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MAPPING TOXICOLOGY TRAINING TRENDS IN EUROPE

REPORT

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INTRODUCTION

EUROTOX, the Federation of European Toxicologists & European Societies of Toxicology has a mission to foster the science and education of toxicology, influence regulatory and policy frameworks to promote the safety of humans, animals and the environment, and protect global health. With these interests in mind, and the concerns about the skills base and in particular the availability of suitably experienced toxicologists to meet the demands of society now and in the future, EUROTOX commissioned the *Mapping toxicology training trends in Europe* project. The overall aim of this project was to gather data to answer the question *"Are we meeting the demands for trained toxicologists through the current training provision in Europe?"* and inform decision-making within the organisation's management. By understanding the nature and trends of the apparent concern, EUROTOX aims to use the results to help plan the next steps that can address the issues, by leveraging the resources and networks of a dynamic European learned society. Indeed, the theme of the 2020 EUROTOX Congress is *'Toxicology of the next generation'* and it is hoped that discussion about training and the future of the toxicology profession will form a key part of the congress programme.

REPORT STRUCTURE

The report is structured in four sections: Section I deals with the Approach and Methods, Section II provides Results and Analysis, Section III provides a Discussion of the Training Landscape. Recommendations have been provided throughout the report in boxes.

SECTION I – APPROACH AND METHODS

Guiding principles

The approach for this project has been broad in an attempt to obtain the views from academia, industry and other actors and to better understand the systemic challenges. In particular, the intrinsic knowledge of the national societies in each country was an invaluable resource. In addition, associated matters of best practice related to engagement, learning and assessment and implementation of training has been considered by means of literature review.

Methods SURVEY OF NATIONAL SOCIETIES

The rationale behind approaching the national societies of toxicology in each country is straightforward: they are representatives of the profession in their country, will understand the training pathways available in their specific geography and would also be able to provide quantitative data regarding their membership numbers. As they are often involved in advising on training requirements or indeed training delivery, it is believed they are best placed to provide insights on the issues in their own country as well as any relevant information pertinent to toxicology training specific to their country.

The questionnaire issued to the National Societies is provided in Annex I.

Of the member societies surveyed, responses where provided by 16 countries, figure 1.



Figure 1 - National societies providing a response

SURVEY OF THE PROFESSION

A short online survey issued to the wider body of toxicologists was conducted, targeting responses from industry and regulators in particular, with the aim of gathering specific insights on the perceptions of training from a broad range of stakeholders. While the national member societies have a membership that includes toxicologists working in industry and regulators, it was decided that a broader sample of information should be gathered.

The survey questions are included in Annex I

SECTION II – RESULTS AND ANALYSIS

1. Membership numbers

Our first question to the national societies was concerned with the number of members in their organisation and European Registered Toxicologists (ERTs), shown in figure 2 below.

From this information, we can draw some high-level conclusions:

- As expected, ERTs represent less than half of the membership in most countries. The portion of ERTs is between 10% and 50% of all membership with the mean proportion at about 20%¹.
- Countries with relatively new member societies such as Albania and Serbia have smaller numbers of members.



National society membership numbers and ERTs

The membership numbers represent a snapshot in time, specifically in August/September 2019 and in some instances included honorary members who do not pay membership fees (*eg* retired professionals, former society presidents). Some countries were unable to provide numbers of ERTs (e.g. United Kingdom).

The data indicates that there are at least 4,857 toxicologists in Europe, representing all the members of all the national societies who participated in the questionnaire. This is believed to be a gross

Figure 2- National society membership numbers and ERTs

underestimate of toxicologists as only 16 countries participated in the survey and not all toxicologists will be paid members of their country's national society. This number also excludes EUROTOX individual members^{II}.

BOX 1 – How should EUROTOX engage with toxicologists, especially those who are not members of their country's national society?

Some individuals might believe that there is no tangible benefit of being members of their country's toxicology society. While participating in a learned society or a professional body may be very rewarding, the benefits and advantages of paying an association or membership fee may not be of importance to these individuals. EUROTOX may wish to conduct focus groups or surveys of these populations of toxicologists to understand what can be done to engage with them more effectively. Given the opportunities to participate on committees, network, attend events, share knowledge as well as forming professional collaborations, EUROTOX may wish to target early career entrants (Mata, Latham, and Ransome 2010) as they are possibly more inclined to engage at an institutional/organised level as this could have a positive career impact. Understanding the perceptions of non-members should therefore also form part of EUROTOX and national societies' strategic thinking regarding membership sustainability.

Recommendations:

1a - Research the needs and perceptions of toxicologists' membership of a toxicology learned society, their expectations and needs.

1b - Review EUROTOX benefits of 'Individual membership' (direct, non-country specific route) to benchmark if it is competitive compared with other professional bodies.

2. Training provided by national society

In the questionnaire, we asked national societies whether they provided training. Responses are gathered in Table 1 (overleaf). In addition, we asked about the nature of the training and numbers of individuals trained. Most of the member societies that provided training did so through workshops and short courses. Information on the numbers of individuals trained was sparse and often relied on estimates indicating that such potentially useful statistics were not necessarily retained for posterity.

Interestingly, even though all the EUROTOX member societies organise a regular conference in their respective countries, only three societies mention that specific training is provided at this event. A point for discussion is what role conferences play in the continuous professional development of toxicologists

^{II} Drafting note: obtain latest number of EUROTOX individual members to insert in footnote

and to what extent conference attendance and participation is considered 'training'? Some academic sources are questioning whether conferences with didactic approaches (i.e. lectures) are useful for effecting practice change (Hollands and Miles 2009). There are also ongoing studies looking at the use of online approaches to conference attendance and participant benefits (Maloney et al. 2017).

Country	National society provides training?
Finland	No
France	No
Italy	No
Norway	No
Sweden	No
Austria	Yes
Belgium	Yes
Bulgaria	Yes
Denmark	Yes
Netherlands	Yes
Serbia	Yes
Spain	Yes
Albania	Yes
Ukraine	Yes
Turkey	Yes
United Kingdom	Yes

Table 1 - National Toxicology societies providing training

BOX 2 – Recording more informative data in a standard format

EUROTOX may wish to develop a reporting template that national member societies can populate which records the training events held [in their country] and number of participants trained as well as the training provider. Such a system would enable meaningful statistics to be collected and curated by EUROTOX for analysis of emerging themes (topic analysis), determining interest in topics and identifying centres of expertise.

Recommendations:

2a – EUROTOX to decide on whether collecting this data may be useful, how it may be curated and how it will be used for decision making.

2b – Improve website navigation for events so that training events by country (and language of training) can be accessed

3. Training provided by other actors and recognition of courses

All respondents (national societies) confirmed that other bodies in their country provide training, primarily within universities. In a few countries, specific institutes or government affiliated departments as well as private training consultancies provide training/workshops. Generally, it is unclear whether there is any specific framework for quality assurance or training structure. Nevertheless, there are clear exceptions, see Box 3.

BOX 3 - In the Netherlands, Universities have come together to offer Postgraduate Education in Toxicology (PET) which is the Dutch national programme for postgraduate training in toxicology. Aspects of this modular short course programme are compulsory and required for registration of professional toxicologists by the Netherlands Society of Toxicology and is also approved by EUROTOX for ERT registration.

National societies also vary in the accreditation, validation, certification or other recognition of courses that are provided by other bodies. There are differing levels of involvement of the national societies in shaping the curriculum within Universities. On the whole, members of the society (whether executive/committee or ordinary) are represented on course teaching and curriculum development committees within their respective academic organisations. It appears that very few national societies (eg The Netherlands) have a specific national programme which organises and manages the certification process and collaborates on curriculum setting. Beyond specific recognition of university modules, the external engagement by the national societies with other stakeholders in industry and regulatory spheres could be further encouraged so that curriculum content provided to students more closely meets the expectations of employers.

Annex III contains a list of current training providers.

4. Route into toxicology career

The primary route into a career within toxicology appears to be via training at University level. Here, there is huge variation between the level of expertise and level of education that constitutes a 'Toxicologist' in each country. In some countries, individuals with a relevant academic background (pharmacology, chemistry, analytical sciences) are trained to a postgraduate level (for example Masters) to perform

specific elements of toxicological analyses and evaluations and the training is relevant to a specific toxicology sub-field such as ecotoxicology. In other jurisdictions, PhD-level training and research in a toxicology discipline is what is needed to be recognized as a 'Toxicologist'. For medical toxicology, a first degree in medicine followed by PhD-level training/research is expected. On the job training is often part of the learning journey as new entrants into the profession are mentored by more experienced colleagues. There is therefore an intrinsic knowledge transfer element which is context dependent (eg industry vs regulatory) which may not form part of conventional academic training at degree level.

BOX 4 – Due to the need for on the job training, EUROTOX may wish to play a role in promoting industrial or work experience placements with different employers, to engage with these stakeholders as part of a user group, or develop a programme that encourages knowledge transfer and capacity building.

5. Government support to Universities for toxicology training provision

Financial incentives to universities for the provision of toxicology courses appear to be limited. Overwhelmingly, the majority of national societies noted that they were unaware of any specific financial or other incentives provided to universities in their country to offer toxicology courses. The only incentive noted is the availability of studentships often for PhD-level studies (paid direct to students), but such funding is not necessarily ring-fenced for toxicology training. It is also challenging to measure funding intensity given the complex way in which research and academic training is funded^{III}. Indeed, toxicology as a discipline is often affiliated with physiology, veterinary, pathology and other disciplines making it unlikely that academic institutions have the capacity to offer comprehensive training in toxicology (Aldridge and Schlatter 1980). Responses also indicated that retired academic staff were not being replaced on a like-for-like basis in universities, indicating a possible capacity building issue in future.

BOX 5 – Funding toxicology departments as a priority

With the growing financial pressures on the public sector, Governments across the world are prioritising their investments particularly in tertiary research and teaching. This means that efforts should be made by all toxicologists to ensure high visibility for the toxicology profession and communicate the importance of toxicology to the public, regulators and policy makers as well as funding agencies to lobby for continued investment in toxicology training and research.

Recommendations:

5a – EUROTOX could consider a communications strategy that involves targeted engagement with policymakers and funders through publication of white papers, manifestos, impact reviews that showcase the importance of the discipline.

The aim is to highlight the real-world impact of toxicology assessment and through using better science communication, influence over public support, funding, and policy can effect change over time.

^{III} The MRC Toxicology Unit, based at the University of Cambridge (England, UK) was established by the Medical Research Council 1947. Very few examples of long-term research-funding of a similar nature are known to exist. See https://www.mrc-tox.cam.ac.uk/about-us [Retrieved 28 Jan 2020]

6. Adequate numbers of trained toxicologists

The national societies were asked if they believe that there is a sufficient number of experienced and trained toxicologists to meet the needs in their country. While there are inherent disadvantages to such subjective questions, we find it useful to assess whether a perceived shortage does indeed exist and if there is any evidence to support this, for example, difficulties in filling vacancies. There is a mixed picture with 60% of respondents (countries) responding to our questionnaire that there is not an adequate number of trained and experienced toxicologists (Fig. 4). From a trend of not replacing academic professors (chairs) in toxicology once they retire, to fewer universities offering full degree programmes in toxicology, the impact on available expertise can potentially be noticed. As the experience and knowledge gained is often linked to the time spent working in the field, effective mechanisms and incentives to ensure that individuals with a significant track record are able to share their knowledge should be assessed.





7. Toxicology networks and closer stakeholder engagement

This section deals with partnerships and stakeholder collaboration. The national societies were asked whether there were any networks from different sectors (eg academic, industry, regulatory) that promoted toxicology issues or contributed to toxicology training.

Such informal/formal collaborations were known to exist in more than half of the respondents (Fig 5). Although a majority confirmed that greater engagement between academia, safety science regulators and industry would change training arrangements or opportunities for toxicologists (Fig.6)



BOX 6 – Stakeholder engagement

EUROTOX could play a critical role in stakeholder engagement and partnership building and development which has the potential to increase dialogue between stakeholders across private, public, and third sectors.

Recommendations:

6a – EUROTOX could consider developing an engagement strategy or act as a facilitator in bringing different parties together. COST funding could be explored to help fund such networks.

Survey of employers

The responses received were limited, however we conducted sentiment analysis on the comments received. The themes that the comments covered are provided in figure 6.



Figure 6 - Sentiment analysis conducted on employer survey

SECTION III – TRAINING LANDSCAPE AND DISCUSSION

EUROPEAN REGISTERED TOXICOLOGIST (ERT)

According to EUROTOX, the European Register of Toxicologists is a register maintained by EUROTOX and constitutes a list of toxicologists who excel by high standards of education, skills, experience, and professional standing and is a voluntary status acquired through meeting requirements set by EUROTOX. Although registration as an ERT is recognised by national and international bodies and by companies, the title, however, is not legally recognised (Wilks et al. 2016). Nevertheless, the aspirations that the EUROTOX executive has documented (Vinken and Wallace 2019; Wilks et al. 2016) include wider recognition and promotion of ERT. While the ERT is a status that is conferred at European level, it is not regulated at European level as national evaluation boards are responsible for assessing candidates'

credentials and competence for inclusion on a national register. This national register is in turn recognised by Eurotox, however, such a system can be prone to specific disadvantages, as discussed in Box 5.

Another issue is the standard of knowledge that is required for the professional practice of toxicology and the associated mechanism for assessing or credentialing that competence. The American Board of Toxicologists has developed such a system (Janis, Lewis, and Bruce 2015) and good practices can be gleaned from their efforts. In addition, commercial providers can support with logistics in administering exams^{IV} reducing the administrative burden on EUROTOX. While a European Standard (CEN/TC 416 EN 16736:2015) for "Health risk assessment of chemicals - Requirements for the provision of training" used to exist, this now appears to be disbanded. The training syllabus or standard is used may be the subject of regulation or credentialing for the purposes of competence baseline.

BOX 5 – In a safety critical discipline such as toxicology (WHO 1984), competence assurance of toxicologists is a key requirement. However, EUROTOX does not currently operate an assessmentbased evaluation of knowledge and understanding of toxicology. This is currently delegated to national evaluation boards which can hinder effective quality assurance given the wide variety of practices in each country/member society. Moreover, with the current system, it is impossible to monitor continuous professional development of currently registered ERTs. Although ERT status must be renewed regularly, there is no publicly accessible register which lists current holders of ERT status.

Recommendations:

5a – EUROTOX could consider the possible advantages of centralising the administration and management of the ERT designation.

5b – *EUROTOX* could consider what ERT designation should mean.

5c – EUROTOX could consider if a new certification should be launched by (For example, European Certified Toxicologist) which is solely managed by EUROTOX and comprehensively covers a curriculum agreed by EUROTOX and involves an assessment on a regular basis (for example every 3-5 years) to ensure working knowledge of key areas of competence. The qualification may be supplemented with a registered database.

FUTURE OF CPD IN TOXICOLOGY

Some professional organisations manage CPD within a structure, usually comprising training courses and workshops, conferences, attendance at events and publication/R&D activities. Demonstrating commitment to updating one's skills and knowledge regularly is a critical part of most CPD activities, yet

 $^{^{\}mbox{\scriptsize IV}}$ Prometric and Pearson VUE are the well-known commercial bodies

the extent of ongoing development that is expected varies considerably and there are huge variations in the usefulness, cost and quality of CPD opportunities. At the same time, opportunities to make use of alternative delivery methods, for example professional development via social media (Maloney et al. 2017) and webinars offer people new learning paradigms in an increasingly digital world.

Many societies and professional bodies have strict rules governing the privileges and expectations of membership or association with their organisation. The intention with many bodies, such as the Project Management Institute (PMI), is to ensure that certified professionals undertake certain upskilling/CPD opportunities on a regular basis, to maintain subject matter working knowledge and keep up to date on developments within the field. The PMI also expects all certified members to re-take the multiple-choice exam every 5 years. This is monitored through an online portfolio which reduces administrative burdens as the workflows are programmed to enable easy onboarding and ongoing management.

Increasingly, online conferences, webinars and discussions are becoming popular low-cost options to enable content-sharing and discussion without the need for travel. Special interest groups drawn from within the society membership can come together voluntarily and organise an interesting roundtable, lecture or interactive tutorial using readily available online tools.

As the biosciences are developing rapidly, and new methods and new developments (lab on a chip, stem cells, gene editing) are becoming mainstream, there is a need to rationalise the inherent crossdisciplinarity and cooperation that is a hallmark of 21st century biology (Carusi, A., Whelan, M. Wittwehr 2019). As other scientific practices, such as Open Science and RRI become increasingly important, there is a need to ensure that training reflects contemporary knowledge practices and insights relevant to other disciplines can be 'bridged' across disciplines.

EUROPEAN PROJECTS AND INITITATIVES

The European Union has funded several projects – as detailed in <u>Annex IV</u> – aimed at reducing the use of animals, developing toxicology *in vitro* models and methods. In addition, the Joint Research Centre recently held a Summer School on 'Non-Animal Approaches in Science - Challenges & Future Directions' where many early career researchers presented a range of *in vitro*, computational, integrated and novel approaches (Joint Research Centre 2019) in bioscience. Here you can already observe emerging trends which will affect the field of toxicology in the area of animal reduction, reproducibility and *in silico* research which toxicologists of the future should be aware of and use their interdisciplinary skills (Vinken

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and Wallace 2019) to productively engage with new research, methods and trends which will undoubtedly affect practices in toxicology.

CONCLUSION

The availability of digital tools provides new opportunities for rethinking how we develop competencies, assess them for assurance purposes, continually educate, and maintain quality assurance over time. With MOOCs and learning platforms that can deliver online learning and assessment, there is an opportunity to combine real-life training approaches with digital learning. As was mentioned above, there are new trends in bioscience alongside cross-disciplinary research that will affect toxicologists and the knowledgebase that they will be expected to know. Thus, EUROTOX, by reflecting on whether toxicology training is effective in meeting society's current and future needs is taking active steps to prepare for a brighter future.

The recommendations contained in this document are a starting point to catalyse discussion and priortisation of strategic objectives related to the ERT and the future of toxicology learning. Of course, there are national traditions in education, as well as differences in economic and governance structures which impact on the approach that is ultimately agreed. Nevertheless, by mediating changes in the recognition of toxicology expertise, there is an opportunity to increase EUROTOX's status, its recognition, and to develop a membership offering that is relevant to users.

ANNEXES

Annex I

Questionnaire to societies "Call for Information"

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Annex II Survey to profession

Annex III Training providers

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Annex IV

EU funded projects as reproduced from AxIr8 [http://www.axIr8.eu/eu-funded-3rs-research/ Retrieved 11 Dec 2019]

- 1. **ACuteTox** Optimisation and pre-validation of an *in vitro* test strategy for predicting human acute toxicity
- 2. **ARTEMIS** *In vitro* neural tissue system for replacement of transgenic animals with memory/learning deficiencies
- 3. **BioSim** Network of excellence on biological, pathological and pharmacological processes
- 4. **CADASTER** Case studies on the development and application of in silico techniques for environmental hazard and risk assessment
- 5. **CarcinoGENOMICS** Development of high throughput genomics-based tests for assessing genotoxic and carcinogenic properties of chemical compounds in vitro
- 6. **COACH** Coordination of projects on alternative approaches to assess repeated dose toxicity of cosmetics and chemicals
- 7. COMICS Comet assay and cell array for fast and efficient genotoxicity testing
- 8. **COSMOS** Integrated *in* silico models for the prediction of human repeated dose toxicity of cosmetics to optimise safety
- 9. **DETECTIVE** Detection of endpoints and biomarkers for repeated dose toxicity
- 10. **ESNATS** Embryonic stem cell-based novel alternative testing strategies
- 11. **EXERA** Development of 3D *in vitro* models of estrogen-reporter mouse tissues for the pharmaco-toxicological analysis of nuclear receptor-interacting compounds
- 12. HeMiBio Hepatic microfluidic bioreactor
- 13. **INVITROHEART** Reducing animal experimentation in drug testing by human cardiomyocyte in vitro models derived from embryonic stem cells
- 14. **LIINTOP** Optimisation of liver and intesting *in vitro* models for pharmacokinetic and pharmacodynamic studies
- 15. **MEMTRANS** Membrane transporters: *in vitro* models for the study of their role in drug fate
- 16. **NanoTEST** Development of methodology for alternative testing strategies for the assessment of the toxicological profile of nanoparticles used in medical diagnostics
- 17. **NOTOX** Predicting long-term toxic effects using computer models based on systems characterisation of organotypic cultures
- 18. **OpenTox** Promotion, development, acceptance and implementation of QSARs for toxicology
- 19. **OSIRIS** Optimized Strategies for Risk Assessment of Industrial Chemicals through Integration of Non-Test and Test Information
- 20. **PREDICT-IV** Profiling the toxicity of new drugs: a non-animal-based approach integrating toxicodynamics and biokinetics
- 21. Predictomics Short-term in vitro assays for long-term toxicity

- 22. **ReproTect** Development of a novel approach in hazard and risk assessment of reproductive toxicity by a combination and application of *in vitro*, tissue and sensor technologies
- 23. SCR&Tox Stem cells for relevant, efficient, extended, and normalised toxicology
- 24. **Sens-it-iv** Novel testing strategies for *in vitro* assessment of allergens
- 25. SEURAT-1 Towards the replacement of *in vivo* repeated dose systemic toxicity testing
- 26. **ToxBank** Supporting integrated data analysis and servicing of alternative test methods in toxicology
- 27. **TOXDROP** Innovative 'cell-on-chip' technology to screen chemicals for toxicity, using cultured cells with tiny 'nanodrops' of culture fluid
- 28. **Virtual Physiological Human** EU network of excellence to support progress in biomedical modelling and simulation of the human body
- 29. **VITROCELLOMICS** Reducing animal experimentation in preclinical predictive drug testing by human hepatic *in vitro* models derived from embryonic stem cells

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WEBSITES Human Toxicology Project https://humantoxicologyproject.org

EMTRAIN http://emtrain.eu

RISK3 http://www.eurotox.com/trisk

Elixir Europe https://elixir-europe.org/about-us/how-funded/eu-projects