Chapter 13

Legislation, regulation and policy relating to scientific procedures on animals

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Introduction

13.1 In this chapter we consider the regulatory framework for research involving animals in the UK. We describe the historical background to the Animal (Scientific Procedures) Act 1986 (A(SP)A), its principal provisions and the three types of licence that it sets forth as requirements (personal licences, project licences and the certificate of designation for the establishment). We explain why the A(SP)A regulates 'procedures', rather than experiments, and how the severity of procedures is classified in regulatory terms. Having set out these general features, we describe how the Act is operated in practice. We consider the role of the Home Office Inspectorate, the Animal Procedures Committee (APC) and the institutional local Ethical Review Process (ERP). The way in which the cost-benefit assessment is undertaken and statistical data about the use of animals are presented are also reviewed. We go on to consider developments in regulation at the international level. Finally, UK and international regulation that either explicitly demands the use of animals for specific purposes, or sets out testing guidelines that are usually interpreted as requiring the use of animals are summarised (see paragraphs 8.22 and 9.4).

Historical background to the A(SP)A

13.2 During the 19th century, legislation relating to animal treatment began to be enacted in the UK. The legal offence of animal cruelty was first introduced in An Act to Prevent the Cruel and Improper Treatment of Cattle ('Martin's Act'), passed in 1822. It stated that 'if any person or persons having the charge, care or custody of any horse, cow, ox, heifer, steer, sheep or other cattle, the property of any other person or persons, shall wantonly beat, abuse or ill-treat any such animal, such individuals shall be brought before a Justice of the Peace or other magistrate'. These provisions were extended in 1835 and 1849, before being consolidated in 1911 in the Protection of Animals Act, which forbade the causing of unnecessary suffering, making it a legal offence to 'cruelly beat, kick, ill-treat, over-drive, over-ride, overload, torture, infuriate or terrify any animal'.[1] By the First World War, domestic and captive mammals, birds, reptiles and fish were all generally protected from cruelty by law.

13.3 In addition, legislation was established to regulate the way in which animals were treated in specific circumstances. This included the Cruelty to Animals Act 1876, which related specifically to scientific experiments. It introduced the requirement of personal licences for those undertaking research and a system of inspection. From the 1960s onwards there was increasing criticism of the 1876 Act, and a series of official and semi-official committees made recommendations for changes to the law.[2] In addition, the European Directive EEC 86/609 required Member States to adopt national legislation, or similar legal instruments to implement its provisions. In the 1980s, the UK Government produced new draft legislation and eventually the 1876 Act was repealed by the A(SP)A.[3]

1 Radford M (2001) *Animal Welfare Law in Britain: Regulation and responsibility* (Oxford: Oxford University Press), Chapter 3.

2 Published reports include that of the Littlewood Committee in 1965, the House of Lords Select Committee on the Laboratory Animals Protection Bill (1980) and the Report of the Secretary of State's Advisory Committee on Animal Experiments (1981).

The A(SP)A: general operational aspects

13.4 The A(SP)A[4] regulates the use of all vertebrate animals[5] (mammals, reptiles, amphibians, birds and fish) and, by a subsequent order in Parliament, the common octopus in 'any experimental or other scientific procedure...which may have the effect of causing that animal pain, suffering, distress or lasting harm'. These purposes are called 'regulated procedures' (see Box 13.1), and may only be undertaken if the Secretary of State has granted the necessary licences (see paragraphs 13.5–13.6).

Box 13.1: Why does the A(SP)A use the term 'procedure' instead of 'experiment'?

The welfare of animals may not only be affected by the consequences of a particular scientific experiment but also by a range of other aspects of their lives. Since the A(SP)A seeks to regulate any activity that involves a protected animal and may cause pain, suffering, distress or lasting harm, the term 'procedure' was introduced to refer to the broad range of events that may affect animals. Thus, under the A(SP)A all aspects of the scientific experiment itself, as well as relatively minor interventions, such as the taking of a blood sample, are all termed regulated procedures and any research study will usually involve a number of these. Similarly, other scientific uses of animals, for example the testing of vaccines, or the use of animals for the production of biological products such as antibodies, are categorised as procedures, as well as the breeding of harmful mutants and GM animals (see paragraphs 13.14 and 13.25).

13.5 The regulatory scheme imposed by the A(SP)A is complex. There are absolute rules that, if broken, will lead to criminal liability. For example, it is a criminal offence to carry out what would qualify as a regulated procedure without the required licences. Such breaches are potentially punishable with an unlimited fine and imprisonment for a maximum of two years.[6] The Act also empowers the Secretary of State to make regulations (secondary legislation) to implement the principles embodied in the statute such as extending the categories of protected animals. Most crucially, the Act grants the Secretary of State extensive discretionary powers in relation to licensing research. This means that the Home Office necessarily develops, within limits, internal guidance and policy with regard to whether and on what terms requests for licences may be granted. The Act sets out the parameters within which discretion is exercised; and in practice they are applied on a case by case basis. So, for example, Section 5 (6) of the Act directs that 'The Secretary of State shall *not* grant a project licence authorising the use of cats, dogs, primates and equidæ[7] unless he is satisfied that animals of no other species are suitable for the purposes of the programme to be specified in the licence or that it is not practicable to obtain animals of any other species that are suitable for those purposes'. In more general terms, Section 5 (5) states that 'The Secretary of State shall not grant a project licence unless he is satisfied (a) that the purpose of the programme to be specified in the licence cannot be achieved satisfactorily by any other reasonably practicable method not entailing the use of protected animals'.

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3 In 1983, the Government produced a White Paper entitled *Scientific Procedures on Living Animals*. This Paper led to extensive consultation, and was followed by a supplementary White Paper with the same name, which appeared in 1985. The Bill that became the A(SP)A was based on the two White Papers. It was introduced in the House of Lords, where it was debated extensively and amended. The amended Bill then passed through the Commons with relatively little discussion.

4 Animal (Scientific Procedures) Act 1986 (A(SP)A), available at: http://www.archive.official-documents.co.uk/document/hoc/321/321-xa.htm. Accessed on: 4 May 2005.

5 Animals at early stages of development are excluded from the Act, see A(SP)A Section 1 (2) which states that: 'Any such vertebrate in its foetal, larval or embryonic form is a protected animal only from the stage of its development when (a) in the case of a mammal, bird or reptile, half the gestation or incubation period for the relevant species has elapsed; and (b) in any other case, it becomes capable of independent feeding.'

6 See A(SP)A Schedule 3 and 22. To inflict pain or suffering on an animal in the course of an unlicensed experiment could also involve criminal liability under the general law against cruelty to animals, contained in the Protection of Animals Act 1911, the Wild Mammals (Protection) Act 1996 and the Protection of Animals (Scotland) Act 1912, although the maximum penalties are lower.

7 The term 'equidæ' refers to the family that includes horses.

13.6 Subject to the general directions set out in the A(SP)A, the Secretary of State enjoys considerable discretion in the exercise of the statutory powers, including the development of both policy and administrative procedures.[8] For example, following an announcement by the Secretary of State before Parliament, the Home Office adopted a policy whereby licences for scientific procedures using animals to test cosmetics, or procedures that involve the great apes would not be issued.[9] The Secretary of State has thereby used the administrative powers to effect a *de facto* ban. Similarly, by attaching a standard condition to all certificates of designation that every establishment shall have a local ERP, this provision has become a mandatory requirement (paragraph 13.21).

13.7 Sections 19 and 20 of the A(SP)A established the APC, which was first appointed in 1987. The APC provides independent advice to the Secretary of State on any matters related to the A(SP)A as it sees fit or as may be referred to it by the Secretary of State (see Box 13.2 and paragraph 13.16).

Box 13.2: The Animal Procedures Committee

The APC is composed of scientists, lawyers, veterinary surgeons, doctors, animal welfarists and philosophers. The Committee was established by the A(SP)A, which specifies that the Committee should comprise a chairman and at least 12 other members. At least two thirds of the members should have qualifications or experience in a relevant biological subject or have full registration as a medical practitioner or veterinary surgeon and at least one member should be a barrister, solicitor or advocate. The Act also states that the Secretary of State, responsible for appointments to the committee, should take into account the desirability of ensuring that the interests of animal welfare are represented. Usually one member of the Committee is an academic philosopher.

The A(SP)A specifies that the APC should have regard to both the requirements of science and industry and the protection of animals against avoidable suffering and unnecessary use. The Committee has the dual function of advising on certain licence applications when asked and independently advising on policy and practice. Most licence applications are assessed by the Home Office Animals (Scientific Procedures) Inspectorate (see paragraph 13.20). However, there are certain categories of project applications that the APC also considers, including those that involve the use of wild-caught primates and primates in procedures of substantial severity. The APC advises the Home Secretary on these applications, but does not itself decide on the outcome.

The A(SP)A in practice

13.8 The A(SP)A requires that three separate licences, which are described in more detail below, must be obtained before any animal is used in a regulated procedure.

i) A personal licence authorises an individual to conduct specified regulated procedures on specified animal species, at a specified place or places. A personal licence by itself does not authorise a person to carry out any procedures. Rather, the authorisation may only be used in conjunction with two further licences (paragraphs 13.12–13.13).

ii) A project licence forms the centrepiece of the licensing process. This licence authorises individuals who hold a personal licence to conduct a particular programme of work, for specific purposes, at one or more specified designated establishments. It also describes the types of animals involved, the estimated numbers of animals that are intended to be used, the prospective severity banding of the project and individual severity limits for the protocols contained in it (paragraphs 13.14–13.18 and Box 13.3).

iii) A certificate of designation is issued to a person authorising a specified facility (called a 'designated establishment') to conduct animal procedures and/or breed or supply animals for use in regulated procedures (paragraph 13.19).

8 Such power may be exercised by the Secretary of State or by members of the Inspectorate acting on his or her behalf.

9 The use of great apes and the testing of cosmetics are not prohibited formally by law, but as a matter of policy. In principle, the policy could therefore be revoked at any time.

13.9 The Secretary of State may add conditions to any licences or certificates as considered reasonable and appropriate. A series of standard conditions are routinely added to every licence and certificate.[10] The Home Office employs Inspectors who assess all applications for licences and certificates and visit designated establishments to verify that procedures are conducted in accordance with the licences (see paragraph 13.20).

13.10 The Home Office also issues a *Code of practice on housing and care of animals used in scientific procedures* (published in 1989). It is widely agreed that the code does not identify best practice. Rather, it sets out the minimum standards expected of designated establishments, including minimum cage sizes, environmental conditions, animal health and welfare, and special considerations for individual species. Compliance with the code of practice is required by making it a condition of granting the certificate of designation. There are separate codes and guidelines for housing and breeding, as well as for animal euthanasia and a number of specific procedures.[11] As in the case of the *Code of practice on housing and care of animals used in scientific procedures*, these documents set out minimum standards.

13.11 The penalties for contravening the provisions of the A(SP)A, licences or certificates include formal admonitions, requirements for retraining, the placing of restrictions on licences, revocation of licences, fines and imprisonment.[12] Normally, the most effective deterrent is the Home Office's authority to revoke certificates or licences, which could have serious consequences for universities or pharmaceutical companies (in cases where certificates of designation are revoked), or individual scientists (where a project or personal licence is revoked, see Box 2.5).

Personal licences

13.12 Before a scientist or animal technician can be granted a personal licence, they must successfully complete a training course covering the legislation, ethical aspects of animal use, animal biology, husbandry, care and welfare and, where appropriate, surgery and anaesthesia. The licence is specific for the designated establishment(s) where research is to be conducted, and applicants must specify the animals for which they are seeking authority to use. The licence also lists the range of techniques to be used, such as giving injections, or carrying out specific types of surgery. The use of any other combination of species, technique or research location not specified in the licence is a legal offence. Personal

10 For example, since 1999, certificates have not been granted unless there is an ERP in place (see House of Commons (2002) *Guidance on the Operation of the A(SP)A 1986* (Norwich: Stationary Office)). Other standard conditions include the requirement that the establishment should be appropriately staffed at all times to ensure well-being of the animals (see *Guidance on the Operation of the A(SP)A 1986*).

11 See *Code of practice for the housing of animals in designated breeding and supplying establishments* (1995), *Humane killing of animals under Schedule 1 to the A(SP)A 1986* (1997) and *Housing and care of pigs intended for use as xenotransplant source animals* (draft). See Home Office website *UK and European legislation and guidance*, available at: http://www.homeoffice.gov.uk/comrace/animals/legislation.html. Accessed on: 1 Apr 2005.

12 The Home Office reports summary details of infringements to the APC, and information with respect to the cases reported are set out in the APC's Annual Reports. For example, in its Annual Report for 2002, the APC reported that the Home Office had revealed that there had been 20 'Class Three' (the most serious) infringements during the period November 2000–December 2001. The same report also specifically referred to research that had gone beyond licensed procedures and recorded: 'One such serious infringement [that impacted negatively on animal welfare] was reported to the Committee… This involved [loud] music being played to over 200 mice dosed with methamphetamine. Some of the mice were said to have suffered 'seizures' and at least 19 of them died as a result of the procedures. The study arose from a larger programme of work conducted as part of a licensed project concerning Huntington's disease, but it went beyond the procedures covered by the licence authorities. The infringement had come to light through the publication of a scientific paper on the work. …the project licensee had been admonished [by the Home Office] and required to undergo training; a personal licence holder had been admonished; and the certificate holder was asked to remedy defects in the record keeping systems in the department concerned.' No prosecution was brought and the APC noted that it was 'particularly concerned about this case'. In 2003, sanctions used by the Home Office were admonishment, ordering retraining and requiring reviews of operational procedures. Revocation of licences was recommended in two cases; both a licence and a certificate were voluntarily returned to the Home Office in advance of any formal action. Home Office (2004) *Statistics of Scientific Procedures on Living Animals Great Britain 2003* (London: HMSO).

licences are not time-limited but are required to be reviewed at no more than five year intervals. Species or techniques may be added or removed in the course of the review.

13.13 The personal licence holders are obliged to ensure that any pain, suffering or distress to the animals is minimised and they bear primary responsibility for the welfare of the animals they use. Proper records must be kept for each project showing the number of animals used and the procedures that have been carried out, and giving information about the supervision of animals.

Project licences and the cost-benefit assessment

13.14 Project licences can only be granted for the following permitted purposes:

- 'the prevention (whether by the testing of any product or otherwise) or the diagnosis or treatment of disease, ill-health or abnormality, or their effects, in man, animals or plants;
- the assessment, detection, regulation or modification of physiological conditions in man, animals or plants;
- the protection of the natural environment in the interests of the health or welfare of man or animals;
- the advancement of knowledge in biological or behavioural sciences;
- education or training otherwise than that in primary or secondary schools;
- forensic enquiries;
- the breeding of animals for experimental or other scientific use'.[13]

13.15 The project licence has a number of functions, including:

- defining the objectives of the project;
- outlining the likely benefits of the project;
- describing the work to be conducted to achieve the objectives;
- listing the specific procedures to be used;
- identifying the likely adverse effects that may be experienced by the animals and how these will be avoided, recognised and alleviated; and
- placing an upper limit on the severity of the adverse effects to the animals (see Box 13.3 for how the severity of procedures is considered in the licensing process).[14]

Box 13.3: How is the severity of procedures considered by the Home Office?

Severity to the animals involved is assessed prospectively, before a licence is granted. There are two main types of assessment, supplied by the licence applicant and evaluated by the Home Office, as follows.*

i) The *overall severity band of a research project* is intended to reflect the number of animals used on each protocol and the suffering likely to be caused as a result. It is based on the overall level of cumulative suffering expected to be experienced by each animal, rather than the single worst possible case. It takes into account the proportion of animals expected to reach the severity limit of the protocol and the duration of the exposure to that severity limit, the nature and intensity of the adverse effects, and the actions to be taken to relieve the suffering. It is therefore a qualitative and quantitative assessment of the anticipated *average suffering experienced by all the animals* used (see paragraph 15.27). In 2003, 39 percent of project licences were assigned

Continued

13 A(SP)A, Section 5 (3).

14 *Guidance on the Operation of the A(SP)A 1986*, Chapter 5, available at: http://www.archive.official-documents.co.uk/document/hoc/321/321.htm. Accessed on: 4 May 2005.

the mild category, 56 percent to the moderate category, three percent to the substantial category and two percent were unclassified (see below).

ii) The *severity limit* of individual *protocols* is determined by the maximum level of the expected adverse effects that may be experienced by an individual animal, taking into account the measures specified in the licence for avoiding and controlling adverse effects. It represents the worst possible outcome for any animal subjected to the protocol, even if it may only be experienced by a small proportion of the animals to be used.

A protocol is a procedure or a series of procedures carried out on an individual animal or group of animals for a single specific purpose within the context of the project. For most purposes, the protocol defines the individual steps or components of a regulated procedure,† usually in chronological order.

One of four levels of severity is assigned based on protocols that are:

Mild: includes procedures that give rise to slight or transitory minor adverse effects, including taking infrequent blood or tissue samples from an animal, and conducting skin irritation tests with substances that are expected to be non-irritant or mildly irritant.

Moderate: includes procedures such as injecting substances to produce antibodies, toxicity tests that do not involve lethal endpoints and many surgical procedures, provided that suffering is controlled and minimised by effective post-operative pain relief and care.

Substantial: includes procedures such as major surgery, toxicity testing leading to significant morbidity or death, and the use of some animals as disease models.

Unclassified: includes protocols in which animals are anaesthetised before a procedure starts and are killed at the end of the procedure without recovering consciousness.

The *Guidance on the Operation of the A(SP)A 1986* advises that the assessments of severity should be reviewed and revised as necessary during the lifetime of a project.

* *See: Guidance on the Operation of the A(SP)A 1986*, Chapter 5; Home Office (2005) *A(SP)A 1986 Application for a Project Licence*.

† See Box 13.1.

13.16 Section 5 (4) of the A(SP)A requires the Secretary of State to weigh the likely benefits from a project against the likely adverse effects on the animals.[15] In practice, this process is carried out by Home Office Inspectors who advise officials who in turn make the decision on behalf of the Secretary of State. This provision is frequently referred to as the 'cost-benefit assessment' (although the term is not itself used in the A(SP)A) and is widely regarded as the cornerstone of the way animal research is regulated in the UK (see paragraphs 3.58–3.61). While the ultimate decision on whether or not to grant a licence is made by the Secretary of State and his advisors, various other people and processes contribute to the cost-benefit assessment. A recent report by the APC, which examined in great detail the ways in which the cost-benefit assessment is, and should be, carried out, emphasised that *primary* responsibility for carrying out the assessment was held by the project licence holders.[16] The roles of other parties involved, such as the Home Office, the ERP and, where relevant, the APC, were described as 'to evaluate, advise, and in some cases adjudicate the researchers' own cost-benefit assessments' (see Figure 13.1).[17]

15 'In determining whether and on what terms to grant a project licence the Secretary of State shall weigh the likely adverse effects on the animals concerned against the benefit likely to accrue as a result of the programme to be specified in the licence.' See also *Guidance on the Operation of the A(SP)A 1986*, Appendix I, available at: http://www.archive.official-documents.co.uk/document/hoc/321/321-xi.htm. Accessed on: 6 May 2005.

16 See also *Guidance on the Operation of the A(SP)A 1986*, Appendix I, available at: http://www.archive.official-documents.co.uk/document/hoc/321/321-xi.htm. Accessed on: 6 May 2005.

17 Animal Procedures Committee (2003) *Review of the cost-benefit assessment in the use of animals in research* (London: Home Office), p77.

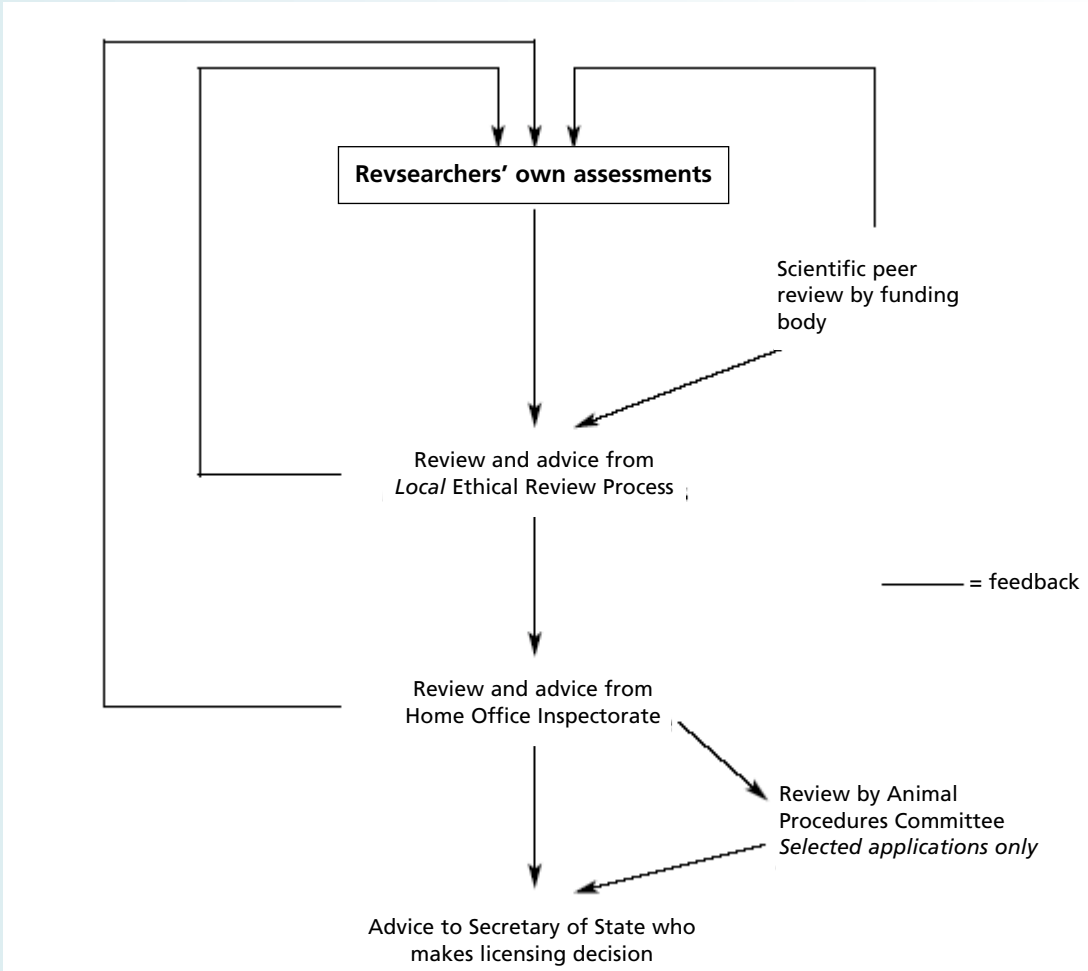

Figure 13.1: Relationship between the different people and processes involved in cost-benefit assessment of applications for project licences*

* Animal Procedures Committee (2003) *Review of the cost-benefit assessment in the use of animals in research* (London: Home Office), p71.

13.17 A project licence is not granted unless the Secretary of State (as advised) is satisfied that:

- the purpose cannot be achieved by any other reasonable and practicable method which does not use regulated procedures on protected animals;
- the minimum number of animals will be used, with the lowest degree of neurophysiological sensitivity;
- the procedures to be used are those that will cause the minimum distress or suffering to the animals;
- procedures are conducted under anaesthetic wherever this can be used to reduce suffering, unless it would interfere with the objective of the experiment.[18]

Animals are not permitted to be used in more than one protocol except in those circumstances where it would result in less animal distress or suffering overall than starting a new protocol with a new animal, or when animals need to be used for a series of procedures for a particular purpose. Any reuse is subject to approval by the Secretary of

18 See A(SP)A, Section 5 (5); *Guidance on the Operation of the A(SP)A 1986*, Chapter 5, available at: http://www.archive.official-documents.co.uk/document/hoc/321/321.htm. Accessed on: 4 May 2005.

State (as advised). Section 14 of the A(SP)A provides that no animal that has been involved in protocols that caused severe pain or distress may be reused. Similarly, animals that have undergone procedures under general anaesthesia cannot be reused unless the Secretary of State has given permission and certain specified conditions are met.

13.18 Project licences last for a maximum of five years. The holder of a licence is personally responsible for all procedures conducted on animals under that licence. Project licences only give authority to perform those procedures stated in the licence. Contract research organisations are granted somewhat broader licences for toxicity testing. These might permit the testing of defined classes of, for example, pharmaceuticals or other chemicals to assess their effects on specific organs of specified animals, or they may be licensed to undertake particular types of research, for example on embryo or fetal development. In quantitative terms, licences may permit the conduct of many individual techniques, ranging from a few to several hundred. To conduct any procedures that vary from the specifications of the licence constitutes a breach of the law or the terms and conditions of the licence, and renders the licence holder liable to disciplinary action (see Box 2.5 and paragraph 13.11).[19]

Certificates of designation

13.19 The holder of the certificate of designation is normally expected to be a senior manager or official in the establishment. This individual is personally responsible for ensuring that the establishment complies with the conditions of the certificate. The certificate holder is also required to nominate at least one person who has day-to-day responsibility for the health and welfare of all the animals in their charge, called the named animal care and welfare officer (NACWO). A named veterinary surgeon (NVS) to advise the certificate holder, licence holders, NACWOs and others about the health and welfare of the animals must also be nominated. As part of the conditions of the certificate, the holder is responsible for ensuring that the establishment complies with the appropriate Codes of Practice (see paragraph 13.10). They must ensure that proper records are kept about the source, use and eventual disposal of all animals.

The Home Office Inspectorate

13.20 The workings of the A(SP)A and the granting of the three types of licence described above is currently administered by the Home Office, rather than by other Government departments, to avoid possible conflicts of interest. Many other departments with responsibility for areas such as human health or the environment may be directly involved in animal research, for example by commissioning or funding research. The Home Office, by contrast, has no such involvement and has therefore been given the task of issuing licences. Its Inspectors are required to have medical or veterinary qualifications and are expected to have experience in scientific research. In 2004, there were 30 Inspectors who assisted in advising the Secretary of State in granting licences and any conditions that should be set. They also provide advice to certificate holders and others with a role under the Act on best practice in laboratory animal welfare. Inspectors make visits to research facilities to ascertain that licence authorities and conditions are being met. They have the right of access to any designated establishment to monitor compliance. At the end of 2003, there were 232 designated establishments in Great Britain. During 2003, the Inspectorate made 3703 visits to departments within establishments in addition to other visits for formal meetings. Over 50 percent of these visits were unannounced.[20]

19 See also footnote 10.

20 Home Office (2004) *Statistics of Scientific Procedures on Living Animals Great Britain 2003* (London: HMSO).

Ethical Review Process

13.21 Since 1999, each establishment is required to have in place an ERP as a standard condition on all certificates of designation.[21] The purpose of this process is to establish a local framework to ensure that all uses of animals are carefully considered and justified. An ethical review committee should provide independent advice to certificate holders and support to other staff with responsibility for animal welfare.

13.22 The provisions in the *Guidance on the Operation of the A(SP)A 1986* require that the review process includes:

- a named veterinary surgeon;
- representative(s) from among the named animal care and welfare officers;
- representative(s) of the project licence holder(s); and
- representative(s) of the personal licence holder(s).

Facilities are also encouraged, but not required, to involve people who do not use animals, including one or more lay members from outside the institution.

13.23 Functions of the ERP include (where appropriate):

- promoting the development and uptake of Reduction, Replacement and Refinement alternatives to animal use in procedures at the establishment;
- examining the likely costs and benefits of each licence application;
- providing a forum for discussion of issues relating to animal research, and consider how staff could be updated on relevant ethical advice, best practice and relevant legislation;
- undertaking retrospective reviews of licensed projects;
- considering the care and accommodation of animals at the establishment and the humane killing of protected animals;
- reviewing the establishment's managerial systems with respect to animal use;
- advising on staff training and ensuring competence.[22]

The order of this list is often understood to express a hierarchy of importance, and hence the two most important functions of the ERP are considered to be the promotion of the Three Rs and the review of the costs and benefits of research. However, depending on the type of research carried out at specific research facilities, those involved in the ERP may spend more time on other activities. In practice the review of protocols is often the primary focus.

Other aspects of the A(SP)A

Obtaining animals

13.24 Rats, mice and other commonly used laboratory animal species must be obtained from suppliers or breeders that have a certificate of designation and are subject to the same system of controls and inspection as establishments using animals in experiments.

21 See *Guidance on the Operation of the A(SP)A 1986*, Appendix J, available at: http://www.archive.official-documents.co.uk/document/hoc/321/321.htm. Accessed on: 4 May 2005.

22 *Guidance on the Operation of the A(SP)A 1986*, Appendix J, available at: http://www.archive.official-documents.co.uk/document/hoc/321/321.htm. Accessed on: 4 May 2005.

Genetically modified animals and harmful mutations

13.25 The breeding of animals that are intended for use as disease models, and the breeding of animals for other purposes which are known to cause pain, suffering or distress are classified as scientific procedures. Similarly, the breeding of any GM animal is currently classified as a scientific procedure, because of possible adverse implications for welfare.[23] In 2003, 27 percent of all animal procedures (764,000 in total) involved GM animals, more than treble that of 1995. Two thirds of these were used solely for the purpose of breeding, in order to develop and maintain 'GM lines'; they were not involved in any other procedure or experiment, although some of these animals, once killed, may also have been used to provide tissue for research purposes. The breeding of phenotypically normal animals (i.e. animals that are said to be as 'healthy' as the average wild type of the animal) does not count as a scientific procedure.[24]

Killing of animals

13.26 Animals that are not used in regulated procedures but killed in designated establishments to obtain tissue samples or because they are surplus to requirements are excluded from the controls of the A(SP)A if they are killed by one of the methods of humane euthanasia listed in Schedule 1 of the Act.[25] Certificate holders must ensure that humane killing is performed by a person who has been trained to use these methods competently.

Statistics about animal use and information about licences granted

13.27 The Home Office publishes detailed Annual *Statistics* on the numbers and species of animals used in scientific procedures in Great Britain, (see Appendix 2).[26] For reasons related to the licensing process and European reporting requirements, the *Statistics* focus on details about the annual number of procedures started and numbers of animals used for the first time in procedures started that year. Animals used in more than one series of procedures are only counted once (see paragraph 13.17). The *Statistics* do not give any information about the degree of pain and suffering that is actually experienced by animals involved in procedures. This is because the severity banding of procedures, protocols and projects is based on prospective assessments, and because information about severity bands assigned to particular projects relates to the estimated average suffering of all the animals involved (see Box 13.3 and paragraphs 15.25–15.34).

13.28 Section 24 of the A(SP)A makes it an offence for individuals with a function under the Act (i.e. the Minister, his officials and the APC) to disclose any information that they have received in carrying out that function and which they believe to be confidential.[27] Until 2005, practical application of this clause meant that very little information about animal research has been made public. Those wishing for more access argue that the recently implemented provisions of the Freedom of Information Act 2000 (FoI, see Box 13.4) imply that there ought to be more openness.

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23 See paragraph 4.57.

24 However, breeding facilities must have a certificate of designation.

25 Schedule 1 of the A(SP)A sets out 'Appropriate methods of humane killing'. For example, all protected animals may be killed by an overdose of an anaesthetic, using a route and an anaesthetic agent appropriate for the size and species of animal. Dislocation of the neck is permissible for rodents up to 500g, rabbits up to 1kg, and birds up to 3kg.

26 Statistics for Northern Ireland are published separately and not included in the Home Office Statistics for Great Britain. In 2000, 14,124 animals were used in Northern Ireland. See House of Lords Select Committee on Animals in Scientific Procedures (2002) *Animals in Scientific Procedures* (Norwich: HMSO), Chapter 1.

27 See also: Ministerial Statement announcing the outcome of the review of section 24 of the Animals (scientific Procedures Act 1986, 1 July 2004, available at: http://www.homeoffice.gov.uk/docs3/animalproc_wms_section24_040701.pdf. Accessed on: 4 April 2005.

Box 13.4: The Freedom of Information Act 2000 and its bearing on information about animal research

In 1997, the Government issued the White Paper *Your Right to Know* which led to the Freedom of Information Act 2000 (FoI Act). The FoI Act creates a statutory right of access to information held by public bodies (a definition that includes the Home Office, universities and publicly funded research institutes), provides for a more extensive scheme for making information publicly available and covers a much wider range of public authorities than previous legislation, including: local government, NHS bodies, schools and colleges, universities, the police and other public bodies and offices.* The Act enshrines in law the general right of access to (non-classified) information held by public authorities.† From 1 January 2005 information must be disclosed in response to any such requests made under the FoI Act.

There are also a number of exemptions from the requirement of disclosure, the most relevant ones being for vexatious or repeated requests, where the cost of providing the information would be excessive, information provided in confidence, information relating to the development of government policy, information which, if disclosed, might endanger the health or safety of any individual, information that constitutes personal data under the Data Protection Act and information that, if disclosed, might prejudice commercial interests. These exemptions are disputed by those who argue that they prevent them finding out sufficient information about licence applications and the results of cost-benefit assessments.

The implementation of the new Act with regard to animal research may not be straightforward. Reasons cited by stakeholders include:†‡

- concerns about further increases in the level of bureaucracy already required for complying with the provisions of the A(SP)A;
- concerns about confidentiality of researchers and targeting by those who use unlawful forms of protest;
- concerns about disclosed information being misinterpreted or misrepresented; and
- the Home Office could be required to make decisions about how commercial confidentiality applies to information it holds that relates to commercial companies.

It is difficult to predict the likely scale of information requests that research establishments might receive, and what kind of information may have to be disclosed. It may depend on the type of institution, research being undertaken and how well-known a particular institute is (as it is expected that the more well-known institutions might receive more requests for information). Before the FoI Act entered into force, details of ten project licences had been released by the Home Office to the BUAV, under a Code of Practice that preceded the full FoI Act. The licence applications were anonymised and the institutions involved were not revealed. Details of the purpose of the research, the number and type of animals to be used and the procedures were included.‡∫ In 2005, the Home Office published the first details of project licences granted under the A(SP)A in 'a contribution to greater openness and to contribute to greater public understanding and debate about the use of animals in science and how it is regulated'. Abstracts for several projects, written by licence holders, have so far been published on the Home Office website. The Home Office has announced its future intention to publish details of all new licence applications in this way.** However, those who would like to find out more information regarding the way the cost-benefit assessment is applied consider that these licences abstracts provide insufficient details. We consider the question of openness further in paragraphs 15.35–15.36.

* The FoI Act applies to all recorded information held by public authorities in England, Wales and Northern Ireland and cross-border public authorities. Scotland is covered by a separate act (Freedom of Information (Scotland) Act 2002).

† HMSO (2000) Explanatory Notes to Freedom of Information Act 2000, available at: http://www.hmso.gov.uk/acts/en2000/2000en36.htm. Accessed on: 4 May 2005; Freedom of Information Act 2000 available at: http://www.hmso.gov.uk/acts/acts2000/20000036.htm. Accessed on: 4 May 2005.

‡ LASA (2004) Freedom of Information *The Forum* **1**(3).

∫ Festing S (2004) Freedom of Information Act deadline looms *RDS News* Autumn 2004.

** Home Office (2005) Animal Procedures: Licence abstracts, available at: http://www.homeoffice.gov.uk/comrace/animals/abstracts.html. Accessed on: 4 May 2005.

Developments in policy

13.29 Since the full implementation of the A(SP)A, a number of changes in the regulatory system have been introduced as a matter of government policy. In the early 1990s, training requirements for all new applicants for personal and project licences were instituted. The Home Office issued a policy statement to make clear that the successful completion of training modules was viewed as necessary in order to meet the requirement in the A(SP)A that licence holders have 'appropriate education and training'.

13.30 In 1997, the Home Office effectively ruled out certain types of animal research: the toxicity testing of cosmetics and (in 1998) their ingredients, alcohol products or tobacco products.[28]

28 House of Lords Select Committee on Animals in Scientific Procedures (2002) *Animals in Scientific Procedures*, Chapter 1; *Guidance on the Operation of the A(SP)A* 1986, Chapter 5, available at: http://www.archive.official-documents.co.uk/document/hoc/321/321.htm. Accessed on: 4 May 2005.

It issued a policy statement to the effect that, in making the cost-benefit assessment, these tests were no longer considered a sufficient benefit to justify any use of animals. In addition, it was announced that, other than in very exceptional circumstances, the use of the great apes would be considered too great a cost to be justified by any possible benefit.[29]

13.31 There have also been other policy developments, concerning controls on the importation of primates,[30] the use of the ascites method to produce monoclonal antibodies (see paragraphs 5.26 and 11.10), the use of certain toxicology procedures (Box 11.2) and the housing and husbandry of certain laboratory species, which have also been introduced by policy statements or the publication of supplementary codes of practice.[31]

Recent issues of public debate

13.32 The debate in the UK about issues raised by the regulation of animal research is led mainly by a number of national campaigning organisations and some local grass-roots activists who are opposed to animal research (Box 2.4). These groups question whether or not the provisions of the A(SP)A are always interpreted correctly and whether, in practice, they are properly implemented. Some campaigning organisations and activists assert that there is a need for undercover investigations (see Box 2.5). Scientific and medical researchers have responded by creating organisations to communicate their views to the public (see paragraph 2.30 and Box 2.4).

13.33 In general, there has been criticism of the lack of openness about animal research in the UK. Some campaigning groups would like access to applications for project licences to comment on, and where necessary challenge, whether they should be granted (see Box 13.4 and paragraphs 15.35–15.36). Notwithstanding their methodological limitations, surveys of public opinion suggest a widespread lack of trust in the regulation of animal research combined with a lack of understanding about what is done and how it is regulated (paragraph 1.14). The use of primates in research and testing has raised ethical and animal welfare related concerns for many years, and has also been the subject of several campaigns by animal protection organisations. For example, the RSPCA has issued several reports on this issue and initiated campaigns 'to reduce the numbers of primates used and to replace them with more humane alternatives'.[32]

13.34 Further issues are provoked by Section 5 (5) of the A(SP)A which prescribes that licences will only be granted if a non-animal method that could produce the knowledge sought by means of the animal procedure is unavailable. Many campaigning organisations assert that a number of alternatives to using animals in research exist but are not used as widely as they could be in research and testing.[33] Some believe that there are already sufficient alternatives for all research uses of animals to be replaced immediately. Others take the view that existing alternatives are used where possible, but believe that with more effort and funding, it would be possible to develop many new alternatives that could reduce the need to use animals (see paragraphs 11.6–11.30). We return to these issues in Chapter 15.

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29 Animal Procedures Committee (2003) *Review of the cost-benefit assessment in the use of animals in research* (London: Home Office).

30 Where an alternative method is practically available and effective. The use of wild-caught primates has also been abandoned as a matter of policy unless exceptional and specific justification can be established.

31 For example Home Office (1995) *Code of practice for the housing of animals in designated breeding and supplying establishments*, available at: http://www.homeoffice.gov.uk/docs/cop_hcasp.html. Accessed on: 4 May 2005.

32 RSPCA (2005) Primates, available at: http://www.rspca.org.uk/servlet/Satellite?pagename=RSPCACampaigns/Primates/PrimatesHomepage. Accessed on: 4 May 2005.

33 For example, Dr Hadwen Trust, available at: http://www.crueltyfreeshop.com/drhadwen/faq.htm. Accessed on 6 May 2005.

International regulation

13.35 The basic principles that underlie the regulation of animal research are very similar in all countries in which animals have legal protection. Regulations specify the conditions under which animals may be used and seek to ensure that harms are minimised as far as possible. They are usually implemented through review of proposed research projects, applying the Three Rs where possible and assessment of the general standards of laboratory animal housing and husbandry.

13.36 However, countries differ in the complexity and detail of regulations, and the manner and strictness with which they are implemented and enforced. Some countries do not have national regulatory systems and use guidelines or policies developed by individual institutions. For example, Canada relies on a well-developed voluntary system of self-regulation based upon protocol review by institutional Animal Care Committees, which operate according to guidelines set out by the Canadian Council on Animal Care.[34]

13.37 The system of project review by an institutional committee is the most common method of self-regulation in most countries. Committees typically involve scientists with experience in the field and veterinary staff. In some cases, these committees have a broader membership which includes animal technicians, non-technical staff of the institution, external lay members or representatives with an interest in animal welfare.

13.38 In many countries, the detailed operation of these committees is controlled by agencies that fund research. The USA has an extensive system of Institutional Animal Care and Use Committees (IACUCs), created by the Animal Welfare Act and its regulations.[35] The Act covers the use of warm-blooded animals in research, but excludes rats, mice and birds. The IACUCs operate according to the more detailed policies and guidance published by the National Institutes of Health.[36] Australia uses a similar system of Animal Ethics Committees, created under state legislation, but operating in accordance with the code of practice produced by the National Health and Medical Research Council.[37]

13.39 Within Europe, there are two, almost identical, legal instruments. They are the Council of Europe *Convention for the protection of vertebrate animals used for experimental and other scientific purposes* (ETS 123, 1986), and the EU *Directive EEC 86/609 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes*. The legal status of these instruments differs. Member States of the Council of Europe can decide whether or not to ratify the Convention by implementing it in their national legislation. By contrast, Member States of the EU are legally obliged to implement the goals set out in the Directive. All have transposed the Directive in their national or regional legislation, although the European Commission has referred several countries to the European Court of Justice to ensure that their legislation is fully in accordance with the Directive.

34 See *Canadian Council on Animal Care*, available at http://www.ccac.ca/. Accessed on: 4 May 2005.

35 US Department of Agriculture *Animal Welfare Act and Regulations*, available at: http://www.nal.usda.gov/awic/legislat/usdaleg1.htm. Accessed on: 4 Apr 2005.

36 See the Report of House of Lords Select Committee on Animals in Scientific Procedures (2002) *Animals in Scientific Procedures* (Norwich: TSO) for a description of the US system of regulating animal research. In the USA there is no legal obligation to report the numbers of mice and rats used in experiments. The system of regulation means that privately funded companies that use only rats, mice and birds are not subject to the same federal regulations or inspections as those that apply for researchers and institutions that receive federal funds.

37 National Health and Medical Research Council (2004) Australian code of practice for the care and use of animals for scientific purposes, 7th Edition, available at: http://www.nhmrc.gov.au/publications/pdf/ea16.pdf. Accessed on: 4 May 2005.

13.40 The main current provisions of the EU Directive are that:

- establishments conducting animal experiments must be registered with the authorities and maintain the housing and husbandry of the animals according to a standard set out in an annex to the Directive;
- experiments must only be conducted by, or under the direct responsibility of, a competent, authorised person, who should have appropriate education and training;
- animals cannot be used if another, scientifically satisfactory, method is available;
- experiments must be designed to use the minimum number of animals, the species with the lowest neurophysiological sensitivity and to cause the least pain, suffering, distress or lasting harm, compatible with the purpose of the experiment;
- wild-caught animals are not used unless necessary for the experiment;
- the experiments to be performed, or the details of the individuals who will perform them, must be notified in advance to the authorities;
- experiments that may cause severe pain that is likely to be prolonged must be justified in advance and authorised by the authorities;
- statistical information on the numbers and types of experiments conducted must be collected by the authorities; and
- breeding and supplying establishments must be registered and comply with the same standards as experimental establishments.

13.41 There is a significant variation in the national systems for regulating animal research introduced under the Directive. Member States are permitted to adopt stricter measures if they wish. Several countries have done so, including the UK. The UK system is widely considered to be the most comprehensive and detailed in the EU (and throughout the world). Nevertheless, there are some countries that regulate specific aspects of animal research that are not regulated in the UK. For example, training requirements are more detailed in The Netherlands, and provisions for freedom of information are more liberal in Sweden.

13.42 Most EU countries originally implemented the Directive with 'external' regulation, which means that authorisations for research projects are given by national or local government officials. Some countries opted for a system in which local or regional animal ethics committees authorise research involving animals. None of the EU countries have implemented systems of self-regulation.

13.43 The system of regulation in most Member States uses either one or two licences. The main licence usually covers the research or testing activities of an institution and serves as the registration of the establishment and the licence for the research to be conducted. Other countries use separate licences for the institution and the projects, which may include details of the personnel who will carry out the research. For example, in France the personal licence is akin to the project licence in the UK; applicants submit an application that includes broad details of the intended project.[38]

13.44 To fulfil the requirement in the Directive for 'verifying that the provisions of this Directive are properly carried out', most Member States have established a system of inspection of establishments that conduct animal experiments. This function is usually added to the role of local veterinary inspectors, whose primary role is to inspect agricultural use of animals. Very few countries have statutory systems of inspection dedicated exclusively to animal research. In

38 House of Lords Select Committee on Animals in Scientific Procedures (2002) *Animals in Scientific Procedures* (Norwich: TSO), Chapter 1.

The Netherlands there are three inspectors for the 600,000 animals used annually (see paragraph 13.20). In the USA, only institutions that conduct research involving certain classes of animal covered by the Animal Welfare Act are subject to inspections from the US Department of Agriculture. Additional levels of inspection operate for institutions that receive federal funds. The non-governmental Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) also carries out inspections of accredited institutions. Accreditation is voluntary but includes most large companies and major universities as accreditation is an important factor for securing contracts and funding.[39]

13.45 Since the Directive was adopted in 1986, there has been a trend towards increased and more detailed regulation in many Member States.

- France, The Netherlands and some parts of Spain have added a system of local animal ethics committees to their previously existing systems of control.
- Austria, The Netherlands, Sweden and the UK have abandoned the use of great apes in scientific procedures, although they had not been used in the UK and Sweden for some years.[40] With the voluntary retirement of a colony used in vaccine development in Austria, no great apes were used in the EU in 2002, the last year for which statistics are available.[41]
- The Netherlands and the UK have ceased using animals for testing cosmetics or cosmetic ingredients. Germany and Austria have introduced partial bans, permitted testing under some circumstances. More recently, a ban on the use of animals within the EU for the testing of cosmetics has been passed and is due to come into force in 2009 (and sales within the EU will not be allowed after 2013). However, there are certain exceptions for particular types of test and the EU Directive on cosmetics testing on animals is currently under legal challenge from the French Government.[42]
- The Netherlands and the UK have banned the acute oral LD_{50} test (see paragraph 9.14 and Box 11.2), with very limited exemptions.

13.46 Under the Council of Europe's Convention ETS 123 there are periodic meetings of representatives of the Member States and relevant non-governmental organisations to 'examine the application of this Convention, and the advisability of revising it or extending any of its provisions'. In 1997, the revision of Appendix A to the Convention, which gives guidelines for the accommodation and care of laboratory animals, was agreed. The revised Appendix A will include details about the husbandry and housing of all the principal laboratory animal species. It is expected that the Council of Europe will adopt the new Appendix in 2005. Since the EU ratified the Convention, Appendix A will be adopted as a revised Annex II to Directive EEC 86/609.

13.47 In 2001 the European Commission proposed that Directive EEC 86/609 should itself be revised. This process started in 2003 when the Commission formed four Technical Expert Working Groups (TEWGs) to offer advice on how the existing Directive could be improved. Discussions are currently in progress but it is likely that a revised Directive will not be adopted for several years. The provisions of the new Directive will be transposed into national legislation once the revisions have been agreed.

39 *Ibid*. Chapter 1.

40 Great apes have not been used for research in the UK since the passing of the A(SP)A in 1986. See House of Lords Select Committee on Animals in Scientific Procedures (2002) *Animals in Scientific Procedures* (Norwich: TSO), Chapter 1.

41 European Commission (2005) *Fourth Report on the Statistics on the number of animals used for experimental and other scientific purposes in the Member States of the European Union* (Brussels: EC).

42 Directive EC 2003/15 amending Council Directive EEC 76/768 on the approximation of the laws of the Member States relating to cosmetic products.

Regulations requiring the use of animals

13.48 So far, we have concentrated on regulation that authorises and prescribes the ways in which animals can be used in research, seeking to minimise possible harm. As we have said (see paragraphs 8.22 and 9.4), animal research is also undertaken because regulations at both the national and international levels stipulate that medicines, vaccines and chemicals for use in agriculture, industry, food and household products must be tested for efficacy and safety. Some regulations require that animals must be used, whereas others merely require that tests must be undertaken according to best practice, which is often interpreted as requiring the use of animals. Companies and institutions within countries such as the UK, which are members of many different international organisations and operate in international markets, are also subject to overlapping legislation and guidelines.

Testing of medicines

13.49 In the UK, new medicines must meet the requirements of the Medicines Act 1968 in order to be licensed. The Act states that a medicine must demonstrate that it is safe, effective and of high quality and this is usually interpreted as requiring testing on animals.[43] EU legislation, particularly Directive EC 2001/83 on the Community code relating to medicinal products for human use, now takes precedence over the Medicines Act, which has been amended several times to align with new requirements. The Directive requires that all new prescription medicines are studied in animals before they are tested in humans. It states that before a new medicinal product can be marketed in the EU, the producer shall obtain authorisation by the appropriate competent authority (either the national regulatory agency or the EMEA). Article 8 (3) stipulates that an application to one of these agencies shall include: 'Results of: physico-chemical, biological or microbiological tests, toxicological and pharmacological tests, [and] clinical trials'. The exact requirements, standards and protocols for both animal and non-animal tests are described in detail. For example, single-dose toxicity shall be assessed by the following protocol:

> 'The acute toxicity test must be carried out in two or more mammalian species of known strain unless a single species can be justified. At least two different routes of administration shall normally be used…'[44]

13.50 In other countries, medicines are licensed through equivalent regulatory authorities such as the Food and Drug Administration (FDA) in the US and the Ministry of Health, Labour and Welfare in Japan. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) coordinates the pharmaceutical regulatory authorities of Europe, Japan and the USA (see paragraph 12.8). It aims to harmonise guidelines on quality, safety and efficacy in its member countries. Certain of its safety guidelines specify that animal research should be performed.[45]

Testing of chemicals

13.51 Primary UK legislation requiring the testing of chemicals includes the following: the Health and Safety at Work Act 1974, the Consumer Protection Act 1987 and the Food Safety Act 1990. These acts mostly implement the provisions of corresponding EU directives. The OECD

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43 See *Animals in Medicines Research Information Centre*, available at: http://www.abpi.org.uk/amric/basic5.asp. Accessed on 5 May 2005.

44 EU Directive EC 2001/83, Annex 1, Part 3 *Performance of Tests: Toxicity*.

45 See *The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)*: Safety Guidelines, available at: http://www.ich.org/UrlGrpServer.jser?@_ID=276&@_TEMPLATE=254. Accessed on: 5 May 2005.

has harmonised the testing of new chemical compounds across member countries, including the UK, USA, Japan, France and Germany. Certain OECD testing guidelines require the use of animals.[46] These are a collection of methods developed by OECD member countries for identifying the hazards of chemical substances (see paragraphs 9.5 and 12.8).

Differences in international test guidelines

13.52 There is some variation in the data and methods that different national regulatory authorities are willing to accept, when assessing, for example, the safety or efficacy of new medicinal or agrochemical products. Although organisations such as ICH and OECD aim to achieve a certain degree of harmonisation, it is often the case that a single chemical that is marketed in a number of countries might need to be tested several times for toxic effects, in order to satisfy national standards. For example, during the Working Party's fact finding meeting with experts from the Home Office, reference was made to a licence that had been granted for vaccine trials on primates involving procedures of substantial severity. This type of animal use typically involves the immunisation of animals with a candidate vaccine, and subsequent exposure to the infective organism. A range of different doses of the vaccine are then administered, to assess its efficacy and safety. The test requirements and methods are generally set at European or higher supra-national levels and usually require that the test be continued until it becomes clear that the animals have not survived the disease. The Home Office took the view that trials should be stopped at an earlier stage if the scientific objective can be achieved. At the time of writing, the matter was being discussed with relevant stakeholders and regulators to encourage the development and adoption of such measures, and to identify earlier endpoints for studies.[47] However, different conceptions of what qualifies as sufficient scientific evidence for the safety and efficacy of new chemicals, different frameworks for liability and compensation, as well as general political disagreements between nations, all contribute to complications in the harmonisation of laws and guidelines on animal testing. We continue the discussion on the international context of animal research in paragraphs 15.84–15.87.

Summary

13.53 We have described important aspects of the national and international regulatory framework governing research involving animals. In doing so, we have focused on legislation for the protection of animals, briefly summarised regulation relating to the requirement of animal tests, and highlighted difficulties in the harmonisation of different national policies. We described the historical background to the A(SP)A, its principal provisions, and the three types of licence that govern all animal research in the UK: personal licences, project licences and certificates of designation. In carrying out the cost-benefit assessment, which is fundamental to the A(SP)A, the primary responsibility lies with the researchers planning a new project. In addition, a number of other people and processes are involved, and it would be fallacious to assume that only the inspectors of the Home Office are responsible for carrying out this assessment. The Home Office publishes annual statistics about the numbers of animals used in research. These contain information about prospectively assigned severity banding of granted project licenses but `do not provide

46 See OECD (1993) *Chemicals Testing: OECD Guidelines for the Testing of Chemicals – Sections 1–5*, available at: http://www.oecd.org/document/22/0,2340,en_2649_34377_1916054_1_1_1_1,00.html. Accessed on: 4 Apr 2005.

47 This is consistent with the current general approach of the Home Office, which requests that a trial should be stopped if signs occur that reliably predict the death of the animal. If such signs manifest themselves, the animal is to be humanely killed, instead of dying from the disease, see Home Office (2003) *Animals (Scientific Procedures) Act 1986: Guidance on the Conduct of Regulatory Toxicology and Safety Evaluation Studies*, revised June 2003, available at: http://www.homeoffice.gov.uk/docs2/regtoxicologydraftrevision4_03.html. Accessed on: 5 May 2005.

details about the levels of pain, suffering and distress actually experienced by animals. The ERP is critically important. Three of its most significant functions are to act as a forum for discussion of the Three Rs, to consider ethical and regulatory issues raised by animal research and to undertake an initial cost-benefit assessment before a licence application is passed to the institute's certificate holder.

13.54 As has become clear during the discussions of members of the Working Party and also from responses to our Consultation, views differ on whether the provisions of the A(SP)A are sufficient in scope and detail; whether they are always interpreted correctly; and whether, in its practical application, the legal requirements are always implemented effectively. For example, respondents to the Consultation made the following observations:

> 'I'm not sure that present regulations are appropriate. For one thing how can researchers tell if there will be welfare problems in advance?'
> *Anonymous*

> 'Current provisions for the assessment of welfare of animals are rigorous and of high quality, but must be continuously revised and improved as our knowledge and understanding increases… Assessments of welfare should be conducted before, during and after a project.'
> *Biosciences Federation*

> 'Although inspection is important, it is the culture of care at a particular establishment which is paramount. In this regard, the Ethical Review Process mandated by A(SP)A is I believe unique to UK legislation. The Home Office Inspectors play a valuable role in education and sharing of best practice in this activity.'
> *Anonymous*

> 'Legal protection for GM animals is inadequate and changes in the law are required in order to afford them due consideration. This is, not least, because their use, certainly on its current scale, was not foreseen when that legislation was introduced.'
> *Animal Aid*

> 'The current licensing system proscribes everything which is not specifically permitted on an individual project basis, rather than legislating what may and may not be done by everybody in order to maintain standards of welfare. This has generated a vast bureaucracy which undoubtedly impedes the progress of science.'
> *Dr R M Ridley and Dr H F Baker*

> 'Significant tightening of regulation would make either research more difficult, increase costs and delay patient benefits or move research off shore to less detailed regulatory climates, at a significant cost to the UK's science base as well as to the welfare of the animals involved.'
> *Genetic Interest Group*

13.55 The Working Party's conclusions and recommendations with regard to regulatory aspects of animal research are presented in Chapter 15 (see paragraphs 15.53–15.56 and 15.84–15.87). So far we have reviewed the wide scope of costs and benefits arising from the uses of animals in different areas (Chapters 4–9), as well as the current state and potential of the Three Rs (Chapters 11 and 12) and the regulatory framework. We now consider how these findings should be viewed from an ethical perspective.