Federation of European Toxicologists and European Societies of Toxicology

The EUROPEAN REGISTERED TOXICOLOGIST (ERT)
Guidelines for Registration 2023

Introduction

The present document is an update of the **Guidelines for Registration** approved by the EUROTOX Business Council Meeting in 2016. 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 25 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 how it is obtained.
- Section B describes the different fields of theoretical knowledge relevant for registration. 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 and how these can be documented.
- Section D contains requirements for maintenance of registration (“re-registration”).
- Section E describes the 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.
- Section G specifies the requirements for Non-European applicants.

The **Guidelines for Registration** is 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, and 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.

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.

B1. Principles of Toxicology
B2. Laboratory Animal Science incl. 3 R
B3. Experimental Design and Statistics
B4. Molecular and Cellular Toxicology
B5. Absorption, Distribution, Metabolism and Excretion
B6. Organ Toxicology and Histopathology
B7. Toxicology of Environmental Pollutants
B8. Exposure Assessment
B9. 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 competencies in a wider field. Candidates must 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 some 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 the 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. To be recognised for ERT registration an examination has to be passed at completion of each topic.

Courses should be taught to at least the Master of Science (MSc) standard. Each topic will probably involve 3-5 days, and 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 need 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, and 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, and 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, databases, 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, and risk-assessment experience under mentorship.

Documentation of practical experience, communication skills, authorship

Candidates for registration will have documented their practical experience with 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 accepted) its criteria for registering toxicologists with the national society of toxicology. The national society, in turn, will have lodged (and 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 ongoing 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 registration applications. 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 if 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. Strenuous efforts must be made to ensure that the quality and performance of participating institutes, programs and teachers, and the standards and conduct of examination are harmonised with 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. 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 the 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 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, to facilitate exchange between national societies, for example in establishing conjoint schemes.

F10. EUROTOX can provide facilitators who can assist in setting up national schemes or support the functioning of existing schemes. Appointment of these facilitators is coordinated 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 with a National Society in identifying an appropriate registry and playing 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 on 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.

G. Requirements for candidates living and working outside Europe (Non-Europeans[1]).

ERT recognition is open to non-European candidates. Non-European candidates interested to obtain ERT recognition may apply directly to any national register according to local requirements. Acceptance of Non-European applications is up to the discretion of the National Register.
All documentation to be submitted by non-European candidates is listed under Section A. Registration: Requirements and Implementation must be translated to English if the original language is other than English.
Professional CV should be submitted in Europass format (https://europa.eu/europass/en)
Documentation of academic education should be authenticated using an apostille issued by an authority designated by the state of origin (HCCH 1961 Apostille Convention).

[1] Any country not listed in UN Eastern European and Western European States is classified as non-European (https://www.un.org/dgacm/en/content/regional-groups)

Candidates must refer to the competent authorities located in their country of origin for assistance regarding the procedure.
https://www.hcch.net/en/instruments/conventions/authorities1/?cid=41
Candidates living and working in countries not part of the HCCH 1961 Apostille Convention, must contact the Consulate office of the country where they are seeking ERT registration to inquire about the process to authenticate documents.
Required letters of recommendation, to verify the candidate's work experience and practical training, must explicitly specify the time period of the position, and must accurately and fully document the applicant's duties, responsibilities and full-time professional experience in toxicology.
For self-employed applicants, letters from clients or contract-base employers are required to verify the candidate's work experience and practical training.

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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

Federation of European Toxicologists and European Societies of Toxicology

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The EUROPEAN REGISTERED TOXICOLOGIST (ERT)
Annex to the ERT Guidelines for Registration

Annex 1 - Aim, content and learning outcomes for core and specialised topics for theoretical training

Section B of the ERT guideline describes the topics that need to be addressed in the framework of the theoretical training to become a European Registered Toxicologist (ERT).

A candidate for registration needs to demonstrate basic knowledge in the core topics (B1-B14) that are considered as being essential for every toxicologist. In addition, the candidate needs to demonstrate knowledge in two specialised topics. The guideline lists a number of specialised topics (B15-B23). National registration boards can decide that they accept additional specialised topics.

Each topic will involve approximately 3-10 days of theoretical training. Annex 1 describes the aim, content and learning outcomes for each topic.

LIST OF DESCRIPTIONS FOR CORE TOPICS

Topic B1: Principles of Toxicology

Aim: Knowledge and understanding of the basic principles of the science of toxicology.

Content:

- History, tasks and scope of toxicology
- Ethical principles
- Spectrum of adverse (toxic) effects
- Association between exposure to chemical substances and adverse effects
- Principles of dose-response relationships
- Modulation of adverse effects (individual and environmental factors, species differences)

Learning outcomes:

- Understand the basic principles of toxicology

Topic B2: Laboratory Animal Science including 3R

Aim: Knowledge and understanding of the main animal species used and their husbandry, and of the performance of animal experiments in the context of the pertinent ethical rules.

Content:

- Husbandry and welfare of laboratory animals
- Genetics, physiology, anatomy, nutrition and frequent diseases of laboratory animals
- Interspecies comparisons and extrapolation to humans, differences in anatomy, physiology, pathology and metabolism between laboratory animals and man
- Genetically modified laboratory animals
- Design protocols and performance of studies on animals
- Legislation and international guidelines on the protection of animals used for scientific purposes
- Implementation of the Refine, Reduce, Replace (3R) principles taking into account progress in new approach methodologies (NAMs)

Learning outcomes:

- Understand the specific conditions, strengths and weaknesses of animal studies
- Be able to plan an animal experiment according to legislation and ethics
- Be able to interpret and evaluate the quality and relevance for humans of animal models in toxicological studies

Topic B3: Experimental Design and Biostatistics

Aim: Knowledge and understanding of major principles of biostatistics and their relevance for the design and statistical evaluation of toxicological studies, and awareness of major terms used in biostatistics.

Content:

- Definition of working hypothesis/experimental question, selection of methodology, data recording, good laboratory practice (GLP)
- Dose selection
- Normal and other distributions
- Principles of hypothesis testing
- The confidence limits approach
- Multiple comparisons problem
- Correlation and regression (linear and logistic)
- Sample size calculation
- Selection of appropriate statistical tests

Learning outcomes:

- Understand the concepts of experimental design and meaning of statistical terms and of statistical results
- Be able to apply statistical concepts, terms and procedures in the design and evaluation of toxicological studies
- Be able to assess and interpret the results of statistical testing

Topic B4: Molecular and cellular toxicology

Aim: Knowledge and understanding of cells as the primary target of organ toxicity, the molecular mechanisms involved in cellular toxicity, and the technological approaches available to identify and understand molecular and cellular toxicity.

Content:

- Normal structure and functions of cells and organs, homeostasis and adaptation, systems biology and toxicology, structure-activity relationships
- Biochemical and molecular mechanisms of cell toxicity in relation to target organs, e.g. necrosis, autophagy and apoptosis, typical endpoints of tissue injury, signalling pathways central to the control of the toxic outcome
- New approach methodologies (NAMs) relevant to molecular and cellular toxicology (molecular, biochemical, *in vivo*, *in vitro*, genetic, cell and animal engineering, reporter systems, bio-imaging, cell-sorting, proteomics, transcriptomics and metabolomics)

Learning outcomes:

- Understand the molecular and cellular concepts of toxicity in relation to target organs
- Be able to assess and use data from appropriate technologies in molecular and cellular toxicology

Topic B5: Absorption, Distribution, Metabolism and Excretion

Aim: Knowledge and understanding of the kinetics of chemical substances: absorption, distribution, metabolism and excretion (ADME).

Content:

- Qualitative and quantitative aspects of ADME processes as well as their importance for the toxicity of the chemical substances
- Relationship between the physico-chemical properties of chemical substances and passive or active (i.e. transporter-driven) membrane transport
- Absorption and tissue distribution of chemical substances
- Biotransformation processes and their role in toxicity and excretion; multiplicity and properties of the xenobiotic/drug metabolising enzymes in activation and inactivation of chemical substances
- Enzyme induction and inhibition and polymorphisms related to metabolism:
- toxicological, pharmacological and clinical consequences
- Species specificities in toxicokinetic/ADME studies
- Biokinetic analysis of concentration vs. time profiles of chemical substances and their metabolites in body fluids and tissues
- Modelling and mathematical description of the time course of disposition (ADME) of chemical substances in the whole organism using classic toxicokinetics model and physiologically based toxicokinetic model approaches

Learning outcomes:

- Understand the principles of absorption, distribution, metabolism and excretion (ADME)
- Be able to describe, qualitatively as well as quantitatively, the biokinetic profile of a chemical substance
- Be able to interpret the biokinetic behaviour of a chemical substance, and how this contributes to the toxicity of the substance

Topic B6: Target Organ Toxicology and Histopathology

Aim: Knowledge and understanding of the pathophysiology of organ systems and the pathological manifestations of toxic effects.

Content:

- Normal physiology of organs and their role in the homeostasis of the organism; normal gross and microscopic morphology
- Fundamental aspects of adverse effects: integrating biochemical, cellular and immunological knowledge of disease mechanisms at the level of cells and tissues
- Different forms of organ dysfunction and its consequences for the organism, as well as means of detecting, diagnosing and interpreting organ dysfunction
- Pathophysiology of the main organ systems involved in toxicology of chemical substances.
- Techniques applied in studying the morphology and histopathology of organs, including functional parameters and microscopic techniques

Learning outcomes:

- Understand the pathophysiological processes underlying toxic effects and the principal aspects of target organ pathology
- Be able to interpret the pathology of toxic effects at the level of organ systems and the macroscopic and microscopic aspects of pathological processes
- Understand the general procedures used in clinical/diagnostic and toxicological pathology (and the application of these techniques/approaches)

Topic B7: Toxicity of Environmental Pollutants

Aim: Knowledge and understanding of the toxicity and toxicology of pollutants in air, dust, sediment, soil and water, and natural toxins in the environment.

Content:

- Environmental pollutants and natural toxins
- Exposure to toxic chemical substances and systems occurring in the natural and living environments
- Models in environmental exposure assessment
- Persistence, bioaccumulation, biomagnification
- Characterization of environmental health risks
- Diseases caused by environmental pollutants
- International and national guidelines and regulations on human health and environmental pollutants

Learning outcomes:

- Understand changes in cells and organs and potential health effects caused by environmental pollutants and natural toxins
- Be able to evaluate potential risks relevant to humans from environmental pollutants and natural toxins
- Be able to apply the knowledge in preventive measures and regulatory decisions

Topic B8: Exposure assessment

Aim: Knowledge and understanding of exposure as an integral and necessary component in the sequence of events leading to potential health consequences.

Content:

- Scenarios, determinants and routes of exposure
- Strategies and design for exposure studies
- Measuring external and internal (biomonitoring) human exposures
- Quality assurance in exposure studies
- Statistical methods in exposure assessment
- Deterministic vs. probabilistic approaches
- Modelling of exposure and dose
- Aggregate and cumulative exposures to chemical substances
- Assessing exposures with biological markers

Learning outcomes:

- Understand the principles of the exposure assessment, differences of routes and absorption of chemical substances as well as limitations and accuracy of exposure measurements in both environmental and biological monitoring
- Be able to apply exposure assessment in multiple contexts
- Be able to use data from exposure measurements and models in risk assessments of chemical exposures

Topic B9: Epidemiology

Aim: Knowledge and understanding of the basic principles of epidemiology in relation to toxicology and how to understand epidemiological studies.

Content:

- Epidemiological study design and analysis
- Statistical methods used in epidemiological studies
- Types, strengths and limitations of epidemiological studies
- Systematic reviews and meta-analyses
- Exposure assessment in epidemiological studies
- Associations and causality between exposure and effect

Learning outcomes:

- Understand the basic terms in epidemiological research, differentiate between study designs and recognise the weaknesses and strengths
- Be able to evaluate epidemiological studies and use the data in risk assessment

Topic B10: Occupational Toxicology

Aim: Knowledge and understanding of the discipline of anticipating, recognising, evaluating and controlling health hazards in the working environment with the objective of protecting worker health and well-being.

Content:

- Principles and scope of occupational toxicology
- Occupational exposure routes
- Toxicity of occupationally relevant chemical substances
- Occupational toxicology of target organs and systems
- Ambient and biological monitoring in workplace assessment
- Principles of measuring airborne gases, vapours, aerosols and particulates
- Regulation of occupational exposures and exposure limits

Learning outcomes:

- Understand the role of occupational toxicology in worker health and safety
- Be able to interpret the results of occupational exposure assessments within the context of safety assessments
- Be able to provide toxicological input into occupational safety assessments

Topic B11: Genotoxicity and Carcinogenicity

Aim: Knowledge and understanding of the concepts by which genotoxic and non-genotoxic chemical substances act.

Content:

- Mechanism of action of mutagenic/genotoxic chemicals incl. metabolic activation and deactivation and repair mechanisms
- Mechanism of action of non-genotoxic carcinogens
- Epigenetics
- Identification of potential mutagenicity/genotoxicity by *in silico*, *in vitro* and *in vivo* methods
- Cancer: Major types and frequency in humans, natural history of cancer, mutation and selection, epigenetic changes, oncogenes and suppressor genes, risk factors
- Testing, evaluation and regulation of genotoxicity and carcinogenicity studies: Assays *in vitro*, short-term and long-term animal studies, QSAR methods, "omics" signature of carcinogens
- International classification schemes (e.g. IARC, CLP)

Learning outcomes:

- Understand main effects and mechanisms of action, testing strategies and human relevance of test results of chemical mutagens as well as genotoxic and non-genotoxic carcinogens
- Be able to design testing strategies for mutagenic and/or carcinogenic properties of chemicals, and to apply information on kinetics and metabolism in the analysis
- Be able to interpret data resulting from such studies

Topic B12: Reproductive and Developmental Toxicology

Aim: Knowledge and understanding of how chemical substances can interfere with fertility and the development of an organism, and how these effects are studied.

Content:

- Physiology and morphology of the male and female reproductive systems in experimental animals and in man
- Prenatal and postnatal organ development
- Effects and mechanisms of action of reproductive and developmental toxicants, role of maternal toxicity
- Germ cell mutations and methods of detection
- Standard testing for fertility impairment and developmental toxicity
- New approach methodologies (NAMs) for assessing reproductive and developmental toxicity
- Hormonally active substances and their role in reproductive toxicology
- International classification schemes (e.g. CLP)

Learning outcomes:

- Understand the function of the reproductive organs, prenatal and postnatal organ development and effects and mechanisms of action of reproductive and developmental toxicants and hormonally active substances
- Be able to interpret data of reproductive and developmental toxicity tests

Topic B13: Risk Assessment of Chemicals

Aim: Knowledge and understanding of the basic principles and methods used in assessment of the risk of chemicals for human and the environment'

Content:

- Problem formulation
- Hazard identification
- Hazard characterisation
- Exposure assessment
- Risk characterisation
- Risk management
- Risk perception and communication
- Application of risk assessment in different chemical sectors (e.g. chemicals, human pharmaceuticals, veterinary pharmaceuticals, pesticides and biocides, cosmetics, household and consumer products, food additives and contaminants)

Learning outcomes:

- Understand the basic principles and methods used in risk assessment and awareness of a role for new approach methodologies (NAMs)
- Be able to interpret and assess a risk assessment report

Topic B14: Clinical and Forensic Toxicology

Aim: Knowledge and understanding of the toxic effects of natural and synthetic chemical substances and products in humans and how to treat patients exposed to toxic substances. Knowledge and understanding of the use of toxicology and related disciplines such as analytical and clinical chemistry to aid medical or legal investigation of death, poisoning and drug use.

Content:

Clinical toxicology

- Signs and symptoms of poisoning
- Important classes of poisons: pharmaceuticals in overdose, alcohol and drugs of abuse, household chemicals, industrial chemicals, pesticides, animal and plant poisons, natural toxins
- First aid and medical management of poisoning; use of antidotes
- Prevention of poisoning
- The role of poison information centres
- Surveillance of poisoning

Forensic toxicology

- Post-mortem toxicology
- Bio-analysis applied to clinical and forensic toxicology (analysis of post-mortem body fluids and tissues)
- Human performance toxicology
- Doping and doping control
- Drugs of abuse

Learning outcomes:

Clinical Toxicology

- Understand signs and symptoms of important toxic syndromes
- Understand the role of poison information services and systems for the surveillance of poisonings
- Be able to use clinical and laboratory findings in the risk assessment of acute toxic exposures

Forensic toxicology

- Understand the role of alcohol, drugs and poisons in causation of death
- Understand of the rules regarding performance enhancing drug use
- Be able to interpret the effects of alcohol and drugs on human performance
- Be able to apply this knowledge in the context of the medico-legal consequences of alcohol and drug use, and doping control

LIST OF DESCRIPTION OF SPECIALISED TOPICS

Topic B15: Drug Safety Assessment

Aim: Knowledge and understanding of the role of safety assessment in the drug discovery and development process, including the post-marketing phase.

Contents:

- The different steps of the entire process of drug discovery and development (including small molecules and biopharmaceuticals), and the role that safety assessment plays in each of them, from target identification to the post-marketing phase
- Toxicologically relevant *in silico*, *in vitro* and *in vivo* methods used during the discovery phase
- Regulatory requirements covering both the preclinical and clinical studies in the development phase
- Translational safety assessment, bridging the gap between animal and human studies
- Pharmaceuticals in the environment

Learning outcomes:

- Understand safety assessment in the process of drug discovery and development, and the types of data required over the course of the process
- Be able to critically discuss how different types of toxicological data (including data from predictive methods) can be assessed
- Understand how assessments affect decisions in a drug project and to identify important parameters when going from preclinical to clinical studies

Topic B16: Regulatory Toxicology

Aim: Knowledge and understanding of methods of toxicological risk assessment in regulatory processes for different categories of chemicals.

Content:

- Methodology for the different steps in risk assessment (hazard identification, hazard characterisation, exposure assessment, risk characterisation)
- Uncertainty in risk assessment
- Use of Adverse Outcome Pathways and Mode of Action Frameworks in risk assessment
- Derivation and use of health-based guidance values (e.g. RfD, ADI, AOEL, DNEL, etc.)
- Application of regulations and guidelines for different sectors (e.g. chemicals, human pharmaceuticals, veterinary pharmaceuticals, pesticides and biocides, cosmetics, household and consumer products, food additives and contaminants)

Learning outcomes:

- Understand the application of risk assessment in different regulatory systems
- Be able to perform a basic risk assessment using toxicological and exposure data
- Be able to interpret data submitted for the purpose of registration and labelling of different types of chemicals substances

Topic B17: Ecotoxicology

Aim: Knowledge and understanding of the toxicology of contaminants and their harmful effects on constituents of the biosphere.

Content:

- Source and stressor characteristics
- Complexity of exposure
- Ecotoxicity tests
- Aquatic, sediment and terrestrial toxicity
- Ecotoxicant effects: change in population structure, health of individual species and damage to ecosystem
- Ecotoxicological endpoints
- Ecosystems potentially at risk
- Interconnections between ecosystems and human health

Learning outcomes:

- Understand the multidisciplinary nature of ecosystem health
- Be able to apply the knowledge in ecotoxicology risk assessment and management

Topic B18: Nanomaterials

Aim: Knowledge and understanding of nanomaterial toxicology concerning natural and engineered materials.

Content:

- Characterisation of nanomaterials
- Special properties of nanomaterials
- Uses and occurrence of nanomaterials
- Exposure of workers and the general population to nanomaterials
- Toxicity study and screening strategy for nanomaterials
- Risk analysis of nanomaterial toxicity

Learning outcomes:

- Understand special properties and toxic effects of nanomaterials
- Be able to interpret data obtained from toxicological studies with nanomaterials
- Be able to apply the knowledge of nanotoxicology in regulatory and safety management purposes

Topic B19: New approach methodologies (NAMs)

Aim: Knowledge and understanding of possibilities and the limitations of new approach methodologies (NAMs) in the process of hazard and risk assessment.

Content:

- Application of *in vitro* methods to assess toxic mechanisms
- Methodologies used in *in vitro* toxicology
- *In vitro-in vivo* extrapolations
- Integrated testing strategies based on NAMs
- Ethical aspects of developing and validating NAMs
- Use of NAMs in hazard and risk assessments

Learning outcomes:

- Understand the possibilities and limitations of NAMs in toxicology
- Be able to compare the different strategies in hazard and risk assessment based on *in vivo* and *in vitro* data
- Be able to apply data produced with *in vitro* methods in hazard and risk assessment strategies

Topic B20: In Silico Toxicology

Aim: Knowledge and understanding of computer-aided methods in the area of toxicology

Content:

- (Quantitative) structural parameters of chemicals in relation to their physico-chemical and toxicological properties (QSAR)
- Read-across
- Data-mining techniques for prediction
- Data clustering tools (K-means, self-organizing maps (SOM), graph-based clustering)
- Use of databases, both relational and object-oriented for the archiving, management and derivation of toxicologically relevant data
- Computer-aided calculations of toxicity and biokinetics/dynamics (PBPK/TD)
- Computational structural biology

Learning outcomes:

- Understand the possibilities and limitations of in silico methods, computational tools and mathematical background for supporting the application of computer-aided new approach methodologies (NAMs) in toxicological analysis and hazard and risk assessment.
- Be able to apply knowledge of computer-aided techniques and technologies in toxicological science and chemical risk assessment

Topic B21: Immunotoxicology

Aim: Knowledge and understanding of the effects of chemical substances on the immune system and immunomodulatory mechanisms.

Content:

- Structure and function of the immune system
- Theory, principles, methodologies and mechanisms in immunotoxicity
- Immunosuppression
- Hypersensitivity and autoimmunity
- *In vivo* and *in vitro* assessment of immunotoxicity
- Regulatory immunotoxicology: examples of drugs, industrial chemicals, household chemicals, plant protection products and food additives affecting the immune system

Learning outcomes:

- Understand the methods and procedures used in immunotoxicology
- Be able to interpret immunotoxicological data

Topic B22: Neurotoxicology

Aim: Knowledge and understanding of the adverse effects of natural and synthetic neurotoxicants on the structure or function of the developing and adult nervous system.

Content:

- Structure and physiology of the (developing) nervous system
- Biochemical and molecular aspects of (developmental) neurotoxicity taking into account both cytotoxicity and functional toxicity
- Selected groups of (developmental) neurotoxicants
- Methods to assess (developmental) neurotoxicity

Learning outcomes:

- Understand (developmental) neurotoxic effects and the testing strategies and methods used in (developmental) neurotoxicology
- Be able to interpret and apply (developmental) neurotoxicity data

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Annex 2 to the ERT Guideline

EUROTOX recognition of courses providing comprehensive training in toxicology for the purpose of registration (ERT courses), or providing continuing professional development for the purpose of maintaining ERT registration (CPD courses)

I. Introduction

EUROTOX has set standards of qualification for European Registered Toxicologists (ERT) in the Guidelines for Registration 2012. There are currently a number of ERT courses available that have been approved by national societies and registers, offering comprehensive theoretical training required for registration of toxicologists.

This document provides guidance for course providers who wish to obtain recognition by EUROTOX for courses as part of the comprehensive theoretical training for registration of toxicologists or continuing professional development (CPD) for the purpose of maintaining ERT registration.

II. Scope and limitations

This guidance applies to the recognition of courses by EUROTOX. Recognition means that EUROTOX is satisfied that a course is suitable for the purpose of providing

a) comprehensive training according to Annex 1 of the Guidelines for Registration (**ERT courses**), or

b) CPD for maintaining ERT registration (**CPD courses**).

Recognition is given for individual courses, not for entire educational programmes (e.g. those leading to an academic degree).

EUROTOX does not promote the attendance at a particular course. Prospective course participants are encouraged to check with their national register whether the course of interest is recognised locally.

III. Evaluation Committee

The process for recognition is overseen by an Evaluation Board appointed by the EUROTOX Education and Registration Subcommittees. Membership and procedures of the Evaluation Board are subject to regulations approved by the EUROTOX Executive Committee.

IV. Process for recognition

1. Course providers who wish to have a course recognised should apply to the Evaluation Board at least 3 months before the start of the course with the following information:
   i. Purpose and aims of the course
   ii. Course provider (e.g. university, scientific society, …)
   iii. Target audience
   iv. Subjects and topics covered (for ERT courses these must correspond to Annex I of the Guidelines)

v. Faculty

vi. Number of teaching hours; where appropriate, credit points offered

vii. Assessment (written examination is mandatory for ERT courses)

viii. Course fees

ix. If appropriate, recognition by other bodies (e.g. learned societies)

2. The Evaluation Board will assess applications in accordance with the provisions of the Guidelines.

    a) For **ERT courses**, particular emphasis will be placed on compliance with the aims, content and learning outcomes listed in Annex 1 of the Guidelines. The number of teaching hours must be appropriate to the subject (for further details see section B of the Guidelines). As a general rule, an appropriate written examination is required.

    b) **CPD courses** can cover a broad range of subjects related to toxicology and the course provider should give sufficient details. An examination is not mandatory for CPD courses.

3. The Evaluation Board will notify the course provider whether the course can be recognised. In cases of doubt it may request additional information, or ask for modifications to be made to the course programme. If the evaluation committee decides not to recognise the course it will provide its reasons to the applicant.

V. Appeals process

Course providers may appeal to the EUROTOX Education and Registration Subcommittees against decisions made by the Evaluation Board.

VI. Statement of recognition

Once recognition has been granted the course provider may use the statement of recognition on information material related to the course. A suggested form of wording is

a) For ERT courses

"This course is recognized by EUROTOX as providing XX hours of comprehensive training in toxicology on the following topic(s) [list all applicable]"

b) For CPD courses

"This course is recognized by EUROTOX as providing XX hours of education for continuing professional development".

The course provider is reminded that they must not use any form of wording that implies EUROTOX is promoting attendance at the course, or that the course is **automatically** accepted by a national register for ERT registration or re-registration.

VII. Duration of recognition

Applications can be made for individual courses as a one-off, or for courses held on an on-going basis. If recognition has been granted for a course held on an on-going basis the duration of recognition is limited to a maximum of 5 years. After this time a new application has to be made. EUROTOX reserves the right to withdraw recognition at any time if it considers that the conditions of recognition are no longer met.

Federation of European Toxicologists and European Societies of Toxicology

The EUROPEAN REGISTERED TOXICOLOGIST (ERT)
Annex to the ERT Guidelines for Registration

Annex 3 - Glossary of Terms

This glossary describes some of the key terms used in the Guidelines and Annexes 1 and 2. As it is intended to be used in conjunction with the other parts of the Guidelines, the terms are described in the context of their use rather than simply providing a definition.

Continuing Professional Development (CPD)	CPD refers to the process of developing, monitoring and documenting the knowledge, skills and competencies necessary to work as a toxicologist, beyond any initial training. It involves formal learning (e.g. attending lectures, courses, workshops) as well as informal development activities (e.g. scientific publications, preparing lectures, structured self-study).
Core Topics	Core topics refer to those elements of the toxicological domain that are generally considered to be essential for every toxicologist to have basic knowledge and understanding. The current list of core topics can be found in Section B of the Guidelines.
DABT	Diplomate of the American Board of Toxicology (ABT). ABT certifies candidates that have the appropriate education, documented active practice of Toxicology and have passed the written ABT examination.
Educational Courses	These are structured training activities designed to provide theoretical knowledge in one or more areas relevant to toxicology. Topics may be presented in different formats including lectures, site visits, demonstrations, practical exercises and case studies. In the context of ERT registration courses form part of the comprehensive theoretical training for registration of toxicologists or continuing professional development (CPD) for the purpose of maintaining ERT registration.
ERT	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).
Europass	Europass is a documentation system initiated by the European Union and the European Economic Area describing a person's CV, language skills and obtained education. In every participating country a National Europass Centre coordinates all activities related to the Europass documents.

Examination	Formal assessment of learning outcome at the end of an individual course or training programme. Examinations may be written or oral and may use many different formats such as essay or multiple-choice questions, home assignments, short oral questions, presentations etc.
National Register	A register of toxicologists maintained by a national registering committee that is recognized by EUROTOX. Registers contain the list of names of persons on whom the national registering committee has conferred the registered title in accordance with the ERT Guidelines.
Practical Experience	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 in the Guidelines in Section C. In addition, an in-depth knowledge and experience will be expected in at least two of these topics. Proof of practical experience should be documented by at least 5 reports (which may be internal and/or confidential), assessments, or publications.
Recognition of Courses	EUROTOX can upon request recognise a course that is considered suitable for the purpose of providing comprehensive training according to Annex 1 of the Guidelines for Registration **(ERT courses),** or continuing professional development for maintaining ERT registration **(CPD courses)**. Recognition is given for individual courses, not for entire educational programmes (e.g. those leading to an academic degree).
Specialised Topics	In addition to the knowledge on core topics, it is expected that toxicologists will specialise in certain areas and obtain specific knowledge, skills and competences in a wider field. It is mandatory for candidates to demonstrate knowledge in at least two topics for specialization (e.g. from the list given in Section B).
Supervisor	A person who oversees the practical training activities carried out by a candidate for ERT registration. This may be the candidate's line manager if training is carried out on the job, or someone overseeing a specific activity such as a research project. The supervisor must be able to provide written confirmation on the nature and content of the training activity.
Theoretical Training	Theoretical training in toxicology is essential and should include the core topics as well as a limited number of specialised topics. Such training can be undertaken on a modular basis and should provide basic knowledge of the major areas of toxicology as described in Section B of the Guidelines.