Large animal use in science and education

Jane Lenehan, veterinary officer, Health Products Regulatory Authority, discusses the regulation of the use of large animals for scientific, research and educational purposes

In Ireland, in 2015, over 14,000 large animals (horses, pigs, goats, sheep and cattle) were reported as being used in 'regulated procedures' for scientific or educational purposes. Veterinary practitioners in Ireland may be involved in research projects, such as research into farm animal production systems and welfare. Some veterinary practitioners may also be involved in providing skills training to undergraduate veterinary students. Certain types of research or educational projects require authorisation by the Health Products Regulatory Authority (HPRA). The purpose of this article is to describe the regulation of this area in Ireland, so that veterinary practitioners are aware of any legal obligations, as well as to introduce the key concepts of the replacement, reduction, refinement (the 3Rs) and a 'culture of care'.

LEGISLATION

On January 1, 2013, an EU Directive (2010/63/EU), to protect animals used for scientific purposes, came into effect and was transposed into Irish law by SI No 543 of 2012 (as amended). The HPRA has been the competent authority responsible for the Directive's implementation since January 2013; this area was previously regulated by the Department of Health with the support of the Department of Agriculture. The Directive is among the world's most advanced pieces of legislation concerning animal welfare. The restrictions and standards set by the Directive aim to enhance animal welfare and ensure that animals are used in studies only when their use is strongly justified and following independent assessment by the HPRA. The HPRA regulates this sector by means of authorisation at three levels:

- Breeder/supplier/user-establishment authorisations;
- Project authorisations; and
- Individual authorisations.

All authorised breeder/supplier/user establishments (ie. research facilities) are subject to HPRA inspections, including unannounced inspections.

AUTHORISATION REQUIREMENTS

Studies that require HPRA authorisation are those that involve the performance of a 'procedure' which is defined in the legislation as: "Any use of an animal for scientific 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."

It is important to note that the above definition does not apply to non-experimental agricultural/husbandry practices (eg. dehorning, castration, tagging) and non-experimental clinical veterinary practices (eg. blood sampling for disease

diagnosis). However, scientific research studies performed by a veterinary practitioner which are not for the direct benefit of the animal may be subject to HPRA authorisation (eg. blood sampling of an animal if this is the subject of a nutritional study). Studies that also fall outside the scope of the legislation include studies involving unauthorised feed additives which do not cause any animal suffering (these may need to be registered with the Department of Agriculture, Food and the Marine [DAFM]), and veterinary clinical field trials (note: there is a separate HPRA authorisation process for these). The HPRA has produced an explanatory guideline (available from the HPRA website – www.hpra.ie/homepage/veterinary/scientific-animal-protection) to help determine whether a particular practice is within or outside the scope of the legislation.

USE OF ANIMALS IN EDUCATION

Veterinary practitioners should note that the use of animals for higher education, or training for the acquisition, maintenance or improvement of vocational skills, may fall within the scope of the legislation. One example of this would be a 'hands-on' tuberculosis (TB) testing training programme. The training of veterinary students may occasionally fall within the scope, but this does not include:

- Use of animals for training in handling skills where the animal does not experience pain, suffering or distress equivalent to or greater than the insertion of a needle; or
- Use of animals by veterinary students for skills such as blood sampling, provided this is under supervision of a veterinary practitioner and is only on animals that have been presented to that veterinary practitioner for diagnosis and/or treatment.

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

THE 3RS

The EU Directive firmly anchors in the legislation the 3Rs, which refer to the principles of replacement, reduction and refinement in the conduct of studies on animals. The 3Rs aim to improve the welfare of animals used in science or education, while advancing the quality of scientific research:

- Replacement means that 'alternative' methods are to be used where possible instead of live animals, eg. simulators, artificial rumens, video presentations;
- Reduction means that it must be ensured that the appropriate number of animals is used for each project, so that statistically robust data are obtained without using more animals than are necessary. The HPRA expects that all experiments are designed in consultation with a person with statistical expertise; and
- Refinement means that animals used are provided with the best possible care and that suffering is reduced to an absolute minimum, eg. careful handling, keeping sampling time-points to the minimum necessary, ensuring high standards of housing and husbandry, and the provision of anaesthesia and analgesia.

CULTURE OF CARE

Culture of care, which is demonstrating a caring and respectful attitude towards animals, is an important concept that should be applied across all research facilities, but is also a concept that is of relevance to commercial farms in order to raise welfare standards. Key factors in fostering a good culture of care include: shared responsibility for ensuring optimal welfare; management support for maintaining standards; the fostering of an understanding and caring attitude among personnel; the improvement of welfare standards proactively (rather than reactively); awareness of good practices and compliance with legislation, empowerment at all levels; and good communication.
In addition, the legislation requires that each authorised establishment set up the Animal Welfare Body (AWB), the role of which is to provide internal oversight and guidance on day-to-day application of the 3Rs, as well as the monitoring of ongoing projects and the outcome of studies. The AWB, which is comprised of both animal welfare personnel and scientific researchers, and which must receive advisory input from the establishment's designated veterinary practitioner, is also key to fostering a good culture of care within an authorised establishment.

CONCLUSION

The HPRA is the competent authority for the implementation of the EU legislation for the protection of animals used in science and education, and is committed to ensuring that the care and use of animals in studies is in line with the 3R principles. Veterinary practitioners involved in research or in providing education or training should be familiar with the HPRA's authorisation requirements. Veterinary practitioners that work with research facilities are encouraged to play their part in championing a good culture of care and promoting the 3Rs.