THE BULGARIAN TOXICOLOGICAL SOCIETY

THE BULGARIAN ASSOCIATION OF CLINICAL TOXICOLOGY

# BULGARIAN REGISTER OF EUROPEAN TOXICOLOGISTS

**Application Form**
(to be filled in electronically)

**Accompanying Documents: Evaluation Sheet, Annex 1, Annex 2**

To send electronically to :
christophord@gmail.com

## The undersigned

| | |
|---|---|
| 1. Name | 2. Surname |
| 3. Title | |
| 4. Institution | |
| 5. Address | |
| 6. Phone | 7. Fax |
| 8. E-mail | |
| 9. Scientific fields of interest (maximum 3 among those in Annex 2)<br>- ..<br>..<br>.. | |
| Member of ☐ Bg Toxicological Society ☐ Bg Association Clinical Toxicology<br>☐ individual member of EUROTOX | |

wishes to apply to the Bulgarian Register of Toxicologists. The applicant engages him/herself to exercise his/her profession according to the Code of Ethics and recommendations in a national and international level, following the rules of EUROTOX (Annex 1).
The undersigned applicant certifies that all declared information in the Application Form, the Evaluation Sheet and in the enclosed documentation are authentic.
The applicant authorises the use and confidential transmission of all the sent information to the people and the institutional offices involved in the evaluation of this application.

Date ……

# BULGARIAN REGISTER OF EUROPEAN TOXICOLOGISTS

Signature ……..

**List of Enclosed Documents**

1. Application Form + Evaluation Sheet
2. A motivation letter
3. Curriculum Vitae with the clear indication of the scientific, didactic and professional activity in Toxicology.
4. The complete list of publications divided in:
   - *in extenso* publications on peer reviewed journals
   - study Reports (for confidential material an abstract of the study omitting the substance name is sufficient)
   - other editorial activity (toxicological evaluations, books chapter, books editor, reviews, etc).
5. Two recommendation letters
6. A copy of the bank transfer (50 ERO /100 BG Lev /-application fee).

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# BULGARIAN REGISTER OF EUROPEAN TOXICOLOGISTS

## Evaluation Sheet

(To be filled in electronically)

**Part A: Personal data**

| | |
|---|---|
| 10. Name | 11. Surname |
| 12. Title | |
| 13. Institution | |
| 14. Address | |
| 15. Phone | 16. Fax |
| 17. E-mail | |
| 18. Scientific fields of interest (maximum 3 among those in Table 2)<br>-<br>-<br>- | |

# BULGARIAN REGISTER OF EUROPEAN TOXICOLOGISTS

**Part B. Evaluation form**

**1. Education**

1.1. Bachelor/MasterDegree (please specify the theoretical courses and an in-depth knowledge and experience practical topics set out in sections A and B of Rules of Registration-ERT-Annex-1)

_____

___

1.2. PhD (to specify if the thesis is experimental)

1.3. Doctor of Sciences (please specify the theoretical courses and an in-depth knowledge and experience practical topics set out in sections A and B of Rules of Registration-ERT-Annex-1)

_____

___

1.4. Post-Doctoral studies

_____

**2. Continuing education**

_____

_____

_____

**3. Research experience (post-graduate)**

3.1. Research projects as main investigator

_____

_____

3.2. Research projects as investigator

_____

_____

3.3. Patent applications or other innovations

_____

_____

3.4. Research awards

_____

_____

# BULGARIAN REGISTER OF EUROPEAN TOXICOLOGISTS

## 4. Professional Experience

4.1. Current position

_____

4.2. Former activities and professional experience

_____

4.3. Membership scientific societies

_____

4.4. International Collaborations, technical and scientific commissions/ committees

_____

_____

## 5. Editorial activity

5.1. Publications in peer reviewed journals

_____

5.2. Reports

_____

5.3. Books

_____

5.4. Other editorial activities

_____

_____

## 6. Teaching experience

_____

_____

_____

Date …….

Signature ……..

# BULGARIAN REGISTER OF EUROPEAN TOXICOLOGISTS

**Annex 1 : EUROTOX Code of Ethics**

All EUROTOX members should conduct the work with high objectivity and integrity, communicate the information concerning health, safety and toxicity in a timely and responsible manner with regards to the significance and credibility of the available data, abstain from professional judgments influenced by conflict of interest, economic as well as “academic”, i.e. connection with special interest groups, observe the spirit as well as the letter of law, regulations, and ethical standards with regard to the welfare of humans and animals involved in experimental procedures and practice high standards of occupational health and safety.

# BULGARIAN REGISTER OF EUROPEAN TOXICOLOGISTS

## Annex 2 : List of Scientific Fields

General toxicology and target organ toxicology

Clinical toxicology

Ecotoxicology

Occupational Toxicology

Military Toxicology

Analytical toxicology

Forensic Toxicology

Environmental Toxicology

Pathological toxicology

Drug metabolism and toxicokinetics

Genotoxicity

Chemical carcinogenesis

Reproductive toxicology

Allergy/immunotoxicology

Food toxicology

Cosmetic toxicology

Regulatory toxicology

Risk analysis

Requirements for acceptance of applicants

| | |
|---|---|
| Bachelor Degree or MSc Degree | Agronomy, Biomedical Sciences, Biology, Chemistry, Food and Environmental, Sciences, Medicine, Pharmaceutical Sciences, Pharmacology, Toxicology, Veterinary<br>Minimum accomplishments during training (*applied knowledge-base*)<br>To be considered a candidate for Registration, in addition to basic academic training in science, an individual will have undertaken further theoretical and practical training, and will have achieved the minimum standards set out in A and B of rules of Registration-ERT-Annex-1) |
| PhD Degree | On a relevant scientific topic<br>Minimum accomplishments during training (*applied* |

| | |
|---|---|
| | *knowledge-base*)<br>To be considered a candidate for Registration, in addition to basic academic training in science, an individual will have undertaken further theoretical and practical training, and will have achieved the minimum standards set out in A and B of rules of Registration-ERT-Annex-1) |
| Publications | 5 in peer reviewed journals |
| Professional Working Experience | 5 years |
| | |

ANNEX-1

EUROTOX
Federation of European Toxicologists & European Societies of Toxicology

**Version as of 10 January 2011**
**Revised June/July 2011**

# The EUROPEAN registered toxicologist (ERT) Guidelines for Registration

## Introduction

The present Guidelines for **Registration** is an update of the "Expectations of a EUROPEAN REGISTERED TOXICOLOGIST" first published in 1995. This first description of common requirements and regulations for registration of toxicologists in Europe was derived by harmonization of three founder schemes (Germany, Netherlands, United Kingdom). The "Guidelines for **Registration"** accommodates scientific and conceptual progress in Toxicology in the years passed and experience made with the existing scheme.

The European Registration of Toxicologists is a service of EUROTOX for Toxicology and for individual toxicologists who excel by high standards of education, skills, experience, and professional standing. These toxicologists, upon application, should be certificated as EUROPEAN REGISTERED TOXICOLOGIST (ERT). In principle, in a first step, National Registration boards in Europe evaluate applications of candidates according to a consensual process and admit successful applicants to the national register. In the second step, upon request, EUROTOX will certificate these individuals as ERT without further evaluation. Obviously, the proper function of this system depends on a high degree of harmonization of standards among the registering national boards.

# BULGARIAN REGISTER OF EUROPEAN TOXICOLOGISTS

The current update from "Expectations" to Guidelines is part of EUROTOX' endeavors to advance harmonization of the national registration procedures, including efforts to provide appropriate training opportunities to all ERT candidates.

In the "Guidelines for **Registration"** scientific progress in Toxicology is reflected by updates in sections A and B. Furthermore, to cope with the increasing need for specialization in toxicology, six special topics are identified in section A, two of which should be selected by candidates for ERT, in addition to a core of 13 obligatory topics. Sections C and D have been expanded in order to provide some certainty on the expectations a candidate should achieve for obtaining Registration or Re-Registration. Finally, tasks and functions of National and EUROTOX Registering bodies are described in sections E and F, with a focus on harmonization of rules and requirements. Obviously, these guidelines constitute a framework. For several items, operational and legal details have to be defined and laid down in accompanying documents by national bodies and/or EUROTOX.

## A. Theoretical curriculum

**Purpose**
Theoretical training in toxicology, with associated practical working to re-enforce concepts, is essential. Such training can be provided on a modular basis and should embrace the topics that are defined below.

**Topics**
A candidate for registration will have undertaken theoretical training in 15 of the following topics areas, of which A1 – A13, and two elective modules out of A14 – A19, are obligatory:

A 0. Introduction: History, Tasks and Scope of Toxicology
A 1. Animal Science incl. Ethical Rules and 3 R Principle
A 2. Experiment Design, Biometry and Statistics
A 3. Cellular Toxicology and Molecular Toxicology
A 4. Metabolism and Kinetics of Xenobiotics
A 5. Organ Toxicology and Toxicologic Pathology
A 6. General Toxicology, Risk Assessment
A 7. Environmental Toxicology, Exposure Assessment and Biomonitoring
A 8. Epidemiology, Toxicogenetics
A.9. Clinical , Occupational and Forensic Toxicology
A10. Mutagenesis and Carcinogenesis
A11. Reproductive and Developmental Toxicology
A12. Immunotoxicology
A13. Regulatory Toxicology

In addition, two modules out of the following are mandatory:
A14. Drug Safety Assessment: Non-clinical, Clinical, Post-Approval Studies,
Safety Pharmacology, Expert Report, Drug Regulation
A15. Safety Assessment of Food, Cosmetics and Other Consumer Products, Regulations
A16. Ecotoxicology
A17. Risk Analysis: Assessment, Communication, and Management of Risk
A18. Neurotoxicology and Behavioural Toxicology
A19. Nanotoxicology
A20. Alternative Testing Methods and their Use in the Regulatory Framework
A21. Computational Toxicology

A22. Mechanistic Toxicology and "Omics" in Toxicology

Topics A0 – A13 and some of the elective topics are essentially covered in the existing ERT courses, although details of contents and sequence may show some variation.
Topics may be presented as modules consisting of lectures, site visits, demonstrations, and exercises. Case studies by individual participants are particularly encouraged to practise risk assessment and classification of chemicals. Distant teaching and learning will be used where feasible. All modules are completed by examinations.

**Time needed**
Each module will probably involve at least 3-5 days, in some cases 10 days or more of contact time, except A0 which may require only a few hours.
If studied from the beginning, with no credit given for content of previous degrees, then about 15-26 weeks of 30 hr per week contact time should be allocated to undertake the theoretical basis needed for eventual registration.

**Credits**
Candidates for registration will be expected to present credits in all 15 topics described above.

It is possible that some parts of this syllabus can be certificated if they have been covered in a basic degree (BS) or a postgraduate degree (MSc, Ph.D.)

In principle, credits may be obtained from modules based in more than one country.

**Follow-up**
It is recommended that course directors and/or national registries monitor the success of ERT courses by follow-up of participants. Indicators may be grades reached at examinations, ERT registration (when? where?), positions obtained, special achievements, etc.

## B. Practical curriculum

Practical experience and training must be related to Toxicology and should be based on laboratory, computer-assisted or regulatory work in one of the areas listed under A (except A0, A2). In some cases toxicologists will undertake research and be based in a single department / under a single named mentor: candidates for registration are advised to ensure at the outset that their intended course of study is seen, by a senior ERT or member of the National Register, as appropriate and applicable to the eventual target of Registration.

**Practical awareness**
During a period of not less than 5 years 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:
B1. Post-mortem Methods, Animal and Human Pathology and Histology. Microscopic recognition of the major pathological processes. Foetal and neonatal examination for malformations
B2. Making Observations and Records of signs in Animals or Humans,
Humane Dosing, Sampling and Euthanasia of animals In vivo Monitoring, Biomonitoring, Biomarkers on animals or in Clinical studies.
B3. Principles and Techniques of Cell Culture

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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.
B4. 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.
B5. Design of experiments, biometric and statistical procedures
Data Retrieval, Data Derivation, Computer assisted technologies, data-bases, data-banks, and data Acquisition.
B6. Determination of pharmacokinetic parameters and compound metabolism.
B7. Procedures in Risk Analysis (Risk Assessment, Management and Communication), Regulatory Toxicology, Data reliability and relevance, Risk-assessment experience under mentorship.

**Documentation of practical expiriance, Communication skills, Authorship**

Candidates for registration will have documented their practical experience by at least 5 publications, confidential reports or assessments. Publications should have appeared in peerreviewed scientific journals. Reports and assessments should be suitable for submission to regulatory agencies or for regulatory decision making.
It is regarded as essential that these papers demonstrate a high standard of critical ability and communication skills. Critical ability and communication skills can be documented further by a record of oral presentations and through authorship of written reviews and a dissertation / thesis. Examples should be included with any application for Registration.

**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.