

Guide to Use of Animals for Educational Purposes under Scientific Animal Protection Legislation



1 SCOPE

Directive 2010/63/EU (the Directive) and S.I. No. 543 of 2012, as amended by S.I. No. 434 of 2013 and S.I. No. 174 of 2014 (hereafter referred to as the Regulations) establish measures for the protection of animals used for scientific or educational purposes.

This guideline is intended to provide advice on the use of animals for education and vocational training, where such use requires HPRA authorisation in accordance with the Directive and the Regulations. Education refers to higher education (e.g. medical students training on animals), and training refers to vocational training (e.g. animal technicians learning new techniques).

The scientific animal protection legislation does not apply to:

- 1 non-experimental agricultural practices;
- 2 non-experimental clinical veterinary practices;
- 3 veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product;
- 4 practices undertaken for the purposes of recognised animal husbandry;
- 5 practices undertaken for the primary purpose of identification of an animal and
- 6 practices not likely to cause 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.

2 INTRODUCTION

Article 5 of the Directive and Regulation 7 of the Regulations state that procedures may be carried out 'for the following purposes only:

- a) basic research;
- b) translational or applied research with any of the following aims:
 - the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants;
 - the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants or
 - the welfare of animals and the improvement of the production conditions for animals reared for agricultural purposes;
- c) for any of the aims in point (b) in the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products;
- d) protection of the natural environment in the interests of the health or welfare of human beings or animals;
- e) research aimed at preservation of the species;
- f) higher education, or training for the acquisition, maintenance or improvement of vocational skills;

g) forensic inquiries.

The wording above indicates that the conduct of procedures on animals for education *other* than higher education or training for the acquisition, maintenance or improvement of vocational skills, is prohibited.

The HPRA expects that a considered and structured approach be taken towards the use of animals in both education and training. The use of alternative strategies should be fully explored and specific objectives and defined benefits be presented in any request for the use of live animals.

3 DEFINITIONS

'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 killing 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.

4 THE USE OF ANIMALS FOR EDUCATIONAL PURPOSES

Projects are limited to training individuals such as medical, life sciences, agricultural or veterinary students who will eventually be carrying out scientific work using living animals and those who need an understanding of *in vivo* biological phenomena and/or who need to gain competence in a particular procedure for medical or surgical purposes.

When considering the use of animals for veterinary or medical education, the HPRA will apply the principles of the 3Rs – replacement, reduction and refinement – and the harm-benefit analysis in assessing applications for such work. The severity of any procedures in such projects should be either non-recovery or mild. The project manager will be required to review the project's objectives at least once a year to consider the latest alternatives for replacing, reducing and refining the use of animals.

4.1 Use of animals in education of agricultural, veterinary, life sciences or medical students

The use of animals in education of third or fourth level students may be divided into the following categories:

4.1.1 Use of live animals for animal handling training

Use of animals for training in proper animal handling does not fall under the scope of the legislation where such use does not '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'. If animals are used for purposes which may cause a level of pain, suffering, distress or lasting harm, breeder/supplier/user, project and individual authorisation(s) will be required.

4.1.2 Use of live animals for clinical skills and surgical training

Undergraduate veterinary students may learn skills such as blood sampling, intravenous cannulation and surgical procedures and techniques, under the supervision of a veterinary practitioner through the use of animals that have been presented to a veterinary practice for diagnosis and/or treatment. In these circumstances, these procedures do not fall under the scope of this guidance provided that the exemptions detailed as section 2 points 1-6 above apply.

The HPRA notes that in accordance with Regulation 55(6)(b) of the Veterinary Practice Act 2005, special provision is made for students of veterinary medicine who carry out certain treatments or procedures to an animal. This guide does not purport to represent any guidance on the use of animals under the Veterinary Practice Act. Queries on the use of live animals for clinical skills and surgical training should be directed to the Veterinary Council of Ireland website.

The use of animals (including surplus animals intended for euthanasia) for the purpose of training in a surgical or other procedure not conducted for the benefit of the animal and/or does not constitute standard clinical veterinary practice requires a project authorisation (along with corresponding breeder/supplier/user and individual authorisations) from the HPRA. Further information is provided in the 'Guide to project applications under Scientific Animal Protection Legislation' which is available on the 'Publications and Forms' section of www.hpra.ie.

4.1.3 Use of cadavers for dissection labs

Animal cadavers are frequently used to train undergraduates in anatomy and physiology. As per Regulation 51(3) and (4) of the Regulations, if these animals have not been euthanised by a registered veterinarian, then the legislation requires that the person(s) carrying out

euthanasia holds a valid individual authorisation, and as per Regulation 8(1), the euthanasia takes place in an authorised breeder/supplier/user.

However, in accordance with the legislation, a procedure 'excludes the killing of animals solely for the use of their organs or tissues'. This means that a project authorisation is not required for the euthanasia of animals in order to use the cadavers for training or educational purposes.

4.1.4 Use of live animals for terminal surgery labs

This practice involves using otherwise healthy animals for teaching surgical procedures under anaesthesia, and euthanising them at the end of the procedure. This practice is generally used in medical education, for the training of surgeons in specialised techniques, where practicing on a human patient would be inappropriate or unethical, for example, the training of surgeons in micro-vascular techniques. This type of non-recovery surgery will always require a breeder/supplier/user authorisation, project authorisation and individual authorisations for trainers and trainees.

4.2 Conduct of surgery in animals

Where an animal is to undergo a surgical procedure for educational purposes, except in exceptional circumstances that have been justified in the project authorisation, the HPRA expects that patient preparation, anaesthesia and surgical techniques should be appropriate to the species undergoing surgery. The planned procedure should be conducted in accordance with international best practice, even when the procedure is a non-recovery procedure. In laboratory animals, the principles of aseptic surgery should be maintained as per *LASA 2010 Guiding Principles for Preparing for and Undertaking Aseptic Surgery: A report by the LASA Education, Training and Ethics section (M. Jennings and M. Berdoy eds.)*.

5 THE USE OF ANIMALS FOR TRAINING PURPOSES IN THE CONDUCT OF PROCEDURES FOR A PROJECT

The use of live animals in procedures for the purposes of training for vocational skills should be restricted to those individuals who are at a stage in their career development where animal use is considered necessary, e.g. those who will use animals in scientific projects e.g. animal technicians and researchers.

For the development of manual procedural skills, the HPRA expects that a tiered approach to training is taken where the trainee must demonstrate competence at each stage, first using non-animal alternatives (theory, observation, simulators, videos etc), then using cadavers, then the use of live animals under general anaesthetic (non-recovery) and finally the use of conscious animals.

Training in animal handling skills does not require a project authorisation, but any procedures that are carried out as part of vocational training on live animals will require a breeder/supplier/user authorisation, project authorisation and individual authorisations for trainers and trainees. The animals involved might be included within the terms of the related project authorisation (i.e. as extra animals within the overall project but mentioned specifically for this purpose in the project application) or as a stand-alone project authorisation. In both cases, the numbers of animals will need to be justified and a harm-benefit analysis undertaken by the HPRA.

6 MAKING AN APPLICATION

Guidelines and application forms for project, breeder/supplier/user, and individual authorisations can be found on the 'Publications and Forms' section of www.hpra.ie. Any additional queries can be e-mailed to sap@hpra.ie.