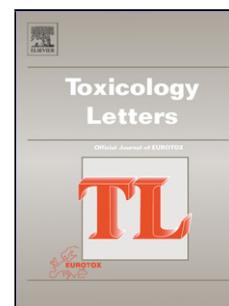


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1                   **The European Registered Toxicologist (ERT):**  
2                   **Current status and prospects for advancement**

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83 **Conflict of Interest**

84

85 All authors have nothing to disclose.

86

87

88

89 **Keywords**

90

91 European Registered Toxicologist; EUROTOX

92

93

94 **Abbreviations**

95

96 CEN = European Committee for Standardization; CPD = Continuing professional

97 development; EAPCCT = European Association of Poison Control Centres and Clinical

98 Toxicologists; ESTIV = European Society for Toxicology in Vitro; ERT = European

99 Registered Toxicologist; EUROTOX = Federation of European Toxicologists and European

100 Societies of Toxicology.

101 **Abstract**

102

103 Following its inception in 1994, the certification of European Registered Toxicologists (ERT)  
104 by EUROTOX has been recognized as ensuring professional competence as well as scientific  
105 integrity and credibility. Criteria and procedures for registration are contained in the ERT  
106 “Guidelines for Registration 2012”. The register of ERT currently has over 1,900 members.

107

108 In order to continue the harmonisation of requirements and processes between national  
109 registering bodies as a prerequisite for official recognition of the ERT title as a standard, and  
110 to take account of recent developments in toxicology, an update of the ERT Guidelines has  
111 been prepared in a series of workshops by the EUROTOX subcommittees for education and  
112 registration, in consultation with representatives of national toxicology societies and registers.  
113 The update includes details of topics and learning outcomes for theoretical training, and how  
114 these can be assessed. The importance of continuing professional development as the  
115 cornerstone of re-registration is emphasised.

116

117 To help with the process of harmonisation, it is necessary to collate and share best practices of  
118 registration conditions and procedures across Europe. Importantly, this information can also  
119 be used to audit compliance with the EUROTOX standards. As recognition of professionals in  
120 toxicology, including specialist qualifications, is becoming more important than ever, we  
121 believe that this can best be achieved based on the steps for harmonisation outlined here  
122 together with the proposed new Guidelines.

123

124

125

126

## 127 **Introduction**

128

129 Toxicology is a broad scientific discipline practised by scientists from different educational  
130 backgrounds and professions. As early as the 1980s an increasing need for professional  
131 recognition of qualified toxicologists was identified. As a result several toxicological  
132 societies in Europe in particular Germany, the Netherlands and the UK, started to develop  
133 national registers to recognize qualified toxicologists. For this purpose senior toxicologists  
134 were nominated by their societies to form national boards for identification of individuals  
135 qualified for registration. In the early 1990s experts from several European countries, under  
136 the umbrella of the Federation of European Toxicologists and European Societies of  
137 Toxicology (EUROTOX), jointly defined criteria for registration of qualified toxicologists.  
138 These criteria were comparable to those in use in the USA and elsewhere. The resulting  
139 common requirements were adopted by a number of European toxicology societies allowing  
140 for mutual recognition albeit with some national specificities. Joint European registration  
141 according to the “EUROTOX model” was started in 1994 by the three founding registers  
142 (UK, Germany, Netherlands). Requirements for EUROTOX registration were first published  
143 in preliminary form in 1995 as “Expectations of a EUROTOX REGISTERED  
144 TOXICOLOGIST (ERT)” (Fowler et al. 1995, Savolainen 1998). The title was later re-named  
145 “European Registered Toxicologist”. The common requirements of the EUROTOX model of  
146 registration defined five basic conditions for registration:

- 147 • An academic degree in a related subject
- 148 • Theoretical knowledge of major areas of toxicology
- 149 • A minimum of 5 years of practical experience
- 150 • Current professional engagement in toxicology
- 151 • Renewal at 5 years intervals

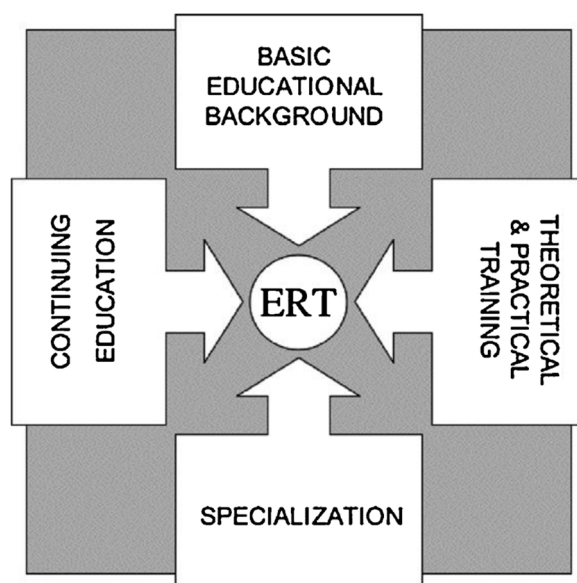
152 Furthermore, the “Expectations” contained short summaries of the theoretical knowledge  
153 and practical experience required, as well as some administrative and procedural guidance for  
154 registration and re-registration. In order to provide the expected theoretical knowledge several  
155 toxicology societies developed courses, most of them jointly with academic institutions.

156

157 For practical reasons, and to comply with the federal structure of EUROTOX, the model of  
158 registration was designed as a two-step procedure. Firstly, at the national level independent  
159 boards of expert members of each national toxicological society evaluate applications of  
160 candidates. Subsequently, the EUROTOX Secretariat would certify successful individuals as

161 European Registered Toxicologist (ERT) without further evaluation. Over the years most  
162 European societies of toxicology which are members of EUROTOX joined the registration  
163 scheme which now includes 21 national registries. A review in 2007 highlighted the critical  
164 importance of education and training (Fig. 1) and recognised that “significant work remains to  
165 further align the national registries and reviewing panels to identify as much as possible the  
166 requirements and characteristics for the accreditation of toxicologists in Europe” (Fowler and  
167 Galli, 2007).

168



169

170

171 Fig. 1 Summary of ERT requirements (reproduced with permission from Fowler and Galli, 2007)

172

## 173 **Development of the ERT guidelines 2012**

174

175 In the years 2010 – 2012, the EUROTOX sub-committees for education and registration  
176 jointly developed an update of the “Expectations of a Registered Toxicologist” in order to  
177 further increase harmonisation and conformity of criteria and procedures among the national  
178 registers. The update took into account the evolution of toxicology since the 1990s, such as  
179 progress of science, increasing needs for specialisation, shifts of focus in the field e.g. in  
180 favour of risk assessment. Criteria for registration and administrative procedures for  
181 registration and re-registration were evaluated and revised where appropriate. Following  
182 extensive review and comments by the member societies, the “ERT Guidelines for  
183 Registration” were ratified by EUROTOX initially in 2011 and, after further adjustments,  
184 were finally adopted and published in 2012 (<http://www.eurotox.com/ert/>). They provided a

185 template covering the entire process of education, practical experience, documentation, and  
186 registration.

187  
188 Subsequent to the publication of the ERT guidelines in 2012, the sub-committees for  
189 education and registration organised five workshops to publicise the updated concepts and  
190 regulations in the ERT guidelines in discussions with national registries. The aim was to  
191 establish the requirements for content and learning outcomes of educational offers, and to  
192 consider the needs for future development. This position paper is the result of the work  
193 accomplished in the last three workshops and in particular the workshop held in Paris in May  
194 2016 in which the authors of this paper participated. The two sub-committees also prepared a  
195 **mission statement for the registration and educational activities of EUROTOX** which  
196 was adopted by the EUROTOX Business Council Meeting in Porto, Portugal, in September  
197 2015 (see text box).

198

#### **Mission statement for the registration and educational activities of EUROTOX\***

##### **Mission**

*To provide Europe with*

- *well-trained toxicologists*
- *a system to recognise qualified toxicologists (ERT) to ensure the safety of society in general*

##### **Aims**

- *facilitate and support the education process*
- *harmonise and set training standards leading to ERT*
- *promote ERT and further specialisation in toxicology*
- *contribute to international efforts for worldwide recognition of qualified toxicologists*

*In order to achieve these aims the sub-committees seek the cooperation of national societies and international organisations.*

\* Prepared by the sub-committees for education and for registration and adopted by the EUROTOX Business Council Meeting in Porto, Portugal, in September 2015

199

## **200 Current standing of the ERT**

201

202 The ERT system has proven successful over the years. Currently, the 21 European registers  
203 have more than 1900 registered members who are recognised as ERT by EUROTOX. This  
204 development reflects the advantages perceived by European toxicologists of being an ERT.  
205 For example, the proprietary designation “European Registered Toxicologist” (indicated by



206 the post-nominal letters ERT) distinguishes a registered toxicologist from other, often self-  
207 proclaimed “experts“ who may be called upon in particular by the media to comment on  
208 toxicological issues of public concern. The ERT designation provides assurance of  
209 professional competence, scientific integrity and credibility. It certifies common high  
210 standards and, by acceptance in all registering countries, facilitates mobility of members.  
211 Furthermore, it is appreciated by employers in Europe and worldwide, thus providing better  
212 job opportunities.

213

## 214 **Future harmonisation of national registration processes**

215

216 Several aspects of the 2012 ERT guidelines were identified as needing improvement and  
217 updating. Some of these have now been accomplished, for others possible solutions have been  
218 discussed and, at least in part, agreed. In particular, the list of educational topics provided in  
219 the theoretical part (section B of ERT guidelines) has been revised and the definitions of aim,  
220 content and learning outcomes were developed in the ERT workshops. These will be  
221 published as an annex to the revised guidelines.

222

223 The guiding principle in considering needs for education and registration continues to be  
224 **harmonisation on a high level** of the respective activities of European national registers and  
225 EUROTOX. This is particularly important with regard to the different routes for registration  
226 ((a) education and training and (b) experience and practical “on the job” training). A  
227 requirement for all candidates for registration to demonstrate the required theoretical  
228 knowledge (e.g. by formal assessment) is considered as an essential part of further  
229 harmonisation. Such an assessment could be offered by EUROTOX as a service for  
230 candidates who have not gone through a formalised process of attending educational courses.

231

232 Some providers of educational courses for the purpose of a) ERT registration and b)  
233 continuing professional development (CPD) have indicated that they would value a process  
234 for recognition of courses by EUROTOX. This has now been defined and will be added as an  
235 annex to the revised guidelines. In an effort to strengthen international cooperation on  
236 education of ERT candidates and CPD of ERTs, exchange of information on the various  
237 educational activities in European countries would be a step forward. For example, it is  
238 essential that the list of available courses presented on the EUROTOX website is updated on a  
239 regular basis. Likewise, exchange of lecturers and of students should increase consistency

240 between the various courses. The rapid development of internet-based educational tools such  
241 as e-learning platforms and webinars also provides additional opportunities to share  
242 educational offers e.g. by arranging joint course programmes.

243  
244 In the field of education and practical training, current cooperation with universities who are  
245 offering master programmes in toxicology should be extended to facilitate their use for ERT  
246 requirements. Furthermore, doctoral programmes based on practical work and training in  
247 fields relevant to toxicology are currently available in some universities, and should be  
248 offered more widely. Also, participation of universities in formal assessments (examinations)  
249 of candidates who have not attended educational courses, in accordance with ERT guidelines,  
250 may be a possibility worth considering. Participation of universities in the educational  
251 programmes for toxicologists seeking registration would increase the prospect of worldwide  
252 recognition of the ERT qualification. Additionally, it would be advantageous for both  
253 EUROTOX and academia, and may help to reverse the current reduction of academic  
254 positions in toxicology (Gundert-Remy et al., 2015, Wallace et al., 2016).

255  
256 Sharing of best practices concerning education and registration procedures among national  
257 registers requires detailed information to be collated from every registering national society.  
258 EUROTOX will then use this information to identify best practice across Europe and offer  
259 this to all e.g. via further revisions in the ERT guidelines. Importantly, the information can  
260 also be used in an auditing process to ensure compliance with the standards established by  
261 EUROTOX.

262  
263 Essentially, this requires regular exchange of information between national course directors  
264 and representatives of registration boards with the EUROTOX sub-committees for education  
265 and registration. In order to manage common tasks including statistics, administration, record  
266 keeping of registration and re-registration activities, the central ERT functions and services of  
267 EUROTOX should be coordinated by a single body working with the sub-committee for  
268 registration but also including a number of elected national representatives (e.g. registry  
269 chairs, course directors).

270  
271 Further development and harmonisation are also required with regard to the national  
272 processes for re-registration. The demonstration of CPD is a cornerstone of the re-registration  
273 process, and some national registers have, from their inception, required records of the

274 personal development activities of registered toxicologists to support periodic re-registration.  
275 The recent creation of online-based systems in some national registers and the use of credit  
276 points (e.g. ECTS = European Credit Transfer System)<sup>1</sup> have facilitated the transparent  
277 recording of CPD activities. In the first instance, EUROTOX will be able to share best  
278 practice among the national registers but future possibilities include establishing a central  
279 register available to all registered toxicologists for documenting their CPD.

280

## 281 **Recognition of the ERT qualification in Europe and worldwide**

282

283 Recognition of professionals in scientific disciplines such as toxicology is becoming more  
284 important than ever in our increasingly globalised environment. The needs of international  
285 employers in industry, government offices, European agencies, scientific panels, contract  
286 research organisations, international regulatory bodies and academia require demonstration of  
287 proficiency and comparable educational standards (Bass and Vamvakas, 2000). Responsibility  
288 for quality of reports, risks assessments and scientifically-based regulatory decisions often has  
289 to be documented by the personal signature of a qualified toxicologist. Therefore, the goal of  
290 future development of the ERT system has to be the formal recognition of its value by  
291 appropriate European bodies.

292

293 Although certification as an ERT is widely appreciated by national and international agencies  
294 and authorities and by companies, the title is not legally recognized so far. Such official  
295 recognition has been identified as an urgent goal by EUROTOX. The following concept has  
296 evolved from the joint workshops of the education and registration sub-committees as a  
297 possible starting point for achieving this goal in the future.

298

299 The ERT guidelines have attained a degree of standardisation and precision which will be  
300 further enhanced by current work and the activities described above. On this basis it seems  
301 reasonable to start a process for recognition of the ERT training as a European Standard e.g.  
302 by the European Committee for Standardization (CEN). This perspective is supported by the  
303 recent approval of the European Standard of “Health risk assessment of chemicals -  
304 Requirements for the provision of training - Complementary element” (CEN, 2015; Galli and  
305 Altenpohl, 2014). Standardisation of the ERT system could be either for the training program

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<sup>1</sup> ECTS = European Credit Transfer System. ECTS credit designates an amount of workload. Typically, one year corresponds to 60 ECTS-credits. A 3-year Bachelor program has therefore usually 180 ECTS-credits; a 2-year Master program usually 120 ECTS-credits.

306 or the required knowledge/skills, or for the process of registration. This would not necessarily  
307 change the ERT Guidelines but would serve to maintain and increase harmonisation.  
308 Inclusion of the ERT in an external system would help to elevate the branding and  
309 international recognition and promotion of ERT. National societies and EUROTOX also need  
310 to consider ways of better fostering the ERT concept in order to achieve increased recognition  
311 in European countries and supranational bodies.

312

### 313 **Specialisation of registered toxicologists**

314

315 Registered toxicologists frequently undertake specialisation over and above ERT  
316 requirements. This specialisation of experts in certain areas or fields of toxicology needs to be  
317 recognised. Some possible examples of specialist areas are listed in the educational topics in  
318 the Guidelines. For official use, all fields accepted for specialisation should be entered into a  
319 list following approval by EUROTOX which also defines relevant criteria for each field.  
320 Proposals for recognition of defined fields of specialisation may come from groups interested  
321 in having their expertise recognised, such as specialist organisations who are members of  
322 EUROTOX, e.g. the European Association of Poison Control Centres and Clinical  
323 Toxicologists (EAPCCT), or the European Society for Toxicology in Vitro (ESTIV). For  
324 defining criteria and evaluation of candidates, specialists from ministries, universities and  
325 state authorities can be co-opted into their national registration committees. Depending on the  
326 specialist field, communication and liaison with scientific societies or bodies outside  
327 EUROTOX may also be required, as may external financial support, e.g. via EU tender  
328 projects. Clearly, the subject of officially registering fields of specialization of ERT will be  
329 important in the future, but currently priority needs to be given to the structural work on ERT  
330 and the formal recognition described above.

331

### 332 **Conclusions**

333

334 The EUROTOX system for recognizing the professional qualifications and experience of  
335 toxicologists has proven a valuable asset for European toxicologists since its inception more  
336 than 20 years ago. The development of detailed guidelines for content and processes of  
337 registration and re-registration has helped to improve harmonisation among national  
338 registration systems. This process will continue with the immediate focus being on

339 • common assessment procedures,

- 340 • enhanced collaboration in education,
- 341 • mutual recognition of educational offers,
- 342 • sharing of best practice,
- 343 • auditing of registration and re-registration procedures.

344 The explicit goal is to achieve formal recognition of the ERT as a professional qualification  
345 by competent bodies in Europe and worldwide. This may in the future include recognition of  
346 specialist qualifications for toxicologists.

347

348

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350

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352 this paper were discussed and the revised guidelines prepared, as well as the EUROTOX  
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354 Switzerland, Austria and France for their support which allowed the workshops to take place.

355

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