HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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.

1 SCOPE

This guide expands on the education and training requirements for personnel involved in breeder, supplier or user establishments in accordance with Directive 2010/63/EU and S.I. No. 543 of 2012 as amended by S.I. No. 434 of 2013 and S.I. No. 174 of 2014 (all hereafter known as the 'Regulations').

The guide also provides clarity on how the requirements for obtaining, maintaining and demonstrating specific requisite competencies for the conduct of procedures and ancillary functions should be achieved and supervised in the breeder/supplier/user establishment in accordance with Article 23(3) of the Directive and Regulation 43(5) of the Regulations.

This document is also intended to advise of the requirements for maintaining requisite competence through continuous training and education.

2 INTRODUCTION

In accordance with Article 23(3) of the Directive and Regulation 43(5) of the Regulations, the HPRA is required to publish minimum requirements with regard to the education and training as well as requirements for obtaining, maintaining and demonstrating competence for those persons involved in carrying out procedures on animals, designing procedures and projects, taking care of animals and euthanising animals (which are kept or used for scientific purposes).

The basis of these requirements is the list of elements defined by Annex V of 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.

The European Commission established a working group which developed a common, non-binding education and training consensus document which can be viewed on their website. The HPRA has adopted the Commission approach in this guide to assist persons engaged by breeder/supplier/user establishments authorised under Directive 2010/63/EU in the design, conduct or management of procedures or projects on animals used for scientific purposes or in respect of personnel involved in taking care of animals or in euthanising animals. The Commission document should be referred to for further detail on the topics discussed in this guide.

Article 23(2) of the Directive and Regulation 43(2) of the S.I. require that each breeder, supplier and user of animals used for scientific purposes shall ensure that the staff involved are adequately educated and trained before they perform any of the following activities:

- carrying out procedures on animals,
- designing procedures and projects,
- taking care of animals or
- euthanising animals.

Additionally, the project manager (defined by Regulation 47 of the S.I. and referred to under Article 40(2)(b) of the Directive) should have a relevant level of understanding of how best to manage their project and their legal responsibilities for the proper conduct, management and reporting of projects.

This guidance attempts to distinguish between the requirements for education and training (theoretical aspects) and for obtaining, maintaining and demonstrating requisite competence (practical competency aspects). Fundamental to this concept is an understanding of the role and responsibility of the breeder/supplier/user establishment's training officer.

In addition, Article 23(3) of the Directive 2010/63/EU and Regulation 43(5) of the S.I. require that personnel shall not only obtain and demonstrate competence, but must also maintain competence. This is interpreted as referring to a process of continuous training, as well as continuing education, also known as Continuing Professional Development (CPD). This requirement is intended to ensure that all those involved in the breeding, use and care of animals remain competent and up-to-date on new developments in the field.

The maintenance of competence is vital as it should enable an individual to meet high professional standards in order to deliver high quality scientific results. It ensures that the breeder/supplier/user establishment responds to new knowledge and developments in research, technology, the 3Rs and societal views as well as any regulatory or legislative changes. It also ensures that the welfare of animals is maintained to a standard that reflects current best practice. Finally, it ensures that standards are continuously improving and animal carers, technicians and professional researchers have the most up-to-date knowledge and skills.

The HPRA's policy on the maintenance of competence will be revised in the light of experience, as well as national or international developments. The policy recognises continuous training as a shared responsibility between the individuals themselves and their breeder/supplier/user establishments. It will be successful only when those involved approach the task with enthusiasm and openness to change.

3 DEFINITIONS

'Designated veterinarian or expert' means a person designated by a breeder, supplier or user pursuant to Regulation 48 of the S.I.

'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 S.I.

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

4 ROLE AND RESPONSIBILITIES OF THE TRAINING OFFICER

Regulation 46 of the S.I. 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 following their appointment and to ensure that systems are in place to verify that the personnel concerned are trained to the necessary standards and supervised until they have demonstrated the requisite competence. In the case where the training officer may not be in a position to certify competence attainment in specific procedures where they themselves do not have competence, another expert may be enlisted

for this purpose and must sign off the individual's training record in respect of the specific procedure.

The training officer need not personally deliver the 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 is delivered by experts and assessment of competency is carried out impartially by experts (who ideally should not be the same experts).

Following training in the conduct of a procedure or method of euthanasia, the trainee should be supervised in the conduct of that procedure or when performing that method of euthanasia. 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 as being sufficiently trained to carry out the procedure or perform that method of euthanasia competently on their own. After the individuals have been assessed as competent they can then carry out procedures or perform that method of euthanasia without supervision. Competence should be subject to periodic review in accordance with the training system in place in the breeder/supplier/user establishment.

Training is considered to be a continuous process and a process of continuing professional development should be put in place for all relevant personnel.

The training officer is responsible to the HPRA for the training system in place and for ensuring compliance of the relevant personnel with the requirements. The training officer has overall responsibility for ensuring that the training records of personnel are kept updated.

Where the training officer delivers training in the conduct of a procedure, the procedure(s) involved must have been authorised by the HPRA under a project authorisation, where the training officer has been named on that project authorisation.

In accordance with the national legislation, no person may carry out procedures on animals or perform a method of euthanasia otherwise than in accordance with an individual authorisation granted by the HPRA. Experts from overseas recruited by the training officer to train personnel in a new procedure or a method of euthanasia will also require individual authorisations. In such applications, the HPRA may recognise the qualifications and status of personnel licensed overseas in making its decision to grant authorisation.

Note that projects licensed by the Department of Health before 31 December 2012 continue to have legal validity until the expiry of the licences concerned; the HPRA recognises persons named under these licences as being authorised, but these persons are subject to the training and competency requirements of the new legislation.

During inspection, the training officer may be requested by the HPRA to explain the types of training available for personnel who are responsible for caring for animals, carrying out

procedures, designing projects or euthanising animals and to verify the contents and accuracy of the relevant section of the site master file for the breeder/supplier/user establishment concerned.

5 THE COMMISSION FRAMEWORK DOCUMENT

The consensus view within the European network of competent authorities is that basic theoretical training will be required for all personnel carrying out any of the functions (a) to (d) of Article 23 of the Directive. The Commission document is not legally binding on individual member states, but has been developed to facilitate a common framework and free movement of personnel between countries. Refer to the Commission document which outlines the principles on education and training and the proposed modular course structure.

The HPRA is currently considering how this framework can be implemented by training course providers in Ireland.

6 HPRA REQUIREMENTS

In order for an individual to perform project management, procedures or euthanasia, they must first obtain an individual authorisation from the HPRA. Details of the application procedure for an individual authorisation are available on the HPRA website.

Authorisation to carry out procedures on animals or perform euthanasia will only be granted if the applicant has completed a relevant HPRA approved scientific animal training course. Applicants who completed a training course in Ireland prior to September 2012 or applicants who completed a course abroad may be required to complete an additional module on the topic of 'national legislation'. This will be assessed and communicated on a case-by-case basis.

Procedures, including procedures conducted solely for the purposes of training, can take place only within the context of a project authorisation and in an authorised breeder/supplier/user establishment. Surplus animals that are intended for euthanasia are not to be used for training in procedures, except in accordance with a project authorisation (and associated individual authorisations for the trainer and the trainees) granted by the HPRA. However, the use of animal cadavers for training or educational purposes does not require a project authorisation. For further details refer to the 'Guide to Use of Animals for Educational Purposes under Scientific Animal Protection Legislation'.

Once granted an individual authorisation by the HPRA, 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 euthanasia, may carry out the tasks listed in their approved individual authorisation if that member of staff is appropriately supervised in the performance

of his or her tasks. Individuals must be strictly supervised at all times during the course of this training.

Training and supervision of personnel may be delegated by the training officer to an expert or the designated veterinarian as appropriate. This expert, or another person suitably qualified to assess competence, may sign off on the individual's training record. The training officer manages the overall system and is responsible to the HPRA for ensuring compliance of the relevant personnel with the requirements.

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 and/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. The use of cadavers is strongly encouraged where appropriate for certain aspects of training in methods of euthanasia. Cadavers can be used to demonstrate the required techniques and anatomical considerations.

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.

6.1 General training requirements

As per the Commission guidelines, there are specific training requirements for all personnel who are:

a) Carrying out procedures on animals,
b) Designing procedures and projects,
c) Taking care of animals,
d) Euthanising animals.

Particular additional requirements are listed separately below for the specific categories of personnel. In addition, there are specific training requirements in Articles 24 and 25 and Regulations 45, 46 and 48 for the following named persons: the training officer, animal care and welfare officer and designated veterinarian. Further details on the requirements for these persons are found in the Commission document.

6.2 Requirements for training in euthanasia

In accordance with Article 23(2)(d) and Regulation 43(2)(d), persons performing euthanasia must be supervised in the performance of this task until requisite competence has been demonstrated. Training should include theoretical aspects as well as practical skills. The HPRA requires that records of the individual having achieved competence in performing euthanasia

must be retained at the breeder/supplier/user establishment. This should be done by way of sign-off of the requisite training records by the breeder/supplier/user establishment's training officer or training expert. Attainment of competency in euthanasia will follow the model of training competency for procedures i.e. the trainee observes euthanasia being carried out initially, then carries out euthanasia under close supervision until competency is acquired, with the method of euthanasia only being conducted unsupervised when full competency has been attained. The training and competency assessment processes in place in the breeder/supplier/user establishment are one of the focal points of inspections carried out by the HPRA.

Personnel who wish to be trained in euthanasia will need to possess a HPRA individual authorisation for this purpose before beginning training on live animals. Personnel will therefore need to apply to the HPRA for an individual authorisation in advance of conducting training in euthanasia on live animals.

An individual authorisation for the exclusive purposes of euthanasia does not have to be linked to a specific project authorisation, but must be linked to an authorised breeder/supplier/user establishment.

Euthanasia must be performed using the methods set out in Annex IV of 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 in the Directive, scientific justification must be provided in accordance with Regulation 8(4) and Article 6(4) at the time of applying for individual authorisation.

6.3 Requirements for training in carrying out procedures

In accordance with Article 23(2)(a) and Regulation 43(2)(a), persons carrying out scientific procedures and projects 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.

Individuals applying for authorisation should apply for the appropriate categories of procedures as listed in the individual application form. The HPRA will seek evidence that the person concerned has received appropriate education e.g. successful completion of a HPRA approved scientific animal training course. Individuals should not perform any procedures unless they have a HPRA individual authorisation to do so and an appropriate HPRA project authorisation is in place (with the individual named on that authorisation), or they are named on an active Department of Health licence. The training and/or assessment of competency in the conduct of the procedures is the responsibility of the breeder/supplier/user establishment.

The training and competency assessment processes in place in the breeder/supplier/user establishment are one of the focal points of inspections carried out by the HPRA.

6.4 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 still required to complete the training and education as outlined in the Commission guidelines. However, they do not need to complete the requisite training and education prior to commencement of their work. They must undertake the necessary study within a six-month period and must work under supervision until they have completed the training.

An individual authorisation from the HPRA is not necessary for persons engaged solely in the provision of everyday husbandry and nutrition to animals.

6.5 Requirements for training for those designing procedures and projects

In accordance with the legislation, persons designing procedures and projects must have completed a degree or higher qualification in a scientific discipline relevant to the work being undertaken and have species-specific knowledge. They will also be expected to complete a training and education course as per the Commission guidelines.

An individual authorisation from the HPRA is not necessary for personnel engaged solely in designing procedures and projects. 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 records.

6.6 Requirements for training for project managers

In accordance with Article 40(2)(b) of the Directive and Regulation 47 of the S.I., the HPRA expects the person responsible for overall implementation of the project and its compliance with the project authorisation to have undertaken the same training as required for those designing projects and procedures, with the exception of training on experimental design. It is not a mandatory requirement that such persons have completed a degree or higher qualification in a scientific discipline, but they must have the necessary experience for the role. They will also require an individual authorisation in accordance with Regulation 51(2) of the S.I.

6.7 Requirements for continuous training and maintenance of competence

Continuing education 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 in the field of research animal science such as CPD events.

The contents of training courses for persons carrying out procedures, designing and managing projects, caring for animals and carrying out euthanasia are constantly being updated. Therefore personnel who have already received their basic training in these areas still need to receive regular relevant updates in order to build on and develop their existing proficiency. Currently a formal CPD scheme specific to those involved with scientific animals has not been established in Ireland. At present, CPD is required by the Veterinary Council of Ireland only for designated veterinarians who must complete 20 CPD hours annually. Until such time as relevant accredited scientific animal training CPD scheme is in place in Ireland, the HPRA will apply the following two requirements:

6.7.1 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 would expect 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 in order 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 or amended 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.

6.7.2 Attendance at conferences/symposia/workshops

The HPRA would expect that all persons involved in project management and/or the performance procedures or euthanasia, would regularly attend meetings, conferences or seminars appropriate to their line of work, 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. This requirement 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 8 hours per year as an average over a five year time period. Records of attendance of such training events should be maintained and these records are subject to inspection.

From January 2015, the HPRA has implemented the requirement that all personnel undergo a combination of continuous practical and theoretical training, appropriate to their needs. The HPRA will regularly review its position on continuing education and consideration will be given to providing further advice on the content of a mandatory formalised CPD scheme. The framework for the successful application of continuous training programmes is sufficiently wide to allow it to be customised to the needs of the individual, while retaining flexibility. The HPRA hopes that everyone involved will play their part in ensuring it is successfully applied and will work with service providers and stakeholders to achieve this goal.