

Croatian Society of Toxicology

Rules of The Croatian Register of Toxicologists Certified as European Registered Toxicologists

Introduction

The Rules of the Croatian Register of Toxicologists Certified as European Registered Toxicologist (R-CRT-ERT) is strictly based on **The European Registered Toxicologist (ERT) Guidelines for Registration 2012** (version Aug 28, 2012). The European Registration of Toxicologists is a service of EUROTOX for toxicology and for individual toxicologists who excel in 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 according to a consensual process and admit successful applicants to their national register. In the second step, upon request, EUROTOX will certify these individuals as ERT without further evaluation. The standards set up by R-CRT-ERT are set by the **Guidelines for Registration of Croatian Registered Toxicologist (GR-CRT)** and harmonized with those indicated in ERT Guidelines for Registration 2012.

The **R-GR-CRT** consist of Introduction, General Provisions, Sections A – F, Final Provisions, Annex 1 (Expectations of a EUROTOX Registered Toxicologist), and Annex 2 (Application and Evaluation Form). Formal requirements and procedures for Registration and Re-Registration are presented in Sections A and D. Sections B and C describe fields of theoretical and practical knowledge and experience relevant for Registration, and how they can be acquired. Furthermore, to cope with the increasing need for specialization, several elective topics are identified in section B, in addition to the core of 13 obligatory topics. Finally, tasks and functions of Croatian Registering body and EUROTOX are described in sections E and F, with a focus on harmonization of rules and requirements.

General Provisions

Objectives

The goal of these rules is to establish executive organs, criteria and procedures for registration of toxicologists in Croatia. In the following, these operative parts as a whole will be denoted as “Croatian Register of Toxicologists”, “CRT”.

The objectives of the CRT-ERT are

1. to recognize experienced scientists and clinicians who are actively engaged in the field of toxicology.
2. to ensure that Registered Toxicologists observe and maintain high standards of professional competence and ethical conduct.

Definitions

1. "Toxicologist" is a professional involved in clinical and/or experimental toxicology, the study of hazard and risk of different chemical, physical and/or biological noxes to human health and/or ecosystem. He/she may study adverse effects of exposure to specific noxes, mechanism of action, toxodynamics, toxokinetics, ecological fate, procedures and approaches in diagnostics, treatments and therapies, prevention of intoxication and poisoning caused death cases.
2. "The Registration Panel" means the committee that assesses candidates for inclusion on the register and/or for maintenance of registration.
3. "The chairman" is the person so elected for a specified period of time by the registration committee.
4. "The vice-chairman" is the person so elected for a specified period of time by the registration committee.
5. "The secretary" is the person so elected for a specified period of time by the Registration Panel.
6. "The Register", without qualification, shall mean the register of toxicologists in Croatia containing the list of names of the members on whom the CRT has conferred a registered title, their affiliations and area of expertise.
7. "Croatian Registered Toxicologist" shall mean a person whose name appears on the Register.
8. "EUROTOX Registered Toxicologist (ERT) shall mean a person whose name appears on the EUROTOX register.
9. "Croatian Society of Toxicology" (CROTOX) means the association of toxicologists in Croatia.
10. "EUROTOX" means the association of European Toxicologists & European Societies of Toxicology
11. "IUTOX" means the International Union of Toxicology, a worldwide scientific organization that promotes the field of toxicology
12. "Appeals Committee" shall comprise of a panel of three individuals eminent in the field of toxicology.

A. Registration and Membership in Croatian Register of Toxicologists (Procedures and Requirements)

A1. Registration Procedure

Toxicologists wishing to apply for inclusion in the Register should use the approved application form, which is available from the office of the chairman.

Toxicologists eligible for application should be members either of CROTOX, EUROTOX, IUTOX or their associated societies. The applicant should be in good standing regarding the

application fee, and confirm in writing the acceptance of the “Rules of the Croatian Register of Toxicologists Certified European Registered Toxicologist”.

Applications for membership should be sent to the Croatian Registration Panel. 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 Panel before October 31 in this year and shall be notified regarding decision, in writing, not later than December 31 of this year.

Application dossier should contain:

1. Annex 2 – Application and Evaluation Form
2. Motivation Letter
3. Detailed CV
4. List of Publications
- 2 Recommendation Letters (as stated under the Article A2. Alinea 4.)

In the event that the Croatian Registration Panel declines to approve membership for any particular applicant, the applicant may apply at a second and subsequent occasions as soon as she/he has met the admission criteria.

If an applicant does not agree with the decision of the Croatian Registration Panel, upon her/his request, in writing, pointing out the possibly inconsistencies in evaluating the eligibility for the CRT the application will be reconsidered. In the event that the applicant does not agree with the decision after reconsideration by the Croatian Registration Panel, she/he will be given an opportunity for independent appeal to the Croatian Appeals Committee.

A1.1. Fees

A fee of 1000 kn has to be paid in advance with each application for registration and maintenance of registration, respectively. For non-members of CROTOX but of EUROTOX, IUTOX or their associated societies the fee amounts of 2.000 kn has to be paid likewise in advance.

If necessary, the fees may be adapted by the Registration Panel in consultation with the Presidium of CROTOX. Charges are set such that the register shall be self-financing. Any net profit will be retained by CROTOX and used to promote the register and help provide continuing professional development/education for members.

A1.2. Membership Implementation

The registered professional title of the CRT shall be “Croatian Registered Toxicologist”. Members of the CRT are entitled to be registered by EUROTOX as EUROTOX Registered Toxicologist.

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

Registration expires on December 31 of the fifth year following the date of registration or maintenance of registration.

A2. Requirements

The prerequisites for registration include fulfillment of the recommendations of EUROTOX as last amended for certification as EUROTOX Registered Toxicologist:

- An academic degree in a toxicology relevant discipline, e.g. medicine (human, veterinary), biomedicine sciences, and natural sciences (pharmacy, chemistry, biochemistry, molecular biology, biology, nutritional, agricultural, environmental and health sciences) from a recognized European Union university or its equivalent
- Basic knowledge of the major areas of toxicology. There are two routes to meet this requirement:

Route 1 is by attendance of appropriate courses

Route 2 by practical experience and on the job training

- At least 5 years of relevant toxicological experience
- Suitability for Registration, e.g. by published works, confidential reports or assessments
- Current professional engagement in the practice of experimental/clinical toxicology

To apply for Registration, the applicant should provide to the Croatian Registration Panel following documentation:

1. A CV containing relevant information such as details of scientific education, of current and past employments and of professional activities performed.
2. Documentation of academic education before commencing further higher-level education and professional 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 as stated in the first Article of Requirements. 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.

3. Minimum accomplishments during further higher-level education and professional 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.

3.1. Acquisition of basic theoretical knowledge will be documented by credits/certificates from appropriate courses, workshops or equivalent qualification.

3.2. Alternatively basic theoretical knowledge can be acquired by long-standing experience and on the job training, and will be documented by peer-reviewed publications, confidential reports, assessments, teaching activities, knowledge-based decision-making or advisory activities, delegation into expert committees, internal studies (information on numbers, topics and methods used), names of customers or indication of branch or other achievements, subject to expert opinions.

3.3. Practical training and acquisition of hands-on experience and communication skills will be shown by publications, reports, or assessments, subject to expert opinions.

4. Expert opinions (Letter of Recommendation) evaluating the candidate's knowledge, skills, experience, and professional standing should be provided by two eminent toxicologists who are registered ERT, or are familiar with ERT requirements. They should know the applicant personally as well as his/her background and professional

performance. One reviewer, but not both may be from the applicant's current place of employment.

B. Theoretical Training

B1. Purpose

Theoretical training in toxicology, with associated practical working to re-enforce concepts, is essential. Such training can be provided on a modular basis. It should provide basic knowledge of the major areas of toxicology and embrace at least the topics defined in B2. Section.

B2. Topics

A candidate for registration will have undertaken theoretical training in the following core topics areas B1 – B13 and in at least one elective topic such as listed under B14 – B22:

- B 0. Introduction: History, Tasks, Scope and Ethical Principles of Toxicology
- B 1. Animal Science incl. Ethical Rules and 3 R Principle
- B 2. Experiment 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. Clinical, Occupational and Forensic Toxicology
- B10. Mutagenesis and Carcinogenesis
- B11. Reproductive and Developmental Toxicology
- B12. Immunotoxicology
- B13. Regulatory Toxicology

In addition, two topics, or one comprehensive topic, such as listed below are mandatory:

- 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

Additional elective topics can be offered by the Croatian Registration Panel upon prior notification of EUROTOX (Education and Registration Subcommittees).

Topics B0 – B13 and some of the elective topics are essentially covered in the existing ERT courses in Europe. Course directors and national registering bodies decide details of contents and sequence. Curricula of ERT courses currently offered should be notified to EUROTOX (Education and Registration Subcommittees).

Topics may be presented as modules consisting of lectures, site visits, demonstrations, and exercises. Case studies by individual participants are particularly encouraged to practice risk assessment and classification of chemicals. Distant teaching and learning will be used where feasible. At completion of each topic an examination has to be passed.

B3. Course level and time needed

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.

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

Comprehensive topics: Some elective topics such as B14, B15, B16, B17, may be organized to offer comprehensive specialized training. They will usually consist of more than one module and will need more than 10 days of contact time.

B4. Credits

Applicants for registration will be expected to present credits in all 13 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 higher academic degree (MSc, PhD) or course.

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

B5. Follow-up

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, positions obtained, special achievements, etc.

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 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 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 CRT, as appropriate and applicable to the eventual target of Registration.

C1. 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:

1. Post-mortem Methods, Animal or Human Pathology and Histology. Microscopic recognition of the major pathological processes. Foetal and neonatal examination for malformations.
2. 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.
3. 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.
4. 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.
5. Design of experiments, biometric and statistical procedures. Data Retrieval, Data Derivation, Computer assisted technologies, data-bases, data-banks, and data acquisition.
6. Determination of pharmacokinetic parameters and compound metabolism.
7. Procedures in Risk Analysis (Risk Assessment, Management and Communication), Regulatory Toxicology, Data reliability and relevance, Risk-assessment experience under mentorship.

C3. Documentation of practical experience, communication skills, authorship

Candidates for registration will have documented their practical experience by at least 5 confidential reports, 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 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.

C4. Confirmation

For all the above mentioned the candidate for registration will be expected to provide written confirmation from relevant supervisors.

D. Maintenance of Registration (Re-Registration)

On a 5-year 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 as a toxicologist, and according to the recommendations of EUROTOX in the valid version of certification as “EUROTOX Registered Toxicologist”, must submit to the Croatian Registering Panel:

1. 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.
2. Confirmation of professional toxicological activity in responsible position 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.
3. 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.

As stated under the Subsection **A1.1. Fees**, a fee for re-affirmation is 70 % of registration fee has to be paid in advance with each application for maintaining registration.

E. The National Registering Body (Croatian Register of Toxicologists)

E1. Relationship of a registering body with its national body and EUROTOX

The Croatian Register of Toxicologists (participating registering body) will have lodged (and had accepted) its criteria for registering toxicologists with the Croatian Society of Toxicology (national body). The Croatian Society of Toxicology in turn, will have lodged (and had accepted) these criteria with EUROTOX. One registering body only is accepted per country. The CRT will notify significant changes of their criteria to the EUROTOX Registration Subcommittee.

E2. Criteria of the Croatian Register of Toxicologists as 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, which 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

E3. Executive Organs

E3.1. Croatian Registration Panel

E3.1.1. Authorities and duties of the Croatian Registration Panel are:

1. Assessment of candidates for inclusion in the register or maintenance of registration.
2. Exclude or remove a member from the Register.
3. Advising and contributing to the development of Croatian Register of Toxicologists.
4. Preparing an annual report and submitting it to CROTOX.

5. Setting and, if necessary adapting fees for registration and maintenance of registration in consultation with CROTOX.

E3.1.2. Composition of the Registration Panel

The Registration Panel consists of 5 members, preferably 2 of them should be male. Four members are elected by the General Assembly of CROTOX at the period of 5 years and one is a nominated representative of the EUROTOX Registration Sub-Committee. Registration Panel members may be re-appointed with no limitation in the number of terms of office.

E3.1.3. Registration Panel Sessions

The Panel will meet at least twice a year (June and December) to evaluate applications for the Registration and Re-Registration, send reports on approved applications to EUROTOX, re-evaluate the applications upon first-level appeal submitted by an applicant whose request for registration has not been approved, and ensure continuing registration. A quorum of 3 members must be present and decisions should be made by simple majority. The member nominated by the EUROTOX registration committee can deliver his founded vote in writing before the session. If there is an equality of votes, the voting may be repeated two more times. If still no decision is reached, the chairman has a casting vote.

Non-voting observers may be invited to session at the discretion of the chairman.

Members of the Registration Panel are obliged to keep in strict confidentiality any information provided by applicants in their applications or first-level appeals if designated by the applicant as confidential.

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

E3.1.4. Registration Panel chairman and vice-chairman

The registration committee members will elect a chairman and a vice-chairman from amongst their number every 5 years.

The chairman will manage the day-to-day affairs, including statutory obligations of the CRT and shall implement the decisions of the CROTOX in relation to the CRT specifications and any requirements arising from new regulations for membership of the European Register of Toxicologists.

The chairman or in case of her/his absence the vice-chairman will chair the sessions of the Registration Panel.

E3.1.5. Secretary

The Secretary and the Vice-Secretary are provided by CROTOX. The secretary shall take minutes of the Registration Panel sessions.

The secretary shall have custody of all the documents and records belonging to the CRT and shall maintain the CRT.

The secretary maintains the register and accounts of the CRT. Subject to the available funds of the CRT she/he refunds any travel cost of members of an executive organ and any other additional costs resulting from related activities of panel members.

She/he advises interested applicants on the requirements for registration.

She/he notifies and informs the applicants for registration of the Registration Panel's decisions as soon as feasible.

She/he prepares Registration Certificates once the applicants have been admitted and fees have been paid. He notifies EUROTOX of the registered members of the CRT including dates of registration.

The secretary prepares a draft annual report for submission to CROTOX, addressing at least the following:

1. 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.
2. The names of those who have been removed from the register.
3. Needs for continuing professional development of members.
4. A review of the current financial status of the register.

E3.2. Appeals Committee

The appeals committee is elected by the general assembly of CROTOX. It comprises 3 members eminent in the field of toxicology. Current members of the Croatian Registration Panel 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 a honorary basis. Travel cost and any additional related activities can be refunded.

The Appeals Committee elects a chairman and a keeper of the minutes from amongst their number.

The Appeals Committee decides to the best of its knowledge in the presence of all members with simple majority.

The decision of the Appeals Committee will be binding on all parties

Appeals against the decisions of the Registration Panel to the Appeals Committee are at the appellant's cost in the form of a bond that is reimbursable if the appeal is successful.

F. Tasks to be undertaken by the lead body (EUROTOX)

F2. Training

F2.1. 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.

F2.2. 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).

F2.3. Each course or module, from EUROTOX or Non-EUROTOX organizers, which a CRT has evaluated, recognized and recommended for approval by EUROTOX Education and Registration Subcommittees, will be approved at the next meeting of the two

subcommittees. Subcommittees can decide, for a specific course/module, to request further information and, based on re-evaluation, recommend alterations or reject approval. In general, accreditation can be allotted to entire programs or several or single modules. Approvals are to be renewed after major changes.

F2.4. 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.

F2.5. EUROTOX Education and Registration Subcommittees / the EUROTOX secretariat maintain records of all curricula / course programs and modules accredited for registration.

F2.6. A list of all accredited courses and modules is shown on the webpage of EUROTOX.

F3. Registration

F3.7. 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 society seeks to set up its own national scheme within the EUROTOX guidelines.

F3.8. Existing registration bodies are encouraged to adapt their regulations in order to ensure concordance with the template describing the criteria of Registration (see F3.7.).

F3.9. 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.

F3.10. EUROTOX provides observers who can assist in setting up of national schemes. Appointment of these observers is co-ordinated by the Registration Subcommittee.

F3.11. 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.

F3.12. 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 co-ordinated by the EUROTOX Registration Subcommittee with help from the EUROTOX Executive Committee as necessary.

F3.13. If a national scheme or procedures exhibit serious deficiencies, which are incompatible with the quality standards observed by the majority of registering bodies (and described in the present guidelines), the EUROTOX Education and Registration Subcommittees will give advice how to improve procedures/contents concerned. If improvements are rejected or performed insufficiently, the EUROTOX Executive Committee, upon notification by the Education and Registration Subcommittees, will decide whether registrations by that registering body will be excluded from EUROTOX registration. The registering body can appeal against exclusion to the Appeals Committee. This committee comprises three members eminent in Toxicology, namely a former president of EUROTOX and two current chairpersons of national registering bodies. The Business Council elects members, along with 3 deputies, every 4 years.

Current members of EUROTOX organs are not eligible. If the chairperson of the excluded register is an elected member, he/she is replaced by a deputy.

Final Provisions

Expulsion

The Registration Panel may expel from the CRT any member whose alleged misconduct is, in the opinion of the registration committee, injurious to the character or interests of the CRT. In the event of proposed removal from the Register a minimum of one month's notice should be given to provide an opportunity for personal representation, or through an authorized representative, to the Registration Panel. The person concerned may appeal against the decision. The responsible body in this case is the Appeals Committee. Neither the CRT, its officers, nor the Registration Panel nor any member thereof shall have any liability to the expelled in respect of such expulsion.

Alteration to Rules

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 CROTOX by simple majority of the members present pass a resolution.

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 CROTOX.

If a resolution is passed the secretary shall within 14 days thereafter lodge the amendments to the rules.

Disputes and Differences

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 CROTOX whose decision shall be final and binding on all members.