The Animals (Scientific Procedures) Act 1986 under the microscope

An exemplary regulatory scheme

On paper the Animals (Scientific Procedures) Act 1986, which governs the controversial area of animal experimentation, looks impressive. It appears to permit only those experiments on animals that are absolutely necessary. In 2002 the House of Lords Select Committee on Animals in Scientific Procedures described the Act as "*the tightest system of regulation in the world*". This article puts the Act under the microscope to examine whether it is as stringent in its protection of animals as its wording suggests or whether its words offer a hollow promise of protection to laboratory animals.

A licensing system

The statutory regime consists of a licensing system whereby anyone carrying out an experimental procedure on a protected animal i.e. a non-human vertebrate, which may have the effect of causing that animal pain, suffering, distress or lasting harm must first obtain certain licences from the Home Secretary. A project licence must be obtained which authorises the research and personal licences are required for each individual involved in the animal experiments. In addition, the place in which the experiment is conducted must be certified as a designated establishment.

The cost-benefit assessment

Section 5 of the Act incorporates a utilitarian cost-benefit assessment so that a project licence cannot be granted unless the benefit to be derived from the experiment outweighs the costs, in terms of animal suffering. In assessing benefit, s.5(3) sets out a list of permissible purposes, for example, the "advancement of knowledge in biological or behavioural sciences"; but these are sufficiently wide to encompass a whole array of purposes. The benefit to be derived from the experiment still needs to be quantified in some way. It is not enough that the experiment satisfies one of the permissible purposes. How does one quantify potential benefit that may or may not be discovered in the course of scientific research? Clearly this is a very difficult test to apply in practice and one wonders how exactly the Home Secretary assesses benefit for the purposes of the utilitarian calculation.

Assessing the benefits

In the context of medical research Drs Greek have compiled a large list of examples of experiments which, they submit, demonstrate that the use of the animal model is detrimental to humans. Their book *'Sacred Cows and Golden Geese: The Human Cost of Experiments on Animals'* provides example after example of instances in which animal experimentation has hindered medical progress. Not only can the animal model fail to predict the toxic effects of drugs (for example, Zimeldine caused a paralyzing illness in humans); but reliance on the animal model can also lead to potentially useful drugs been needlessly abandoned. Penicillin provides a powerful illustration of this. Fleming tested penicillin on rabbits but it did not work so he gave up his work with it. Later, in desperation, he administered penicillin to a sick person who subsequently recovered. Fleming later admitted "How fortunate we didn't have these animal tests in the 1940s, for penicillin would probably never have been granted a license, and possibly the whole field of antibiotics might never have been realised" (ATLA 1994;22:207-209). It is unlikely that the Home Secretary looks at the wider picture of the efficacy of the animal model when assessing benefit, but rather concentrates on the specified predicted benefits of a particular project as stated by the applicants. Nevertheless, the utilitarian nature of this legislation begs the wider question of the extent to which the animal model in medical research benefits (or harms?) humans and it is appropriate for those implementing the legislation, and their lawyers, to grapple with these difficult debates.

Assessing the costs

Leaving aside the difficulty of assessing the benefit of the experiment, the 'cost' part of the equation proves to be equally problematic. The Home Secretary must weigh up the adverse effects of the experiment in terms of potential animal suffering. To this end the licence applicant relies on a system for categorising severity of animal suffering. This classification system is not mentioned at all in the Act, but instead is detailed in the Guidance Notes. Severity is classified as Mild, Moderate, Substantial or Unclassified. The project as a whole is given a severity *band* and this reflects the likely suffering of the *average* animal used in the project. Thus it is based on the overall cumulative suffering of all the animals concerned. Each separate protocol (procedure) within the project is given a severity *limit* which indicates the maximum level of suffering that an individual animal *may* suffer. This represents the worse case scenario for a single animal. The nature of the severity band of a project i.e. the cumulative suffering of all, means that it can hide the fact that a number of substantial procedures will be carried out on animals for the purposes of that project. The Guidance Notes recognise this difficulty noting that, "a project containing ten mild protocols, each involving 10,000 animals, and one substantial protocol involving fifty animals, could well be classified as mild". On this basis, an experiment could include acute toxicity tests on fifty monkeys resulting in prolonged pain but nevertheless the project may only be classified as 'mild'.

In 2004 a report by the Boyd Group and the RSPCA '*Categorising the severity of scientific procedures on animals*' recognised the need for a severity categorisation system but felt that there was significant difficulties with the current system. The report highlights the difficulties faced by applicants for licences due to the inadequate guidance provided by the Home Office on how to decide which category to apply. It recommends that more examples and case studies are needed to illustrate the different categories. It also suggests that the use of the word 'moderate' is too comfortable a term for many of the adverse effects that it encapsulates with the consequent risk of down playing the animal suffering involved.

Categorising severity in practice

This area of the law recently came under judicial scrutiny in the case of *R (on the application of the British Union for the Abolition of Vivisection) v Secretary of State for the Home Department* [2007] EWHC 1964 (Admin). The case arose out of an undercover investigation by Buav concerning experiments on marmoset monkeys at Cambridge University. The purpose of the experiments was to research into the functioning of the human brain and illnesses affecting it such as Parkinson's disease. The experiments involved inducing strokes or brain damage in the marmosets, for example, by cutting or sucking out parts of the brain or by injecting toxins. In the applications for the project licences, these adverse effects on the marmosets were categorised as moderate. Buav argued that these had been miscategorised and that they should have been classified as substantial. The Guidance Notes to the Act state that procedures are substantial if "they result in a major departure from the animal's usual state of health or well-being" and relates specifically to "major surgery where significant post-operative suffering may result". One consequence of a substantial classification is that the procedure will then be referred to the Animal Procedures Committee, whereas a moderate one is not. Mitting J emphasised the importance of correctly identifying the severity band of a project so that Parliament and the general public are accurately informed about the number of projects banded as substantial.

Mitting J examined a number of 'moderate' procedures in detail to decide whether they had been wrongly classified. He observed that, "two involved general anaesthesia and a craniotomy, cutting through the skull and turning it on a hinge of bone to expose the meninges beneath, and resecting the meninges to expose the brain. In one protocol part of the brain was removed by suction ablation. In another a cerebral artery was to be tied to produce a stroke intended to affect one limb." He noted that the effects of these surgical procedures, following the marmosets' recovery from anaesthesia, were such that any persistent changes in movement or mood, or persistent epilepsy, had to be dealt with by humane killing. Mitting J accepted that where, following surgery, an animal suffers a persistent alteration of mood or movement, severe enough to require the animal to be killed, then this is capable of amounting

to a major departure from health and well-being and would warrant a substantial rating. In this respect Mitting J held that the Chief Inspector had erred in law. Mitting J observed that, "where the adverse effects of a procedure can only be controlled by killing the animal, that is a clear indication that a higher severity limit is justified than when the adverse effects can be controlled by analgesics".

The availability of non-animal alternatives

Section 5(5) requires that the Home Secretary be satisfied that the purpose of the programme "cannot be achieved satisfactorily by any other reasonably practicable method not entailing the use of protected animals". Therefore the availability of non-animal alternatives is an integral part of the protection afforded to animals under the Act. The Home Secretary must always be satisfied that the use of animal experiments is absolutely necessary in each individual case and that there is no other 'reasonably practicable' alternative. It is perplexing how this clear and stringent test did not prevent the use of animals in testing cosmetic products for 10 years until the ban in 1997. At a time when a number of companies such as The Body Shop, were producing cosmetics without animal testing, the Home Secretary was still granting licences for the testing of cosmetics on animals in the UK. Why did the availability of the alternative non-animal methods, used by the likes of The Body Shop, not prevent the grant of licences for cosmetics testing? Do the words *'reasonably practicable'* in the obligation of the Home Secretary to consider methods not entailing the use of protected animals contain a legal loophole that allows the use of alternative non-animal methods to be ignored if other factors (perhaps company profits?) are affected?

A recent Buav report by Dr Taylor, '*Creatures of Habit: Animals in Recreational Drug Research'* 2007 indicates that licences are still being granted in instances where alternative non-animal methods of research are available. This seriously challenges the efficacy of s.5(5) to achieve what it purports to achieve, i.e., the limitation of experiments on animals to those instances where it is absolutely necessary. In one experiment at Cambridge University rats were used to investigate the addictive nature of cocaine (2004, Science 305:1017-1019). The procedure involved surgically inserting a catheter into the jugular vein of the rats and conditioning them, by the use of electric shocks to their feet, to be frightened of loud sounds. The research discovered that the addicted rats would still seek more cocaine even when it was associated with electric shocks. Clinical observation of human patients has already established the addictive nature of cocaine and it is difficult to see in what way the above experiment added to our current knowledge.

Conclusion

The stringent tests in s.5 of the Act set a high threshold of protection to laboratory animals suggesting that only those experiments that are absolutely necessary will receive licences. Only those experiments that offer considerable benefits (since these benefits must outweigh the animal suffering) and where no non-animal alternatives exist will be granted a licence to proceed. Unfortunately, on closer inspection, how the Act works in practice offers a bleaker picture. The cost-benefit assessment, which looks so promising on paper, is difficult to implement. The benefit is limited to the projected optimism of the researchers rather than the wider picture of the efficacy of the animal model. The costs are difficult to quantify and the severity classification scheme needs to be modernised. The obligation to use non-animal alternatives appears to have little weighting in practice. The UK boasts an exemplary regulatory system on paper but its practical implementation does not approach its potential.

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