



Directive 2010/63/EU

**Commission Expert Working Groups
on Education and Training and on
Project Evaluation**

Linz, Austria
17.9.2013

Susanna Louhimies
DG Environment, European Commission



Commission EWG on E&T and on Project Evaluation

- *The legal framework and transposition*
- *EWG on Project Evaluation and Retrospective Assessment*
- *EWG on Education and Training*
- *Future work and conclusions*



Legal framework

- Directive 2010/63/EU entered into force in 2010
- Possibility for the maintenance of existing stricter measures
- Adoption of national measures by 10 Nov 2012
- Directive fully applicable from 1 Jan 2013

Correct and complete transposition a key priority



- *The Commission examines the **completeness** as well as the **correctness** of transposition*
- *The first letters of formal notice were sent to those MS that have not yet transposed the Directive*
- *Follow-up through initiation of a formal infringement, where appropriate, including a possibility of fines*

Tools to promote uniform transposition



The Commission facilitates the process through

- Twice yearly National Contact Point (NCP) meetings
- Legal and technical questions – Q&A published and updated when new questions arise
- NCP discussion
- ***Expert Working Group discussions***
- Information portal at the Commission web-site

Expert Working Groups (EWG) to work together at EU level



- Reach common ***understanding*** of the issues
- Agree on a ***common framework and approach***
- Recommend ***good practice and optimum processes***
- Provide practical, illustrative examples to facilitate understanding
- Seek ***Member State endorsement*** for outcomes





Project Evaluation – Project application

- ***Information provision is crucial: correct, complete, current and relevant (vs TMI)***
- *Use of template(s) to invite provision of information*
- *Developed pre-formulated questions to build templates*



Project Evaluation – Requirements for PE

- 1. Availability of suitable expertise*
- 2. Impartiality – lack of conflict of interest*
- 3. Proportionality*
- 4. Consistency*
- 5. Efficiency*



Project Evaluation – Requirements for PE

6. *Transparency of the process*
7. *Access to an independent appeals process*
8. ***Training of evaluators***
9. *Sufficient resources*
10. *Knowledge of local culture and practices*



Project Evaluation – Process and its components

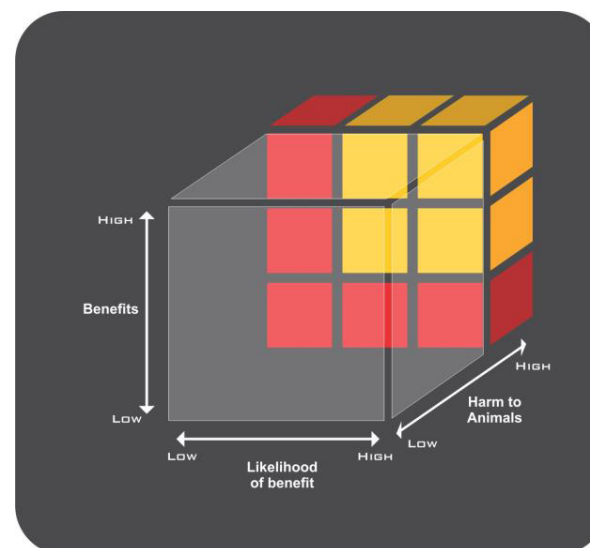
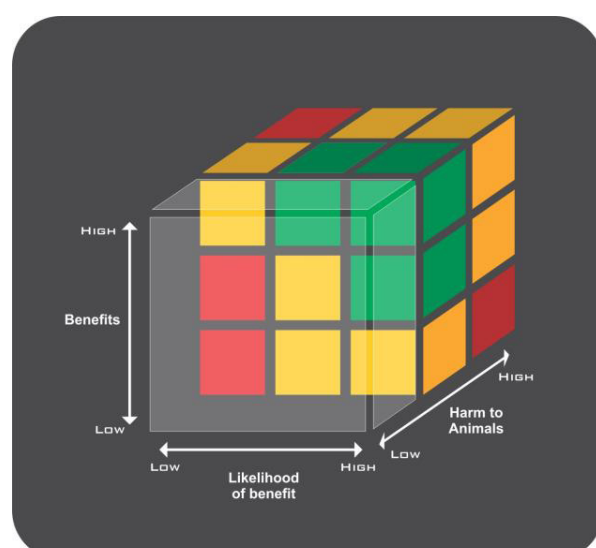
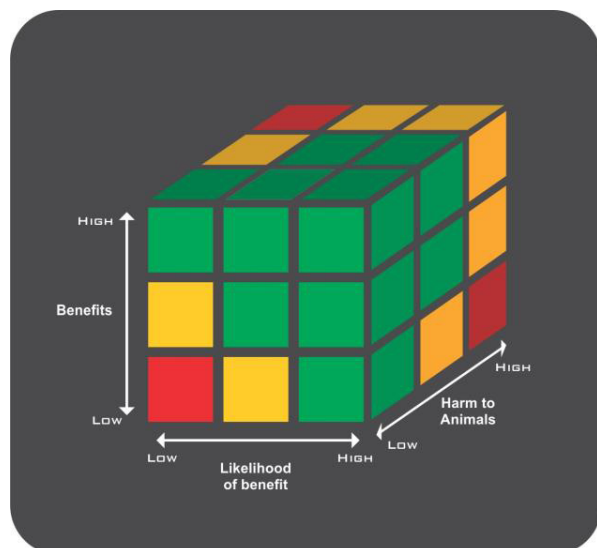
- *Assessment of*
 - **scientific justification**
 - **application of the Three Rs** (Annex VI)
 - **benefits** (what, who, how, when)
 - **harms** (N.B. Severity Assessment Framework)
 - **likelihood of success**
- *Harm – benefit assessment*



Project Evaluation – Harm-benefit assessment

- *No simple numerical method exists*
- ***A systematic approach*** to the process is a pre-requisite
- ***Informed discussion*** among ***well-trained*** evaluators with relevant ***expertise*** is required
- ***Consistency*** should improve over time

Project Evaluation – Modified Bateson Cube



Project Evaluation – Retrospective Assessment



- ***Benefits** of Retrospective Assessment (RA)*
- *Factors determining **whether** and **when** RA should be carried out*
- *Guidance on **securing necessary information***
- *Outcomes to derive from RA*



Commission EWG on E&T and on Project Evaluation

- *The legal framework and transposition*
- *EWG on Project Evaluation and Retrospective Assessment*
- *EWG on Education and Training*
- *Future work and conclusions*

Education and training – legal requirements



Art 23(2) requires that

*"..The staff shall be **adequately educated and trained** before they perform any of the following functions" ...*

*"...Staff carrying out functions referred to in points (a), (c) or (d) shall be **supervised** in the performance of their tasks until they have **demonstrated the requisite competence**"...*

Education and training – objectives

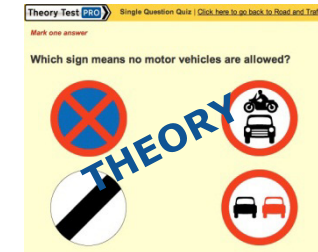
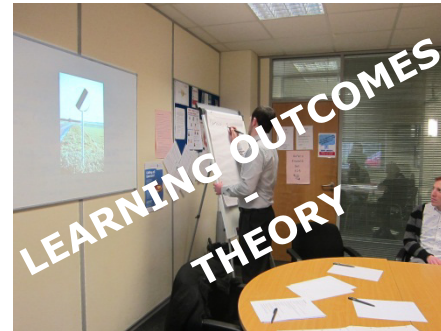
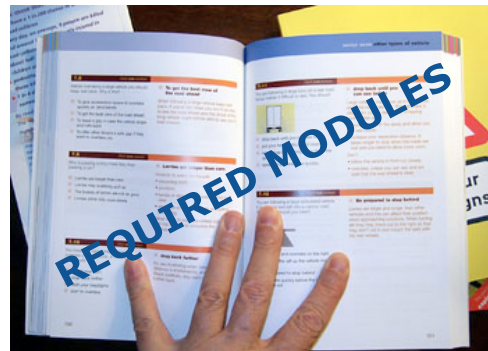


Key criteria

- Flexible
 - Available and accessible
 - Affordable
 - Of agreed quality
- **Ensure competence of staff**
 - **Facilitate free movement of personnel**



ASSESSMENT OF LEARNING OUTCOMES



'DRIVING' UNDER SUPERVISION



COMPETENCE ASSESSMENT

COMMON TRAINING RECORDS





Modular training

- **Core modules** = a compulsory module for **all functions** with same Learning Outcomes
- **Function specific modules** = a compulsory module for (a) specific function(s)
- **Task and skill specific modules** = recommended modules specific to a particular task or skill
- **National and local modules** = covering relevant national legislation or specificities of the local environment (establishment)

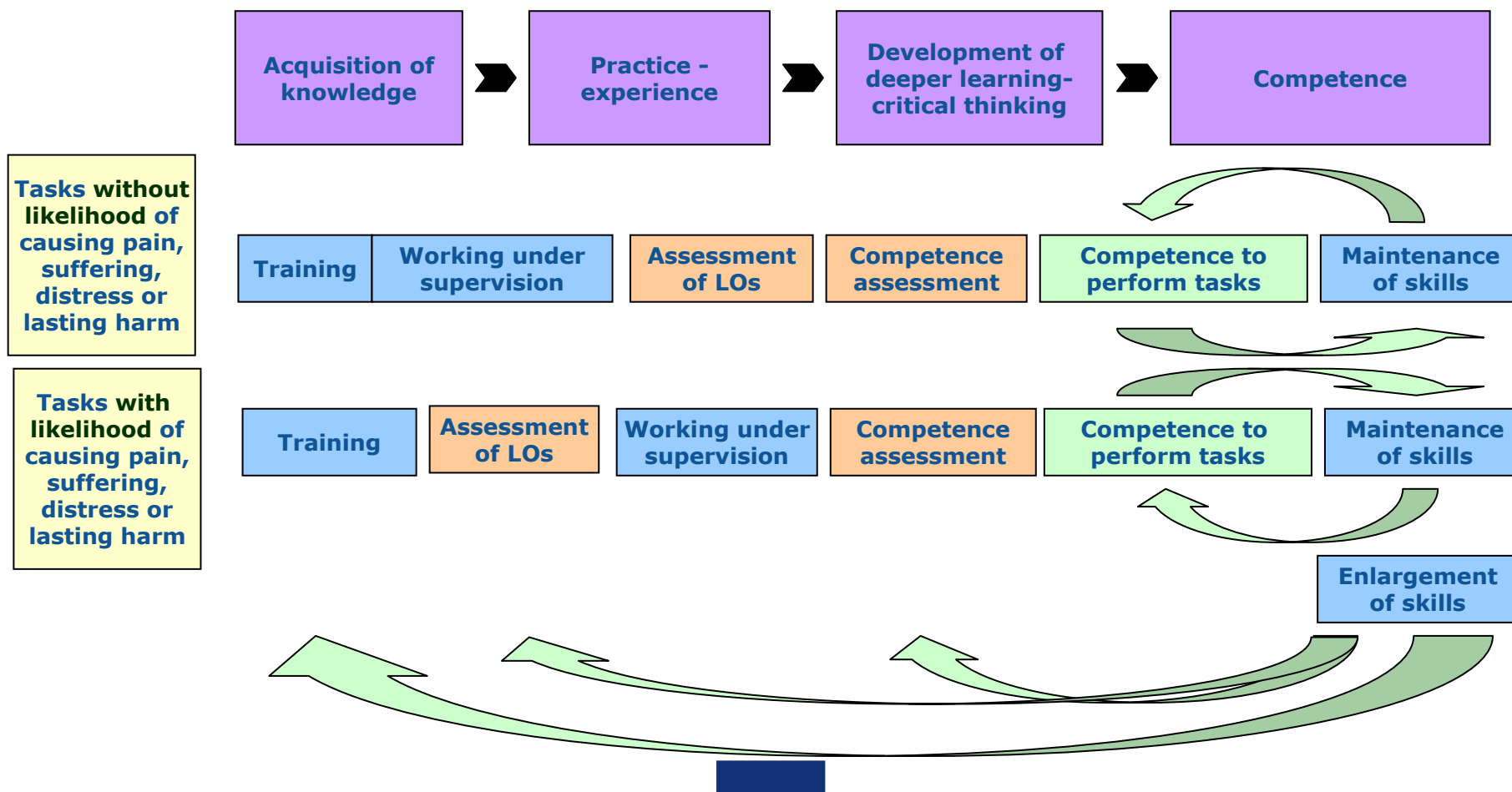


Learning outcomes (LOs)

LOs describe what a student should know, understand, or be able to do at the end of that module.

- LOs do ***not*** represent a course syllabus/a list of topics to be covered
- Deal with output rather than processes
- Training / LOs do ***not*** deliver ***competence***

Putting the pieces of puzzle together for attainment of competence





Training modules developed

- *Article 23 functions*
 - a) persons carrying out procedures on animals*
 - b) persons designing projects/procedures*
 - c) taking care of animals*
 - d) persons killing animals*
- *Functions in Article 24*
 - *person(s) **responsible** for the welfare and care of animals*
 - *person(s) **responsible** for access to information*
 - *person(s) **responsible** for staff's E&T and competence*
- *Project evaluators*
- *Designated veterinarians*

Framework for mutual acceptance



1. **Training courses** on the basis of **agreed Modules and LOs** with pass/fail criteria defined by the course provider
2. **Approval/accreditation of training courses** on the bases of mutually **agreed principles**
3. Common **training records** to detail passed training and confirmed (assessed) competences
4. **Exchange of information** at EU level between course providers, approval/accrediting bodies and MS authorities

EU Platform proposed to be established to continue the development of the framework

Standards for training courses presented for approval / accreditation



- *Module content (course syllabus and material)*
- *Teaching methods, trainers*
- *Theoretical vs Practical Teaching*
- *Assessment (Methods, **Pass-fail criteria**)*
- *Reviews, communication with applicants*
- *Distance learning*
- *Time planning etc ...*

Principles for approval / accreditation



- *Independence from the training provider*
- *Competent assessors*
- *Proportionality and affordability*
- *Sustainability of the system in place*
- *Confidence*

EU Platform for Education and Training



- *A need for a **light-touch framework** to promote mutual recognition and quality of training*
- *Provide contact points for liaison*
- ***Repository** of approval / accrediting bodies, training providers and courses*
- *Share information, **develop & maintain principles and criteria** for modules and LOs, supervision, assessment, CPD and record keeping*

Use of live animals for education and training



- *Justification*
- *Project application and evaluation*
 - pre-formulated questions for the template(s)
 - **tiered approach**: no animal use, use of cadavers, live animals (non-recovery, conscious)
- *Acceptable harms: 'non-recovery' and 'mild' with rare but justified exceptions*
- *Importance of supervision*



Laboratory Animals

Legislation

Statistics

Opinions of European
Commission Expert
Committees

Alternative methods

Related topics

Events

Links

Contact Us

Interpretation and terminology of Directive 2010/63/EU



The following documents are intended as guidance to assist Member States and others affected by this Directive to arrive at a common understanding of the provisions contained in the Directive. All comments should be considered only within the context of Directive 2010/63/EU on the protection of animals used for scientific purposes.

Only the Court of Justice of the European Union is entitled to interpret EU law with legally binding authority.

Legal understanding

The following documents are intended to assist the legal understanding of specific provisions of the Directive for the benefit of all those affected by the Directive.

The National Contact Points (NCP) for the protection of animals used for scientific purposes are responsible for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes. The Commission agreed to discuss a number of articles of the Directive with the NCPs throughout the EU.

Some elements of the Directive have been/are subject to specific Expert Working Group (EWG) meetings to which all Member States and main stakeholder organisations are invited to nominate experts. The outcome of the EWG meetings is then presented to NCP for endorsement.

The consensus on the understanding of the elements discussed at the NCP meetings are presented below to promote uniform implementation and application of the Directive. It is important to note that some of these documents may present "work in progress" (indicated as such). However, it was felt important to inform all those affected by the Directive as soon as progress is made.

[The consensus document II of 22-23 March 2012](#) covers the principles of creation, establishment and maintenance of **genetically altered animal** lines and how these are considered within project authorisation and statistical reporting.



Commission EWG on E&T and on Project Evaluation

- *The legal framework and transposition*
- *EWG on Project Evaluation and Retrospective Assessment*
- *EWG on Education and Training*
- *Future work and conclusions*



Future work

Meeting of National Contact Points 18-19.0.2013

- EWG results: Information on the Three Rs*
- EWG results: PE/RA*
- EWG results: Education and Training I-III*

- *Enforcement and inspections Dec 2013*
- *Illustrative examples for PE/RA?*



Conclusions

Transposition and enforcement are key priorities for the Commission

Project Evaluation at the core of the new Directive

- *Correct, complete, current and relevant information is crucial to a PE*
- *Ten key requirements for an efficient PE process*
- *Systematic approach for harm-benefit assessment
– no tools replace informed discussion among well-trained experts*



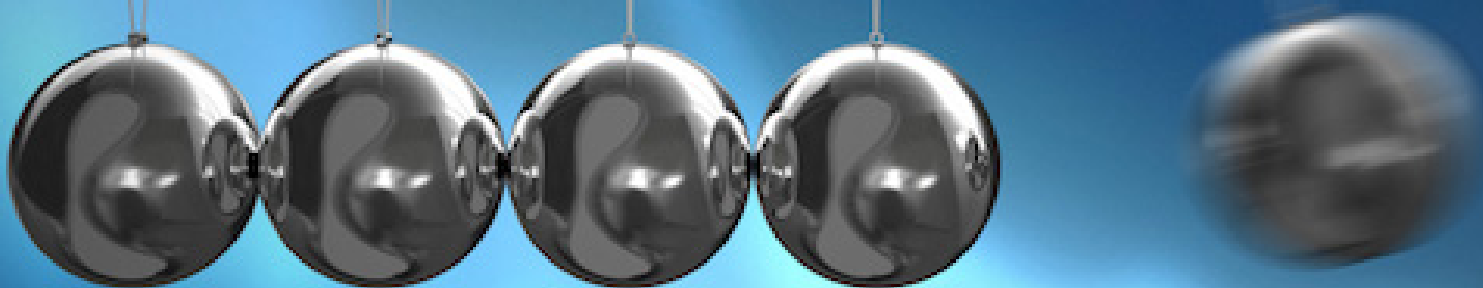
Conclusions

EU wide Education and Training framework

- *Based on flexible, modular training structure*
- *Output driven with agreed Learning Outcomes*
- *Mutual recognition achievable through agreed standards and principles*
- *EU platform proposed to support the framework*



**The work continues –
let's keep the
momentum going!**





Thank you for your attention!

http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm

