

The EUROPEAN REGISTERED TOXICOLOGIST (ERT) Suggested Swedish Guidelines for Registration (date/year of approval)

Introduction

A European Registered Toxicologist (ERT) is a toxicologist who meets specific requirements in education as well as professional skills and experience. Toxicologists¹ can, upon application, be certified as ERT. A registration committee nominated by the Swedish Society of Toxicology (SFT) will evaluate applications of candidates according to the guidelines described herein, and admit successful applicants to the national ERT register. EUROTOX will then, without further evaluation, include these individuals in a master list of registered toxicologists from all national societies belonging to EUROTOX.

The Swedish Guidelines for Registration are based on the EUROTOX Guidelines from August 2012. As the EUROTOX Guidelines are updated, the Swedish Guidelines will be reviewed accordingly, or as needed, by the board of SFT.

Applications to the Swedish ERT Register are open to toxicologists¹ from Sweden and elsewhere. Membership in SFT is not necessary for applying.

A. Registration: Requirements and Documentation

Requirements

Requirements for registration include:

- Current professional engagement in the practice of toxicology² (see section A1).
- Basic academic degree (see section A2).
- Theoretical toxicological training in the major areas of toxicology. There are two routes to meet this requirement:
 - Route 1 is by attendance of appropriate courses (see sections A3.1 and B).
 - Route 2 is by practical experience and on the job training (see section A3.2).

¹ Toxicologist is here defined as a professional in human toxicology and/or ecotoxicology.

² Toxicology is here defined as human toxicology and/or ecotoxicology.

- Practical toxicological training. At least 5 years of relevant toxicological working experience, as shown by e.g. published works, reports or assessments (see sections A4 and C).

Documentation

The following documentation must be submitted for evaluation by the Swedish registration committee:

A1. A CV containing relevant information about past and current professional activities and education.

A2. Documentation of a basic academic education:

A candidate must have a basic academic education (at least a BSc) with a relevant link to toxicology, such as biomedical sciences, medicine, veterinary medicine, pharmaceutical sciences, biochemistry, biology, food and environmental sciences, agronomy, chemistry, nutrition. This basic academic education must be documented by a university degree.

A3. Documentation of theoretical toxicological training

A candidate for registration must provide evidence that he or she has undertaken further training in toxicology as follows:

A3.1. Theoretical training in toxicology can be acquired from appropriate courses (course topics are described in section B) or equivalent qualification, e.g. DABT (Diplomate of the American Board of Toxicology). The courses must be documented by e.g. credits or certificates.

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

A4. Documentation of practical toxicological training and experience.

The applicant must have at least 5 years of relevant toxicological working experience. Practical training and acquisition of hands-on experience and communication skills must be shown by publications, reports, or assessments, subject to expert opinions. Section C describes the requirements for practical toxicological training and experience in more detail.

A5. Upon request by the registration committee, expert opinions evaluating the candidate's knowledge, skills, experience, and professional standing must be provided by two experienced toxicologists who are registered ERT, or are familiar with ERT requirements. They should know the applicant's background and professional performance. One reviewer, but not both, may be from the applicant's current place of employment. Such expert opinions will primarily be requested when the theoretical training in toxicology has been obtained on the job but may also apply when the

submitted documentation of academic education is not sufficient for the registration committee to make a decision.

B. Courses requirements for theoretical toxicological training

Purpose

Theoretical training in toxicology is essential. It should provide basic knowledge in the major areas of toxicology and include at least the topics defined below.

Topics

Core Topics

A candidate for registration must have undertaken theoretical training in the core topics (B1 – B12).

- B 0. Introduction: History, Tasks, Scope and Ethical Principles of Toxicology
- B 1. Animal Science incl. Ethical Rules and 3 R Principles
- B 2. Experimental 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. Mutagenesis and Carcinogenesis
- B10. Reproductive and Developmental Toxicology
- B11. Immunotoxicology
- B12. Regulatory Toxicology

Elective Topics

In addition, two topics, or one comprehensive topic, of the elective topics listed below (additional topics can be suggested by the applicant), are mandatory.

- B13. Clinical, Occupational and Forensic Toxicology
- 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

Course levels and time per topic

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. Comprehensive topics will usually need more than 10 days of contact time.

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

Credits

Candidates for registration will be expected to present credits in all 12 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, PhD) or course.

Credits may be obtained from modules based in more than one country.

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 e.g. toxicological research, laboratory, clinical, or regulatory work, or other relevant tasks. Practical training within doctoral (PhD) or master (MSc) education can be counted within the 5 years of practical training and experience.

Practical Awareness

A candidate for registration must have obtained knowledge of major techniques and their merits and limitations (not necessarily hands-on experience) in the majority of the topics listed below. In-depth knowledge and experience will be expected in at least some of them:

C1. Post-mortem methods, animal or human pathology and histology. Microscopic recognition of the major pathological processes.

C2. Making observations and records of signs of toxicity in animals or humans. Humane dosing, sampling and euthanasia of animals.

C3. In vivo monitoring, bio-monitoring, biomarker studies on animals or humans.

C4. Prevention, diagnosis and treatment of acute or chronic chemical exposure and poisoning.

C5. Principles and techniques of cell culture and in vitro toxicity testing.

C6. Biochemical and molecular techniques.

C7. Standard analytical methods and techniques.

C8. Experimental design and/or study design including statistical procedures.

C9. Data retrieval, data derivation, databases, data banks, and data acquisition.

C10. Determination of pharmacokinetic parameters and compound metabolism.

C11. Procedures in risk analysis (risk assessment, management and communication), regulatory toxicology, data reliability and relevance.

Documentation of practical experience, communication skills, authorship

Candidates for registration will have documented their practical experience (as described above) by at least five confidential reports, assessments, or publications. The reports and assessments should be suitable for decision-making by regulatory agencies or companies. Publications should have appeared in peer-reviewed scientific journals.

It is 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.

Confirmation

For all the above, the candidate for registration will be expected to provide examples and/or written confirmation from relevant supervisors.

D. Re-registration

On a five-year basis, Registered Toxicologists will be expected to re-affirm their registration credentials and document their continued professional awareness, education and practice. To remain registered, a candidate must be working as a toxicologist, and must submit the following 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 activity as a toxicologist in responsible positions 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. Application procedure

The application form can be downloaded from the SFT webpage <http://toxikolog.se/> and must be sent to the secretary of the registration committee. Information on the current registration fees and deadlines can be found on the SFT webpage.

Applicants will usually be notified of the committee's decision within one week of the meeting. Appeals can be submitted to the SFT board (see the Annex for more details on appeals).

Removal from the registry will occur if no application for renewal of the certification after 5 years has been submitted.

Annex: Rules for the Swedish Registration Committee

It is the registration committee that decides upon inclusion, renewal and removal from the register. It is possible to appeal (see below).

The registration committee is responsible to the board of SFT. The SFT board appoints members of the committee for a four-year period at a time. Committee members should represent a wide range of toxicological expertise and employments. The committee comprises five members, of whom at least one must be an SFT board member. During the first three years, one member must come from EUROTOX' Registration sub-committee.

The SFT board appoints the chairperson of the committee. The committee chooses a secretary and other possible officers from its members. The committee will meet twice a year (meeting dates will be posted in advance on the SFT webpage). The committee maintains the national list of registered toxicologists and gives out certificates as proof of registration.

In the event of a proposed removal from the register, a minimum of one month's notice will be given to provide an opportunity to appeal.

Appeals committee

Appeals against any decisions of the registration committee can be made to an appeals committee, by first notifying the board of SFT. An appeals committee will convene on a "need basis", decided by the SFT board. Members of the appeals committee will include a representative of the SFT board, a representative of the EUROTOX registration sub-committee (not the same as sits on the Swedish registration committee), and at least two additional representatives from other national toxicology societies.