ERT Guidelines for Registration

History and Recent Development

1st International Workshop on ERT, Stockholm, Sweden
November 8, 2012

Rolf Schulte-Hermann
Prof. em. of Toxicology
ERT
Institute of Cancer Research
Unit Toxicology and Prevention
Vienna, Austria

Member of EUROTOX Subcommittee Education (2007-2012)

1

Registration

First steps in Europe in the late 80ies

Registration of qualified toxicologists by some European societies (UK, D, SF, NL,…).

Early 90ies: Discussions on a joined European Registration

In 1994: Foundation of the **EUROTOX Register of Toxicologists (ERT)**

- to sponsor toxicology standards
- allow for mutual recognition of educational qualifications within Europe

(the „Eurotox Model of Registration“)

2

The Eurotox Model of Registration

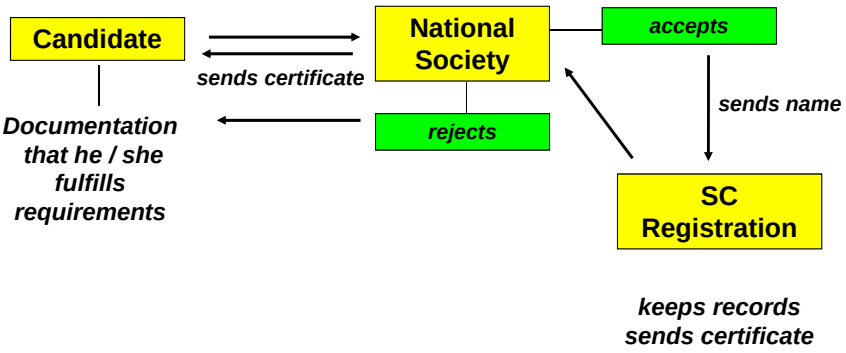
defined (1) 5 basic requirements for candidates striving towards registration:

- An academic degree in a related subject
- Theoretical knowledge of major areas
- 5 years of practical experience
- Current professional engagement in toxicology
- Renewal at 5 years intervals

3

The Eurotox Model of Registration

defined (2)
a 2-step procedure for registration:



From: J. Fowler & D. Schrenk, 2007, modified

4

The Eurotox Model of Registration

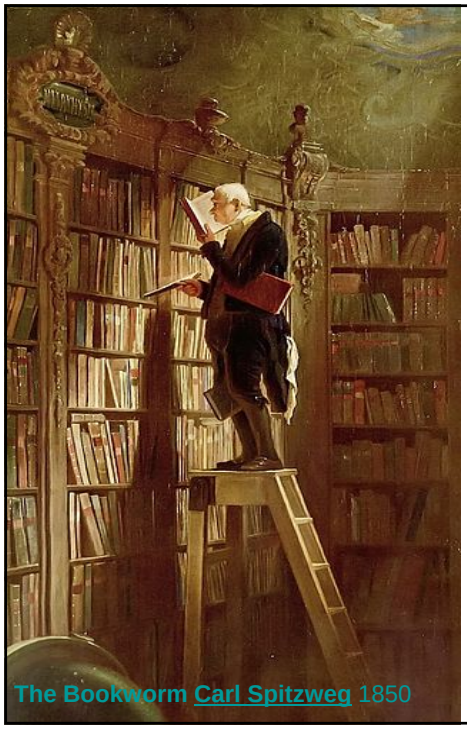
Registration criteria were agreed on by all societies
and, with some details of regulation,
first published in preliminary form in 1994/1995,

later developed to

„Expectations of a EUROTOX Registered Toxicologist“

Expectations proved very useful for many years

5



The Bookworm Carl Spitzweg 1850

Toxicology is a rapidly moving Science.

Opportunities of our young colleagues for education and career development should just be **up-to-date**

Concepts of the early 90ies, described in the „Expectations..“ needed an update.
In addition, significant gaps...

6

In 2010 EUROTOX Subcommittees for Education and Registration jointly decided to update and expand the *„Expectations …".*

The SubCommittees' draft

- was discussed by individuals and member societies,
  numerous constructive, valuable comments
- were used for amendments
  resulting in

  ERT Guidelines for Registration 2011
- accepted and ratified by EC and BC in Paris, August 2011.

- Since then, additional amendments were requested and performed,
  resulting in

ERT Guidelines for Registration 2012

- accepted by BC at EUROTOX Congress, Stockholm 2012
  and now in force, identified as version of August 28.

7

Guiding Principles during updating

1) **Maintain** basic criteria and procedures of the Eurotox model of Registration

2) **Extend** the regulations to provide a complete template covering the entire process

3) **Promote harmonization** of quality standards and registration procedures of national societies
   = a key purpose of the Guidelines
   to increase credibility and general recognition of the ERT

However: **The Guidelines for Registration remain a framework.**
They are not obligatory. Details can be decided at the **National level** in order to cover specific national needs.

8

The principal common standards defined in the Guidelines should be used by societies as far as possible

As expressed in several articles, for example:

The proper function of the EUROTOX model ***depends on harmonization*** *of standards among registering national boards* (INTROD).

Registration bodies ***should...have accepted their criteria with EUROTOX*** *(E1),* ***adapt their regulations*** *accordingly (F8).*

Curricula *of ERT courses ..****be notified*** *to EUROTOX SC Edu & Reg* (B).

Courses ..will be ***approved by SC****..or rejected (F3).*

If *a national scheme or procedure exhibit* ***serious deficiencies****,…and improvements are rejected,.. registrations by* ***that registry can be excluded*** *from EUROTOX registration (F13).*
The registry can appeal…

9

Guiding Principles

4) Clear Structure of Guidelines: 3 Themes, 6 Sections

Requirements on candidates
Contents of education and training
Administration

Introduction

Section A. Registration: Requirements, Implementation

Section B. Theoretical Training

Section C. Practical Training and Experience

Section D. Maintenance of Registration (Re-Registration)

Section E. The National Registering Body

Section F. Tasks of the Lead Body (EUROTOX)

10

Section A, Requirements and Implementation

To consider a candidate for Registration, national registering bodies will require and evaluate:

A1. A CV containing relevant information such as…

A2. Documentation of academic education

A3. Documentation of further theoretical and practical training and of achievement of standards set out in sections B, C:

A3.1 Acquisition of basic theoretical knowledge by **attendance of courses**, documented by credits/certificates (route 1)

A3.2 Alternative: Theoretical knowledge by **long-standing experience and on the job training**, documented by… (route 2)

A3.3 Practical training and acquisition of hands-on experience and communication skills will be shown by publications, reports, or assessments

A4. Expert opinions evaluating the candidate's knowledge, skills, experience, and professional standing by two eminent toxicologists.

11

- Route 1 (attendance of courses)
  for young fellows on the ERT track
- Route 2 (training on the job, long-standing experience) *
  for societies newly starting to register
  for countries without adequate courses
  for excellent, established toxicologists,
  who are not yet registered.

*Quality to be documented by peer-reviewed publications, confidential reports, assessments, teaching activities, knowledge-based decision-making or advisory activities, or other achievements, subject to expert opinions.

12

Education:

Guiding Principles (5)

A. The educational part of the Guidelines should embrace the **entire spectrum** of scientific backgrounds and professional activities of Toxicologists:

Education / Basic and applied research / Risk assessment / Regulation

as carried out in

- Academia (education, basic research)
- Industry (applied research, risk assessment)
- Advisory (clinical, occupational and forensic toxicology)
- Authorities (Regulation)

B. Update the concepts of Education and Training to cope with scientific progress since 1995,
allow for **Flexibility & Diversity** in training programs to encourage specialization

13

Section B. Theoretical Training

Purpose

Theoretical training in toxicology, with associated practical work to re-enforce concepts, is essential.
*Can be modular, should provide **basic knowledge** of major areas.*

Guidelines lists 13 core fields (similar to current ERT or Karolinska programs)
These are **obligatory** for registration candidates

In addition, there are currently 9 elective fields for specialization (more can be suggested)
Two fields, or one comprehensive field, are **mandatory**.

Comprehensive fields: offer comprehensive specialized training,
e.g. in Risk Assessment, Drug Safety, Eco- & Environmental Toxicology,
>1 module, >10 days

14

Core Topics

B 0. Introduction: History, Tasks, Scope and Ethical Principles of Toxicology
B 1. Animal Science incl. Ethical Rules and 3 R Principle
B 2. Experiment Design, Biometry and Statistics
B 3. Cellular Toxicology and Molecular Toxicology
B 4. Metabolism and Kinetics of Xenobiotics
B 5. Organ Toxicology and Toxicological Pathology
B 6. General Toxicology, Introduction to Risk Assessment
B 7. Environmental Toxicology, Exposure Assessment and Biomonitoring
B 8. Epidemiology, Toxicogenetics
B 9. Clinical, Occupational and Forensic Toxicology
B10. Mutagenesis and Carcinogenesis
B11. Reproductive and Developmental Toxicology
B12. Immunotoxicology
B13. Regulatory Toxicology

Details of Topics Contents and expected Learning Outcomes will be defined and included in the Guidelines as **Annex 2**.

Elective Topics

B14. Drug Safety Assessment: Non-clinical, Clinical, Post-Approval Studies, Safety Pharmacology, Expert Report, Drug Regulation
B15. Safety Assessment of Food, Cosmetics and Other Consumer Products, Regulations
B16. Ecotoxicology
B17. Risk Assessment
B18. Neurotoxicology and Behavioural Toxicology
B19. Nanotoxicology
B20. Alternative Testing Methods and their Use in the Regulatory Framework
B21. Computational Toxicology
B22. Mechanistic Toxicology and “Omics” in Toxicology

16

Section C. Practical training and experience

- **Practical training > 5 years**, related to Toxicology.
  Usually on the job, based on laboratory, clinical, computer-assisted or regulatory work…
- **Practical awareness**

  A candidate for Registration will have obtained **Practical Awareness** (knowledge of major techniques and their merits and limitations, not necessarily hands-on experience) in the topics listed.

  In addition, **in-depth knowledge and experience** in two of the topics (at least) is expected.
- **Documentation** of practical experience, communication skills, authorship by…
- **Confirmation** by supervisors…

17

Topics of practical awareness:

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

18

C4. 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

C5. **Design of experiments**, **biometric** and **statistical procedures**

Data Retrieval, Data Derivation, Computer assisted technologies, data-bases, data-banks, and data acquisition

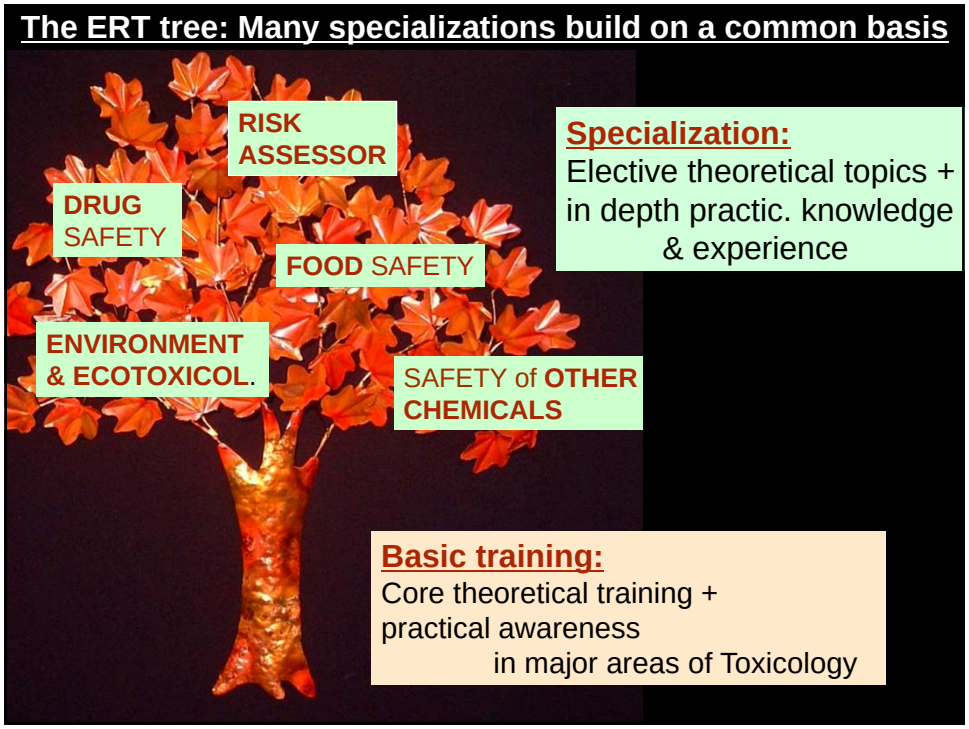
C6. Determination of **pharmacokinetic** parameters and compound **metabolism**

C7. Procedures in **Risk Analysis** (Risk Assessment, Management and Communication),

Regulatory Toxicology, Data reliability and relevance,

Risk-assessment experience under mentorship.

19



Section D. Maintenance of Registration (Re-Registration)

On a **5-yearly** basis, ERT have to re-affirm registration credentials, and submit to the registering body:

D1. An **updated CV**, information on **post(s)** held & **professional activities** during the past 5-year period of registration.

D2. Confirmation of professional toxicological activity in **responsible position** by evidence …

D3. Documentation of **continued professional awareness** and education: attendance of educational courses, presentation of lectures, teaching activities, publications, activities in expert committees…

21

Section E. The National Registering Body

- E1. Relationship of a registering body with EUROTOX

  A registering body will have **lodged (and had accepted) its criteria** …with the national society.
  The society in turn will have lodged (and had accepted) these criteria **with EUROTOX**.
  The national registry will **notify significant changes** of their criteria **to EUROTOX** Reg SC.

- E2. Criteria of a participating registering body

  - An outline of **expectations** from candidates, **in local terms**. Responsibility for quality control of the assessment process.
  - A **constitution** and **modus operandi** for the panel assessing the candidate's application.
  - An outline of **steps** taken **if there is an objection** to the panel's decision.

22

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

Subsections: Training, Registration

describe support by EUROTOX for national societies in setting up Registration boards, by delegating experienced advisors, providing templates, etc.

harmonization of quality standards,

approval of course programs,

fostering of cross-border exchange,

etc.

23

Comment on Guidelines 2012

Obviously, the Guidelines are far from perfect,
and are not, and will never be, finished.

Subcommittees feel they should now be probed in practise.

The multiple options to improve education, harmonization, cross-border work... now need to be implemented and used.

Future updates and amendments should be done
in about 3 years, as described in the Introduction,
in close collaboration
with national societies / registries and ERT course directors.

24

Guiding Principles (6) and Outlook

a) Promote collaboration among national societies

Collaborative training schemes are encouraged where several institutes and countries contribute modules (F4)*

Conjoint Registration schemes can be established by different Societies (F9)*

Cross-National collaboration will be needed to offer **elective modules**

Harmonization of course programs to allow for **exchange of students** and teachers between ERT courses**
→increase international experience, help to establish networks
→ → better job chances

*Useful in particular for small countries

**supported by newly created EUROTOX Fellowships for cross-border exchange

25

Guiding Principles (6) and Outlook

b) Promote exchange and cooperation of EUROTOX with national societies/registries/course directors

Already in last year: Guidelines developed with constructive suggestions from societies.
Hopefully, similar collaboration in 3 years for update of Guidelines.

Expected: Cooperation in defining course contents and outcomes (annex 2 of current Guidelines)

European Toxicologists, join forces
to foster Education and Registration!

→best for the future of our young colleagues and of the Science of Toxicology

26

At the onset of winter let‘s look forward to spring:

Anemone hepatica
Liverwort

Elected flower of 2013