

Guide to Training, Education and Competency Requirements under Scientific Animal Protection Legislation

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.



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1 SCOPE

This guidance sets out the education and training requirements for personnel involved in the use of animals for scientific or educational purposes within breeder/supplier/user establishments in accordance with Directive 2010/63/EU and S.I. No. 543 of 2012 ('the Regulations'). Hereafter all will be referred to as 'the legislation'.

Article 23(3) of the Directive and Regulation 43(5) of the Regulations require the competent authority (the Health Products Regulatory Authority (HPRA)) to publish minimum requirements with regard to education and training, and the requirements for obtaining, maintaining and demonstrating requisite competence for persons performing the following functions:

- a) carrying out procedures on animals,
- b) designing procedures and projects,
- c) taking care of animals, and
- d) killing animals.

This document outlines advice on these requirements. The basis of these requirements is the list of elements defined by Annex V to the Directive and listed as follows:

- 1 National legislation relevant to the acquisition, husbandry, care and use of animals for scientific purposes
- 2 Ethics in relation to the human-animal relationship, intrinsic value of life and arguments for and against the use of animals for scientific purposes
- 3 Basic and appropriate species-specific biology in relation to anatomy, physiological features, breeding, genetics and genetic alteration
- 4 Animal behaviour, husbandry and enrichment
- 5 Species-specific methods of handling and procedures, where appropriate
- 6 Animal health management and hygiene
- 7 Recognition of species-specific distress, pain and suffering of most common laboratory species
- 8 Anaesthesia, pain relieving methods and euthanasia
- 9 Use of humane end-points
- 10 Requirements of Replacement, Reduction and Refinement
- 11 Design of procedures and projects, where appropriate

2 INTRODUCTION

The legislation requires breeder/supplier/user establishments to have sufficient staff (personnel and researchers) on site and to ensure they are adequately educated, trained and supervised in the performance of their tasks until they have demonstrated the requisite competence.

To ensure compliance with the legislation, and to minimise any pain, suffering, distress or lasting harm to animals, proper training of staff at breeder/supplier/user establishments is essential. Proper training also facilitates good animal welfare and good science.

Training is a continuous process, starting with initial theoretical training, followed by practical training under supervision, to a period of being supervised in the performance of tasks until competence is achieved. Once competence is achieved, it must be maintained and new competencies can be obtained. This process can only be successful if breeder/supplier/user establishments have a defined and robust training system in place. Refer to Appendix I for a schematic illustration of how the learning process should proceed.

The European Commission previously established a working group which developed a common [education and training framework](#). It should be referred to for further detail on the topics discussed in this guide. The HPRA uses this framework as the basis for the guidance we provide.

This guide summarises the HPRA's requirements for training and education. It focuses on the role of the training officer and the specific training requirements for persons carrying out procedures on animals, designing procedures and projects, taking care of animals, and killing animals. It also outlines the training requirements for the project manager and the HPRA's expectations for the maintenance of competence and continuous education, known as Continuing Professional Development (CPD).

3 DEFINITIONS

Refer to Appendix II for relevant definitions relating to this guide.

4 ROLES AND RESPONSIBILITIES

4.1 Training officer

Regulation 46 of the Regulations places a significant responsibility on the designated training officer(s) of the breeder/supplier/user establishment. This person(s), named in the breeder/supplier/user establishment authorisation, is expected to have overall responsibility for the education and training of staff and is expected to ensure that systems are in place to verify that the personnel working with animals are trained to the necessary standards and supervised until they have demonstrated the requisite competence. The training officer also has overall responsibility for ensuring that the training records of personnel are kept updated. In addition, the training officer should ensure that a process for CPD is in place for all relevant personnel.

The training officer need not personally deliver training. They are not required to judge whether or not competency has been achieved by a particular individual. However, they are regarded as the custodian of the overall training and competency system, whereby training in specific techniques is delivered and competency assessed by experts in those techniques (trainers).

During inspection, the training officer may be requested by the HPRA inspector to describe the training system in place at the breeder/supplier/user establishment and explain how competency is achieved and maintained, and how expectations in respect of CPD are met.

4.2 Compliance officer

The compliance officer is ultimately responsible for ensuring compliance with the legislation in the breeder/supplier/user establishment concerned, and this includes making sure that (*via* the training officer) staff are adequately educated and trained and are supervised until they are competent.

4.3 Individual authorisation holder

All individual authorisation holders are responsible for complying with the general conditions of their individual authorisation, which require them to undergo 'an appropriate period of training' prior to performing euthanasia or procedures on animals.

5 GENERAL TRAINING REQUIREMENTS

5.1 Training courses

Individual authorisation (for the purpose of project management, carrying out procedures or performing euthanasia) will only be granted if the applicant has completed a relevant HPRA-approved scientific animal training course. Details on approved training courses are available on the HPRA website. Applicants who completed a training course in Ireland prior to the introduction of the current legislation (September 2012), or applicants who completed a relevant, species-specific course abroad may be required to complete an additional module on the topic of 'National Legislation'. This will be evaluated and communicated to applicants on a case-by-case basis.

5.2 Authorisation requirements

Training in animal handling skills, when carried out in an authorised breeder/supplier/user establishment, does not require a HPRA individual authorisation. However, for an individual to manage a project, carry out procedures or perform euthanasia, they must first obtain an individual authorisation from the HPRA. In addition, procedures, including procedures conducted solely for the purposes of training, can take place only within the context of a HPRA project authorisation. This means that if the training officer, or another expert, delivers training in the conduct of a procedure, the procedure(s) involved must have been authorised by the HPRA under a project authorisation. Details of the application procedure for an individual authorisation are available on the HPRA website.

Experts from outside the breeder/supplier/user establishment (e.g. overseas) approved by the training officer to train personnel in a new procedure or a method of euthanasia will also require individual authorisations. The HPRA may recognise the qualifications and status of personnel licensed overseas in making its decision to grant authorisation. Short-term authorisations for these individuals may be granted, rather than standard full-term five-year individual authorisations.

5.3 Provision of practical training

Training and supervision of personnel may be performed by the training officer or delegated by the training officer to an expert in that technique, or to the designated veterinarian as appropriate. The trainer must have up-to-date knowledge and competence in the techniques they are demonstrating and assessing. The trainer must also have appropriate teaching skills. This person may sign-off on the individual's training record. The responsibility for the correct performance of a task remains with the supervising trainer (and ultimately with the training officer) in all cases, until such time as the trainee has completed training and the requisite competence has been demonstrated.

5.4 Obtaining competence

Regulation 43(4) of the Regulations provides that a member of staff who has not yet demonstrated the requisite competence for carrying out procedures or performing euthanasia, may carry out the tasks listed in their approved individual authorisation if they are 'appropriately supervised' in the performance of their tasks. The duration of supervision and time taken to achieve the requisite competency will vary on a case-by-case basis. The trainee should contribute to the decision as to whether or not they consider themselves sufficiently trained to carry out the procedure or perform that method of euthanasia competently without supervision.

Only after an individual has been assessed as competent, and their training records signed off, can they then carry out procedures or perform that method of euthanasia without supervision. It is important to note that competence is not static, so it is essential that it is subject to periodic review in accordance with the training system in place within the breeder/supplier/user establishment. It is vital that staff and researchers critically evaluate their own level of competence, and they do not perform any techniques they are not comfortable with, as this can pose a risk to animal welfare and potentially increase study variability.

5.5 Animals used for training

5.5.1 Training in euthanasia

The animals used for training in euthanasia may be animals which are destined to be euthanised as part of an ongoing project, or surplus animals which are destined for culling. Where training in euthanasia cannot be completed because animals are not available or scheduled for euthanasia, the HPRA would expect that animals are **not** used and/or produced or procured solely for the purposes of training in a particular method of euthanasia. Instead, applicants

should await the availability of a suitable opportunity to train. Cadavers should be used as part of a tiered approach to training in methods of euthanasia. Cadavers are useful for demonstrating the required techniques and anatomical considerations.

5.5.2 Training in procedures

Surplus animals that are intended for euthanasia are not to be used for training in procedures, except in accordance with a project authorisation granted by the HPRA. Associated individual authorisations for the trainer and the trainees must also be in place.

However, the use of animal cadavers for training or educational purposes does not require a project authorisation or any individual authorisations..

6 SPECIFIC TRAINING REQUIREMENTS

As per the Commission framework, there are specific training requirements for all persons who are:

- a) carrying out procedures on animals,
- b) designing procedures and projects,
- c) taking care of animals, and
- d) killing animals.

Training requirements are outlined below for these specific categories of personnel and additional requirements are also listed for the role of project manager. In addition, there are specific training requirements for the following named persons: the training officer, information officer, animal care and welfare officer and designated veterinarian. Further details on the requirements for these persons are outlined in the Commission framework.

6.1 Requirements for training in carrying out procedures

In accordance with Regulation 43(2)(a) of the Regulations, persons carrying out scientific procedures and projects on animals must have the necessary education and training and must be supervised in the performance of this task until the requisite competence has been demonstrated. They are not required to have been educated to third level but are required to complete the training and education as outlined for 'function (a)' in the Commission framework.

6.2 Requirements for training for those designing procedures and projects

In accordance with Regulation 43(3) of the Regulations, persons designing procedures and projects must have received instruction in a scientific discipline relevant to the work being undertaken (i.e. an academic degree) and have species-specific knowledge. They are expected to complete the training as outlined for 'function (b)' in the Commission framework.

An individual authorisation from the HPRA is not required for personnel engaged solely in designing procedures and projects. However, the HPRA will look to ensure that such persons have met their training and educational requirements during the conduct of inspection of the breeder/supplier/user establishment's training system.

6.3 Requirements for training for those taking care of animals

Persons who are charged with taking care of animals, but do not conduct procedures or perform euthanasia (and therefore do not require a HPRA individual authorisation), are not required to have been educated to third level but are still required to complete the training and education as outlined for 'function (c)' in the Commission framework. While they are not required to complete the requisite training and education prior to commencement of their work, they must undertake the necessary study within **a six-month period** of commencing employment and must work under supervision until they have completed the training.

6.4 Requirements for training in euthanasia

In accordance with Regulation 43(2)(d) of the Regulations, persons performing euthanasia on animals must have the necessary education and training and also be supervised in the performance of this task until the requisite competence has been demonstrated. They are not required to have been educated to third level but are required to complete the training and education as outlined for 'function (d)' in the Commission framework.

Euthanasia must be performed using the methods set out in Annex IV to the Directive, unless otherwise justified in accordance with Regulation 8(4). If another method of euthanasia is to be used or if the method is not to be carried out according to the strict limitations (e.g. weight specifications) set out in the Directive, scientific justification must be provided at the time an application for an individual authorisation is made.

6.5 Requirements for training in project management

In accordance with Regulation 47 of the Regulations, the project manager is the person responsible for overall implementation of the project and its compliance with the project authorisation. The HPRA expects this person to have undertaken the same training as required for those designing projects and procedures. It is not a mandatory requirement that such persons have been educated to third level but they must have the necessary experience for the role. They will also require an individual authorisation from the HPRA and must be named on any project authorisation(s) that they wish to manage (or be named as a deputy project manager).

7 TRAINING RECORDS

The HPRA expects that verified and accurate records of education and training, including CPD, are maintained by all persons holding HPRA individual authorisation. Records should be species-specific and detailed down to the level of specific procedures and methods of euthanasia. They should include details on the level of competence achieved, and whether the person is experienced enough to supervise and train others in those techniques. Records should include sign-off from the trainer or training officer. A sample training record template can be downloaded from the HPRA website. The HPRA inspector can ask individuals for their training records during inspection, so it is important that these are kept up to date at all times.

8 CONTINUOUS PROFESSIONAL DEVELOPMENT

CPD is a process of life-long learning and is essential to continually maintain, improve and broaden one's skills and knowledge, and to ensure the maintenance of competence. CPD enables individuals to meet high professional standards to deliver high quality scientific results. It also ensures that establishments respond to new technologies, the developments in relation to the 3Rs and societal views and are able to provide animals with optimal standards of care and maximise their welfare. It should commence when a person starts working with animals and should continue throughout their working career. It should be achieved by a combination of frequent in-house reviews of competence in conjunction with the relevant practical training, alongside external activities / web-based learning in the field of research/laboratory animal science, welfare and the 3Rs.

Although there is currently no mandatory accredited scientific animal training CPD scheme in place in Ireland, the HPRA expects the following:

8.1 In-house reviews of competence

The training officer(s) in each breeder/supplier/user establishment is responsible for overseeing the process of continuing education. Therefore, the HPRA expects to see a programme in place in each breeder/supplier/user establishment whereby the competence of all personnel is subject to periodic review. This should be considered an ongoing process to maintain acceptable standards. For example, where procedures are performed intermittently/rarely and/or individuals have not performed procedures for some time, consideration should be given to the provision of additional training and supervision. Similarly, the introduction of new, amended or refined procedures should also trigger a review of competence. The HPRA will review this programme of continuing education when evaluating the overall training system of a breeder/supplier/user establishment during inspection.

8.2 Attendance at conferences/symposia/workshops

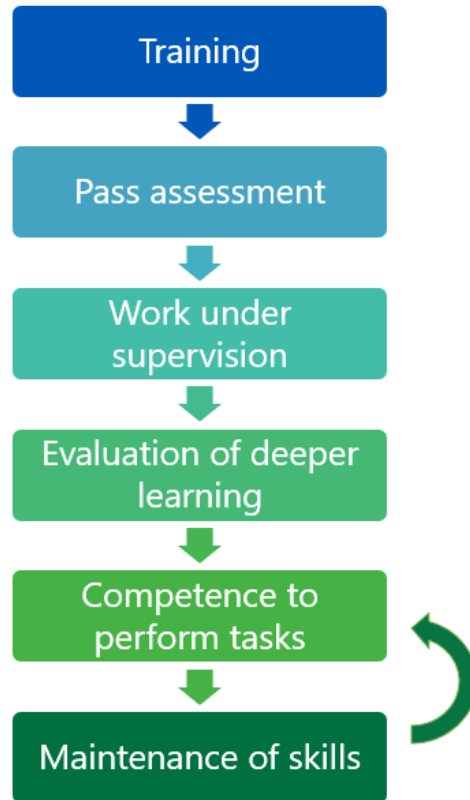
The HPRA expects that all persons involved in project management and/or the performance of procedures or euthanasia regularly attend meetings, conferences or seminars appropriate to their line of work and/or participate in web-based learning opportunities, the purpose of which is to provide them with the necessary updates in relation to areas such as study design, technology, the 3Rs and animal welfare. Workplace training courses and seminars can be a useful source of CPD. In addition, since 2023, members of local ethics committee and/or animal welfare bodies can claim two CPD hours annually for this purpose, in recognition of the commitment involved in participation and the learnings assimilated from ethics committee and AWB membership. (Note: individuals cannot claim four hours for membership of both groups as the allocation is strictly two hours per individual per year.)

The establishment's training officer can certify attendance at CPD events and should oversee compliance with the HPRA requirements.

This requirement for attendance at CPD events does not apply to persons solely caring for animals; however, they are still expected to undergo regular in-house reviews of competence.

The HPRA expects that the amount of time dedicated to attendance of these activities should be at least eight hours per year as an average over a five-year time period (i.e. 40 hours in five years). At least 50% of these hours should comprise relevant 3Rs/animal welfare content, and general training in unrelated areas (e.g. Health and Safety) should not be counted as CPD. Records of attendance/participation should be maintained as part of the individual's training records and may be requested by the HPRA inspector.

APPENDIX I THE LEARNING PROCESS



APPENDIX II DEFINITIONS

Compliance officer means a person designated by a breeder/supplier/user pursuant to Regulation 44 of the Regulations, who is responsible for ensuring compliance with the Regulations.

Designated veterinarian or expert means a person designated by a breeder, supplier or user pursuant to Regulation 48 of the Regulations, who is charged with advisory duties in relation to the well-being and treatment of animals.

Establishment means any installation, building, group of buildings or other premises and may include a place that is not wholly enclosed or covered, and mobile facilities.

Procedure means any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than that caused by the introduction of a needle, in accordance with good veterinary practice. This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition but excludes the euthanasia of animals solely for the use of their organs or tissues.

Project means a programme of work having a defined scientific objective and involving one or more procedures.

Training officer means a person designated by a breeder, supplier or user pursuant to Regulation 46 of the Regulations, who is responsible for ensuring that staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence.

User means any natural or legal person using animals in procedures, whether for profit or not.