

# **EU 2010/63**

## **Training, Supervision & Competence**

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- Output of EC Expert Working Group (EWG) on Education & Training
- Functions of personnel to be trained
- EWG Agreed Approach
- NCP Endorsement
- Modules and Learning Outcomes
- UK Course Accreditation

# Training

- Flexible
- Available and accessible
- Affordable
- Of agreed quality

## 4 'functions' to be trained

**Function A** - Persons performing procedures

**Function B** - Persons designing procedures

**Function C** - Persons caring for animals

**Function D** - Persons killing animals



Persons carrying out **Function B** shall have received instruction in a **scientific discipline** relevant to the work being undertaken and shall have **species-specific** knowledge.

Persons carrying out **Function A, C or D** shall **be supervised** in the performance of their tasks until they **have demonstrated the requisite competence**.

# EWG Agreed Approach

- Sufficiently **detailed** learning outcomes
  - ☑ **Theoretical** knowledge to be gained
  - ☑ **Practical** skills to be obtained
- **Pass / Fail** Criteria
- **Defined** Assessment



## Modules & Learning Outcomes

- The **training modules** and their associated **learning outcomes** provide guidance to **Competent Authorities** throughout Member States on the minimum training requirements under EU Directive 2010/63/EU (Article 23 & Annex V).
- This is intended to enable the development of an Education and Training **framework** within the EU which will ensure the **competence** of staff and facilitate the free **movement** of personnel within and between Member States.

# NCP Endorsement

It was agreed that the training should be on a **modular** structure. The modules should be:

- **Compulsory** to all functions as in Article 23 (2)
- Required only for **(a) specific function(s)**
- Of **National** relevance
- Additional modules facilitating learning **specialised** skills as well as **lifelong** learning



## Modules & Learning Outcomes

- The modular structure and learning outcomes approach is not **prescriptive**.
- The learning outcomes deal with **outcome** rather than **processes** and help to define the skills and knowledge that course participants should be able to demonstrate by the time these learning outcomes are **assessed**.
- Learning outcomes are the **specific intentions** of a training programme or module, written in **specific terms**.

**They describe what a course attendee should know, understand, or be able to do at the end of that module.**

# Modules

The modules do not represent a course syllabus or a list of topics to be covered.

.Trainers are **free to select** course content, training materials and delivery methods to deliver the learning outcomes in a manner that meets their national / local / institutional and/or individual / group requirements.

.The achievement of **practical** learning outcomes may be **separate** from theoretical/knowledge based learning outcomes.

.Skills transfer is important in all cases.

## Module delivers...

- Knowledge
- Theory of the **correct** techniques to be applied for practical skills (not excluding hands-on training)
- The transfer of knowledge should be **tested** with the appropriate pass/fail criteria
- Should provide **acceptable** level of knowledge and skills for working under **supervision**
- Modules not sufficient to achieve "**competence**"

## NCP Agreement on Academic Qualifications for functions A,C & D

With the **focus on competence**, on the basis of training modules which **fulfil the agreed quality criteria** and are **assessed** in a **consistent manner**, **passing successfully** the required modules infers a level of schooling and maturity sufficient for these functions.

**Functions A, C and D should not require any specific educational qualifications.**

## NCP Agreement on Academic Qualifications for function B

The National Contact Points consider that individuals responsible for designing procedures and projects under Article 23(2)(b) **should normally** hold an **academic degree or equivalent** in an **appropriate scientific discipline**. This will be important to ensure such individuals are able to apply the 3Rs effectively in the design of the procedures and projects and make appropriate ethical and scientific judgments.

There may be some individuals who are **recognised as qualified** to perform any of the tasks identified in Article 23 of Directive 2010/63/EU prior to its entry into force for whom recognition should be continued.

It is important to note in this context that Art 40(2)(b) **describes no educational requirements** for the person **responsible** for the **overall implementation** of the project.

# Learning Process

In **general** a period of **working under supervision** will be necessary. This allows for:

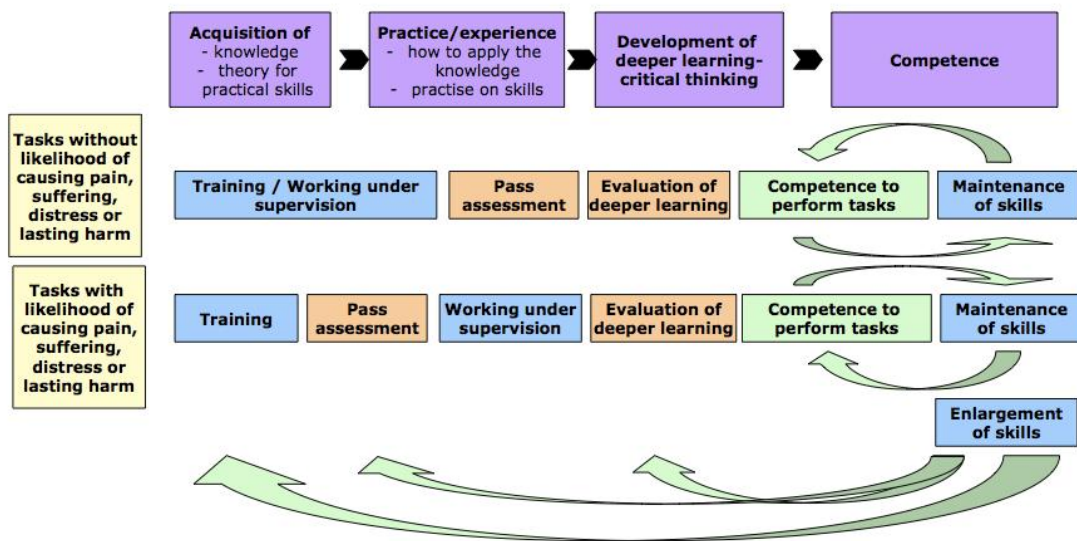
- the **knowledge** to be turned into application
- the **skill** to be practised to gain sufficient **experience**

Only after this period, the person should have **developed the required competence** which should then **be assessed**.

# Supervision

- ✳ In cases where there is **no risk of causing pain, distress, suffering or lasting harm to the animals**, the trainee can proceed to work **under supervision** before achieving the Learning Outcomes.
- ✳ In all other cases, learning outcomes need to be attained in line with the agreed pass criteria before proceeding to work under supervision.
- ✳ The learning outcome approach should allow the achievement of an **acceptable level of understanding** of the subject to ensure that no unnecessary pain, suffering, distress or lasting harm is inflicted when working under supervision.

## Education and training framework





# Competency

- The attainment of the learning outcomes does not mean that the trainee has achieved **competence**.
- Competence and competencies are achieved through **practical application of the acquired knowledge and experience gained through working**.
- Competencies are assessed **separately** from learning outcomes.

## Core, Pre-requisite & Additional

- The modules are split into three types: Core, Pre-requisite and Additional.
- Completion of all **Core** modules is **compulsory** and provides the basic training for all personnel performing any of the **functions A-D of Article 23**.
- A **Pre-requisite** module is a module which is required **in addition to** the Core modules to meet the minimum training needs for a specific function.

## Core, Pre-requisite & Additional

The **exception** is for those persons performing only function D (killing animals) where a **simplified single module** was developed combining the necessary learning outcomes from the respective Core and Pre-requisite modules and may be completed as an **alternative**.

# Modules

- After **successful** completion of the initial training module for a species/group of species, skills expansion to further species will require demonstration of attainment of learning outcomes for the new species within the same module.
- However, it may not be necessary to repeat all elements of the initial training module for the new species.

## Home Office Licence Categories

There will be six licence categories available to apply for and licensing staff should be able to assess and grant Category A, B, C and E. Category types D (NMBA) and F (Other) will be a small subset requiring referral to an Inspector.

- **Category A** Minor/minimally invasive procedures not requiring sedation, analgesia or general anaesthesia
- \* **Category B** Minor/minimally invasive procedures involving sedation, analgesia or brief general anaesthesia. Plus – surgical procedures conducted under brief terminal general anaesthesia
- \* **Category C** Surgical procedures involving general anaesthesia
- \* **Category D** Use of neuromuscular blocking agents
- \* **Category E** Procedures conducted in accordance with a project licence for education and training
- \* **Category F** Other

# Named Persons



- Person for ensuring **access to information** (Information Officer)
- Person responsible for ensuring adequate **education, training, appropriate supervision and competence** (Training & Competence Officer - TCO)
- Person responsible for ensuring **conditions of establishment licence** are complied with (Compliance / Certificate Holder)
- Veterinary Surgeon with **expertise** in lab animal medicine, or other suitably qualified person, to provide advice on welfare and treatment (NVS)
- Person responsible for **overseeing care and welfare** (NACWO)

## Eligibility for PIL A, B and C Home Office Licences

- \* Eligibility for PIL A, B and C licences will be based upon modules completed together with a declaration by the TCO that supervision will be provided until competence is demonstrated.
- \* Authorisation will be done by ASRU Licensing staff (referring to Inspectors when necessary) in most cases.
- \* The Home Office expect the entry point for most applicants to be at PIL B but they are proposing to allow for a PIL A for those few licensees who may never need to use anaesthetics (eg, some summer students; licensees who only perform dosing and sampling, etc).
- \* Home Office recognise that the boundary between PIL B and PIL C will need to be explained in the Guidance Notes.

## Elegibility for PIL D Home Office Licences

- Eligibility for licence **PIL D** will be based upon assurances that the applicant has extensive experience of anaesthesia making them competent to use NMBAs safely - Inspectors will normally be consulted to advise on these applications.
- Licences under category **PIL E** will fall into **special** categories. For example, the Home Office currently have a special licensing arrangement for microsurgery training courses.



## Proposed Module Training for E&T Under the new ASPA – PIL A, B and C



Animals in Science Regulation Unit

### UPDATED CORE AND PRE-REQUISITE MODULES FOLLOWING 2ND EWG

module		Function A - Carrying out procedures (PIL A)	Function A - Carrying out procedures (PIL B)	Function A - Carrying out procedures (PIL C)
1	National and international laws and guidance			
2	Ethics, animal welfare and the Three Rs - Level 1			
3	Ethics, animal welfare and the Three Rs - Level 2			
4	Basic and appropriate species specific biology (note 1)			
5	Minor/Minimally invasive procedures, generally not requiring anaesthesia - species specific - theory			
6	Procedures generally not requiring anaesthesia - species specific - skills			
7	Animal care, health and management - species specific			
8	Recognition of species specific pain, suffering and distress (including humane end-points)			
9.1	Humane methods of killing - Theory			
9.2	Humane methods of killing - Skills			
9.3	Humane methods of killing - Stand alone module for function D			
10	Anaesthesia for minor procedures			
10	Anaesthesia for surgical procedures			
12	Design of Procedures and projects - Level 1 (note 3)	(as relevant)	(as relevant)	(as relevant)
13	Design of Procedures and projects - Level 2			
14	Occupational health and safety (note 4)			
15	Animal husbandry, care and enrichment practices - level 2			
16	???			
17	Principles of surgery			
18	?			
19	?			
20	?			
<b>Key</b>	Core module for all functions			
	Pre-requisite module for anyone who will be carrying out a specific function			
	Commitment from TCO to ensure provided under supervision after licence granted			
Notes:				

Paul Vallender & Bernie Godson

## UK Modular Courses

- \* Home Office have agreed that it would be unreasonable to require the new EU modules to be introduced from 1<sup>st</sup> January 2013.
- \* The new structure has not yet been approved by the National Contact Points (NCP) nor information provided to all stakeholders.
- \* EWG is still a work in progress
- \* The existing modules will be compatible with the new modules.

# UK Modular Courses

- \* Home Office will **continue to accept** the current UK modules until such time as trainers have been able to realign their courses to fit with the EU modular structure.
- \* It is envisaged that this will take **most of 2013**.



# UK Modular Courses

- \* The overall **content** of modular courses is unlikely to change dramatically, but there is likely to be an impact on **context**.
- \* Training will be broken down into a greater number of modules.



# UK Modular Courses

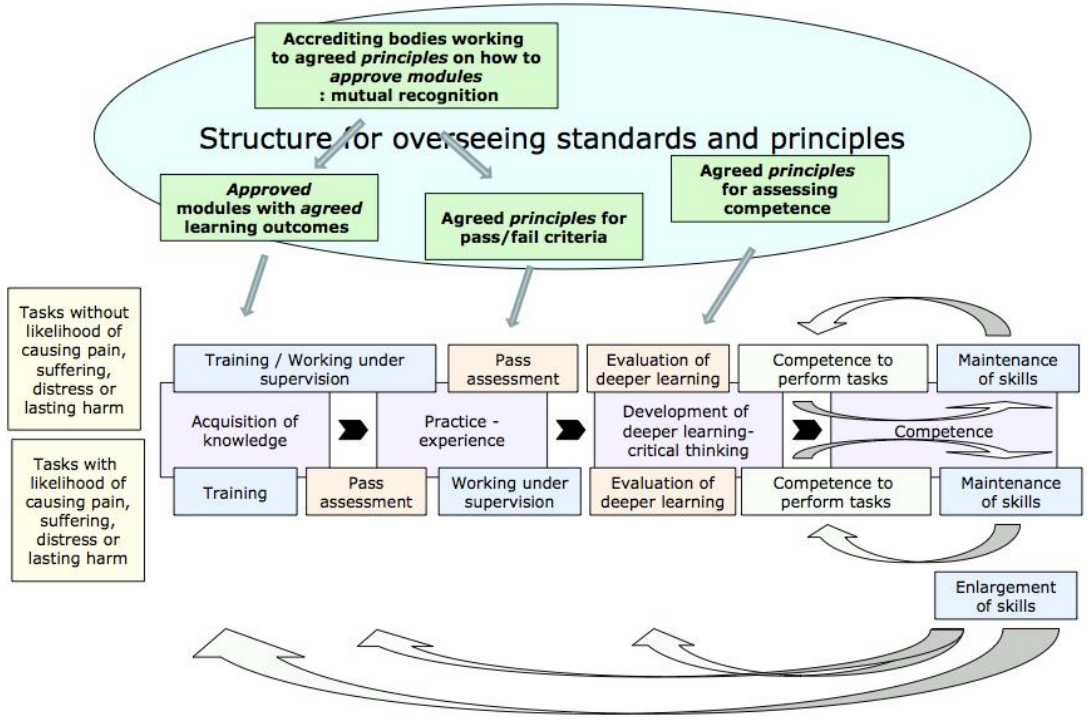
- \* Some will have to be **tailored** to the needs of the individual according to **function**.
- \* Some will have to be delivered at different **levels** according to function/role.
- \* New **assessment criteria** will need to be developed for theoretical and practical teaching.



# Society of Biology

- Course Organisers are preparing **new** Modules for courses held after 1<sup>st</sup> January 2013
- These will include **revised** information on the transposed UK legislative framework.
- Modules will **evolve** as more information becomes available from the EWG.
- Number of meetings arranged between UK Accrediting Bodies and Course Organisers throughout 2013.

# Education and training framework



# Stages of Supervision

EXAMPLE FROM LASA GUIDING PRINCIPLES ON THE SUPERVISION REQUIREMENTS FOR PERSONAL LICENSEES (2010)

- A.** Direct - supervisor **present** (for new trainees).
- B.** Supervisor **aware and available locally** to provide assistance.
- C.** Supervisor **aware and available to attend** if needed at short notice.
- D.** Supervisor **aware and available by telephone**.



# Assessment of Competence

- \* **Separate** supervision and competence assessment **where possible**.
- \* **Objective** assessment - expectations known to trainee; **Pass / Fail** parameters.

**Objective assessment** is a form of questioning which has a single correct answer.



**Guiding Principles on  
the Supervision Requirements  
for Personal Licensees**

EXAMPLE TAKEN FROM LASA GUIDING PRINCIPLES ON THE SUPERVISION REQUIREMENTS FOR PERSONAL LICENSEES (2010)

**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

EXAMPLE TAKEN FROM LASA GUIDING PRINCIPLES ON THE SUPERVISION REQUIREMENTS FOR PERSONAL LICENSEES (2010)

(ii) **Basic *in vivo* Procedures (examples)**

		Level 1		Level 2			Level 3	
		Working under supervision		Competence Assessed			Competence as Trainer	
Technique	Species	Date	Signature of Trainer	Date	Signature of Assessor	Signature of Licensee	Date	Signature of Assessor
Animal handling and restraint	Mouse							
	Rat							
Oral administration of substances	Mouse							
	Rat							
Intraperitoneal administration of substances – small animals	Mouse							
	Rat							
Subcutaneous administration of substances	Mouse							
	Rat							
Withdrawal of blood from superficial blood vessels	Mouse							
	Rat							

**Assessment of Competence**

- Level 1: Records the date that training under close supervision commences.
- Level 2: Records the date that competence has been assessed and agreed by the supervisor and the personal licensee. The trainer indicates that competence has been achieved. The personal licensee agrees that s/he feels competent to carry out the technique unsupervised.
- Level 3: Records the date when a level of competence has been achieved that allows the personal licensee to supervise and train other licensees.

EXAMPLE TAKEN FROM LASA GUIDING PRINCIPLES ON THE SUPERVISION REQUIREMENTS FOR PERSONAL LICENSEES (2010)

(iii) Specialised *in vivo* procedures (examples)

Technique Specialised procedure	Species	Level 1 Working under supervision		Level 2 Competence Assessed			Level 3 Competence as Trainer	
		Date	Signature of Trainer	Date	Signature of Assessor	Signature of Licensee	Date	Signature of Assessor
e.g. pharmacological preparation under terminal anaesthesia								
e.g. Implantation of ICV cannula								

**Assessment of Competence**

- Level 1: Records the date that training under close supervision commences.
- Level 2: Records the date that competence has been assessed and agreed by the supervisor and the personal licensee. The trainer indicates that competence has been achieved. The personal licensee agrees that s/he feels competent to carry out the technique unsupervised.
- Level 3: Records the date when a level of competence has been achieved that allows the personal licensee to supervise and train other licensees.

# EWG Summer 2013

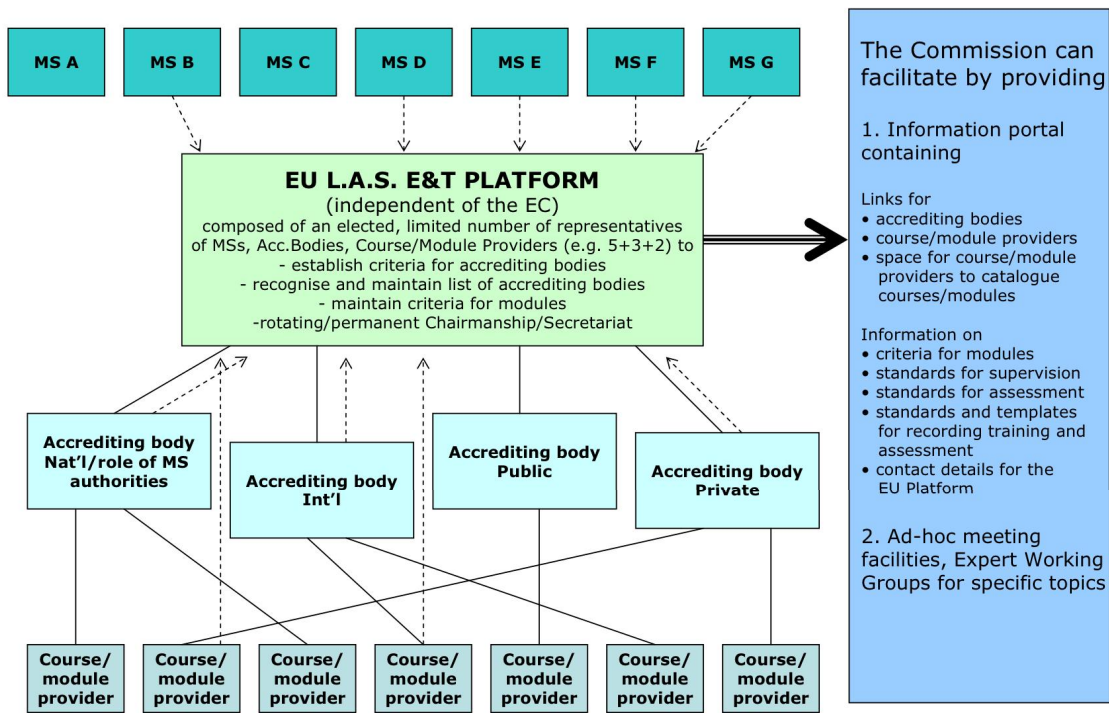
- Role of **Training & Competency Officer (TCO)**
- **Training** for other roles (Veterinarians, Project Evaluators)
- Use of **live** animals for training
- Exemptions / exceptions from training

## Objectives of EWG

- Reach common understanding of the issues
- Acknowledge necessity for expert judgement
- Agree common format and approach
- Promote good practice and optimum processes
- Provide practical, demonstrative examples to facilitate understanding

43

### EU FRAMEWORK FOR A MODULAR TRAINING COURSE ACCREDITATION FOR DIRECTIVE 2010/63/EU







**Level playing field?  
Work in progress...**

**But then acting is all about faking. We're all very good at faking things that we have no competence with.**

**John Cleese**