

**Working Group (EWG) on Education and Training
Directive 2010/63/EU**

Brussels, 19 -20 September 2012

Thought Starter Document

Acknowledgements

We acknowledge the considerable contributions made by the members of the Expert Working Group during the meeting in February 2012, and the further work done by the two sub-groups charged with progressing the Learning Outcomes and developing a framework for assessment. We are grateful for the additional material submitted by Member States and Experts to inform our discussions on developing a framework for mutual recognition of training.

The common desire from contributors remains to develop a common education and training framework which facilitates and assures the competence of all persons involved in the use, care and breeding of animals for scientific procedures, and assists the free movement of personnel.

Background to Education and Training within 2010/63/EU

Directive 2010/63/EU emphasises the importance of training, supervision, and competence of personnel involved in the care and use of animals in scientific procedures.

Article 23 requires that staff shall be adequately educated and trained before they perform any of the following functions: (a) carrying out procedures on animals; (b) the design of procedures and projects; (c) taking care of animals; (d) killing animals.

Persons responsible for the design of procedures and projects shall have received instruction in a scientific discipline relevant to the work being undertaken and shall have species-specific knowledge.

Staff carrying procedures on animals, taking care of animals and killing animals shall be supervised in the performance of their tasks until they have demonstrated the requisite competence.

The outcomes from the EWG will be used to inform the development of EU non-binding guidelines [A23(4)], to assist MS progress their obligations to publish minimum requirements on education and training and to promote free movement of personnel throughout the EU. Furthermore, any agreement at EU level on general principles will assist those developing training courses to work towards common, acceptable standards.

Objectives of EWG on Education and Training

To develop an Education and Training framework within the EU which would assure the competence of staff caring for or using animals in procedures, and facilitating the free movement of personnel within EU.

This framework will include consideration of the training, supervision, competence assessment and continuing training requirements of persons carrying out procedures, taking care of animals, killing animals and the training and continuing training requirements of those persons responsible for the design of procedures and projects.

Outcomes from February 2012 EWG meeting on Education & Training

A number of principles were developed and agreed during the February meeting. These were subsequently endorsed at the March 2012 National Contact Point (NCP) meeting. The document is available at

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

An update on the discussions on Education and Training at the NCP meetings in March and July will be provided at the September meeting.

I. The Educational Process under 2010/63/EU

Directive 2010/63/EU requires that persons designing, supervising and carrying out procedures and persons caring for animals and killing animals are adequately educated, trained and supervised until competent in the tasks they perform.

As discussed at the February meeting, there are many different ways by which training, supervision and competence can be delivered. The objective of the EWG is to develop a framework within the EU which would assure the competence of staff caring for or using animals in procedures, and facilitate the free movement of personnel within EU.

Discussion subsequent to the meeting among the experts and the sub-groups has suggested that some further clarifications are necessary to ensure that our approach offers the necessary flexibility to deliver our objective.

Training alone does not deliver competence.

The Learning Outcome approach with appropriate assessment provides confidence that the trainee has achieved a suitable level of understanding to meet the learning criteria.

A period of supervision will generally be necessary, to re-enforce understanding and to ensure the tasks/duties/procedures are conducted to an appropriate standard, with interventions as necessary by the supervisor(s) to ensure this is attained.

Only after individuals have been assessed as competent, should they work without supervision. By this time, those deemed competent should have attained a deeper understanding of the task.

Competence should be subject to review.

The time taken to achieve individual Learning Outcomes and to complete Modular Training will vary considerably, depending on the individual, their intellectual capacity, the method of teaching and assessment.

Duration of the supervision period and time taken until competence is attained will also vary, for example due to the frequency/availability of the task being performed, technical complexity, and ability of the individual.

It is therefore not desirable to specify any time limits for teaching or supervision periods.

The sub-group tasked with developing Learning Outcomes have included some comments on the attainment of basic knowledge or understanding during initial training, and have explored the concept that a deeper understanding of the knowledge base should have developed and be expected, by the time competence is assessed.

This approach should reflect what happens in practice – after completion of an initial Training Module the expectation is that the student will have a basic understanding of the issues, but during the period of supervision this understanding will continue to improve, such that by the time competence is achieved a much deeper understanding of the task being undertaken can be expected. Proportionality is essential; the more complex the task, the more demanding the learning process and elements to be assessed when evaluating the attainment of competence.

The suggested process is laid out in Annex 1.

II. Outcome from EWG Sub-Groups

A. Learning Outcomes

1. Further Development of Learning Outcomes for Modules

Attached as Annex 2 is the report from the Sub-Group tasked with further developing the Modules discussed in February and developing appropriate Learning Outcomes for the remaining Modules identified at the meeting as Core or Pre-requisite for at least one of the Functions a-d.

The group has identified during the course of their discussions a number of questions to be addressed at the September EWG meeting.

Some additional points have been raised by the second sub-group during their deliberations on assessment criteria.

2. Questions for Consideration raised by the Learning Outcomes Sub-Group

General questions

1. **“Core” Module:** this is a point of definition, but one that we found caused some confusion. The initial, and straightforward, definition was to use the term “core” to describe any module that needs to be taken by all staff performing functions a, b, or c.

However, we considered that it may be possible that some modules may be delivered with different levels of content and detail depending on the functions, and therefore the term “core” may be misleading. It is noteworthy however that this distinction of levels may be related to one concerning “simple recall” (low level of learning) vs ”critical thinking” (higher level of learning), which, in turn, could be reflected in the phrasing of learning outcomes. This is relevant, for example, for Modules 2 and 3, and see also Module 13.

Note – The “assessment” sub-group has raised similar and additional questions re definition of “Core”.

Note – February meeting agreed (further endorsed by NCP), that “core” content should apply to all functions. Further subdivisions would suggest these are no longer core; this could cause confusion.

2. Superficial vs. Deep learning

In relation to point one, the sub-group wanted to raise a more fundamental question concerning the Learning Outcomes which are currently mostly written with “knowledge” in mind and which is considered to be the lowest form of learning/understanding. There is a strong argument that modern teaching should go well beyond that whenever possible and encourage critical thinking (e.g. evaluation; see Bloom’s hierarchy in sub-group’s submission – Appendix 4 of Annex 2) or what some call “deep learning”, rather than just recalling facts or mimicking actions.

Developing this remark from the sub-group further, it could be stated that competence can only be achieved once the acquired knowledge can be turned into a practical tool to solve daily situations. Therefore, the EWG will be tasked to consider whether deeper learning/critical thinking outcomes should be at the core of assessing competence (see also flow chart in Annex 1).

3. Practical Learning Outcomes

Some of the learning outcomes may require the application of practical tasks.

It needs to be considered when and how to assess these. This is relevant to, for example, the anaesthesia module.

4. Miscellaneous

Should there be some information contained generally in the learning outcomes specifically relating to agricultural and farm animals? For example biosecurity issues would differ significantly between a laboratory and farm setting. Or would these differences be appropriately covered in a species-specific module.

Module specific questions

5. Module 1 - Legislation

Should the veterinarian be specifically mentioned in the bullet points of Legislation Module 1 Learning Outcomes or is it sufficient to state that ‘key personnel have statutory duties and other responsibilities under the National Legislation?’

In relation to Legislation Module 1 learning outcome, should one of the learning outcomes be to ‘define which species, including respective stages of development that are included in the scope of the Directive / National Law?’

6. Module 5 – Minimally invasive procedures

Do some of the learning outcomes listed for Module 5 exceed what may be required? Is there a risk of ‘over-educating’ at any stage when this may not be necessary?

7. Module 6 – Theory & Skills

Should it be stated that ‘performing minor techniques competently under supervision’ is more suitable to be taught as part of work under supervision at the place of work, rather than as part of a formal course? Should the term ‘minor’ procedure be more specifically defined?

8. Module 10 - Anaesthesia - one or two modules?

This has generated many comments. The argument for a two-module-model (basic and advanced) is that using anaesthesia, for restraint for example, should not require the same level of training as a lengthy anaesthesia with invasive procedures. The argument for a one-module-model, however, is that the general principles for short anaesthesia are the same, that the effect of physiology are also very profound and that it is a mistake to “dumb down” anaesthesia under a debatable classification of the anaesthetics regimen that will be administered. Moreover points that may be particularly relevant to procedures involving, e.g. long and invasive surgeries, could perhaps best be covered as part of the surgical module rather than a stand-alone “advanced” anaesthesia module.

Thus, having initially written draft learning outcomes for a two-module system (reproduced in the Learning Outcomes document for information) the sub-group has now proposed one anaesthesia module. Coincidentally, this path reflects the result of a National discussion in the UK system. Training in the UK has been operating under a two-model system for many years, but a formal review has now advocated a one module system.

How should anaesthesia be dealt with - should all those involved in animal use and care have some introduction to anaesthesia?

If only performing brief gaseous anaesthesia for tail biopsy in GA mice, is a full anaesthesia course needed?

Should anaesthesia be dealt with in one complete module with learning outcomes, or should this be two distinct modules?

9. Module 12 – Design of Procedures and Projects

Is the Russell and Burch reference the best one to cite, and can we have rephrased wording that is easier to understand for the first learning outcome, rather than ‘fidelity’ and ‘discrimination’.

Note : Further development is required of Modules relating to

- 15. Animal, husbandry and enrichment – Level 2
- 16. Animal production including breeding, genetics and genetic alteration
- 18. Specific modules for persons detailed in Articles 24 and 25 – Wild animals
- 20. Project evaluators

B. Principles and proposed draft recommendations for the assessment/pass/fail criteria for all modules

The second sub-group has prepared two papers for discussion at the September meeting. These are attached as Annexes 3 and 4. These include suggestions for assessment and pass/fail criteria for a number of the Modules discussed in February. Due to time constraints these do not entirely match with revised Learning Outcomes produced by the other sub-group, but this can be done after the meeting if key principles are agreed.

The sub-group has identified a number of issues for discussion in September – these are contained within their documents and should be considered by attendees in advance of the September meetings.

III. Development of Mechanisms for Supervision and Assessment of Competence

Satisfactory completion of a Training Course and attainment of Learning Outcomes are important steps, but these must be followed by a period of appropriate supervision, during which other learning outcomes can be achieved, until the requisite competence has been attained, and before the initial educational process can be considered to have been completed.

Good supervision can re-enforce and enhance learning outcomes, but equally inappropriate supervision can have negative consequences, occasionally promulgating out-of-date or simply poor practices.

Practical training and supervision should be carried out by a person

- appropriately skilled and competent in the techniques,
- having sufficient seniority to command respect and
- who is able to impart skills and knowledge to others.

Such status should be documented by progression in training records. This may not be the same person as that identified on site with the responsibility for ensuring training.

The UK Laboratory Animal Science Association has produced guiding principles on the supervision requirements for personal licence holders which can be found at: http://www.lasa.co.uk/LASA_Guiding_Principles_Supervision_for_PILs_2010.pdf

Ideally, the person who assesses competence should not be the same person as that who trained but this may be difficult for highly specialized skills and in small establishments.

Subsequent to the February meeting, the LASA Education, Training and Ethics section have worked on the development of proposals for a harmonized system for the assessment of competence. LASA has agreed to share these in advance of publication to inform discussions at the EWG. Notes from the meeting are attached as Annex 5.

Recording of Training and Supervision

Training records should reflect the level of training and level of competence to allow skills transfer across the EU. Currently there is a high variability in types of records being kept and in the control of record keeping from centralised facility to individual. The culture and/or compliance history of the establishment influences record keeping. GLP establishments usually have good records of training which may require little / no change.

Records should be detailed down to the procedure level and be species specific.

The LASA document includes some examples of suitable records of supervision – one example is included below for information.

Two Examples of Personal Licensee Supervision and Competency Records

Example 1

NAME:			PIL NO:				DATE GRANTED:			
PPL No	Technique title and species used	Date of procedure	Supervised by (print name)	Supervised by (signature)	Level of supervision current 0 - 4	Level of supervision future 0 - 4	PIL (signature)	Supervisor's signature confirming competence to proceed unsupervised	Date competency confirmed	

Key: Levels of supervision

0 - No supervision required

1 - Supervisor aware when procedures are taking place and available for discussion to provide advice if necessary (i.e. by telephone)

2 - Supervisor aware when procedures are taking place and available to attend to provide advice if required (i.e. in the vicinity of the establishment)

3 - Supervisor aware when procedures are taking place and available for rapid intervention if required (i.e. in the vicinity of the procedure)

4 - Supervisor present when the procedure takes place providing direct supervision and advice

Accurate records are an essential part of all training schemes and should incorporate professional education and relevant competencies acquired prior to present employment.

A common approach in the way training and attained competences are recorded will facilitate movement of personnel.

Workshop

To develop an appropriate EU structure to deliver appropriate methods of supervision and competence assessment which could be transferable between Member States

1. Assessment of competence
 - a. What criteria should be used to assess competency in performing procedures (focussing on practical skills but taking into account knowledge and attitude)?
 - b. Should elements for assessment of competence ('deeper learning/critical thinking') be developed for each modules
 - c. How to cope with training and assessment where there are only a very few people in the country carrying out highly specialist procedures?
2. Maintaining competence and the need for reassessment
 - a. What criteria should trigger reassessment of competence, both scheduled and in event of concerns or transfer in of staff?
 - b. Should re-assessment of competence be a formal requirement if tasks/procedures are not undertaken for a period of time?

3. Develop and agree a template for recording of Supervision and Competence. How much detail of the actual training needs to be included in the records?

IV. Development of a common framework with regard to consistency and quality assurance of the training and development programmes to facilitate free movement of personnel within EU.

While there is a general agreement on the content of training to be provided for persons performing the functions listed in Article 23, unless there is a mechanism by which such training is “recognised” as suitable, there remains a considerable risk that the present difficulties for personnel moving between (and within) MS will continue.

NCPs need to be satisfied that the education and training provided to individuals meets the expectations set out in Article 23 and are required to publish minimum requirements.

What information is required to facilitate mutual recognition/accreditation within a Modular framework?

Three submissions to this EWG are attached for information – Annex 6 - FELASA Accreditation system; Annex 7 a-c Functions of an Accrediting Body provided by the UK Accrediting Bodies; Annex 8 Nicole Linklater, University of Marburg.

Glossary of terms

Quality assurance

The maintenance of a desired level of quality in a service or product

Accreditation

Process in which certification of competency, authority, or credibility is presented.

Mutual recognition

Agreement between two organisations to recognise each other's processes or programmes. Mutual recognition may be between higher education institutions, quality or accrediting agencies or professional bodies.

A standard approach to accreditation/mutual recognition should be developed – this would include recommendations on how modules should be assessed, how frequently this should be done, who should be involved, what documentation should be provided and maintained.

1. Issues for consideration for the contents of the accreditation of a module/course

Module content

Course syllabus; course material; Learning outcomes

Teaching methods

Alternatives vs live animals

Module Delivery

Trainers

Theoretical vs Practical Teaching

Assessment

Methods

Pass-fail criteria

Deeper learning/critical thinking evaluation criteria

Maintaining up to date – Reviews

Communication with applicants

Participant Feedback

Evidence of satisfactory completion

2. Issues for consideration for the accreditation process

Skill set for Accreditors

Issues for consideration – prospective documentation required

Inspection of courses - before accreditation; review dates?

Objective assessments – agreed common quality standards

Feedback

Notification by Module Provider of substantive changes

Time limited Approval

3. Issues for consideration on the Accreditation/Mutual Recognition framework

What systems of Accreditation/Mutual Recognition are available within Europe at present?

A number of Member States “approve” training courses within their own country.

In the UK there are three Accrediting Bodies which accredit training courses for individuals carrying out procedures and for individuals responsible for the design of procedures.

A number of MS already recognise “training” carried out in other MS but this does not seem to be a widespread practice.

It was acknowledged at the previous EWG and also at the NCP meeting, that there is also a likely need for accreditation of MS specific Module dealing with national legislation.

FELASA has accredited 28 courses in thirteen European countries. These include courses for animal care staff, for persons carrying out procedures and for persons designing procedures

What European framework could deliver an effective mutual recognition of Modules to an agreed quality standard?

An effective network of communication and coordination of all organisations/NCPs directly involved in the recognition of training courses would need to be developed.

Initial exchanges of information / development of common database of resources and approaches to accreditation should build confidence.

A common base-line on agreed standards would be required – the present work on Learning outcomes/assessment should facilitate this.

Workshop

To develop a common framework for mutual recognition/accreditation of modules
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1. What elements are required within a framework?
2. What is presently available?
3. What structure/arrangement could deliver this? Define the key components; identify potential problems and consider how these could be addressed, having regard for minimising costs, potential delays to scientific progress and bureaucracy.

Questions for discussion to develop Annex 7 b further: Would each MS have sufficient resources to include this role within the National Committee? Consider the feasibility for National Link bodies? To which National Committee should an

accrediting body report to if it was multinational/EU-wide or international? How could the structure be streamlined to minimise the number of bodies involved and optimise the use of resources?

V. Continuing Professional Development

Meeting requirements of Article 24 with regard to continuous training and maintenance of competence

Article 23(3) requires that staff shall maintain competence through a process of continuing education (Continuing Professional Development - CPD). This process shall be overseen by the person responsible for training, identified in Article 24(1)(c). This requirement is intended to ensure that all those involved in the use and care of animals remain competent and up-to-date on new developments in the field. Of the responses received for the EWG, only Switzerland has a mandatory requirement for CPD.

FELASA has proposed guidelines for continuing education for all persons involved in the care and use of animals for scientific purposes experiments. The system is based on the award of credits, of which 50% must be achieved by attendance at endorsed activities which have been subject to scrutiny by a professional body . The other 50% can be achieved from activities which are recognised by the employer. Spain has implemented this scheme (SECAL) and it in the process of introduction in the UK (LASA). Further details are given on the web site:

<http://www.felasa.eu/recommendations/guidelines/guidelines-for-continuing-education-for-persons-involved-in-animal-experime/>.

It is important that whatever process is established the training is mutually recognized and that the records are transferable. It is also essential that at least some of the CPD is directly relevant to the field of (Laboratory) Animal Science.

Workshop

Consider how continued professional development can be attained, recorded and mutually recognized within a common EU framework

1. Consider the strengths and weaknesses of existing schemes
2. Consider the role of *the person responsible for ensuring that staff are ... continuously trained...*, and how this can be achieved and assured.
3. Develop and agree a template for recording CPD – can this be attached linked to supervision/competence records?

List of Annexes

1. Educational Learning Process
2. Report from Sub-Group developing Learning Outcomes
3. Report from Sub-Group developing Assessment Criteria – Principles
4. Report from Sub-Group developing Assessment Criteria – Modules
5. Developing a harmonized system for assessment of competence (Notes from LASA ETES Meeting – July2012)
6. The FELASA Accreditation Scheme
7.
 - a. General Principles to be applied to a European system for Accreditation and Quality Control
 - b. Suggested framework for European network for accreditation of core and pre-requisite modules
 - c. Functions of an Accrediting Body
8. E&T EWG Nicole Linklater