The Animals (Scientific Procedures) Act 1986 came into force on January 1, 1987 and licensed all research in the U.K. on "living vertebrates which might have the effect of causing that animal pain, suffering, distress or lasting harm." The Act was the culmination of many years of debate and activity by the anti-vivisectionist movement, but perhaps more importantly, by moderate welfare organizations such as The Committee for the Reform of Animal Experimentation (a grouping of moderate animal welfare organizations), the Royal Society for the Prevention of Cruelty to Animals, the British Veterinary Association and Fund for the Replacement of Animals in Medical Experiments. There had also been increasing public concern over the use of animals [1]. Whilst the old 1876 Cruelty to Animals Act had worked well, it had not kept up to date with current ethical thinking (consider for a moment our use of animals in the nineteenth century and now) and its wording and original concepts were clearly dated. For example, although the Home Office Inspectorate in practice had been interpreting the words in the 1876 Act "calculated to give pain" to include other aspects of potential "suffering" in experimental work, it did not refer overtly to distress, discomfort, fear etc.; nor did it effectively limit any such adverse effects (unless the pain was sufficient to be classified as severe and enduring). Moreover, the old Act did not take into account the objectives of the research, or the provenance of animals (the public believed—and some still do—that pet cats and dogs are used in research). In addition, it did not apply to those animals used in potentially severe non-experimental (sic) procedures, for example tumour and parasite passage, raising antisera. Today, under the new 1986 Act, the purpose of the research is considered when granting a licence, the supply of animals is controlled carefully and licensed, and all scientific procedures are covered, not simply those deemed to be an "experiment"—that is, that by definition had an unknown outcome.

Before any animal research may be carried out, three types of licence are needed. The first is a Certificate of Designation which approves the Establishment's facilities for keeping, or for breeding and supplying experimental animals. This places a fairly heavy responsibility on a senior person in the designated establishment (such as the Vice-Chancellor or Registrar in a University, or a board member in a commercial company) to provide and maintain adequate staffing and facilities, and to ensure the main provisions of the Act are observed by members of the institution. The certificate holder has to appoint two named persons: a veterinary surgeon, and a person in day-to-day care of the animals. These named persons have a statutory responsibility to take remedial action whenever the health or welfare of an animal gives rise to concern—whether it is a stock or experimental animal.

The second type of licence is a Project Licence which licenses a programme of research work. This is the most effective part of the new Act, as it aims to ensure good laboratory animal science—ensuring the science is soundly based and that the animals do not suffer unnecessarily or unwittingly. The application for a project licence has to provide details of the background to the research, the broad objectives, the number of animals to be used, and the potential benefit (a gain in fundamental knowledge is acceptable, in addition to applied research directed towards some human or animal disease or hazard). Details of the research programme, as one might draw up for an Ethics Committee or grant application, must be given and the applicant also must testify there are no in vitro or ex vivo alternatives to using living animals. All animals to be used on the project must have come from registered Breeders or Suppliers (unless the animals are not on Schedule 2, for
example farm species, or a specific exception has been approved) and this may increase the price of some species, for example dogs. At the end of every year the project licence holder has to inform the Home Office of the number of animals used under the licence.

Perhaps the most interesting part of the project licence is the classification of the predicted adverse effects on the animal (termed "severity") as mild, moderate and substantial—but how does one measure and grade these adverse effects? (There is also a fourth grade, as there is a termination condition attached to every Personal Licence (see below) and "severe pain or severe distress" will not be permitted—and therefore has to be recognized.) These adverse effects are then balanced against the potential benefits from the research—in a type of cost–benefit analysis. In practice, a recommendation is made by the Home Office Inspector on behalf of the Secretary of State. The moral principle is obvious and laudable, as nobody would wish to see an animal suffer for trivial gain, and most would find it acceptable that mild pain or discomfort could be caused to relieve human suffering—it is the area in between that may be difficult to judge and gain a consensus [2]. In practice, the mere fact that scientists have been asked to specify the likely adverse effects and their incidence, and then to detail how these adverse effects will be mitigated has highlighted the wellbeing of the animals and also, therefore, the dilemmas. Scientists, by and large, endorse the concept and it behoves them to consider their personal ethical stance before embarking on any animal research; they may even be reassured by such an analysis. A moment's thought will show that good animal welfare and a reduction in suffering will, more often than not, lead to better science, as pain and distress are usually unwanted side effects in experimental work (e.g. a kidney transplant) and lead to unnecessary suffering and reduced scientific accuracy.

What might be of interest to anaesthetists is how one can recognize pain, distress and discomfort in animals, and how it can be relieved [3]. There are analogies between animals and babies/children in their lack of verbal communication, but then "they cannot mislead you either". There is a further complication as there are few licensed analgesic and anxiolytic drugs in the U.K. for many laboratory animal species (ironically, as such drugs almost certainly will have been researched, developed and safety tested using them). In essence, measuring these adverse effects becomes an assessment of deviation from normality and this requires considerable expertise when one considers the many species and strains (breeds), and the varied physiological, psychological and behavioural patterns that can be exhibited, even in their restricted environment. Here advice from animal technicians, the named veterinary surgeon and the named person in day-to-day care becomes invaluable. One anomaly is the public's (misguided?) concern for dogs, cats, horses and primates, resulting in special justification having to be given for the use of those species. However, the evidence for pigs or rats "suffering" less than dogs or cats is highly debatable—such is the public's logic and morality!

The third type of licence is a Personal Licence—in effect, a certificate of competence to carry out a regulated procedure on an animal—that is, any scientific technique which may have the effect of causing pain, suffering, distress or lasting harm; even taking a blood sample will require a licence. The licence details each technique by species and whether an anaesthetic is required. All new licensees (regardless of whether they have a medical or veterinary training) must be supervised for their first year (or until their supervisor considers them competent, when an application can be made to the local Home Office Inspector to remove the restriction). No one may carry out any research even with a personal licence unless they are covered by a project licence and for the first year applicants have to specify the project licence under which they wish to work. Giving an anaesthetic or analgesic is considered as having the potential to cause animal suffering and so requires both project and personal licences. A new applicant requires a sponsor who will testify that (s)he has the necessary background knowledge, has practised where appropriate on dead animals, and is of a suitable character. The sponsor and supervisor are normally senior licensees and may be the same person. Training in scientific techniques can thus be phased, culminating in direct assistance on living animals when the licence has been granted. It is not permitted to use animals for the purposes of demonstrating or for gaining manual skills. Some 25 conditions are attached to a personal licence which, by and large, are common sense but should be read carefully. (Eleven are considered serious offences and a breach may result in a gaol sentence of up to 3 years or a large fine; the other 14 are less serious
and may incur suspension or revocation of the licence, or a shorter holiday at Her Majesty's pleasure.)

Euthanasia is also controlled under the 1986 Act and Schedule 1 lists those methods that are permitted without the authority of a personal licence, are relatively easy to carry out (do not require special skills or strength), and which leave minimum room for misuse. Other methods can be used, but they have to be justified and licensed.

Neuromuscular blocking agents may be used, but are of obvious concern and their use is tightly controlled. The use of a neuromuscular blocking agent in place of an anaesthetic, or their use without the authority of a personal licence, are considered serious offences; the Home Office Inspector has also to be given 48 h notice of intended use. The Home Office and the Physiological Society have produced excellent guidelines on the use of muscle relaxants, and they perhaps raise a few points worthy of consideration in human clinical practice.

Reuse of animals is permissible, but is carefully controlled through the “donor” and “recipient” Project Licences and should be discussed with the Home Office Inspector.

In conclusion, the 1986 Animals (Scientific) Procedures Act seems to be working well to the benefit of science and animals. Its major provisions inevitably mean more paperwork and outside scrutiny than before but morally, perhaps that is a “right price” to pay for the responsibility of using sentient animal species in research. Whether we can look forward to Ethics Committees considering animal research, as in some other countries, remains to be seen.

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REFERENCES