SWEDISH SOCIETY OF TOXICOLOGY
SINCE 1969

Swedish Society of Toxicology

Revised Swedish guidelines based on European guidelines 2016

EUROPEAN REGISTERED TOXICOLOGIST (ERT)
Swedish Guidelines for Registration (Approved 23 January 2020 by SFT board)

Introduction

The European registration of toxicologists is a service of EUROTOX for toxicology and for individual toxicologists who meet specific requirements in education, skills, experience and professional standing. Toxicologists can, upon application, be certified as European Registered Toxicologists (ERT). A registration committee appointed by the board of the Swedish Society of Toxicology (SFT) will evaluate applications of candidates according to the guidelines described herein, and admit successful applicants to the Swedish ERT register. EUROTOX will then certify these individuals as ERT, without further evaluation.

The Swedish Guidelines for Registration were introduced in 2014 and were based on the EUROTOX Guidelines from August 2012. As the EUROTOX Guidelines are updated, the Swedish Guidelines are reviewed accordingly, or as needed, by the board of SFT with support from the registration committee. This version of the Swedish Guidelines is based on the European ERT Guidelines for Registration 2016.

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

The Guidelines for Registration reflect scientific progress in toxicology with a focus on transparency and harmonisation of rules and requirements between European countries.

- Section A contains the formal requirements and documentation 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. Aim, content 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 procedure for application, appeals and removal from the register.

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 between European countries.

A. Registration: Requirements and Documentation

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, the Swedish registration committee 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.

A2. Documentation of academic education before commencing training (*entry level knowledgebase*)
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 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 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. Upon request by the registration committee, expert opinions evaluating the candidate's knowledge, skills, experience, and professional standing must be provided by at least two senior toxicologists who are ERTs, or familiar with the ERT requirements.

B. Courses requirements for theoretical toxicological 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.

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 or one comprehensive topic 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.

Course levels and time per topic
Course levels will correspond 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 certified 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.

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. Practical training (as opposed to theoretical training) within doctoral (PhD) or master (MSc) education can be counted within the 5 years of practical training and experience.

Practical awareness
A candidate for registration will be expected to have obtained practical awareness (knowledge of major techniques and their merits and limitations, not necessarily hands-on experience) in the majority of the topics listed below. In addition, an in-depth knowledge and experience will be expected in some 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 examples and/or written confirmation from relevant supervisors

D. 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.

E. Application procedure, appeals and removal from registry

The application form can be downloaded from the SFT webpage http://toxikolog.se/ and must be sent to the address indicated on the application form. Information on the current registration fees and deadlines can be found on the SFT webpage.

Appeals can be submitted to the SFT board (see the Annex for more details on appeals).

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

In the event of a proposed removal from the register, a minimum of one month's notice will be given to provide an opportunity to provide re-registration documentation and/or to appeal.

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

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Annex 1 to the ERT Guidelines*:

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.

*This annex was introduced by Eurotox in 2016. The text in the Swedish guidelines is identical to the European guidelines.

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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 (3 R) principles

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, signaling pathways central to the control of the toxic outcome
- State-of-the art methods in 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
- *In vitro* methods 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 risk assessment of chemical substances.

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
- 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 centers
- 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: In vitro Testing Methods

Aim: Knowledge and understanding of possibilities and the limitations of the use of *in vitro* methods 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
- Ethical aspects of developing and validating non-animal methods
- Using *in vitro* methods in hazard and risk assessments

Learning outcomes:

- Understand the possibilities and limitations of *in vitro* methods 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 computational methods 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

Topic B23: Analytical Methods in Toxicology

Aim: Knowledge and understanding on techniques for the identification, characterization and quantification of chemicals in different matrices.

Content:

- Sampling, storage and preservation
- Sample preparation
- State-of-the-art analytical technologies including
    - gas and liquid chromatography, electrophoresis
    - mass spectrometry
    - AAS and ICPMS
    - immunoassays
    - microarrays
- Data processing and analysis
- Analytical method validation (sensitivity, LOD, LOQ, specificity, repeatability)
- Internal and external quality assessment schemes
- Reference values

Learning outcomes:

- Understand analytical techniques to identify and quantify chemicals in the environment and in living organisms
- Be able to apply appropriate analytical techniques for toxicological questions andinterpret the data

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Annex 2 to the ERT Guidelines: Establishment and responsibility of the Swedish Registration Committee

A registration committee appointed by the board of the Swedish Society of Toxicology (SFT) will evaluate applications of candidates according to the guidelines described herein, and admit successful applicants to the Swedish ERT register. EUROTOX will then certify these individuals as ERT, without further evaluation.

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

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

The SFT board appoints the chairperson of the committee. The committee chooses a secretary from its members. The committee maintains the Swedish ERT register and gives out certificates as proof of registration.