

European Registered Toxicologist (ERT) Rules of Registration (version as of 10 January 2011)

- Comments from the Swedish Society of Toxicology (SFT) on the document for consultation

The Executive Committee of the Swedish Society of Toxicology (SFT) has reviewed the revised Rules of Registration for European Registered Toxicologist (ERT) and our comments on the document are hereby provided.

The Swedish Society of Toxicology does not have a national register of toxicologists certified by EUROTOX. Some general questions and concerns with the concept are presented below. Specific comments on the details of the document are also provided.

General comments

1) As emphasized in the introduction to the Rules and Registration, the “proper function of this system depends on a high degree of harmonization of standards among the registering national boards”. We agree with this statement and we appreciate the difficulties in ensuring that the standards as well as the application and interpretation of the standards are truly harmonized between countries. How is harmonization of the standards between countries ensured? Is there a control mechanism to ensure that agreed standards are followed by the national organizations?

Registration also requires a quality control mechanism *within* countries and a fair, unbiased, and transparent process which is consistent over time. What processes are in place to ensure quality control of the process both between and within countries?

2) Is there a true need for registration of general toxicologists? What is driving this need and are there different needs in different countries? Registration requires substantial resource provided by senior toxicologists to evaluate the applications, and appropriate quality control as mentioned above, and to justify this significant amount of work and resource, a clear need must be identified.

The Swedish Society of Toxicology has so far not identified a desire from the members to introduce a certification process. Neither is there a pressure from Swedish employers to present evidence of ERT certification in job applications, and therefore our society has not been able to justify the required resource and effort. We would be interested to know if this is different in other member countries; Do employers in other member countries require ERT? If so, what type of employers – private industry, academia, regulatory bodies?

3) There is a growing interest for certification/accreditation of human health risk assessors at a European level, and there are a number of initiatives in this area linked to e.g. DG SANCO, RAAP etc. How do these initiatives relate to ERT and is there a potential for overlap between ERT and accredited risk assessors? Considering the resources and efforts involved in maintaining the systems, is there room for both or will the national organizations have a preference for one or the other?

Specific comments on the sections of the document

Overall, many of the criteria specified in the document are appropriate and applicable. Specific comments on each section are presented below:

A. Theoretical Curriculum

We recommend that predictive power, data reliability and relevance for various types of methods are included (in silico, in vitro, in vivo, epidemiology) in the theoretical training. We also recommend that Module A14 (Computational toxicology) and A18 (Alternative methods) are compulsory.

B. Practical Curriculum

The majority of listed items are lab based practical experience. We are concerned that it may be too demanding to expect practical awareness in all areas listed. Many excellent toxicologists do not have experience in all those areas and we would recommend that the wording is changed to "...will be expected to have obtained practical awareness in most of (or e.g. 5 out of 7 of) the topics listed below"...

The requirement to demonstrate in-depth knowledge and experience in at least two of the areas is particularly difficult for those who have developed into theoretical fields of toxicology, such as regulators and risk assessors, since all areas except one involves practical, lab based work. Toxicologists in theoretical roles would in many cases fail registration due to this requirement. We recommend that the criteria are changed to acknowledge theoretical aspects of toxicology such as risk assessment and regulatory toxicology.

Communication skills, authorship: No quantification of the requirements is specified, which could result in large differences in interpretation by national organizations. We recommend that a quantification of the presentations, papers and reports are introduced.

C. Implementation of registration

C5: "Recommendation letters should be submitted from two eminent toxicologists (at least one of whom should be ERT)...". We recommend that any eminent toxicologist could submit the recommendation letter and that the requirement for an ERT toxicologist is dropped, since this will be very difficult and impractical to fulfill in some situations, for example in countries such as Sweden where ERT certifications have not yet been offered.

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

"Evaluation", "accreditation", "approval" of courses/institutes/programmes/teachers are mentioned in the text. The criteria for these evaluations etc must be clearly specified. Are the current EUROTOX sub-committees resourced to do this? What educational programmes are currently considered acceptable? We recommend that the process is very transparent and that the national organizations are consulted in these decisions. We do not believe that EUROTOX should evaluate the teachers, which would require extensive work at a very detailed level and would introduce significant bureaucracy.