The EUROPEAN REGISTERED TOXICOLOGIST (ERT)

Guidelines for Registration 2012 (version Aug 28, 2012)

Introduction

The **Guidelines for Registration** is a thorough revision of the "Expectations of a EUROTOX REGISTERED TOXICOLOGIST", first published by EUROTOX in preliminary form in 1995 (Annex 1). The revision was performed by the Education and Registration Subcommittees to accommodate scientific and conceptual progress in toxicology in the years passed and experience gained through the existing registration schemes.

The European Registration of Toxicologists is a service of EUROTOX for toxicology and for individual toxicologists who excel in standards of education, skills, experience, and professional standing. These toxicologists, upon application, can be certified as EUROPEAN REGISTERED TOXICOLOGIST (ERT). In a first step, national registration boards evaluate applications of candidates according to a consensual process and admit successful applicants to their national register. In the second step, upon request, EUROTOX will certify these individuals as ERT without further evaluation. The proper function of this system depends on a high degree of harmonization of standards among the registering national boards. The current Guidelines provide a framework for assisting national societies' endeavours to advance harmonization of requirements and registration procedures, including provision of training opportunities to all ERT candidates.

The **Guidelines for Registration** consist of Introduction, Sections A – F, and 2 Annexes. Formal requirements and procedures for Registration and Re-Registration are presented in Sections A and D. Sections B and C describe fields of theoretical and practical knowledge and experience relevant for Registration, and how they can be acquired. Furthermore, to cope with the increasing need for specialization, several elective topics are identified in section B, in addition to the core of 13 obligatory topics. Finally, tasks and functions of National Registering bodies and EUROTOX are described in sections E and F, with a focus on harmonization of rules and requirements. Operational and legal details should be defined at the national level or by EUROTOX and laid down in accompanying documents.

Drafts and the 2011 edition of the Guidelines were discussed by member societies of EUROTOX. Comments obtained were taken into account by numerous modifications. After approval and ratification by EUROTOX Executive Committee and Business Council in 2011, some final amendments were requested, resulting in the present 2012 version as accepted at the Annual Congress in Stockholm 2012.

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. The EUROTOX Education and Registration Subcommittees will do this in close collaboration and consensus with national societies / registries and ERT course directors. Significant changes are subject to approval by the Executive Committee.

A. Registration: Requirements and Implementation

Membership in the European Register of Toxicologists aims to recognize high standards of knowledge, skills, experience, and professional standing of scientists professionally engaged in the field of Toxicology. Requirements for Registration include

- An academic degree (MD, or BSc, MSc in a relevant subject)
- Basic knowledge of the major areas of toxicology. There are two routes to meet this requirement:
  - Route 1 is by attendance of appropriate courses
  - Route 2 by practical experience and on the job training
- At least 5 years of relevant toxicological experience
- Suitability for Registration, e.g. by published works, confidential reports or assessments
- Current professional engagement in the practice of toxicology

To consider a candidate for Registration, national registering bodies will require and evaluate the following documentation:

A1. A CV containing relevant information such as details of scientific education, of post(s) held and of professional activities performed.

A2. Documentation of academic education before commencing training (*entry level knowledge-base*)
Before starting toxicological training leading to registration a candidate 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.

A3. Minimum accomplishments during training (*applied knowledge-base*)
In addition to basic academic training in science, a candidate for Registration will have undertaken further theoretical and practical training, and will provide evidence for achievement of the minimum standards set out in sections B and C.

A3.1. Acquisition of basic theoretical knowledge will be documented by credits/certificates from appropriate courses or equivalent qualification, e.g. DABT.

A3.2. Alternatively basic theoretical knowledge can be acquired by long-standing experience and on the job training, and will be documented by peer-reviewed publications, confidential reports, assessments, teaching activities, knowledge-based decision-making or advisory activities, or other achievements, subject to expert opinions.

A3.3. Practical training and acquisition of hands-on experience and communication skills will be shown by publications, reports, or assessments, subject to expert opinions.

A4. Expert opinions evaluating the candidate's knowledge, skills, experience, and professional standing should be provided by two eminent toxicologists who are registered ERT, or are familiar with ERT requirements. They should know the applicant personally as well as his/her background and professional performance. One reviewer, but not both may be from the applicant's current place of employment.

B. Theoretical Training

Purpose

Theoretical training in toxicology, with associated practical working to re-enforce concepts, is essential. Such training can be provided on a modular basis. It should provide basic knowledge of the major areas of toxicology and embrace at least the topics defined below.

Topics

A candidate for registration will have undertaken theoretical training in the following core topics areas B1 – B13 and in at least one elective topic such as listed under B14 – B22:

B 0. Introduction: History, Tasks, Scope and Ethical Principles of Toxicology
B 1. Animal Science incl. Ethical Rules and 3 R Principle
B 2. Experiment Design, Biometry and Statistics
B 3. Cellular Toxicology and Molecular Toxicology
B 4. Metabolism and Kinetics of Xenobiotics
B 5. Organ Toxicology and Toxicological Pathology
B 6. General Toxicology, Introduction to Risk Assessment
B 7. Environmental Toxicology, Exposure Assessment and Biomonitoring
B 8. Epidemiology, Toxicogenetics
B 9. Clinical, Occupational and Forensic Toxicology
B10. Mutagenesis and Carcinogenesis
B11. Reproductive and Developmental Toxicology
B12. Immunotoxicology
B13. Regulatory Toxicology

In addition, two topics, or one comprehensive topic, such as listed below are mandatory

B14. Drug Safety Assessment: Non-clinical, Clinical, Post-Approval Studies, Safety Pharmacology, Expert Report, Drug Regulation
B15. Safety Assessment of Food, Cosmetics and Other Consumer Products, Regulations
B16. Ecotoxicology
B17. Risk Assessment
B18. Neurotoxicology and Behavioural Toxicology
B19. Nanotoxicology
B20. Alternative Testing Methods and their Use in the Regulatory Framework
B21. Computational Toxicology
B22. Mechanistic Toxicology and “Omics” in Toxicology

Additional elective topics can be offered upon prior notification of EUROTOX (Education and Registration Subcommittees).

Topics B0 – B13 and some of the elective topics are essentially covered in the existing ERT courses in Europe. Course directors and national registering bodies decide details of contents and sequence.

Curricula of ERT courses currently offered should be notified to EUROTOX (Education and Registration Subcommittees).

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. At completion of each topic an examination has to be passed.

Course level, and time needed

Course levels will correspond at least to the Master level.

Each topic will probably involve 3-5 days, in some cases up to 10 days of contact time, except B0, 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.

Comprehensive topics: Some elective topics such as B14, B15, B16, B17, may be organized to offer comprehensive specialized training. They will usually consist of more than one module and will need more than 10 days of contact time.

Credits

Candidates for registration will be expected to present credits in all 13 core and the (1 or 2) elected topic(s).

This syllabus can be certificated partly or entirely if the respective content has been covered in an appropriate previous degree (MSc, Ph.D.) or course.

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.

C. Practical training and experience

Practical training and experience, for a period of not less than 5 years, must be related to Toxicology. Training will usually be on the job, based on laboratory, clinical, computer-assisted or regulatory work. 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

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:

C1. Post-mortem Methods, Animal or Human Pathology and Histology. Microscopic recognition of the major pathological processes. Foetal and neonatal examination for malformations.

C2. 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.

C3. 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.

C4. 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.

C5. Design of experiments, biometric and statistical procedures. Data Retrieval, Data Derivation, Computer assisted technologies, data-bases, data-banks, and data acquisition.

C6. Determination of pharmacokinetic parameters and compound metabolism.

C7. 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.

D. Maintenance of Registration (Re-Registration)

On a 5-year basis, Registered Toxicologists will be expected to re-affirm their registration credentials and document their continued professional awareness, education and practice. 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 the national 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, which 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. Each course or module, from EUROTOX or Non-EUROTOX organizers, which a National Registry has evaluated, recognized and recommended for approval by EUROTOX Education and Registration Subcommittees, will be approved at the next meeting of the two subcommittees. Subcommittees can decide, for a specific course/module, to request further information and, based on re-evaluation, recommend alterations or reject approval.

In general, 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 society 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. 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.

F13. 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), the EUROTOX Education and Registration Subcommittees will give advice how to improve procedures/contents concerned. If improvements are rejected or performed insufficiently, the EUROTOX Executive Committee, upon notification by the Education and Registration Subcommittees, will decide 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. The Business Council elects members, along with 3 deputies, 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.

Annexes

Annex 1: Expectations of a EUROTOX Registered Toxicologist

Annex 2: Contents and Learning Outcomes of ERT courses (in preparation)