The EUROPEAN REGISTERED TOXICOLOGIST (ERT)
Danish Guidelines for Registration

Introduction

A European Registered Toxicologist (ERT) is a toxicologist who meets specific requirements in education as well as professional skills and experience. Toxicologists[1] can, upon application, be certified as ERT. A registration committee nominated by the Danish Society for Pharmacology, Toxicology and medicinal Chemistry (DSFTM) will evaluate applications of candidates according to the guidelines described herein, and admit successful applicants to the Danish 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 Danish Guidelines for Registration are based on the EUROTOX Guidelines from August 2012 http://www.eurotox.com/ert/. As the EUROTOX Guidelines are updated, the Danish Guidelines will be reviewed accordingly, or as needed, by the Danish registration board.

Applications to the Danish ERT Register are open to toxicologists[1] from Denmark and toxicologists working in Denmark. . Membership of DSFTM is not mandatory for applying.

A. Registration: Requirements and Documentation

Requirements

Requirements for registration include:

- Current professional engagement in the practice of toxicology[2] (see section A1).
- Basic relevant 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 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 Danish registration committee:

A1. A Curriculum Vitae (CV) including the relevant information about education, past and current professional activities.

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 (Diplomat of the American Board of Toxicology). The courses must be documented by e.g. credits or certificates.
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> A3.2. Alternatively, theoretical training in toxicology can be acquired by long standing experience and on the job training. This must be a broad experience covering relevant topics of toxicology as outlined in section B and must be documented by reports, assessments, peer reviewed publications, teaching activities, knowledge based decision making, advisory activities, or other achievements in various fields of toxicology, 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, and/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 at least 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 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. Immune Toxicology
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. Neuro-toxicology and Behavioral Toxicology
B19. Nano-toxicology
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, molecular or analytical techniques and methods.

C7. Experimental design and/or study design including statistical procedures.

C8. Data retrieval, data derivation, databases, data banks, and data acquisition.

C9. Determination of pharmacokinetic parameters and compound metabolism.

C10. 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.

A toxicology professor or senior lecturer (docent in the field of toxicology) may be included in the register directly based on application and detailed CV.

Confirmation

For all the above, the candidate for registration will be expected to provide names of at least two relevant colleagues or supervisors.

D. Re-registration

On a five year basis, Registered Toxicologists will be expected to reaffirm 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. REGISTRATION PANEL

Inclusion, exclusion or removal from this Register will be decided by a Registration Panel consisting of at least 5 members appointed for 5 years by DSFTM / Toxicology Section and a representative of EUROTOX Registration Sub-committee. The current Registration Panel consists of:

- **from the EUROTOX** Registration/ERT Sub Committee**:**

- Associate Director Marie Haag Groenlund, Occupational Health, Stockholm, Sweden

- **for the DSFTM / Toxicology Section:**

- Chairman and secretary: Prof. Dr. MSc, PhD, ERT, Eva C. Bonefeld-Jørgensen; Professor in Human Environmental Toxicology, Faculty of Health, University of Aarhus, Denmark; President of DSFTM.
- Vice-chairman: Prof. MSc, PhD, ERT Anne Marie Vinggaard; Professor in Molecular Toxicology, Technical University of Denmark.
- Prof. MSc, PhD, ERT Ulla Vogel; Professor in Nano Toxicology, the National, Research Centre for the Working Environment, Copenhagen.
- Prof. Lisbeth E. Knudsen, MSc, PhD, ERT, Professor in Animal Free Toxicology, University of Copenhagen.
- Senior Scientist Allan Christensen, MSc in Biology & Applied Toxicology. ERT. Toxicology Development Projects, Novo Nordisk A/S, Novo Nordisk Park

The registration panel members have elected a chairman and a vice-chairman from amongst their number. The chairman, or in case of his/her absence, the vice-chairman, will chair the sessions. He/she will manage the day-to-day affairs, including statutory obligations of the Register and will implement the decisions of the registration panel and any requirements arising from new regulations for membership of the European Register of Toxicologists.

The Panel will meet twice a year (June and December) to review and evaluate new applications, report to EUROTOX, and ensure continuing registration. These meeting can be virtual (i.e. tele-meetings) or physical. A quorum of 3 members must be present and decisions of the registration panel shall be made by simple majority.

Non-voting observers may be invited to meetings at the discretion of the chairman. The registration panel and each of its regular members will keep in strict confidentiality all information provided by an applicant if designated by the applicant as confidential.

F. SECRETARIAT

The Secretariat is provided by DSFTM and is in cooperation with the chairman of the registration panel responsible for:

- Collection and processing of applications for registration.
- Communications between applicants and the Registration Panel.
- Keeping records of the dates for the forthcoming Registration Panel meetings as well as the results of the past meetings.
- Maintaining updated the registration register.
- Communication with registrants inviting them to submit an application for re-registration, at the appropriate time (at five-year intervals). Registrants should supply information to the Registration Panel at least 6 weeks before the Panel meeting date. Verification of the facts so provided may be requested.

The Secretariat prepares a draft annual report every January for submission to DSFTM and addressing at least the following:

- the number of those applying for inclusion in the register or maintenance of registration, the outcome of applications and the names of those approved for inclusion in the register or the maintenance of registration.
- the names of those who have been removed from the register.
- a review of the current financial status of the register.

Members of the Register must inform the Secretariat if they retire or if they are no longer working directly in toxicology.

In the case of proposed removal from the Register a minimum of one month's notice will be given to provide an opportunity for personal representation, or through a representative, to the Registration Panel.

F. Application procedure

The application form can be downloaded from the DSFTM webpage. Please fill out this application and attach it to the online application form found at http://www.dsftm.org/en/ert-application. Information on the current registration fees and deadlines can be found on the DSFTM webpage.

Applicants will usually be notified of the registration panel's decision within approximately one week of the meeting. Appeals can be submitted to the DSFTM 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 Danish Registration Panel

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

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

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

To ensure recognition, lists of new registered individuals should periodically be sent to the EUROTOX Secretariat (secretariat@eurotox.com) using the attached template with copy to the Registration SC Chair, Prof. Bas Blaauboer (b.blaauboer@uu.nl).

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 panel can be made to an appeals committee, by first notifying the board of DSFTM. An appeals committee will convene on a "need basis", decided by the DSFTM board. Members of the appeals committee will include a representative of the DSFTM board, a representative of the EUROTOX registration sub-committee (not the same in the Danish registration panel), and at least two additional representatives from other national toxicology societies.