Directive 2010/63/EU

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

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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
The Three Rs

- EDUCATION & TRAINING
- PROJECT EVALUATION
- COMMUNICATION
- SEVERITY FRAME WORK
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**
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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
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

Tasks without likelihood of causing pain, suffering, distress or lasting harm:
- Acquisition of knowledge
- Practice - experience
- Development of deeper learning - critical thinking
- Competence

Tasks with likelihood of causing pain, suffering, distress or lasting harm:
- Training
- Working under supervision
- Assessment of LOs
- Competence assessment
- Competence to perform tasks
- Maintenance of skills
- Enlargement of skills
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**
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.

The legal understanding

The National Contact Points (NCP) of the stakeholders involved in the implementation of the Directive are responsible for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes. The NCPs are supported by the European Commission and the Member States. The NCPs are responsible for the implementation of the provisions of the Directive within their respective Member States. The NCPs are supported by the European Commission and the Member States. The NCPs are responsible for the implementation of the provisions of the Directive within their respective Member States.
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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