EUROTOX
Federation of European Toxicologists & European Societies of Toxicology

The EUROPEAN REGISTERED TOXICOLOGIST (ERT)
Guidelines for Registration

Introduction

The present **Guidelines for Registration** is an update of the "Expectations of a EUROPEAN REGISTERED TOXICOLOGIST" first published by EUROTOX in 1995. This first description of common requirements and regulations for registration of toxicologists in Europe was derived by harmonization of three founder schemes (Germany, Netherlands, United Kingdom, 1994). The "**Guidelines for Registration**" was written by the Subcommittees for Education and Registration and accommodate scientific and conceptual progress in Toxicology in the years passed and experience made with the existing registration schemes.

The European Registration of Toxicologists is a service of EUROTOX for Toxicology and for individual toxicologists who excel by high standards of education, skills, experience, and professional standing. These toxicologists, upon application, should be certificated as EUROPEAN REGISTERED TOXICOLOGIST (ERT). In principle, in a first step, National Registration boards in Europe evaluate applications of candidates according to a consensual process and admit successful applicants to the national register. In the second step, upon request, EUROTOX will certificate these individuals as ERT without further evaluation. Obviously, the proper function of this system depends on a high degree of harmonization of standards among the registering national boards. The current update from "Expectations" to Guidelines is part of EUROTOX' endeavors to advance harmonization of the national registration procedures, including efforts to provide appropriate training opportunities to all ERT candidates.

In the **Guidelines for Registration** scientific progress in Toxicology is reflected by updates in sections A and B. Furthermore, to cope with the increasing need for specialization in toxicology, nine special topics are identified in section A, two of which are elective for ERT candidates, in addition to the core of 13 obligatory topics areas. Sections C and D have been expanded in order to increase transparency of Registration and Re-Registration procedures. Finally, tasks and functions of National and EUROTOX Registering bodies are described in sections E and F, with a focus on harmonization of rules and requirements. Obviously, these guidelines constitute a framework. For several items, operational and legal details have to be defined and laid down in accompanying documents by national bodies and/or EUROTOX.

A draft of the Guidelines was sent for discussion to National Societies and Registering Bodies in EUROTOX early in 2011. Comments obtained were taken into account by a number of modifications of the text, resulting in the present version. This was approved by the EUROTOX Executive Committee and ratified by the Business Council during the Annual EUROTOX Congress in Paris August 28-31, 2011.

In the future, the **Guidelines for Registration** will be updated at regular intervals (approx. every 3 years) according to the development of science and educational as well as harmonization needs. This will be done by EUROTOX Subcommittees for Education and Registration in close collaboration and consensus with national societies / registries and ERT course directors. Significant changes are subject to approval by the Executive Committee.

A. Theoretical curriculum

Purpose
Theoretical training in toxicology, with associated practical working to re-enforce concepts, is essential. Such training can be provided on a modular basis and should embrace at least the topics that are defined below.

Topics
A candidate for registration will have undertaken theoretical training in 15 of the following topics areas A1 – A22, of which A1 – A13 and two elective modules out of A14 – A22 are obligatory:

A 0. Introduction: History, Tasks and Scope of Toxicology
A 1. Animal Science incl. Ethical Rules and 3 R Principle
A 2. Experiment Design, Biometry and Statistics
A 3. Cellular Toxicology and Molecular Toxicology
A 4. Metabolism and Kinetics of Xenobiotics
A 5. Organ Toxicology and Toxicological Pathology
A 6. General Toxicology, Risk Assessment
A 7. Environmental Toxicology, Exposure Assessment and Biomonitoring
A 8. Epidemiology, Toxicogenetics
A 9. Clinical, Occupational and Forensic Toxicology
A10. Mutagenesis and Carcinogenesis
A11. Reproductive and Developmental Toxicology
A12. Immunotoxicology
A13. Regulatory Toxicology

In addition, two modules out of the following are mandatory:
A14. Drug Safety Assessment: Non-clinical, Clinical, Post-Approval Studies, Safety Pharmacology, Expert Report, Drug Regulation
A15. Safety Assessment of Food, Cosmetics and Other Consumer Products, Regulations
A16. Ecotoxicology
A17. Risk Analysis: Assessment, Communication, and Management of Risk
A18. Neurotoxicology and Behavioural Toxicology
A19. Nanotoxicology
A20. Alternative Testing Methods and their Use in the Regulatory Framework
A21. Computational Toxicology
A22. Mechanistic Toxicology and "Omics" in Toxicology

Topics A0 – A13 and some of the elective topics are essentially covered in the existing ERT courses, although details of contents and sequence may show some variation.

Topics may be presented as modules consisting of lectures, site visits, demonstrations, and exercises. Case studies by individual participants are particularly encouraged to practise risk assessment and classification of chemicals. Distant teaching and learning will be used where feasible. All modules are completed by examinations.

Current Theoretical Curricula should be notified to EUROTOX (Subcommittees Education and Registration).
Additional elective modules can be offered upon prior notification of EUROTOX (Subcommittees Education and Registration).

Time needed
Each module will probably involve at least 3-5 days, in some cases 10 days or more of contact time, except A0 which may require only a few hours.

If studied from the beginning, with no credit given for content of previous degrees, then about 15-26 weeks of 30 hr per week contact time should be allocated to undertake the theoretical basis needed for eventual registration.

Credits
Candidates for registration will be expected to present credits in all 15 topics defined above.

It is possible that some parts of this syllabus can be certificated if they have been covered in a basic degree (BS) or a postgraduate degree (MSc, Ph.D.)

In principle, credits may be obtained from modules based in more than one country.

Follow-up
It is recommended that course directors and/or national registries monitor the success of ERT courses by follow-up of participants. Indicators may be grades reached at examinations, ERT registration (when? where?), positions obtained, special achievements, etc.

B. Practical curriculum

Practical experience and training must be related to Toxicology and should be based on laboratory, clinical, computer-assisted or regulatory work in one of the areas listed under A (except A0). In some cases toxicologists will undertake research and be based in a single department / under a single named mentor: candidates for registration are advised to ensure at the outset that their intended course of study is seen, by a senior ERT or member of the National Register, as appropriate and applicable to the eventual target of Registration.

Practical awareness
During a period of not less than 5 years a candidate for Registration will be expected to have obtained Practical Awareness (knowledge of major techniques and their merits and limitations, not necessarily hands-on experience) in the topics listed below. In addition an in-depth knowledge and experience will be expected in at least two of them:

B1. Post-mortem Methods, Animal and Human Pathology and Histology. Microscopic recognition of the major pathological processes. Foetal and neonatal examination for malformations

B2. Making Observations and Records of signs in Animals or Humans. Humane Dosing, Sampling and Euthanasia of animals;

In vivo Monitoring, Biomonitoring, Biomarker studies on animals or humans. Prevention, Diagnosis and Treatment of acute or chronic chemical exposure and poisoning.

B3. Principles and Techniques of Cell Culture
Testing for compound effects on cells in culture, including applied methodology such as the Ames Test; recognition of basic chromosomal aberrations, blood film analysis, subcellular fractionation techniques

B4. Standard Analytical Methods and Techniques, e.g. spectrophotometry, gas and high performance liquid chromatography, mass spectrometry;
Biochemical and molecular techniques: e.g. protein determination, enzyme activity, blotting and antibody-based techniques, radiochemistry, Reverse-transcriptase (RT) and Real time (RT)-polymerase chain reaction (PCR), "omics" techniques

B5. Design of experiments, biometric and statistical procedures
Data Retrieval, Data Derivation, Computer assisted technologies, data-bases, data-banks, and data acquisition

B6. Determination of pharmacokinetic parameters and compound metabolism

B7. Procedures in Risk Analysis (Risk Assessment, Management and Communication), Regulatory Toxicology, Data reliability and relevance,
Risk-assessment experience under mentorship

Documentation of practical experience, Communication skills, Authorship

Candidates for registration will have documented their practical experience by at least 5 confidential reports, assessments, or publications. Reports and assessments should be suitable for submission to regulatory agencies or for regulatory decision making. Publications should have appeared in peer-reviewed scientific journals.
It is regarded as essential that these papers demonstrate a high standard of critical ability and communication skills. Critical ability and communication skills can be documented further by a record of oral presentations and through authorship of written reviews and a dissertation / thesis. Examples should be included with any application for Registration.

Confirmation
For all the above mentioned the candidate for registration will be expected to provide written confirmation from relevant supervisors who are also prepared to act as sponsors.

C. Implementation of registration

In order to qualify for Registration, candidates have to demonstrate their current active professional participation in the field of Toxicology. They must submit to the registering body:

C1. A CV containing relevant information such as details of scientific education, of post(s) held and of professional activities performed.

C2. Documentation of academic education before commencing training (*entry level knowledge-base*)
Before starting toxicological training leading to registration an individual will have been educated in a science subject with a relevant link to toxicology such as biomedical sciences, medicine,

veterinary medicine, pharmaceutical sciences, biochemistry, biology, toxicology, food and environmental sciences, agronomy, chemistry. This basic educational background will have been acquired by attendance of a full-time taught course at a university for at least three years and documented by a university degree.

C3. Minimum accomplishments during training (*applied knowledge-base*)
To be considered a candidate for Registration, in addition to basic academic training in science, an individual will have undertaken further theoretical and practical training, and will have achieved the minimum standards set out in A and B above.

C4. In the event that uncertainty still exists (for example where experience has been claimed at institutes not known to the board) the registering board may request that in addition to the above, a formal examination (such as DABT, FRCPath (Toxicology)) be attempted.

C5. Recommendation letters should be submitted from two eminent toxicologists familiar with ERT requirements, who know the applicant personally as well as his background and professional performance.

D. Maintenance of Registration (Re-Registration)

On a 5-yearly basis, Registered Toxicologists will be expected to re-affirm their registration credentials and illustrate their currency.
As a minimum, to remain registered, a candidate must be working as a toxicologist, and must submit to the registering body:

D1. An updated CV containing relevant information such as details of post(s) held and of professional activities performed during the past 5-year period of registration.

D2. Confirmation of professional toxicological activity in responsible position by evidence such as list of internal studies (with information on numbers, topics, methods used, branch of customers), list of publications, employment references, delegation into expert committees, teaching and mentoring.

D3. Documentation of continued professional awareness and education in Toxicology such as yearly attendance of educational courses and meetings, presentation of lectures or posters, teaching activities, publications, activities in expert committees and similar. These activities will comprise at least five working days per year.

E. The National Registering Body

E1. Relationship of a registering body with its national body and EUROTOX
A participating registering body will have lodged (and had accepted) its criteria for registering toxicologists with an appropriate national body (e.g. society of toxicology). The national society in turn, will have lodged (and had accepted) these criteria with EUROTOX. One registering body only is accepted per country. The national registry will notify significant changes of their criteria to the EUROTOX Registration Subcommittee.

E2. Criteria of a participating registering body
The criteria will address the following:
- Legislative Aspects (= application)

An outline of what is expected from candidates, expressed in local terms. There is an ongoing responsibility for quality control of the assessment process.
- Executive Aspects (= evaluation)

A constitution and modus operandi for the assessment panel, whose task is to validate the individual's candidature and application for registration.
- Judicial Aspects (= appeal)

An outline of what steps will be taken in the event that there is an objection to the panel's decision.

F. Tasks to be undertaken by the lead body (EUROTOX)

Training

F1. Through monitoring schemes designed to facilitate the registration of toxicologists, the lead body (EUROTOX Education and Registration Subcommittees) seeks to identify training needs and encourage the provision of such training.

F2. Although national differences will be encountered, it is desirable that strenuous efforts are made to ensure that the quality and performance of participating institutes, programs and teachers, and the standards and conduct of examination are harmonised as fully as possible. Individual scientists must reach or exceed a common acceptable standard as set out from time-to-time by an overarching body (presently EUROTOX).

F3. EUROTOX Education and Registration Subcommittees can decide to evaluate the institutes, programs and faculty of Toxicology courses before approval of accreditation for Registration. Such evaluation will be necessary for approval of accreditation of courses developed and organised by institutions other than EUROTOX and its member societies or representatives. Accreditation can be allotted to entire programs or several or single modules. Approvals are to be renewed after major changes.

F4. In collaborative training schemes, more than one institute and country may contribute modules. In order to stimulate a wide range of teachers, these should be encouraged, if necessary, from outside the training establishments.

F5. EUROTOX Education and Registration Subcommittees / the EUROTOX secretariat maintain records of all curricula / course programs and modules accredited for registration.

F6. A list of all accredited courses and modules is shown on the webpage of EUROTOX.

Registration

F7. In order to enforce harmonization of standards for registration the EUROTOX Registration Subcommittee will provide a template describing in detail how the criteria outlined under E2 should be implemented, if a member nation seeks to set up its own national scheme within the EUROTOX guidelines.

F8. Existing registration bodies are encouraged to adapt their regulations in order to ensure concordance with the template describing the criteria of Registration (see F7).

F9. The EUROTOX Registration Subcommittee is able to provide information regarding National Registries that are envisaged, in order to facilitate participation between National Societies, for example in establishing conjoint schemes.

F10. EUROTOX provides observers who can assist in setting up of national schemes. Appointment of these observers is co-ordinated by the Registration Subcommittee.

F11. One of the members of newly approved National Registration Committees and Appeal's Committees should be delegated by the EUROTOX Registration Subcommittee (preferably the chair and a present or former member) during the National Committee's first 3 years at least to assist in running the registration processes.

F12 The EUROTOX Registration Subcommittee can decide to delegate observers to attend meetings of any or all National Registration Committees.

F13. Individual members - EUROTOX will provide an advisory role for its individual members; for those not adhering to a National Society, the Registration Subcommittee may be able to guide applicants to an appropriate registry and to play a judicial role in some cases. Such tasks are co-ordinated by the EUROTOX Registration Subcommittee with help from the EUROTOX Executive Committee as necessary.

F14. If a national scheme or procedures exhibit serious deficiencies which are incompatible with the quality standards observed by the majority of registering bodies (and described in the present guidelines), EUROTOX Education and Registration Subcommittees will give advise how to improve procedures/contents concerned. If improvements are rejected or performed insufficiently, the EUROTOX Executive Committee, upon notification by Education and Registration Subcommittees, decides whether registrations by that registering body will be excluded from EUROTOX registration.
The registering body can appeal against exclusion to the Appeals Committee. This committee comprises three members eminent in Toxicology, namely a former president of EUROTOX and two current chairpersons of national registering bodies. Members are elected, along with 3 deputies, by the Business Council every 4 years. Current members of EUROTOX organs are not eligible. If the chairperson of the excluded register is an elected member, he/she is replaced by a deputy.