To Toxicology Societies, Registries and other institutions
responding to the invitation for Consultation on the draft Rules of Registration

July 11, 2011

Dear Colleagues,

The EUROTOX Subcommittees for Education and Registration thank all of you for critical reading our draft "Rules of Registration". We greatly appreciate your comments which contained numerous constructive suggestions and a few points of valuable criticisms. We have taken these into account as completely as possible. Please find the new, substantially modified version and all responses we received in the attachments.

In the following we first provide a brief overview of some of the important points raised in your comments, and how we dealt with them to revise the previous version. Obviously, not all points could be incorporated, but we hope you find the present text sufficiently well balanced between the tasks of EUROTOX (harmonization) and the (sometimes divergent) objectives of individual societies/bodies. In the 2nd part of this letter, several specific questions and criticisms will be addressed.

A major point in some comments (incl. Norway, Finland) seemed to be that EUROTOX might be too demanding, want detailed reporting, prescribe too many details of education etc. However, EUROTOX does not intend to dictate; it strives for harmonization, not identity. The goals are
to harmonize criteria at a minimal, but satisfying level, in consensus with national bodies
to provide guidance and advice
to serve as a central deposit for the national programs and procedural schemes.

The following changes should visualize this intention of EUROTOX more clearly:
- use of "Guidelines" instead of "Rules" in the title
- update of the syllabus every 3 years in cooperation/consensus with national bodies (end of Introduction);
- expansion of F3 (previously F4). As a rule, detailed evaluation will not be done for courses developed by Toxicological Societies and their representatives in universities, but is considered necessary for courses offered by other institutions.
- expression that EUROTOX should be notified by national bodies of programs of ERT courses, registration schemes ("criteria"), and significant changes thereof (A, E1; F5).
- only if a registering body fails to meet the quality standards observed by the other registries to a serious extent and rejects advise for improvement, registrations by this registry can be excluded from EUROTOX registration, see new point F14 (specific question of Sweden). (This item, as many others, constitutes a frame which requires definition of operational and legal details after principal acceptance of the Guidelines, cf. paragraph 3 of the Introduction.)

Other major points addressed Section A - as expected. It was argued that the program might require too much time (NL), and that certain topics were missing. Consequently, in the

obligatory part (A0-A13) several subtopics were eliminated, and one, Environmental Toxicology, was added (A7), making this part more slender and closer to current practice in several countries. Under "Time needed" more precise data are provided reflecting the ranges in current courses. The elective part was expanded by 3 further modules to cover subtopics shifted from the obligatory part as well as topics newly proposed (A16: Norway, A18: Belgium). A new subsection "Follow-up" was included.

As acknowledged now in Section A, some variations of contents and sequence of topics exist between the EUROTOX topics list and programs of national courses. Such differences are usually minor and should not hamper recognition as ERT (concern raised by NL). Further progress in harmonization may be obtained at future updates at 3-year intervals. Given the existing differences in course programs no attempt was made to define ECTS as suggested by Finland. If necessary these should be defined later in consensus with national bodies.

In section B, Norway and Sweden requested some specification of expressions and of quantitative requirements which is now provided in the 1st and 2nd paragraph: "Practical Awareness" *(knowledge of major techniques and their merits and limitations, not necessarily hands-on experience)* and in subsection "**Documentation of practical experience**,..." .

Sweden argued that candidates who have developed into theoretical fields of toxicology, such as regulators and risk assessors, can only take 2 fields to fulfil the requirement to demonstrate practical experience. However, it may be considered very useful if regulators have at least some practical lab experience in order to adequately evaluate experimental toxicity studies.

Para C5: changed in response to Swedish point.

Section D: Question from NL concerning the requirement of 5 working days per year to document continued professional awareness and education: how to quantify time needed for CPA and education when writing publications and preparing for educational activities. We recommend to estimate the time from the extent of activities documented.

Sections E and F: Changes made are addressed above.

Suggestions by EMA were largely taken into account or are contained in the modules without specific mention in the topic heading.

As to some specific comments and questions:

According to the comment from Finland it's scheme should be mentioned as one of the founder schemes (Introduction, 1st para). However, our present statement has been taken unchanged from the "Expectations ..." published in 1995 and has recently been confirmed upon specific request, although Finland was said to have been very constructive in establishing the European register in the first years after foundation. Nevertheless, if our present version is historically incorrect, it should be changed upon appropriate documentation from our Finish or other colleagues.

General comments of the Swedish Society
A considerable number of important questions are raised at least some of which require longer answers and discussion. Can we postpone these to another occasion, perhaps during the

meeting in Paris?

Sweden and Poland: What are the merits of ERT?
Employers (private industry and regulatory bodies) in other member countries do prefer job applicants with ERT qualification. Also supranational agencies (ECHA) have started to consider this qualification as an asset.
Discrimination of toxicologists, who are well trained and experienced according to Europe-wide standards, i.e. ERT, from "self-registered" persons who call themselves "toxicologist".
Standards similar to ERT exist in other regions (US, Asia; see below). Currently IUTOX has started a move for world-wide harmonization of certification/registration criteria of toxicologists. EUROTOX participates in this endeavour and should be supported by all European countries with strong education in toxicology.

Comments from the Belgian register state the following:
This ERT Rules of registration draft appears to depart significantly from the philosophy of the existing framework in which ERT is a recognition by peers meaning that the toxicologist in question has had an adequate training and sufficient professional experience. The draft rules now put much more emphasis on the educational aspects and their content, which in our view is not the best way to reflect the overall experience base of a toxicologist.

We would like to invite our Belgian colleagues to consult the "Expectations of a EUROPEAN REGISTERED TOXICOLOGIST" first published by EUROTOX in **1995** (attached). You will see that our present Guidelines for Registration do not significantly depart from the original philosophy. There, theoretical and practical training have similar weight as in the present version, and credits and publications are expected for documentation. Thus, also in the past, for harmonisation of the registration procedures, EUROTOX has set minimum requirements for education, skills and experience of toxicologists throughout EUROPE, in consensus with member societies.

The comment further states that
ERT is not a diploma; it should not be seen as an examination to become a toxicologist but rather as the recognition of being a professionally active toxicologist. Universities are in charge of basic and specialized training, the program contents as well as the examinations are their responsibility and Eurotox should not be involved there.

Being an *active toxicologist* is one of the prerequisites of the ERT among others (please see "Expectations.." and Guidelines). However examination is universally accepted as evaluation of the trained individuals. We believe that examination is one of the important first parts of the process and essential for evaluating young Toxicologists who are candidates for ERT. As in EUROPE, the professional credibility of toxicologists has been recognised by national registries and certifying boards across the USA (e.g. ABT) and Asia (e.g. Japanese Society of Toxicology, Korean Society of Toxicology and Chinese Society of Toxicology). For eligibility for registration/certification all these bodies require examination, based on schemes broadly similar to ERT. Thus, societies and not universities define the requirements for certification and take exams. Moreover, currently IUTOX has initiated an approach to globally harmonize the aforementioned registration/certification schemes under the umbrella of IUTOX. In conclusion, we believe that the updated content of the guidelines for registration of ERTs meets the need for appropriate training schedules and harmonization of the EUROTOX national registration procedures and in addition is compatible with the existing schemes around the world.

Dear colleagues, we hope that you can agree to the revised version of the **Guidelines for Registration** in the form attached, which would include its regular revision.

We also hope that your national society will accept it at the Business Council at the Toxicology Congress in Paris.

On behalf of the EUROTOX Subcommittees for Education and Registration
we remain with best regards

Yours Sincerely

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