

RULES OF THE Austrian Register of Toxicologists (AR-TOX)¹

First Section

General Provisions

Objectives

- (1) The goal of these rules is to establish executive organs, criteria and procedures for registration of toxicologists in Austria. In the following, these operative parts as a whole will be denoted as “Austrian Register of Toxicologists”, “AR-TOX”.
- (2) The objectives of the AR-TOX, a body in the frame of the Austrian Society of Toxicology (ASTOX), linked to the EUROTOX Register, are
 - a) To recognize experienced scientists who are actively engaged in the multi-disciplinary field of toxicology.
 - b) To ensure that Registered Toxicologists observe and maintain high standards of professional knowledge, competence, experience, and ethical conduct.
 - c) To ensure the description “Registered Toxicologist” or the use of initials or letters having a similar meaning to be confined to persons who have satisfied the Registration Committee of their professional competence and experience.

Gender neutrality

- (3) Except for articles (20) and (28) all person designations are to be understood in a gender neutral way and are not given separately for both genders merely for reasons of readability.

Definitions

- (4) The following definitions shall apply:
 1. “The Registration Committee” means the committee that assesses candidates for inclusion in the Register and/or for maintenance of registration.
 2. “The Chairman” is the person so appointed for a specified period of time by the Registration Committee.
 3. “The Vice-chairman” is the person so appointed for a specified period of time by the Registration Committee.
 4. “The Secretary” is the person so appointed for a specified period of time by the Registration Committee.

¹ Translation of the “Verfahrensregeln für die Registrierung von Toxikologen in Österreich“ adopted at the 29th General Assembly of ASTOX, 21st April 2017

5. “The Vice-secretary” is the person so appointed for a specified period of time by the Registration Committee.
6. “The Cash auditor” is the person so appointed for a specified period of time by the Registration Committee.
7. “The Register”, without qualification, shall mean the register of toxicologists in Austria where the context so admits or requires and contains the list of names of the members on whom the AR-TOX has conferred a registered title.
8. “Registered Toxicologist (AR-TOX)” shall mean a person whose name appears on the Register.
9. “EUROPEAN Registered Toxicologist (ERT)” shall mean a person whose name appears on the EUROTOX Register.
10. “Austrian Society of Toxicology” (ASTOX) means the association of toxicologists in Austria.
11. “EUROTOX” means the association of European Toxicologists & European Societies of Toxicology.
12. “IUTOX” means the International Union of Toxicology, a worldwide scientific organization that promotes the field of toxicology.
13. “Appeals Committee” shall comprise of a panel of three individuals eminent in the field of toxicology.

Financial Liability

- (5) Subject to the rules of AR-TOX, no member of the AR-TOX shall, by reason of membership of the AR-TOX, be under any financial liability whatsoever, except for payment of the membership fees to ASTOX or an association stated under article (9), and except for payment of the registration fees and fees for maintenance of registration and for the cost of goods and services provided at the request of the member.

Second Section

Executive Provisions

Membership

- (6) Toxicologists wishing to apply for inclusion in the Register should use the approved application form, which is available from the office of the Chairman.
- (7) A member of the AR-TOX shall be duly accepted having met the required standards after evaluation by the appointed Registration Committee, is in good standing regarding the application fee, and having accepted in writing the “Rules of the Austrian Register of Toxicologists”, and is member of ASTOX or an association stated under article (9).

- (8) The prerequisites for registration include fulfillment of the recommendations of EUROTOX (ERT Guidelines for Registration) as last amended (see Annex) for certification as EUROPEAN Registered Toxicologist (ERT).

Therewith, the requirements for inclusion in the Register are identical with those of the ERT Guidelines for Registration, except when otherwise stipulated in these rules.

These are:

1. An academic degree in a relevant discipline, e.g. medicine (human, veterinary), or natural sciences (pharmacy, chemistry, biochemistry, molecular biology, biology, nutritional, agricultural, environmental or health sciences) from a recognized European Union university or its equivalent;
And
 2. Currently engaged in practicing toxicology;
And
 3. Basic theoretical knowledge of the major areas of toxicology, documented by successful completion of the Postgraduate Course in Toxicology organized by the Medical University of Vienna, or by other equivalent postgraduate training, particularly by an ERT course approved by EUROTOX;
 4. If a candidate wishes to demonstrate basic theoretical knowledge of relevant topics by longstanding 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 indent 6);
And
 5. At least 5 years practical professional training and experience in toxicology.
 6. To assess the fulfilment of the requirements, written expert opinions of two renowned toxicologists who are ERTs or familiar with ERT rules may be used. In case of drawing upon the fulfilment of the requirements according to indent 4, these expert opinions are mandatory. Experts may be proposed by the applicant; they shall be appointed by the Registration Committee which will also provide guidance on the level of evidence required.
- (9) Toxicologists meeting the criteria given under articles (7) and (8) who are not members of the Austrian Society of Toxicology shall be likewise accepted provided that they are members either of EUROTOX or IUTOX or their associated societies.
- (10) Applications for membership should be sent to the Registration Committee. They can be made at any time, but cut-off date is May 31. The applicant's suitability for membership shall be considered by the Registration Committee before October 31 in this year and shall be notified, in writing, as to whether or not the applicant has been approved for membership by the Registration Committee as soon as practicable thereafter.
- (11) In the event that the Registration Committee declines to approve membership for any particular applicant, he shall be entitled to apply at a second and subsequent occasions for admission to the Register until such time as he has met the admission criteria as specified in articles (7) and (8).

- (12) Registration expires on December 31 of the fifth year following the date of registration or maintenance of registration.
- (13) Maintenance of registration requires re-affirmation of registration credentials and illustration of currency according to the recommendations of EUROTOX (ERT Guidelines for Registration) as last amended (see Annex).

In particular the following is required:

1. A detailed and current CV with the following information on professional activities during the past 5-year period of registration:

Place of employment, e.g. toxicological working groups in Industry and at university institutes for toxicology or toxicology units, contract laboratories for toxicological studies, authorities and private companies involved in toxicological issues.

Professional activities: application or design and evaluation of toxicological standard tests, experimental work in a toxicological area in responsible position, development and improvement of toxicological tests, performance of risk evaluation, preparation of expert reports, expert opinions and assessments.
 2. Documentation of professional activities in a field of toxicology in responsible position, list of publications, list of internal studies (information on numbers, topics and methods used), names of customer or indication of branch, 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.
 3. Documentation of continued professional development and awareness and education in toxicology such as attendance of educational courses and meetings, activities in expert committees and similar, presentation of lectures or posters, teaching activities or publications, comprising at least five working days per year.
- (14) The registered professional title of the AR-TOX shall be “Registered Toxicologist (AR-TOX)”.
- (15) Members of the AR-TOX are entitled to be registered by EUROTOX as EUROPEAN Registered Toxicologist.
- (16) Members of the EUROTOX Register who wish to describe themselves otherwise than in full may use the following abbreviation: ERT (for EUROPEAN Registered Toxicologist).

Fees

- (17) A fee of EUR 120. - has to be paid in advance with each application for registration and maintenance of registration, respectively. For non-members of ASTOX who however fulfil the requirements given under article (9) the fee amounts to EUR 180. - which has to be paid likewise in advance.

- (18) If necessary, the fees may be adapted by the Registration Committee. Charges are set such that the Register shall be self-financing. Any net profit will be retained by AR-TOX and used to promote the Register and help provide continuing professional development/education for members.

Executive Organs

Registration Committee

(19) Functions of the Registration Committee

- a) The assessment of candidates for inclusion on the Register and/or maintenance of registration.
- b) To exclude or remove a member from the Register.
- c) To advise and contribute to the development of Registered Toxicologists in Austria.
- d) To co-opt new members to the Registration Committee to replace resigning members until election by the next General Assembly.
- e) To prepare an annual report.
- f) To set and, if necessary, adapt fees for registration and maintenance of registration.

(20) Composition of the Registration Committee

The Registration Committee shall have seven members; at least three of them should be female. The members shall be appointed by simple majority by the General Assembly of ASTOX. To be eligible, a person has to be member of ASTOX or another member society of EUROTOX, or an individual member of EUROTOX. EUROTOX may send observers to the meetings of the AR-TOX. If a member resigns prematurely, a new holder of the vacant position shall be appointed by simple majority by the next General Assembly of ASTOX.

(21) Registration Committee Chairman and Vice-chairman

The Registration Committee members shall elect a Chairman and a Vice-chairman, from amongst their number every three years.

The Chairman or in case of his absence the Vice-chairman shall chair the sessions of the Registration Committee.

The Chairman or, if he is temporarily unable to carry out his duties, the Vice-chairman shall manage the day-to-day affairs, including statutory obligations of the AR-TOX and shall implement the decisions of the ASTOX in relation to the AR-TOX specifications and any requirements arising from new regulations for membership of the European Register of Toxicologists.

In case of need, the Chairman shall be responsible for establishing detailed provisions on the procedures of the Registration Committee in operational issues (internal rules of procedure) within the rules, after proposal by and in agreement with the members of the Registration Committee.

(22) Secretary and Vice-secretary

The members of the Registration Committee shall elect a Secretary and a Vice-secretary, from amongst their number every three years. The Secretary or when he is prevented from doing so the Vice-Secretary shall have the following duties:

He shall take minutes of the Registration Committee sessions.

He shall have custody of all the documents and records belonging to the AR-TOX and shall maintain the AR-TOX. He shall keep full and correct minutes of all proceedings and records of the Registration Committee.

He maintains the Register and accounts of the AR-TOX. Subject to the available funds of the AR-TOX he refunds any travel cost of members of an executive organ and any other additional costs resulting from related activities of Committee members.

He advises interested applicants on the requirements for registration.

He notifies and informs the applicants for registration of the Registration Committee's decisions as soon as feasible.

He prepares registration certificates once the applicants have been admitted and fees have been paid. He notifies EUROTOX of the registered members of the AR-TOX including dates of registration.

He prepares a draft annual report for submission to ASTOX, addressing at least the following:

- a) The numbers 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.
- b) The names of those who have been removed from the Register.
- c) Needs for continuing professional development of members.
- d) A review of the current financial status of the Register.

(23) Cash auditor:

The members of the Registration Committee shall elect a Cash auditor, from amongst their number, not having other functions within the Committee, every three years. The Cash auditor has to audit the accountancy of the Secretary as well as the balance of accounts. He shall report his findings to the General Assembly of ASTOX.

(24) Period of service

Registration Committee members are elected for a period of 3 years.

Registration Committee members may be re-appointed with no limitation in the number of terms of office.

Basically, all related activities of Registration Committee members are exerted on an honorary basis. Travel cost and any additional related activities can be refunded depending on the available funds.

(25) Meetings

- a) The Registration Committee may meet at least once annually, but in any case if applications for inclusion in the Register or for maintenance of registration exist.
- b) The Secretary shall, following consultation with the Chairman, summon a meeting of the Registration Committee, or if requested to do so by four members of the

Registration Committee. Reasonable notice shall be given of all meetings, a minimum of fourteen days in advance stating the purpose of the meeting.

- c) The Chairman chairs the sessions of the Registration Committee. In his absence, the Vice-chairman will chair the meeting.
- d) A quorum of 4 Registration Committee members must be present. Members having personal or business interest in an applicant have no voting rights concerning this applicant.
- e) Decisions of the Registration Committee shall be made by simple majority. If there is an equality of votes, the Chairman has a casting vote.
- f) Non-voting observers may be invited to meetings at the discretion of the Chairman.

(26) Appeals against the decision of the Registration Committee

If an applicant does not agree with the decision of the Registration Committee the application will be reconsidered. In the event that the applicant does not agree with the decision after reconsideration by the Registration Committee, he will be given an opportunity for independent appeal to the Appeals Committee.

(27) Confidentiality

The Registration Committee and each of its regular or co-opted members will keep in strict confidentiality all information provided by an applicant if designated by the applicant as confidential.

Appeals Committee

- (28) The Appeals Committee is elected by the General Assembly of ASTOX. It comprises 3 members eminent in the field of toxicology. Current members of the Registration Committee are not eligible. Preferably at least one member should be female. The period of service is 3 years. Members can be re-elected. Basically, all related activities of Appeals Committee members are exerted on an honorary basis. Travel cost and any additional related activities can be refunded.
- (29) The Appeals Committee elects a Chairman and a keeper of the minutes from amongst their number.
- (30) The Appeals Committee decides to the best of its knowledge in the presence of all members with simple majority.
- (31) The decision of the Appeals Committee will be binding on all parties.
- (32) Appeals against the decisions of the Registration Committee to the Appeals Committee are at the appellant's cost in the form of a bond that is reimbursable if the appeal is successful.

Third Section

Final Provisions

Expulsion

- (33) The Registration Committee may expel from the AR-TOX any member whose alleged misconduct is, in the opinion of the Registration Committee, injurious to the character or interests of the AR-TOX. The person concerned may appeal against the decision. The responsible body in this case is the Appeals Committee. The rules laid down under articles (30) to (32) shall apply accordingly. Neither the AR-TOX, its officers, servants or agents, nor the Registration Committee nor any member thereof shall have any liability to the expelled in respect of such expulsion.

Alteration to Rules

- (34) A rule shall not be revoked or amended and new rules shall not be made except where the Registration Committee by majority and the General Assembly of ASTOX by simple majority of the members present pass a resolution.
- (35) Notice of intention to propose a new rule, or to revoke or amend an existing rule, may be given to the Secretary in writing by the Registration Committee or by not less than one third of the members of ASTOX.
- (36) If a resolution is passed the Secretary shall within 14 days thereafter lodge the amendments to the rules.

Disputes and Differences

- (37) Save as hereinafter specified, any dispute or difference which may arise as to the interpretation of these rules or as to the powers or validity of any proceedings of a meeting shall be determined by the Registration Committee in accordance with ASTOX whose decision shall be final and binding on all members.

Furthermore, the provisions of the Austrian Associations Act (Vereinsgesetz) 2002-VerG, BGBl. I Nr. 66/2002 as last amended apply accordingly, as far as appropriate.

Fourth Section

Entry into Force

- (38) These Rules shall enter into force immediately after adoption by the General Assembly of ASTOX. Applications submitted up to 31st May 2017 shall be treated under the rules hitherto applicable, though.



FEDERATION OF EUROPEAN TOXICOLOGISTS & EUROPEAN SOCIETIES OF TOXICOLOGY²

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.

² www.eurotox.com - secretariat@eurotox.com

- 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