RISK ASSESSMENT TRAINING AND ERTs

Corrado Lodovico Galli
ERTs AND RISK ASSESSMENT TRAINING

Corrado Lodovico Galli
Identification of adverse health effects
- Animal-based toxicological studies
- In vitro toxicology data
- Structure-activity consideration
- Human data

Quantification of adverse health effects
- Dose-response for critical effect
- Selection of critical data
- Mode/mechanism of action
- Kinetic variability
- Dynamic variability

Active principle
- Dose of toxicant
- Dose in individuals
- Dose in special population groups
- Max/min, chronically/occasionally

“Risk = hazard × exposure”
EUROPEAN REGISTERED TOXICOLOGIST (ERT RECOGNITION)

• “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).” *

*The EUROPEAN REGISTERED TOXICOLOGIST (ERT) Guidelines for Registration
• Safety of chemicals is a primary demand of our populations. Modern Societies need Toxicology.
• Availability of well trained, competent toxicologists will convince stakeholders that toxicology is a useful and necessary science
• High quality training of toxicologists now will secure the future of toxicology in the next generation

*The EUROPEAN REGISTERED TOXICOLOGIST (ERT) Guidelines for Registration
• **Theoretical Training:** 13 core modules + 2 mandatory modules out of 9 modules

• **Practical Training:** 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 7 listed topics. In addition an in-depth knowledge and experience will be expected in at least 2 of 7 topics (B1 to B7).
  - B7. Procedures in Risk Analysis

*The EUROPEAN REGISTERED TOXICOLOGIST (ERT) Guidelines for Registration*
• **Risk assessment** communicate the key strengths and weaknesses of the toxicological assessment through a conscious and deliberate effort to bring all the important considerations about risk into an integrated picture.

• **Risk characterization** is an integral part of a risk assessment that summarizes the key findings and the strengths and weaknesses of the available toxicological data for risk managers giving the quantitative risk estimate or health-based values (“the numbers”).
• The procedure is based upon the concept of setting residue limits that correspond to the intended usage of the chemicals, i.e., short-term use, prolonged use, and/or lifetime use.

• Data pertaining to chemical and toxicologicall properties, occurrence and use, and possibly effects in people are used.

• After evaluation of these data, acceptable health based values are derived using a safety margin approach for short-term and prolonged exposure limits.

• The safety margin approach combines the use of safety factors and professional judgment for noncarcinogens and for some carcinogens.

• A weight-of-evidence test determines the use of each approach.

• Finally health based values from relevant routes and endpoints are compared and a residue limit or residue limits are estimated.
The number of chemicals, their metabolites and side-products is getting more attention and for many of them little knowledge is available on possible health risks. EU has placed food and drug safety and safe handling of chemicals as a high priority, as exemplified by REACH.

Is of high concern in Europe today the need of implementation of reliable and efficient risk assessment procedures for the exposure to various types of chemicals.
LACK OF TRAINED RISK ASSESSORS

• Shortage of Risk assessors trained in risk assessment required by European agencies such as DG SANCO, EFSA, ECHA and EMA, as well as corresponding Member State governmental organisations, and the European industry.
<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core/Modular program</td>
<td>Consists of xxxx stand-alone modules of intensive, self-contained advanced classroom lectures. Teaching methods may include lectures, discussion panels, syndicate groups, tutorials, case studies, demonstrations, e-learning, and home assignments.</td>
</tr>
<tr>
<td>Practical training</td>
<td>A practical training period lasting .....months, years.... at institutions performing toxicological risk assessments as their daily activity will allow trainees to acquire hands-on experience following the consecutive steps of the toxicological risk assessment process.</td>
</tr>
<tr>
<td>Final assessment</td>
<td>The final assessment is based on the presentation and defence of the case study to the accreditation body.</td>
</tr>
</tbody>
</table>
• Today, risk assessor training is usually achieved on an individual basis through many years of experience in regulatory toxicology and risk assessment work.

• Training deals with specific hands-on, practical supervised training in risk assessment and continuous practical exercise in the area of human health risk assessment of chemicals.
The accreditation must be recognised by all stakeholders.

The accreditation has to be awarded by a recognized body responsible for the standards to ensure a wide acceptance of the accreditation system.
• DG SANCO is currently working with CEN (European Committee for Standardization) to develop European standards supporting accreditation of human health risk assessors in the field of chemicals.
Based on a harmonised acknowledgement of the requirements and characteristics of a European risk assessor.

“Standardization of the knowledge, skills and experience required of a risk assessor in the area of human health risk assessment of chemicals in order to competently perform such risk assessments”.

- CEN Guidelines document
Why Risk Assessor Accreditation?

- Benefits of a dedicated and widely recognised training in risk assessment resulting in a European accreditation as a European risk assessor are many.
Strongly support the future development of high quality risk assessment in Europe and provide the European agencies, Member State organisations and European industry with well-educated experts.
• Ensure that the risk assessors’ knowledge, skills and ability for reasoning are of a high recognised standard.
• High and even quality of the risk assessments performed by the European agencies and industry.
Contribute to harmonisation in the risk assessment procedures between the different agencies and enable work sharing.
### Component Description

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
</table>
| Core/Modular program    | Consists of stand-alone modules of intensive, self-contained advanced classroom lectures.  
Teaching methods may include lectures, discussion panels, syndicate groups, tutorials, case studies, demonstrations, e-learning, and home assignments. |
| Practical training      | A practical training period lasting .....months, years.... at institutions performing toxicological risk assessments as their daily activity will allow trainees to acquire hands-on experience following the consecutive steps of the toxicological risk assessment process. |
| Final assessment        | The final assessment is based on the presentation and defence of the case study to the accreditation body.                                    |
THANK YOU

TOXICOLOGY LABORATORY