



FEDERATION OF EUROPEAN TOXICOLOGISTS & EUROPEAN SOCIETIES OF TOXICOLOGY

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## European Registered Toxicologist (ERT) Rules of Registration

(Version as of 10 January 2011)

### Introduction

This **Rules of Registration** draft document updates of the “*Expectations of a European Registered Toxicologist*” first published in 1995. The 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). The **Rules of Registration** currently under consultation accommodates scientific and conceptual progress in Toxicology in the years passed and experience made with the existing scheme.

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.

This draft **Rules of Registration** reorganizes the original structure by creating new sections and subsections in order to enhance overall clearness. Scientific progress in Toxicology is reflected by updates in sections A and B. Furthermore, to cope with the increasing need for specialization in toxicology, six special topics are identified in section A, two of which should be selected by candidates for ERT, in addition to a core of 13 obligatory topics. Sections C and D have been expanded in order to provide some certainty on the expectations a candidate should achieve for obtaining Registration or Re-Registration. 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.

Consultation of the updated **Rules of Registration** draft document is currently taking place through EUROTOX member societies and registering bodies. Comments must be provided not later than three months after appearance of this announcement on the EUROTOX website or by May 27<sup>th</sup>.

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Following the discussion and execution of changes which may emanate from the comments it is expected that the EUROTOX Executive Committee will decide on the **Rules of Registration** and that the formal approval is given by the Business Council during its meeting at the Annual Congress in August 2011.

## **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 the topics that are defined below.

### **Topics**

A candidate for registration will have undertaken theoretical training in 15 of the following topics areas, of which A1 – A13, and two elective modules out of A14 – A19, 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. Cell and Molecular Biology and Toxicology, “Omics in Toxicology”
- A 4. Metabolism and Kinetics of Xenobiotics
- A 5. General Toxicology, Predictive Toxicology
- A 6. Organ Toxicology and Toxicologic Pathology
- A 7. Exposure Assessment and Biomonitoring Analytic and Forensic Toxicology
- A 8. Epidemiology, Toxicogenetics, and Clinical Studies
- A 9. Clinical and Occupational Toxicology
- A10. Mutagenesis and Carcinogenesis
- A11. Reproductive and Developmental Toxicology
- A12. Immunotoxicology
- A13. Risk Analysis (Risk Assessment, Management and Communication), Regulatory Toxicology

In addition, two elective modules out of the following are mandatory:

- A14. Computational Toxicology (In silico modelling, Systems Toxicology, Toxicoinformatics, Quantitative Risk Assessment)
- A15. Environmental Toxicology
- A16. Special Issues in Drug Safety Assessment: Non-clinical, Clinical, Post-Approval, Safety Pharmacology
- A17. Special Issues in Safety Assessment of Food, Cosmetics and Other Consumer Products
- A18. Alternative Testing Methods and their Use in the Regulatory Framework
- A19. Nanotoxicology

Topics may be presented as modules consisting of lectures, site visits, demonstrations, and case studies. All modules are completed by examinations.

### **Time needed**

Each module will probably involve on average one to two weeks of contact time.

If studied from the beginning, with no credit given for content of previous degrees, then about 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 described 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.

## **B. Practical curriculum**

Practical experience and training must be appropriate. 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.

### **Working areas**

To obtain eventual registration, it is likely that work will be based in one of the areas listed under A (except A0, A2).

### **Practical awareness**

Although toxicologists work under very diverse circumstances, during a period of not less than 5 years a candidate for Registration will be expected to have obtained Practical Awareness 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, Biomarkers on animals or in Clinical studies

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

Candidates for registration will present publications or reports documenting their practical experience.

### **Communication skills, Authorship**

It is regarded as essential that a candidate for Registration will have demonstrated a high standard of critical ability and communication skills. This may be demonstrated by a record of oral presentations and through authorship of written papers or reports.

Examples, whose titles should be included with any application for Registration, may include peer-reviewed scientific papers, confidential reports or similar documents, and a dissertation or thesis.

### **Confirmation**

For all the above mentioned the candidate for registration may 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, 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 (at least one of whom should be ERT) who are familiar with the applicant's background.

## **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 publications, list of internal studies (with information on numbers, topics, methods used, branch of customers), 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, publications, teaching activities, 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.

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. 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.

F4. EUROTOX Education and Registration SubCommittees jointly evaluate the institutes, programmes and teachers of the Basic and Advanced Toxicology Courses for approval to be credited for Registration. Credits can be allotted to entire programs or several or single modules. Approvals are to be confirmed after major changes.

F5. EUROTOX Education and Registration SubCommittees / the EUROTOX Secretariat maintains a list of all courses or modules accredited for registration.

F6. The list described under F5 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 presently co-ordinated by the EUROTOX Registration Subcommittee with help from the EUROTOX Executive Committee as necessary.