Policy Brief: Use of Animals in Research

During the nineteenth and twentieth centuries, a number of pieces of legislation relating to animal treatment were passed in the UK including the 1876 Cruelty to Animals Act. The 1876 Act regulated animal experiments and introduced a licensing and inspection system.

The 1876 Act remained in force in the regulation of animal experiments until 1986. Since then, animal procedures in the UK have been regulated under the Animals (Scientific Procedures) Act 1986 [ASPA]. The British Veterinary Association was amongst the key stakeholders consulted during the drafting of ASPA.

It is generally reported that the UK has the tightest system of regulation in the world. Not only does the 1986 Act require institutional, project and personal licences, but the UK is the only country to require an explicit cost/benefit assessment of every application to conduct animal research.

The principal features of ASPA include:

a) The Act covers all non-human vertebrates and the common octopus (Octopus vulgaris). Mammals, birds, reptiles, amphibians and fish are protected, while invertebrate creatures such as squid, insects and protozoa are, at present, excluded;

b) The Act regulates any experimental or scientific procedure which may have the effect of causing a protected animal "pain, suffering, distress or lasting harm";

c) The Act requires that all regulated procedures are carried out under three licences: a licence for the establishment where the procedure is to take place; a project licence for the programme of work which details the numbers and types of animals to be used, the exact procedures to be performed, and the overall purpose of the project; and a personal licence for the scientific investigator.

d) The key element of the Act is commonly known as the cost/benefit analysis. This is applied to all proposed animal research in a project licence, and is defined as the weighing of "the likely adverse effects on the animals concerned against the benefit likely to accrue";

e) A project licence should not be granted if there is a "reasonably practicable method not entailing the use of protected animals", that is, an animal experiment should not be licensed if there is a realistic non-animal method. Where animals are used, the procedures must use "the minimum number of animals, involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering distress or lasting harm, and are most likely to produce satisfactory results";

f) There is an Inspectorate, whose members advise the Secretary of State on the granting of licences and carry out inspections of designated establishments;

g) An independent committee, the Animal Procedures Committee (APC), advises the Secretary of State on the operation of the Act. The APC membership includes a barrister, philosophers and representatives from industry, academia, funding bodies, veterinarians, and animal welfare and anti-vivisection groups.

A review of the operation of ASPA was published in 1997. It concluded that the Act did not require radical reform but recommended a number of changes so as, inter alia, to help the Inspectorate and give the public a better understanding of the cost/benefit assessment; to document the consideration of non-animal methods in project licences; to provide appropriate training for those involved in the killing of animals; to publicise how infringements of the Act are handled by the Home Office; and to increase the size of the Inspectorate and its administrative support.

Since the reviews a number of other regulatory developments have taken place, including:

a) A ban on the testing of finished cosmetic products on animals (6 November 1997).

b) A ban on the use of great apes (6 November 1997) - though none had in fact been used since the passing of the 1986 Act.

c) A ban on the testing of alcohol and tobacco products on animals (6 November 1997).
d) A de facto ban on the testing of cosmetic ingredients (16 November 1998).

e) A ban on the use of animals to produce monoclonal antibodies in ascites caused by the deliberate establishment of abdominal tumours, save in exceptional cases (from 1 January 1999).

f) The introduction of the Ethical Review Process (ERP) (from 1 April 1999).

g) A ban on the acute oral Lethal Dose 50% (LD50) test save in exceptional circumstances (21 October 1999); and

h) A change in the balance of membership of the APC intended to ensure its greater independence.

Key Facts:

- The use of animals in research is regulated in the UK by the Home Office under the Animals (Scientific Procedures) Act 1986.
- The Act controls any experiment or other scientific procedure applied to a 'protected animal' which may have the effect of causing that animal pain, suffering, distress or lasting harm.
- Three kinds of license authority are required for all work controlled by the Act; a certificate of designation as a scientific procedure establishment' relating to the premises; a project licence authorising the research programme; and a personal license to ensure technical competence of the researchers.
- All designated establishments employ both a Named Animal Care and Welfare Officer, responsible for the day to day care of the animals, and a Named Veterinary Surgeon, to advise on animal health and welfare.
- All designated establishments are required to institute and maintain a local ethical review process acceptable to the Secretary of State. The Named Veterinary Surgeon and the Named Animal Care and Welfare Officer are almost always involved in the ethical review process.
- The Animals Scientific Procedures Division of the Home Office is responsible for operating the licensing system. The Division also provides advice to the Secretary of State on issues relating to the Act and is responsible for inspecting establishments.

General system of control under the Animals (Scientific Procedures) Act 1986

Introduction

The Animals (Scientific Procedures) Act 1986 [ASPA] puts in place a rigorous system of controls on scientific work on living animals (including the need for both the researcher and the project to be separately licensed) to provide stringent safeguards on animal pain and suffering; and general requirements to ensure the care and welfare of animals. ASPA complies with European Directive 86/609/EEC.

The Home Office administers the legislation in England, Scotland and Wales. The Act is separately administered in Northern Ireland (through the Department of Health).

Scope of the Act

The Act controls any experimental or other scientific procedure applied to a 'protected animal' which may have the effect of causing that animal pain, suffering, distress or lasting harm. Such work is referred to in the Act as a 'regulated procedure'. Procedures carried out on decerebrate animals are also subject to the controls of the Act.

'Protected animals' are defined as all living vertebrate animals, except humans, plus one invertebrate species, Octopus vulgaris. The definition extends to foetal, larval or embryonic forms that have reached specified stages in their development. The definition of a regulated procedure encompasses the majority of use of animals for
scientific purposes, including the use of animals in experiments (sometimes also referred to as “animal testing”), the breeding of genetically altered animals with animals with genetic defects, the production of antisera and other blood products, and the maintenance and passage of tumours and parasites in live animals. The administration of an anaesthetic, analgesic, tranquilliser or other drug to dull perception in the course of a scientific procedure is also a regulated procedure. Killing an animal, where it does not follow a method of humane killing listed in Schedule 1 to the Act, also requires licence authority.

The controls of the 1986 Act do not extend to procedures applied to animals in the course of recognised veterinary, agricultural or animal husbandry practice. The testing of veterinary products or other small-scale clinical trials performed under authority of an Animal Test Certificate (issued under the Medicines Act 1968) are also exempt from ASPA.

**Licence Structure**

**General**

Three kinds of licence authority are required for all work controlled by the Act. The procedures must be part of a programme of work authorised by a project licence and the person applying the regulated procedures must hold a personal licence. No work may be done unless the procedure, the animals used and the place where the work is to be done are specifically authorised in both project and personal licences.

![Diagram](image_url)

[ ERP: Ethical Review Process

PCD: Certificate of Designation

NACWO: Named Animal Care and Welfare Officer

NVS: Named Veterinary Surgeon

PPL: Project Licence

PIL: Personal Licence

NB. NACWO is the currently preferred name for the Named Person in Charge of Day to Day Care (NPDDC) cited under the Act].

**Designation of premises**

Except where otherwise authorised in a project licence (e.g. for field work), any place where work is carried out under the Act must hold a certificate of designation as a scientific procedure establishment.

In addition, establishments that breed certain types of animal (mouse, rat, guinea-pig, hamster, rabbit, dog, cat and primate, quail (Coturnix coturnix), ferrets, gerbils, genetically modified pigs and genetically modified sheep) for use in scientific procedures (breeding establishments), and establishments that obtain such animals from elsewhere and supply them to laboratories (supplying establishments) must also hold a certificate of designation.
Designated establishments are required to nominate a person to be responsible for the day-to-day care of animals [Named Animal Care and Welfare Officer (NACWO)] and a veterinary surgeon [Named Veterinary Surgeon (NVS)] to advise on their health and welfare.

Project Licences

The holder of a project licence [PPL] undertakes overall responsibility for the scientific direction and control of the work and is responsible for making the statistical returns on which this publication is based. New project licence applicants are required to complete an accredited training course before the licence is granted.

A project licence is granted when the Home Secretary considers that the use of living animals in a programme of work, for a purpose permitted by the Act, is justified and the methods proposed appropriate. In deciding whether and on what terms to authorise the project, the likely adverse effects on the animals used must be weighed against the potential benefits (to humans, other animals or the environment) which are expected to accrue from the work. Adequate consideration must also have been given to the feasibility of using alternative methods not involving living animals.

The Home Office publish abstracts for each Project Licence issued. The purpose is to contribute to greater openness, and to improve public understanding about the use of animals in science and how such work is regulated. These abstracts are produced by the project licence holders and the Home Office bears no authorial or editorial responsibility for the content of the abstracts.

On December 31 2009 there were 2658 project licences in force; in 2008 the figure was 2652.

Personal Licences

A personal licence [PIL] is the Home Secretary's endorsement that the holder is a suitable and competent person to carry out specified procedures on animals, under supervision where necessary.

On December 31 2009 there were 15,492 personal licences in force; in 2008 the figure was 14,910.

Training of personnel working under ASPA

ASPA imposes clear responsibilities on persons with specific roles in relation to the care and use of animals in scientific procedures. As the roles differ, it follows that the education and training required before assuming these responsibilities will differ:

a) Holders of certificates of designation have responsibility not only for ensuring that the fabric and staffing of designated places are maintained to appropriate standards but also for ensuring that reasonable steps are taken to prevent unauthorised procedures being carried out and that adequate training facilities are available for all animal users.

b) Project licences are issued only to persons with appropriate qualifications to direct a programme of work which is well-justified and takes account of all reasonable possibilities for reducing the number of animals used, refining the procedures to reduce suffering and replacing animal procedures with alternatives which do not involve protected animals.

c) Personal licensees are responsible for the welfare of animals on which they carry out regulated procedures; applicants are granted licences only if adequately trained to take on this responsibility and are required to work under supervision initially.

All training programmes are accredited under a scheme recognised by the Home Office. Accreditation seeks to achieve common and high standards for licensee training that will facilitate free movement of licensees within the UK and Europe as well as ensuring high standards in the use of animals for scientific purposes.

Satisfactory completion of an accredited course prior to application for a personal licence has been a requirement under Home Office policy since 1 April 1994. A similar requirement has applied to new applicants for project licences from 1 April 1995.

Mandatory training for Named Veterinary Surgeons was introduced in 1995. Training requirements for Named Animal Care and Welfare Officers were also introduced in 2004.
Ethical Review

Under ASPA, all designated establishments are required to institute and maintain a local ethical review process acceptable to the Secretary of State.

The aims of the ethical review process are:

a) To provide independent ethical advice to the certificate holder, particularly with respect to project licence applications and standards of animal care and welfare.

b) To provide support to named people [NVA and NACWO] and to provide advice to licensees regarding animal welfare and ethical issues arising from their work.

c) To promote the use of ethical analysis to increase awareness of animal welfare issues and to develop initiatives leading to the widest possible application of the Three Rs [Replacement, Reduction and Refinement].

More specifically, the objectives and outputs of the ethical review process are:

a) Promoting the development and uptake of reduction, replacement and refinement alternatives in animal use, where they exist, and ensuring the availability of relevant sources of information;

b) Examining proposed applications for new project licences and amendments to existing licences, with reference to the likely costs to the animals, the expected benefits of the work and how these considerations balance;

c) Providing a forum for discussion of issues relating to the use of animals and considering how staff can be kept up to date with relevant ethical advice, best practice, and relevant legislation;

d) Undertaking retrospective project reviews and continuing to apply the Three Rs to all projects, throughout their duration;

e) Considering the care and accommodation standards applied to all animals in the establishment, including breeding stock, and the humane killing of protected animals;

f) Regularly reviewing the establishment’s managerial systems, procedures and protocols where these bear on the proper use of animals;

g) Advising on how all staff involved with the animals can be appropriately trained and how competence can be ensured.

h) Developing a promotional role, seeking to educate users (in applying the Three Rs) and non-users (by explaining why and how animals are used), as appropriate. There should be some formal output from the ethical review process for staff and colleagues in the establishment, made as widely available as security and commercial/intellectual confidentiality will allow.

Administration and inspection


The Licensing Section operates the licensing system on behalf of the Secretary of State. They process and grant applications for new licences and certificates on behalf of the Secretary of State; process amendments to existing authorities; and revoke or vary licences and certificates as necessary. They also administer the collection of annual fees from designated establishments and of annual statistical returns of procedures from project licence holders.

The Policy Section is the primary source of advice to the Secretary of State for the Home Office on issues relating to the Act, including the preparation of responses to Parliamentary Questions and correspondence from MPs and the public about the use of animals in scientific procedures.

The Inspectorate comprises Inspectors who hold either a medical or veterinary qualification.

Inspectors assess all applications for new licences or amendments to existing licences in detail and advise the Home Secretary on whether and on what terms to grant the licences or accept the amendments. Inspectors carry
out visits, mainly without warning, to establishments designated under the Act to determine whether scientific
work on animals is authorised, to inspect the premises and to check that the establishment's controls are
adequate and that the terms and conditions of the licences issued under the Act are being observed. Inspectors
also advise the Home Secretary on policy matters connected with the operation of the Act and they are
available to give advice to licensees and other personnel working under the Act.

The Animals Procedures Committee

The Animal Procedures Committee [APC] is an independent body established under ASPA to advise the
Secretary of State on matters concerned with the Act and the Secretary of State's powers under it. The
Committee's primary role is to provide strategic advice to the Secretary of State on policy, practice, ethics,
science and welfare. The Committee may consider and advise on matters of its own choosing, as well as
those that are referred to it by the Secretary of State.

The Committee has no executive powers. It cannot grant, refuse, revoke or vary licences or certificates.
Committee has at least of 12 members and a Chairman. Two-thirds of the members must be registered
medical practitioners or veterinary surgeons or have ‘qualifications or experience in a biological subject'
approved by the Secretary of State; and at least one member must be a barrister, solicitor or advocate. At
least half the members must not currently hold, or have held within the past six years, any licence under the
Act. Members are appointed on personal merit, not to represent interest groups or the organisations by
which they are employed.

In its considerations, the Committee must have regard both to the legitimate requirements of science and
industry and to the protection of animals against avoidable suffering and unnecessary use in scientific
procedures [Section 20(2)].

The Committee publishes an annual report, available from The Stationery Office and at the Committee's
website.

Roles and Duties of the NACWO

The Named Person in Charge of Day to Day Care (otherwise known as the Named Animal Care and Welfare
Officer [NACWO]) is responsible to the certificate holder for the husbandry, care and welfare of the protected
animals. The Institute of Animal Technology, the professional body for animal technologists, has published
guidelines for Named Animal Care & Welfare Officers.

NACWOs ensure that the highest standards of husbandry and care are practised. In designated scientific
procedure establishments, this responsibility extends into all areas approved for the performance of
regulated procedures. If the health or welfare of any protected animal is giving rise to concern, the NACWO
is required to notify the personal licensee who is responsible for the welfare of the animal. If the licensee is
unavailable the NACWO must take steps to ensure that the animal is properly cared for, treated or otherwise
humanely killed. NACWOs generally work closely with the Named Veterinary Surgeon to achieve high
standards of animal welfare.

Roles and Duties of the NVS

The Named Veterinary Surgeon must normally be a member of the Royal College of Veterinary Surgeons.
For the purposes of the Veterinary Surgeons Act 1966, the protected animals at the designated
establishment are deemed to be under the care of the Named Veterinary Surgeon. Thus, in addition to being
accountable to the certificate holder for the provision of expert advice on the health and welfare of protected
animals, Named Veterinary Surgeons are also accountable to the Royal College of Veterinary Surgeons for

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1 The Act makes provision for a person other than a veterinary surgeon to be named on the certificate of
designation. The secretary of State can permit this in exceptional circumstances where no suitable
veterinary surgeon is available and the “other suitably qualified person” has considerable, proven experience
relevant to the health and welfare of the particular types of protected animal held and range of regulated
procedures performed at the establishment. To date, this has been deemed acceptable only when the
protected animals involved were embryonated avian eggs or fish.
their professional standards and conduct. The Royal College of Veterinary Surgeons has produced specific guidance for Named Veterinary Surgeons. It appears under Appendix K of the Guide to Professional Conduct.

The principal duties of the Named Veterinary Surgeons include:

a) To ensure that adequate veterinary cover and services are available at all times.

b) To visit all parts of the establishment designated in the certificate at a frequency which will allow effective monitoring of the health and welfare of the protected animals.

c) To notify the personal licensee who is in charge of a protected animal if the health or welfare of that animal is giving rise to concern. If the licensee is unavailable, the Named Veterinary Surgeon should take steps to ensure that the animal is treated, cared for or, if necessary, that it is humanely killed.

d) To be familiar with relevant methods of humane killing listed in Schedule 1 to the Act, together with any additional approved methods set out in the conditions of the certificate of designation.

e) To have a thorough knowledge of the husbandry and welfare requirements of the species kept at the establishment (including the prevention, diagnosis and treatment of disease); and be able to advise on quarantine requirements and health screening, and the impact of housing and husbandry systems on the welfare and needs of a protected animal.

f) To control, supply and direct the use of controlled drugs, prescription-only medicines and other therapeutic substances for use on protected animals in the establishment.

g) To maintain animal health records to the required professional standard relating to all the protected animals at the establishment, including advice or treatment given; and ensure that such records are readily available to the Named Animal Care & Welfare Officer, the certificate holder and (if requested) the Home Office.

h) To have regular contact with the certificate holder and the Named Animal Care & Welfare Officer(s); and

i) To take an active part in the ethical review process at the establishment.

At a scientific procedures establishment, the Named Veterinary Surgeon should also:

a) Advise licensees, applicants and others on how to implement the principles of replacement, reduction and refinement. In particular, to advise about the impact of experimental procedures on the welfare of protected animals; the recognition, assessment and alleviation of any pain, suffering, distress or lasting harm; general and experimental surgical techniques, and post-operative care; appropriate methods of general anaesthesia, analgesia and euthanasia; strategies to minimise the severity of protocols, including the recognition and implementation of suitable humane end-points.

b) Be familiar with the main provisions of the project licences in use, in particular the adverse effects expected for each protocol; the means by which they are to be avoided, recognised and alleviated; and the humane endpoints to be applied

c) Ensure that an appropriate clinical investigation or therapy is undertaken for the welfare of a protected animal undergoing regulated procedures, but that the data or other products being collected as part of the programme of work are not compromised as a result; and

d) When appropriate, determine that an animal may remain alive at the conclusion of a series of regulated procedures (and returned to stock or possibly re-used in further procedures), or certify that its welfare will not be compromised if it is removed from the designated place (e.g. re-homed as a pet, or released to the wild).

**Latest Statistics**

The Home Secretary publishes statistics on the use of animals in scientific procedures in Great Britain annually, usually in July or August. Statistics for Northern Ireland are published separately.

The latest figures are for the year ending **31 December 2009**.
Summary:

1. Just under 3.6 million scientific procedures were started in 2009, a drop of about 36,500 (1%) on 2008. The decrease in animal use was reported to be due to a decrease in procedures for applied studies in human medicine and dentistry.

2. Mice, rats and other rodents were used in the majority of procedures: eighty one percent (81%) of the total. Most of the remaining procedures used fish (11%), and birds (3.5%).

3. Dogs, cats, horses and non-human primates, afforded special protection by the Act, were collectively used in less than half of one percent of all procedures.

4. Procedures using non-human primates were down 7% from 2008, mainly due to decrease in the use of macaques.

5. Over a third of all procedures in 2009 were accounted for by breeding procedures (38%), for the production and maintenance of mutant and genetically modified animal lines. Mainly mice (77%) and fish (15%) were used in these procedures.

6. Around ninety-nine percent of procedures carried out on animals listed in Schedule 2 of the Act used animals acquired from designated sources in the United Kingdom.

7. Genetically normal animals were used in 48% of all procedures where as genetically modified animals were used 42% of all regulated procedures.

8. Around thirty-three percent of all procedures used some form of anaesthesia to alleviate the severity of the interventions. For many of the remaining procedures the use of anaesthesia would have potentially increased the adverse effects of the procedure.

9. Non-toxicological procedures accounted for about eighty-eight percent of the procedures started in 2009. The main areas of use were for Immunological studies, pharmaceutical research and development, cancer research, anatomy and physiology.

10. Procedures for toxicological purposes accounted for twelve percent of all procedures started in 2009. Most (78%) toxicology procedures were for pharmaceutical safety and efficacy evaluation, and seven tenths (72%) involved rodent species; while non-human primates accounted for less than one percent of such procedures.

Further Information

Home Office website
Guidance on the Operation of the Animals (Scientific Procedures) Act 1986
Codes of Practice on housing and care
Annual statistics

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