Regulation of animal use in research, testing and teaching in New Zealand

- the black, the white and the grey

The law requires those who manipulate live vertebrate animals for the purposes of research, experimentation, testing, teaching or the production of biological agents to do so in accordance with an approved code of ethical conduct. Deciding which activities are encompassed by this requirement and which are not is not always straightforward.

Since 1983 there has been statutory provision for regulations to control the use of live animals in research, experimental, diagnostic, toxicity or potency testing work and teaching. This was the result of an amendment to the Animals Protection Act 1960 following submissions made by the Royal Society of New Zealand to the Minister of Science. [1] The amendment removed the exemption from the provisions of the Act previously enjoyed by 'bone fide research workers'. The regulations, the Animals Protection (Codes of Ethical Conduct) Regulations 1987, came into force in early 1987 and took effect from 1 September that year. The scope of the regulations was later extended to include work for the purposes of producing antisera or other biological agents (from 1 July 1988).

As also required by the 1983 amendment, the National Animal Ethics Advisory Committee (NAEAC) was created by the Minister of Agriculture (the Minister responsible for administration of the Act). Its function is to advise the Minister on matters related to the use of animals in research, testing and teaching and in particular, the content of codes of ethical conduct.

The Animals Protection (Codes of Ethical Conduct) Regulations require that any organisation or individual which/who manipulates live animals for any of the purposes cited above do so in accordance with a code of ethical conduct which has been approved by the Minister of Agriculture. In this context the terms 'animal' and 'manipulation' assume significance. These terms are legally defined. (See the appendix.)

The regulations also prescribe matters which must be incorporated into codes of ethical conduct. These requirements have been expanded upon by NAEAC, first into guidelines [2] and later into a model code of ethical conduct, [3] for the guidance of organisations affected by the regulations.

Issues

The identification of those affected by regulations, ie manipulators, is an ongoing task as there are always "new players" who may be unaware of their legal obligations. Having identified the potential manipulator, it must be decided whether their activities fall within the purview of the regulations. In the majority of instances, the answer is readily apparent but there are some activities which are less clear-cut.

In trying to determine whether some of the latter constitute a manipulation for the purposes of the regulations, it is useful to use a three step test:

1 Is the activity being performed on a live animal (as defined in the law)?
2 Does the activity constitute a manipulation (as defined in the law)?
3 Does the reason that the activity is being performed fall into the category of research, experimentation, diagnostic, toxicity or potency testing, work for the purposes of producing biological agents or teaching?

If the answers to all three questions are 'yes' then the activity must be performed in accordance with an approved code. If the answer to any of the questions is 'no' then a code is not necessary.

The black and the white

Some examples of activities which clearly require a code of ethical conduct are:

- basic biological, biomedical, veterinary and agricultural research using live animals;
- non-recovery surgery carried out by veterinary students as part of their training;
- testing animal vaccines on laboratory rodents;
- regular blood harvesting from animals to produce antiserum;
- the manipulation of animals for teaching purposes.

Although it may not be the first legal issue which springs to mind when considering rabbit calicivirus disease (RCD), the spreading of the RCD virus by injecting caged rabbits with the virus mixture for the production of additional virus material and releasing them into the wild is also an activity which falls within the regulations. The decision-making process for this example is as follows:

- caged rabbits fall within subsection (d) of the definition of animal (ie they are in a state of captivity);
- injecting them with a viral mixture is exposing them to a micro-organism, and is therefore a manipulation;
- the purpose of the activity is the production of biological agents.

Note, however, that harvesting dead rabbits for the same purpose does not require a code.

There are other activities which definitely do not require a code of ethical conduct. For example, keeping animals in kindergartens/classrooms as pets or for purely observational purposes does not involve a manipulation and thus does not require a code.

Contrary to an apparently common belief, dissections on carcass material do not require ethical approval either. The regulations are specifically restricted to live animals. The Animals Protection Act provides an exemption for the humane killing of animals. Killing an animal humanely is therefore not covered by the regulations, regardless of what is done to the body subsequently.

For the same reason, farming practices which involve surgical procedures (such as tailing or castration) when done in the context of routine farm management are not manipulations, because they are not being performed for the purposes of research, testing and teaching. However, it is worth noting that the same procedures do require ethical approval in some circumstances. One example would be where the procedures were being carried out as part of a research programme to compare different methods of castration.

The grey

There are a number of activities which fall within a "grey" area ie where the answer to one or more of the questions in the three step test is not immediately clear or is a matter of judgement.

One such grey area is the use of foetuses. The law does not define the point at which an animal becomes an animal (eg only once it has been born, or at conception, or at some point in between). This is a matter which could only be determined by the courts. However, foetuses are used in research, testing and the production of biological agents. Two questions arise - whether the procedures need to be covered by a code of ethical conduct and whether their use needs to be reported by animal ethics committees (AECs) as part of their obligatory statistical return to the Ministry of Agriculture.

In terms of statistics, a further complication arises if more foetuses are present than are required for the intended purpose. Some schools of thought would suggest that any extra foetuses sacrificed in this process should be included in the animal use statistics.

In a similar vein, NAEAC has considered the 'harvesting' of foetuses at slaughter premises for the purposes of producing biological agents. In this instance, the foetuses were not merely an occasional by-product of the routine culling of ewes, but rather the ewes were to be slaughtered primarily so that foetal tissue could be harvested.

These issues raise some technical points of law which are currently under discussion.

Bird banding is another issue which NAEAC has been considering in recent times. Bird banding (a term which encompasses ringing, tagging and other marking) is an activity which has been performed in New Zealand as part of official schemes administered by various agencies (currently the Department of Conservation) for about 50 years. It was considered that the activity was exempt from the provisions of the Animals Protection Act by section 19(1) (a) and (c), which provide that nothing in the Act "shall render unlawful ... the earmarking or branding of any animal..." or the "... capturing of any animal in a wild state".

It has recently been suggested, however, that bird banding is carried out for the purposes of "research" in a broad sense and that it constitutes, broadly speaking, a manipulation. On the other hand, it is argued that the National Banding Scheme already regulates the practice of bird banding through a permit system which controls personnel, species, method of capture and method of identification. To impose a further approval system from an AEC is regarded as an unnecessary burden.

NAEAC has not yet made any definitive decisions on whether bird banding is, or should be, classed as a manipulation. As some bird banding techniques could be categorised as invasive (eg when tags are applied through the skin or the suturing of transmitter base plates to birds), NAEAC is seeking further information on these techniques.

Another grey area relates to what might be termed "incidental" manipulations. Wild animals (eg possums) may be required for research projects so they are captured. In order to ensure that there are sufficient animals to meet any age or sex ratio requirements more animals are captured than are needed for the project. Some surplus animals are euthanased, others may die before being assigned to a specific research project. The question is, should

these animals be regarded as having been manipulated? NAEAC concluded that capturing wild animals is exempted by the Act, as is killing them. Thus possums which are not actually used in a research project are not manipulated and numbers should not be included in statistical returns.

Further debate arises regarding training courses. There are a number of courses at the senior secondary school, pre-employment or polytechnic level which teach animal handling/husbandry skills. The animals involved are generally livestock but companion animals would be involved in veterinary nursing courses for example. Two of the criteria are clearly met - the animals fall within the definition and the activity is for teaching purposes. The question to resolve is, is it a manipulation? Docking tails certainly interferes with the anatomical integrity of an animal. One may decide that teaching people to dock dairy cattle tails during a training course is a manipulation. The ramifications of this are possible perceptions of 'bureaucracy gone mad', not to mention an argument for saying that every farmer who teaches a new farmhand some animal handling skills needs a code of ethical conduct.

On the other hand, bringing the family pet into a veterinary nursing course so that students can practise injection techniques may be an activity that more readily suggests the need for ethical approval.

The rule of thumb developed to cover these types of situations is that if the procedure that is performed in a teaching situation would be performed anyway (eg the trainees are learning how to drench sheep that were due to be drenched) then coverage by a code is not necessary. However, if the procedure is one which would not have been carried out at the time, or if the procedure is repeated a number of times, then a code of ethical conduct is advisable.

Similarly, farmers and veterinarians conduct on-farm trials to improve stock health, growth rates, fertility and productivity. Some trials may involve sporidesmin challenge testing, selection for parasite resistance, artificial breeding, libido testing and so on. [4] Such procedures may, strictly speaking, require a code of ethical conduct even though this appears not to have been intended in the original regulations. However, a very recent amendment to the Animals Protection (Codes of Ethical Conduct) Regulations exempts animal evaluations carried out by a veterinary surgeon on any animals in his or her immediate care - with certain provisos.

Conclusion

The Animals Protection (Codes of Ethical Conduct) Regulations have been operating now for ten years and more than 80 organisations/individuals have a code of ethical conduct which has been approved by the Minister of Agriculture. Such codes ensure that the welfare and humane treatment of live animals used for research, testing, teaching and the production of biological agents is fully considered by an AEC (which includes at least three members from outside the organisation) prior to any manipulations being performed.

If anyone is unclear whether particular activities should be covered by a code of ethical conduct, they are advised to contact MAF's Animal Welfare and Environment Section (which services NAEAC).

Appendix
The Animals Protection (Codes of Ethical Conduct) Regulations definitions

'Animal'
"(a) Any horse, cattle, sheep, pig, goat, dog, cat, mule or ass, of whatever age or sex and whether in a domestic or wild state:
(b) Any bird, whether in a domestic or wild state:
(c) Any marine mammal found on, or in the vicinity of, the seashore:
(d) Any vertebrate animal that is kept in a state of captivity or is dependent on man for its care and sustenance:
(e) Any animal of a species that is declared by the Minister, by notice in the *Gazette*, to be a species of animal for the purposes of the Act."

'Manipulation'
"Manipulation, in relation to any live animal, means interfering with the normal physiological, behavioural, or anatomical integrity of the animal by deliberately -
(a) Exposing it to any parasite, micro-organism, drug, chemical, biological product, radiation, electrical stimulation, or environmental condition:
(b) Subjecting it to enforced activity, unusual restraint, abnormal nutrition, or surgical intervention:
(c) Depriving it of usual care; -
but does not include any therapy or prophylaxis necessary or desirable for the welfare of the animal."

Acknowledgements
The author wishes to thank Professor David Mellor, Mr Keith Robinson and Mr David Bayvel for their valuable comments on the draft manuscript.

References
(1) Reid CSW. Ethics, animals, science and the Royal Society. In: Royal Society of New Zealand. The Use and Welfare of Experimental Animals. Pp 79-82. The Royal Society of New Zealand, Wellington 1990.
(2) National Animal Ethics Advisory Committee. Guidelines for Institutional Animal Ethics Committees, September 1988.
(3) Animal Welfare Advisory Committee. Code of Recommendations and Minimum Standards for the Care and Use of Animals for Scientific Purposes. Wellington, August 1995.
(4) Mackintosh CG et al. Professional and animal ethics issues for veterinarians conducting on-farm clinical trials. Deer Branch, New Zealand Veterinary Association, Course No.11, 132-137.

Linda A Carsons
MAF Regulatory Authority, Wellington

Published in Surveillance Volume 25, No1, March 1998