protection to the public and needed handling precautions, for instance, providing doctors with important information on how to administer new medicines.

Table 3
Summary of the ERT templates

Template	Current position	Degree	Years of experience	Number of publications or reports	Eligible for
Cristina	Student	MS, BS	3–4	3–5	National register
Jan	Researcher	MS, PhD	5–10	10–20	ERT
Hilary	Expert teacher advisor	PhD	10–20	40–50	ERT
Theophrastus	Risk assessor	PhD	≥20	≥100	ERT

Regulatory toxicologists collect, process and evaluate experimental toxicology and epidemiology data for submission to Government employed regulatory toxicologists in order to ensure that chemical industries have fulfilled all the regulatory requirements. In addition, they advise the regulatory bodies at various levels on decision-making processes on issues concerning health and environmental protection. Government agency regulators, who are also versed in toxicology, must review this data and advise their respective agencies on the risk and benefits of the release of these chemicals to the general population.

4. The ERT templates

Developed by EUROTOX, the purpose of these templates is to further promote the harmonisation criteria and procedures of the national registration in Europe and to serve as a self-evaluation tool for individuals seeking ERT recognition. The following four hypothetical professional profiles, summarised in Table 3, are proposed as examples of individuals found at various levels of the criteria for ERT recognition. They have been chosen to ideally represent various phases of training and experience, ranging from an entry-level position to one describing a well-established professional career in toxicology.

4.1. Template 1: Cristina. A student completing her studies and starting a career in toxicology

- You have received an MSc in a relevant discipline (biomedical sciences, biology, pharmaceutical sciences, medicine, veterinary, food and environmental sciences, pharmacology, toxicology chemistry and agronomy).
- You are in the process of doing laboratory experiments for a thesis in a toxicology-related project leading to a PhD degree, either in University or in other public or private institutions.
- You are attending/have attended PhD courses in the following subjects: general toxicology, cellular and

molecular toxicology, pathobiology, organ toxicity, genetic toxicology, Laboratory animal science, environmental toxicology, risk assessment, epidemiology, legal and regulatory toxicology. Furthermore, you chose two out of the following courses: immunotoxicology, reproductive toxicology, neurotoxicology, occupational toxicology, clinical and forensic toxicology, food toxicology.

- You have determined your programme of courses in consultation with your PhD supervisor and with the Registration Authority of your National Society of Toxicology.
- When you will have successfully defended your PhD Thesis, concluded your research project and written three to five publications in peer reviewed journals (for certain countries) you will receive the title of national registered toxicologist from your local society. This is the first step to become an ERT!

4.2. Template 2: Jan. Presently active in an early career and preparing as a self-sustaining toxicologist

- You are in a biomedical or environmental science and you have an interest in human health and welfare or in environmental integrity. You may have obtained a PhD in your chosen field.
- For the last 5–10 years you have been involved in practical studies working on aspects of chemical interactions with biological systems, either in academia, governmental or private institutions (for instance performing toxicological studies in the pharmaceutical industry, or working in information technology, in a hospital or in other analytically based laboratories).
- You are presently active in your field and during the last few years you have written testing protocols or study reports, have carried out data analysis on experimental results or have otherwise interpreted findings.
- You have contributed to several (at least 10–20, depending on the complexity) publications or confidential (proprietary) technical reports, suitable for submission to regulatory agencies. You may have pub-

lications (ideally five or more) in refereed scientific journals.

- You are continuing your education by attending national or international meetings, symposia or training courses whenever possible.
- You are prepared to take a higher qualification (given the opportunity) at a convenient location and in your chosen language (including Spanish, English, Japanese, Chinese).

4.3. *Template 3: Hilary. A self-sustaining toxicologist in her mid career ready for international recognition*

- You have a PhD or equivalent experience in toxicology, pharmacology, biochemistry or any related discipline. During the last 10–15 years and you have been working as an experimental toxicologist in aspects related to human health and welfare or for environmental integrity.
- You may have completed a post-doctoral training at a major University department, governmental or private laboratory associated with your original or related degree.
- You are presently active in your field and for the past few years you have been in charge of research programmes, writing experimental design, doing data analysis on results and interpreting findings and their implications to human, animal and environmental issues.
- In addition to signing study reports, publications and reviews, you may be involved in training or as a toxicology mentor to less experienced colleagues and graduate students.
- You may be designated assistant professor, lecturer or scientific officer.
- You have several publications (e.g. over 50), perhaps 10–20 in refereed Journals and/or you have a substantial number of confidential study reports (50 or more, on varied topics) for which you were the main author.
- You apply for and receive substantial grants for research, or are responsible for significant resources and are involved in making decisions about research projects for your employer.
- You have specific fields of interest pertaining to toxicology in which you undertake basic and/or applied research.
- You may regularly or occasionally teach in the field of toxicology.
- You regularly partake of opportunities for continuing professional development.

- You are presently qualified to take a higher qualification in toxicology.

4.4. *Template 4: Theophrastus Paracelsus. In a well-established, higher-ranking career and governing opinion and resources in the field of toxicology*

- You are a senior person, spending significant time in aspects of risk assessment, and perhaps in regulatory advisory roles within your organisation/country/abroad.
- You started out 20–25 years ago and may have completed a PhD in addition to your degree.
- Currently you are professor of toxicology or of similar status at a major university or you hold a high responsibility as chief officer in the government or in private institutions.
- You and your team have published extensively in clearly defined fields pertaining to toxicology.
- Whether in Academia or in a Government agency, typically you may have 125 papers in refereed Journals, two or more textbooks; also perhaps you are in an editorial role regarding a major textbook, or serve as editor for widely referenced journals on toxicology.
- You have written or signed off many (at least 100) multidisciplinary study reports in the industry.
- You may be the recipient of national and international awards for excellence in research and/or teaching, or have contributed at this level to the future of toxicology.
- You serve on national or international governmental advisory boards for agencies regulating toxic substances, and food safety issues.
- Your main role is risk assessment and resource allocation.
- You do not have or do not need to take a certification examination, although you can demonstrate your continuing professional development.

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improve the manuscript. Ellaine is a freelance professional with extensive experience in the area of marketing communication, advertising and international account management. She has a BS in advertising from The University of Texas in Austin and a specialisation in international business and trade from ESF.

John Fowler (PhD, ERT) is an independent veterinary pathologist specialising in toxicology. His main involvement is confidential reviews of newly derived and bibliographic data on a daily basis, whether pharmacology, toxicology or pathology. Present research interests include safety aspects of chemicals as candidate pharmaceuticals, chemicals of natural-origin, aspects of ecotoxicological, environmental and animal

well being. Active in training, recognition, registration and accreditation of toxicological scientists and in the Corporate Membership Programme of EUROTOX.

Corrado L. Galli (PhD, ERT) is currently a full professor of toxicology and director of the Laboratory of Toxicology at The University of Milan in Italy. His major research area includes exposure to low levels of chemicals in combination with other chemicals and environmental factors (i.e. food additives, food allergens, pesticides, contaminants). Prof. Galli is author of more than 200 publications and serves in several Italian and EU scientific committees and professional organisations, including EUROTOX as president of the Executive Committee (2006–2008).