



The EUROPEAN REGISTERED TOXICOLOGIST (ERT)

Guidelines for Registration 2016

Introduction

The present document is an update of the **Guidelines for Registration** approved by the EUROTOX Business Council Meeting in 2012. The update was warranted to accommodate scientific and conceptual progress in toxicology as well as experience gained through the existing registration schemes.

The European Registration of Toxicologists is a service of EUROTOX for toxicology and for individual toxicologists who attain appropriate 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 and admit successful applicants to their national register. In 2016 national registers in 21 countries in Europe are recognized by EUROTOX. In the second step, upon request from the recognized national registers, EUROTOX will certify these individuals as ERT without further evaluation. The external recognition of the ERT title depends on a high degree of harmonization of standards among the registering national boards. The current Guidelines provide a framework for assisting national societies in advancing harmonization of registration procedures, including provision of training opportunities to all ERT candidates.

The Guidelines for Registration reflect scientific progress in toxicology with a focus on transparency and harmonisation of rules and requirements:

- Section A contains the formal requirements and procedures for registration. The emphasis is put on the need for candidates to demonstrate their knowledge in the core disciplines of toxicology regardless of the way in which it is obtained.
- Section B describes the different fields of theoretical knowledge relevant for registration. The update reflects scientific progress and the increasing need for specialization. Core (obligatory) topics (currently 14) and specialized (elective) topics (currently 9, to be expanded in future) were partly re-organized and re-phrased. Contents and learning outcomes of all topics in B are provided in Annex 1 of these Guidelines.
- Section C lists areas of practical training and experience (with some updates) and how these can be documented.
- Section D contains requirements for maintenance of registration (“re-registration”). The requirements for granting of re-registration are now described in more detail.
- Section E describes status and functions of the National Registering Committee.
- Section F specifies the tasks and functions of EUROTOX, in particular the subcommittees on education and registration, in assisting national societies on education and registration matters. Criteria for the recognition of educational courses have been developed and are provided in Annex 2 of these Guidelines.

The **Guidelines for Registration** are a living document and will continue to be updated at regular intervals according to the development of science and educational as well as harmonization needs.

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 encompass:

- An academic degree (e.g. BSc, MSc, MD, DVM or equivalent in a relevant subject)
- Basic competence in the essential areas of toxicology (see topics in section B) through attendance of appropriate courses, recognised qualifications, or by demonstration of specific practical experience and structured on the job training
- At least 5 years of relevant toxicological experience
- Documentation of the practical experience, evidenced by published works, confidential reports or assessments
- Current professional engagement in the practice of toxicology

To consider a candidate for registration, national registering committees 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. Preferably, the CV should be in the format of Europass.

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 can be documented by credits/certificates from appropriate courses or equivalent qualification, e.g. DABT.

A3.2. If a candidate wishes to demonstrate basic theoretical knowledge of relevant topics by long-standing experience and/or structured on the job training this needs to be appropriately documented e.g. by examination, peer-reviewed publications, evidence of confidential reports, assessments, teaching activities, knowledge-based decision-making or advisory activities, or other achievements, subject to expert opinions (see A4).

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 (see A4).

A4. Expert opinions evaluating the candidate's knowledge, skills, experience, and professional standing should be provided by at least two senior toxicologists who are ERTs. Experts may be proposed by the applicant and should be appointed by the national registration committee which will also provide guidance on the level of evidence required.

B. Theoretical Training

Purpose

Theoretical training in toxicology is essential. Such training can be undertaken on a modular basis and should provide basic knowledge of the major areas of toxicology.

Topics

A candidate for registration will need to demonstrate basic knowledge in all of the following core topic areas (B1 – B14) that are considered as being essential for every toxicologist. Note however that toxicology too is an evolving science and that it is anticipated that changes in this list of core elements will occur in future. Moreover, to adapt to local and regional needs national registration bodies will have some flexibility in the implementation of these guidelines.

- B 1 Principles of Toxicology
- B 2 Laboratory Animal Science incl. 3 R
- B 3 Experimental Design and Statistics
- B 4 Molecular and Cellular Toxicology
- B 5 Absorption, Distribution, Metabolism and Excretion
- B 6 Organ Toxicology and Histopathology
- B 7 Toxicology of Environmental Pollutants
- B 8 Exposure Assessment
- B 9 Epidemiology
- B10 Occupational Toxicology
- B11 Genotoxicity and Carcinogenicity
- B12 Reproductive and Developmental Toxicology
- B13 Risk Assessment of Chemicals
- B14 Clinical and Forensic Toxicology

In addition, it is expected that toxicologists will specialise in certain areas and obtain specific knowledge, skills and competences in a wider field. It is mandatory that candidates will demonstrate knowledge in two topics for specialization, e.g. from the list below. The list (B15 – B23) mentions a number of these specific areas. It should be emphasised, however, that this list is not exhaustive but rather provides a number of example topics for this purpose.

- B15 Drug Safety Assessment
- B16 Regulatory Toxicology
- B17 Ecotoxicology
- B18 Nanomaterials
- B19 In vitro Testing Methods
- B20 In silico Toxicology
- B21 Immunotoxicology
- B22 Neurotoxicology
- B23 Analytical Methods in Toxicology

Learning objectives as well as expected level of knowledge, skills and competencies for core and specialised topics are described in Annex 1 of these Guidelines. Additional specialised topics can be offered by national registers or course providers and can be recognised by EUROTOX according to the process described in Annex 2.

Educational courses

Theoretical knowledge in toxicology can be obtained e.g. by attending courses offered for the purpose of ERT registration (ERT courses). Details of contents and sequence are decided by course directors and national registering bodies.

Curricula of ERT courses are to be notified to EUROTOX (Subcommittees Education and Registration) and can be recognised by EUROTOX for this purpose (see Section F and Annex 2 of these Guidelines). Topics may be presented as modules consisting of lectures, site visits, demonstrations, practical exercises and case studies. In order to be recognised for ERT registration an examination has to be passed at completion of each topic.

Courses should be taught to at least Master of Science (MSc) standard. Each topic will probably involve 3-5 days, in some cases up to 10 days of teaching time.

The syllabus can be certificated partly or entirely if the respective content has been covered in an appropriate previous degree (e.g. MSc or PhD course).

Credits may be obtained from modules offered in different courses and countries. If studied from the beginning, with no credit given for previous degrees or demonstrated knowledge, then a total study time equivalent to approximately 30 ECTS credits (European Credit Transfer System: 1 credit corresponds to 30h of study) should be allocated to undertake the theoretical training needed for eventual registration.

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 needs to be demonstrated for a period of not less than 5 years and 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 supervisor: candidates for registration are advised to ensure at the outset that their intended course of study is evaluated 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. Computer-aided technologies in toxicology. (Quantitative) structure-activity relationships, read-across, calculations of toxicity and biokinetics/dynamics (PBPK/TD) and computational structural biology.

C5. 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.

C6. Design of experiments, biometric and statistical procedures. Data retrieval, data derivation, computer-assisted technologies, data-bases, data-banks, and data acquisition.

C7. Determination of pharmacokinetic parameters and compound metabolism.

C8. 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 reports (which may be internal and/or confidential), 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 reports and 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-yearly 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 in the field of toxicology, and must submit to the registering committee:

D1. A detailed and current CV containing relevant information such as details of post(s) held (e.g. in industry, academia or regulatory authorities, contract laboratories, consultancies, etc.) and of professional activities as part of employment performed during the past 5-year period of registration.

D2. Evidence of toxicological activity e.g. list of publications (peer-reviewed, book chapters), list of internal studies (information on numbers, topics and methods used), employment references, delegation into expert committees, lecture-, professor-, and mentorship. If internal studies or practical work cannot be made available a detailed description and evaluation of the candidate by his/her manager is required. If the candidate has written, or contributed to, reports or assessments without nomination of authorship, the approximate share of the candidate should be confirmed by the manager or an expert with an overall responsibility for the project or work.

D3. Documentation of continued professional development and 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.

The National Registering Committee decides on the detailed requirements and documentation of educational activities.

E. The National Registering Committee

A participating registering committee 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. Only one registering committee will be accepted per country. The national registering committee will notify significant changes of their criteria to the EUROTOX Registration Subcommittee. There is an on-going responsibility for quality control and monitoring of the assessment process.

The approved criteria for registration of a participating registering committee will be made available to candidates (e.g. on the organisation's website) and will include details of:

E1. Legislative Aspects (= application for registration and re-registration):

An outline of the information and level of documentation required from candidates applying for registration or re-registration based on Sections A – D of these Guidelines.

E2. Executive Aspects (= evaluation of the application):

The constitution, regulations and modus operandi of the assessment panel whose task is to evaluate the individual applications for registration. This will also include a description of fees for processing the registration and annual membership of the national registration scheme.

E3. Judicial Aspects (= appeal against decisions):

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

F. Tasks to be undertaken by EUROTOX

Training

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

F2. It is necessary 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 to the standards defined in these Guidelines and associated documents. Individual scientists must reach or exceed a common acceptable standard as set out from time-to-time by EUROTOX.

F3. Upon application, courses offered by EUROTOX member societies or other organizers will be evaluated and, if appropriate, recognised by the EUROTOX Education and Registration Subcommittees. Recognition can be given for the purpose of ERT registration and/or continuing professional development. It is given for individual courses, not for entire educational programmes (e.g. those leading to an academic degree). Recognition is to be renewed after major changes and is limited to a maximum of 5 years. After this time a new application has to be made. Details of the information needed for recognition and of the recognition process are given in Annex 2 of this Guideline.

F4. More than one institute and country may contribute modules to collaborative training schemes. In order to stimulate a wide range of teachers, exchange between different courses and involvement of teachers from outside the training establishments are encouraged.

F5. EUROTOX maintains records of all curricula / course programs and modules recognized for registration as well as of applicants for registration and ERT.

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

Registration

F7. The EUROTOX Registration Subcommittee assists and advises national registering committees to ensure harmonization of standards for registration and re-registration. For this purpose it provides a template describing in detail how the criteria outlined in Section E should be implemented.

F8. Existing registration committees 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 can provide information regarding the establishment of national registries that are envisaged, in order to facilitate exchange between national societies, for example in establishing conjoint schemes.

F10. EUROTOX can provide facilitators who can assist in setting up of national schemes or support the functioning of existing schemes. Appointment of these facilitators is co-ordinated by the Registration Subcommittee.

F11. Newly approved National Registration Committees should co-opt one of its members together with the EUROTOX Registration Subcommittee during the National Committee's first years to assist in running the registration processes.

F12. The EUROTOX Registration Subcommittee will provide advice for its individual members and others not affiliated to a National Society in identifying an appropriate registry and to play a judicial role in some cases.

F13. If a national scheme or procedures exhibit serious deficiencies which are incompatible with the quality standards described in the present guidelines, the EUROTOX Registration Subcommittee will provide advice how to improve procedures. If the proposed improvements are rejected or performed insufficiently, the EUROTOX Executive Committee, upon notification by the Registration Subcommittee, decides whether registrations by that registering committee will be excluded from ERT registration.

The registering committee can appeal against exclusion to an Appeals Committee. This committee comprises three members one of whom should be a former president of EUROTOX and two current chairpersons of national registering committees. Members are elected, along with 3 deputies, by the Business Council every 4 years. Current members of EUROTOX organizations are not eligible. If the chairperson of the excluded register is an elected member, he/she is replaced by a deputy.

Annexes:

Annex 1: Learning outcomes, expected skills and competences for core and specialised topics

Annex 2: EUROTOX recognition of courses providing comprehensive training in toxicology for the purpose of registration (ERT courses) and continuing professional development

Annex 3: Glossary of terms