Home Office

Guidance on the operation of the Animals (Scientific Procedures) Act 1986

March 2014

Revisions

In December 2023, this guidance was amended to:

- delete Chapter 9 on Training, which has been replaced by the Guidance on Training and Continuing Professional Development under the Animals (Scientific Procedures) Act 1986 (ASPA), published on GOV.UK;
- replace references to Chapter 9 with references to the Guidance on Training and Continuing Professional Development under ASPA;
- make minor grammatical corrections following proof-reading.

Further review and substantive update to this guidance is planned.

CONTENTS

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FOREWORD

Changes to the Animals (Scientific Procedures) Act 1986

The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (SI 2012/3039) amend the Animals (Scientific Procedures) Act 1986 (ASPA) to transpose European Directive 2010/63/EU on the protection of animals used for scientific purposes. The Directive sets out revised measures for the protection of animals used for scientific purposes.

What this guidance covers

This guidance is issued under the terms of section 21(1) of ASPA and provides information about the way in which the Secretaries of State for the Home Department and for Northern Ireland propose to exercise their powers under the Act.

The guidance provides information and advice on:

- the scope and main provisions of the amended Act;
- the responsibilities of those with roles under the Act;
- licences granted under the Act, including the terms and conditions of their issue;
- severity classification, humane killing and the accommodation and care of animals, including the status of Annex 3 to the Directive and current UK Codes of Practice.

The guidance is intended to be a reference document that explains how ASPA is administered and enforced. In general, we use the term ‘must’ to indicate mandatory elements, ‘should’ to indicate what we strongly recommend, and ‘may’ to indicate optional elements. Those working under the Act are expected to be aware of all sections of the guidance and should be familiar with those sections that are relevant to their activities and responsibilities. The guidance does not set any additional compliance requirements beyond those of the Act and the conditions included in licences.

What this guidance replaces

This guidance replaces the “Guidance on the operation of the Animals (Scientific Procedures) Act 1986 (HC321)” published on 23 March 2000.

Who this guidance is for

This guidance is for everyone involved with animals that are bred for, supplied for, or used in scientific procedures. This includes:

- holders of establishment licences, project licences and personal licences;
- those killing animals;
- named persons such as Named Veterinary Surgeons (NVSs);
- members of establishment Animal Welfare and Ethical Review Bodies (AWERBs);
- others working in licensed breeding, supplying and user establishments;

- new licence applicants and prospective named persons;
- Home Office inspectors;
- members of the Animals in Science Committee (ASC);
- others with an interest in this area.

How the guidance is arranged

Section 1 sets out the background to the Animals (Scientific Procedures) Act 1986 (ASPA).

Section 2 describes the principles of replacement, reduction and refinement (the 3Rs) and choice of methods.

Sections 3 to 5 give details of establishment licences, personal licences and project licences respectively.

Section 6 covers humane killing of protected animals and Section 7 the Code of Practice on the care and accommodation of protected animals.

Section 8 describes the duties of named persons, including Named Animal Care and Welfare Officers (NACWOs), Named Veterinary Surgeons (NVSs), Named Information Officers (NIOs) and Named Training and Competency Officers (NTCOs).

Section 9 covers Training and Section 10 Animal Welfare and Ethical Review Bodies (AWERBs).

Sections 11 to 14 give details of Home Office inspections, non-compliance, the Animals in Science Committee (ASC) and other advisers to the Secretary of State.

Standard conditions for section 2C (establishment), personal and project licences are contained in the Appendices A to C.

Appendix D contains Schedule 1 on appropriate methods of killing.

Appendix E sets outs procedures for representations under ASPA.

Appendix F contains Annex 6 of the Directive, listing elements referred to in Article 37(1)(c).

Appendix G reproduces Annex 8 of the Directive on severity classification.

Appendix H contains Home Office guidelines on the use of neuromuscular blocking agents.

Appendix I describes how we carry out a harm–benefit analysis of each application for a project licence.

How to submit applications

Application forms and details of where to send them are available on the Research and testing using animals page on the GOV.UK website.

Where to go for more information

General enquiries about this guidance and the ASPA should be sent to our central email address (ASPA.London@homeoffice.gsi.gov.uk) where they will be dealt with and a response sent as soon as practicable. You can also telephone us on 020 7035 0477.

If you have specific queries relating to an establishment or a programme of work you may need to contact your local inspector. You can obtain contact details for your inspector either through your local Home Office liaison contact, or by using the above email address or phone number.

GLOSSARY OF TERMS

3Rs	The principles of replacement, reduction and refinement
ACHM	Animals containing human material – as categorised in the AMS report on that subject
Actual severity	The actual intensity of pain, suffering, distress or lasting harm experienced by an animal in a procedure or series of procedures. It should be the highest level experienced at any point during the course of the procedure and should take into account any cumulative effects
AMS	Academy of Medical Sciences
Animals Directive	European Directive on the protection of animals used for scientific purposes (2010/63/EU)
ASC	The Animals in Science Committee – the independent, non-departmental public body set up under ASPA sections 19 and 20
ASPA	The (Scientific Procedures) Act 1986 as amended by the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 incorporating changes brought in by the European Directive (2010/63/EU) on the protection of animals used for scientific purposes – also referred to as the Act
ASRU	The Animals in Science Regulation Unit. ASRU is the unit of the Home Office responsible for implementing ASPA and comprises inspectors, licensing officers and those responsible for policy
Authorised breeder or supplier	A breeder or supplier in another EU Member State, authorised in accordance with Article 20 of the Directive
AWERB	Animal Welfare and Ethical Review Body
Benefits	See "Likely benefits" below
Codes of Practice	Codes issued under section 21 of ASPA
Commission	European Commission
Complex or multidisciplinary programme	A programme of such complexity that it requires an additional 15 days for assessment over and above the usual 40 days
Cumulative effect	The effect which occurs where, in a series of procedures, a second or subsequent procedure has a compound effect, which may be positive or negative, in terms of causing pain, suffering, distress or lasting harm
Directive	Unless otherwise stated, this refers to the European Directive on the protection of animals used for scientific purposes (2010/63/EU)
Establishment	A place holding a licence which has been granted under section 2C of ASPA
Establishment licence	A licence granted under section 2C of the Act, also known as a 'section 2C licence'
EU	European Union
EU Directive	European Directive on the protection of animals used for scientific purposes (2010/63/EU)
Harms	See "Likely harms" below
Harm–benefit analysis	An analysis in which the likely adverse effects ofa procedure within a project are weighed against the potential benefits of the project for people, animals or the environment
HOLC	Home Office liaison contact. This title is often used by establishment licence holders to denote one or several key contacts for communication with the Home Office

Humane end-point	Clear, predictable and irreversible criteria that allow early termination of a procedure before an animal experiences harm that is not authorised or scientifically justified
IAT	Institute of Animal Technology
Inspector	An inspector in ASRU appointed under ASPA section 18
LASA	Laboratory Animal Science Association
LAVA	Laboratory Animals Veterinary Association
Licensed breeding Establishment	An establishment which is authorised by a licence granted under ASPA section 2C to breed Schedule 2 animals for use in regulated procedures, or for their tissues, or to breed any other protected animals primarily for those purposes
Licensed supplying Establishment	An establishment which is authorised by a licence granted under ASPA section 2C to hold Schedule 2 animals bred elsewhere for supply to another establishment
Licensed user Establishment	An establishment which is authorised by a licence granted under ASPA section 2C to use animals in regulated procedures
Likely benefits	The benefits for people, animals or the environment which are considered achievable if the project objectives are successfully met
Likely harms	The pain, suffering, distress or lasting harm likely to be experienced by animals during the course of the procedures within a project after applying all appropriate refinement techniques
Member State	Member State of the European Union
NACWO	Named Animal Care and Welfare Officer
NC3Rs	National Centre for the Replacement, Refinement and Reduction of Animals in Research
NCO	Named Compliance Officer – a term sometimes used for the Named Person Responsible for Compliance
NIO	Named Information Officer
NPRC	Named Person Responsible for Compliance (the preferred term, also sometimes referred to as a Named Compliance Officer)
NTCO	Named Training and Competency Officer
NVS	Named Veterinary Surgeon
Pain, suffering, distress and lasting harm	Includes anything that affects the animal's physical, mental and social well-being, including disease, injury and physiological or psychological discomfort, whether occurring immediately (such as at the time of an injection) or in the longer term (such as the consequences of applying a carcinogen)
PEL holder	The holder of a section 2C (establishment) licence under ASPA
PIL holder	The holder of a personal licence under ASPA
POLE	Place other than a licensed establishment (formerly known as a 'PODE')
PPL holder	The holder of a project licence under ASPA
Primate	Non-human primate
Procedure	An act of commission, deliberate omission or permission applied to, or having any effect on, an animal
Prospective Severity	The intensity of pain, suffering distress or lasting harm which any animal subjected to a protocol is likely to experience during the course of that protocol after applying all the appropriate refinement techniques
Protected animals	All living vertebrates, other than a human, including certain immature forms, and any living cephalopod

Protocol	A procedure or series of procedures carried out for a particular purpose as part of an authorised project
RCVS	Royal College of Veterinary Surgeons
Regulated procedure	A procedure which is regulated under ASPA
Retrospective assessment	The formal assessment required in the Directive (Article 39) of specific types of projects, either during or at the end, to determine, amongst other things, whether the objectives have been achieved and whether lessons can be learnt to further the implementation of the 3Rs
Retrospective review	One of the tasks set out in the Directive (Article 27(d)) requiring the AWERB to follow the development and outcome of all projects carried out at the establishment and identify and advise on the implementation of the 3Rs
RSPCA	Royal Society for the Prevention of Cruelty to Animals
Severity	The intensity of the pain, suffering, distress or lasting harm experienced by an animal during a procedure
Severity classification	The process of assigning a severity category to a protocol. It may be sub-threshold, mild, moderate, severe or non-recovery. It is based upon the greatest degree of pain, suffering, distress or lasting harm likely to be experienced by any animal within that protocol after applying all appropriate refinement techniques
Severity limit	The highest level of pain, suffering, distress or lasting harm that may be experienced by any animal undergoing an authorised procedure (or series of procedures). It should normally be expressed as a humane end-point in relation to an adverse effect which may be expected to occur. Hence a procedure may have a number of severity limits which apply at different times in relation to different adverse effects
Technique	A single action carried out on an animal as part of a procedure or series of procedures
The Act	The Animals (Scientific Procedures) Act 1986 as amended by the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 incorporating changes brought in by the European Directive (2010/63/EU) on the protection of animals used for scientific purposes – also referred to as ASPA

1. BACKGROUND TO THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

1.1 What does the Act cover?

The Animals (Scientific Procedures) Act 1986 (ASPA) regulates procedures that are carried out on 'protected animals' for scientific or educational purposes that may cause pain, suffering, distress or lasting harm.

The Act also regulates the breeding and supply of certain species of animals for use in regulated procedures or for the scientific use of their organs or tissues.

The Act also regulates the methods used to kill protected animals.

1.2 What licences are required?

ASPA has a three-level licensing system (for the *person*, the *project* and the *place*):

- those carrying out regulated procedures must hold a 'personal licence', which authorises them to apply those procedures to specified animals, initially under supervision until they have demonstrated competence;
- the regulated procedures to be carried out must be authorised by a '*project licence*', which specifies the programme of work within which the procedures are being performed;
- the place at which the work is carried out must normally be specified in an '*establishment licence*'.

Those breeding and/or supplying the species of animal listed in ASPA Schedule 2 must also hold an establishment licence.

The conduct of regulated procedures may be authorised at Places Other than Licensed Establishments (POLEs) when the nature of the work makes this necessary, and these places will be specifically identified in the relevant project licences.

1.3 Who issues licences?

Licences are issued by the Home Office in England, Scotland and Wales and by the Department of Health, Social Services and Public Safety (DHSSPSNI) in Northern Ireland.

1.4 What is a protected animal?

1.4.1 Definition

Under the Act, a 'protected animal' is 'any living vertebrate, other than man, and any living cephalopod'.

1.4.2 Embryonic and fetal forms of mammals, birds and reptiles

Embryonic and fetal forms of mammals, birds and reptiles are protected animals once they have reached the last third of their gestation or incubation period.

Larval forms of fish and amphibians are protected animals once they are capable of feeding independently. Cephalopods are protected animals from the point when they hatch.

A procedure carried out on a fetal, larval or embryonic form at an earlier stage of development may be a regulated procedure (see **Section 1.6** below).

NB. Before you plan or perform regulated procedures on fetal, larval or embryonic forms, you should have a thorough knowledge of the gestation and incubation periods of the animals you are using and the stage of development they will reach during the course of your work.

1.5 How does the Act define 'living'?

A protected animal is living until its circulation stops permanently or its brain is destroyed.

ASPA considers a *decerebrate animal* to be living, and therefore protected, because its circulation is functioning and its brain is not completely destroyed.

You will need personal and project licence authority to decerebrate an animal and to use these animals in regulated procedures.

1.6 What is a regulated procedure?

A procedure is regulated if it is carried out on a protected animal for a scientific or educational purpose and may cause that animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by inserting a hypodermic needle according to good veterinary practice. This is referred to as the 'lower threshold'.

Regulated procedures may be acts:

- of commission, for example, an action such as dosing or sampling; or
- of deliberate omission, for example, withholding food or water; or
- of permission, for example, the natural breeding of animals with harmful genetic defects.

There are also established thresholds for regulating these and other procedures, such as psychological stress, changes to diet and environmental changes. Please refer to **Section 5.12** on severity categories. We can also advise you about these on a case-by-case basis. Please seek advice from an inspector or contact us on our central email address (ASPA.London@homeoffice.gsi.gov.uk) or telephone us on 020 7035 0477.

A procedure is also regulated if it is performed on an embryonic, fetal or larval form of a protected animal that has not yet reached the stage of development when it becomes a protected animal if the immature form is allowed to live until after it reaches that stage of development and at that stage the procedure may cause the animal pain, suffering distress or lasting harm above the lower threshold.

For example, you will need personal and project licence authorities to carry out regulated procedures on an embryonated bird egg if you manipulate the embryo during the first two-thirds of the incubation period and then allow the embryo to survive into the final third of the incubation period. If, on the other hand, you kill the embryo before the start of the final third of the incubation period, you will not need licence authorities for this procedure.

1.7 What procedures are regulated?

Procedures that are regulated include:

- *modifying the genes of a protected animal* if this has the potential to cause the animal pain, suffering, distress or lasting harm; for example, breeding mice with harmful genetic defects is a regulated procedure if you intend to keep the animals produced beyond two-thirds of the way through their gestation period;
- *those performed under anaesthesia or analgesia* if the effect on the animal without the anaesthetic or analgesic would be to cause pain, suffering distress or lasting harm;

- *administering an anaesthetic, an analgesic or other measure* to sedate or dull the perception of pain in a protected animal (unless used as part of a Schedule 1 method of killing – see **Section 6** on Humane killing);

- *humane killing of a protected animal* at a licensed establishment other than by either a method described as appropriate in Schedule 1 or a method specified on your establishment licence (see **Section 6** on Humane killing);

- *removing organs, blood or other tissue* under general anaesthesia even if the animal is not allowed to recover consciousness (as neither has the circulation ceased nor has the brain been destroyed, the animal is still living and therefore is a protected animal).

Procedures may also be regulated under ASPA if they are:

- *part of a series or a combination of non-regulated procedures* which together may cause the animal pain, suffering, distress or lasting harm – for example, multiple or cumulative minor changes to the environment may disturb the animal sufficiently to be regulated, even if each individual change would not warrant regulation in itself;

- anything that is done *for the purpose of, or liable to result in, the birth or hatching of a protected animal* that may, as a result of the procedure, experience pain, suffering, distress or lasting harm.

1.8 What procedures are not regulated?

These are not regulated procedures.

- *Non-experimental clinical veterinary practices:* You should consult the Royal College of Veterinary Surgeons (RCVS) on what constitutes non-experimental clinical veterinary practices and the related professional standards. The clinical investigation and management of the health or welfare of animals is generally considered to be non-experimental clinical veterinary practice when it involves an intervention which is of direct benefit to the animal or its immediate peer group. See the RCVS website for further guidance.

- *Veterinary clinical trials:* Veterinary clinical trials required to be carried out for marketing authorisations of veterinary medicinal products are a requirement of the Veterinary Medicines Regulations 2011 (et seq.). Applications for Animal Test Certificates should be submitted to the Veterinary Medicines Directorate. If you propose to carry out procedures which are likely to exceed Recognised Veterinary Practice (in the view of RCVS), including withholding veterinary treatment, you should consult the Veterinary Medicines Directorate.

- *Non-experimental agricultural practices and practices undertaken for the purpose of recognised animal husbandry:* These are not regulated procedures as long as they comply with other animal welfare legislation and regulations and are being used to manage or conserve animals. *The procedures are regulated if they are being performed for a scientific purpose and may cause pain, suffering, distress or lasting harm above the lower threshold.*

- *Identifying animals:* Ringing, tagging or marking an animal primarily to identify it as a specific individual, or using any other humane way to do so, are not regulated procedures if they cause no more than momentary pain and no lasting harm. For example, micro-chipping or ear-marking a rodent is not a regulated procedure if it is being done *primarily* to identify the animal. Tissue obtained as a genuine by-product of ear marking may be used for genotyping without altering the non-regulated status of the procedure. *Blood sampling or DNA sampling using a method likely to cross the lower threshold of pain, suffering, distress or lasting harm, such as removal of the tail tip in mice, are not methods used to individually identify an animal and would therefore be regulated.* For practical purposes, this means that if the same technique is applied to an animal

for both identification and genotyping simultaneously, this should be interpreted as having been primarily for identification and therefore not a regulated procedure.

- *Humane killing of animals:* Killing a protected animal in a licensed establishment by an appropriate humane method listed in **Schedule 1**, or by a method specified in that establishment's licence, is not a regulated procedure. This is still the case if the animal is killed by these methods at the end of a series of regulated procedures, or to provide material for scientific use. Killing a protected animal at a POLE by an appropriate humane method listed in **Schedule 1**, is not a regulated procedure. The killing of protected animals, whether by a **Schedule 1** method or another method, must comply with the requirements of **ASPA section 15A** (see **Section 6**). A copy of Schedule 1 detailing approved methods of humane killing is at **Appendix D**.

1.9 Preventing public displays

It is an offence under ASPA to perform procedures as an exhibition to the general public or to be shown live on television. It is also an offence to advertise such events.

Filming of procedures for later editing or broadcast is not an offence. However, conducting a procedure for the sole purpose of broadcast is not permitted.

2. THE 3RS AND CHOICE OF METHODS

European Directive 2010/63 and the amended ASPA require that comprehensive project evaluation, taking into account ethical considerations associated with the use of animals, forms the core of project authorisation, and requires the implementation of the principles of replacement, reduction and refinement (the 3Rs) in those projects. Furthermore, the principles of the 3Rs also extend to the breeding, accommodation and care of protected animals.

2.1 The principles of replacement, reduction and refinement (the 3Rs)

For the purposes of **ASPA** section **2A**:

- *Replacement* is the principle that, wherever possible, a scientifically satisfactory method or testing strategy not entailing the use of protected animals must be used instead of a regulated procedure.

- *Reduction* is the principle that, wherever a programme of work involving the use of protected animals is carried out, the number of protected animals used must be reduced to a minimum without compromising the objectives of the programme; on occasions it may be necessary to use a greater number of animals than the absolute minimum scientifically justifiable if each individual animal will suffer less as a consequence of the greater number being used. The principle of reduction should apply to methods of breeding protected animals as well as their use in procedures.

- *Refinement* is the principle that, wherever a programme of work involving the use of protected animals is carried out (after rigorously applying the principles of replacement), the regulated procedures applied to those animals must be refined so as to eliminate or reduce to the minimum any possible pain, suffering, distress or lasting harm. As indicated above, refinement and reduction must be considered in balance. Refinement applies to the methods of breeding, accommodation and care of protected animals as well as the methods used in procedures.

2.2 How should the 3Rs be applied?

2.2.1 Establishment licence holders' responsibilities for the 3Rs

The first standard condition of the establishment licence requires that the holder must put in place measures to ensure that the regulated activities carried on at the establishment are carried out in a manner that is consistent with the principles of replacement, reduction and refinement (the 3Rs) **[Standard Condition 1]**.

The Animal Welfare and Ethical Review Body (AWERB) should be a key source of advice to the establishment licence holder on these matters (see **Section 10**), as also should all the Named Persons (see **Section 8**).

2.2.2 Project licence holders' responsibilities for the 3Rs

Project licence holders are required to ensure that their programme of work does not involve any regulated procedures for which there is a scientifically satisfactory alternative method or testing strategy that does not entail the use of a protected animal. Such methods may include specific *in vitro* or *in silico* procedures as well as consideration of weight-of-evidence decision strategies. Such decision strategies may indicate that no animal tests, or no further animal tests, are reasonably justified in order to address the question posed **[Standard Condition 2]**.

In relation to regulatory requirements, where an alternative non-animal test exists for obtaining the result sought and is recognised as meeting the European regulatory requirement, an animal test may not be carried out (see **Directive Article 13**[1]).

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF

As per **Standard Condition 4** of a project licence, the programme of work must, as far as practicably possible, ensure that the regulated procedures are those which:

- use the minimum number of animals to achieve the objectives;
- involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;
- cause the least pain, suffering, distress or lasting harm; and
- are most likely to provide satisfactory results.

See Section 5.11 for further details on the 3Rs in relation to project licences.

2.2.3 Personal licence holders' responsibilities for the 3Rs

The responsibilities conferred on personal licence holders through standard licence conditions include the requirement that the licence holder shall act at all times in a manner that is consistent with the principles of replacement, reduction and refinement **[Standard Condition 1]**.

These responsibilities are further expanded upon in Section 4.13.3.

2.3 Death as an end-point

Death as an end-point must be avoided as far as possible and replaced with an early and humane end-point.

Where death as an end-point is unavoidable for the purpose of achieving the scientific aims of the procedure, measures should be taken to ensure as few deaths as possible and to reduce the duration and intensity of suffering prior to death to the minimum possible. The responsibility for implementing this requirement lies with both project and personal licence holders.

Project Licence **Standard Condition 9:**

> 9 The licence holder shall ensure that where a regulated procedure is applied to an animal as part of the specified programme of work, death as the end-point of the procedure is avoided as far as possible and is replaced by an early and humane end-point; and as soon as the purpose of the procedure has been achieved, the procedure is stopped and appropriate action is taken to minimise the suffering of the animal.

Personal Licence **Standard Condition 4:**

> 4 The licence holder shall ensure that where the holder applies a regulated procedure death as the end-point of the procedure is avoided as far as possible and is replaced by an early and humane end-point.

Appropriate analgesics or anaesthetics must be used wherever necessary unless specifically contra-indicated; for example, if there is compelling scientific justification to withhold them and this is justified in the project licence. Additional methods of ameliorating suffering should also be employed, such as the provision of extra nesting material or heat pads, or ensuring animals can easily remain hydrated.

Development of expertise in predicting the clinical signs that indicate that death is inevitable must be used to refine the humane end-points as the work progresses. Where death as an end-point is being justified at the time of application for a project licence, the applicant must commit to developing and using such expertise. Frequent monitoring during periods of expected high incidence of deaths must be used to ensure timely application of humane end-points.

2.4 Surplus animals from breeding programmes

Proper management of breeding programmes should ensure that the correct number of animals are produced to meet requirements and that the breeding of animals unsuitable for procedures is minimised. Where animals are being bred under a project licence (e.g. genetically altered animals), it is the responsibility of the project licence holder to minimise surplus breeding. Where animals are being bred under a breeding establishment licence, it is the responsibility of the establishment licence holder to minimise surplus breeding.

The following approaches should be used to minimise surplus breeding:

- plan projects carefully and with sufficient time built in to breed animals for specific requirements;
- apply proper experimental and statistical designs in advance to accurately predict and minimise the number of animals you need;
- justify any rigid requirements for particular characteristics (for example, sex, weight or age) within a properly designed study; for example, requiring only one sex is likely to result in 50% of the animals bred being surplus;
- collaborate with other users at your establishment and other places to share animals and tissues wherever feasible;
- question the need for small, often in-house, breeding colonies of common strains where acquiring animals from larger colonies may lead to less surplus being bred;
- cryopreserve strains, or share with others who can cryopreserve;
- keep records of surplus animals and regularly review the reasons for surplus being bred.

A helpful role for your AWERB may be to:

- raise awareness of surplus breeding with the aim of minimising any wastage of animals;
- devise policies and controls to minimise surpluses;
- co-ordinate and rationalise users' needs, animal production and breeding facilities.

2.5 Data sharing

Article13 of the Directive requires that procedures must not be applied to an animal if the data are already available (e.g. published and readily accessible) in another Member State and have been obtained by procedures which satisfy (i.e. validated and recognised by) any relevant regulatory requirements of the EU. It follows that we encourage the sharing of data wherever possible, whether generated for regulatory purposes or otherwise, to ensure that studies are not duplicated. This is achieved through peer-reviewed publications and presentations at scientific meetings.

In addition, as part of the delivery of the Government's commitment to work to reduce the use of animals in scientific research, an effort is being driven by Research Councils and the NC3Rs to improve resource sharing, including outcomes of research, resources, animals and data. Examples include the NC3Rs' Infrastructure for Impact scheme, the ShARM biorepository of aged mouse tissues, the Centre for Macaques' efforts to share non-human primate tissues and co-ordinated mouse phenotyping efforts (e.g. the International Mouse Phenotyping Consortium). NC3Rs and other research funders are also considering additional ways to enhance data sharing and to give access to negative results.

We expect all those authorised to use animals in their research to also play a part in such data-sharing opportunities.

2.6 Duplication of studies

Whilst measures to avoid duplication of studies should be taken, including search and review of available data, good scientific practice may sometimes require the replication of studies, either to confirm their accuracy or to validate the methodology. In these circumstances, replication may be permitted if scientifically justified in a project licence.

2.7 Thematic reviews of the 3Rs

Article 58 of the Directive requires the Commission to carry out periodic, thematic reviews of the 3Rs in consultation with Member States. Although the obligation to carry out reviews is on the Commission and does not require transposition, we believe that similar reviews can play an important part in ensuring the effective operation of ASPA. We therefore propose to carry out our own thematic reviews and to consult the Animals in Science Committee, practitioners and other interest groups, including animal welfare and patient advocacy groups, in determining suitable topics as well as on the reviews themselves. We will also encourage the Commission to ensure that Europe-wide thematic reviews are carried out.

3. ESTABLISHMENT LICENCES

3.1 What does an establishment licence cover?

Under **ASPA section 2B**, you may not carry on an undertaking involving any of the activities listed below unless you are authorised to do so in an 'establishment licence' granted under **ASPA section 2C**. In this context 'undertaking' means 'enterprise, venture, business or operation'. In this guidance we refer to a licence granted under section 2C as an 'establishment licence'. The activities referred to above are:

a) applying regulated procedures to protected animals (referred to in this guidance as a *licensed user establishment*);

b) breeding protected animals listed in **ASPA Schedule 2** with a view to (i) their use in regulated procedures, or (ii) the use of their tissues or organs for scientific purposes (referred to in this guidance as a licensed breeding establishment);

c) breeding other protected animals (not listed in **ASPA Schedule 2**) *primarily* for the same purposes (also a *licensed breeding establishment*);

d) the keeping of **Schedule 2** animals which have been bred elsewhere and are to be supplied with a view to (i) their use elsewhere in regulated procedures, or (ii) the use elsewhere of their tissues or organs for scientific purposes (referred to in this guidance as a *licensed supplying establishment*).

An establishment engaging in any of the activities listed above must be authorised for each of the activities accordingly. For example, a user establishment in which genetically altered mice of a potentially harmful phenotype are bred under the authority of a project licence must also be authorised as a breeding establishment if it also breeds genetically normal mice for use in procedures there or somewhere else.

Similarly, a breeding establishment must also be authorised as a user establishment if, for example, any of the animals bred there are genetically altered and of a potentially harmful phenotype.

Authorisation as a supplying establishment is required only for establishments holding Schedule 2 animals that have been bred elsewhere, including outside of the UK, and are to be supplied to another establishment for use in regulated procedures or for scientific use of their tissues or organs.

A breeding establishment does not require authorisation as a supplier to hold and supply animals that have been bred on its premises for scientific use elsewhere.

3.2 What must an establishment licence include?

An establishment licence must include:

- details of the holder of the licence;
- details of the 'named persons' required by **ASPA section 2C(5)**; and
- a schedule of premises.

3.3 Who can hold an establishment licence?

An establishment licence may be held by a natural person (an individual) or a legal person (a corporate entity such as a pharmaceutical company or a university or research institute with corporate status).

An establishment licence holder must be subject to jurisdiction within the United Kingdom in order that the Secretary of State can apply sanctions under ASPA should that become appropriate. Hence an establishment licence holder must have either personal residence or company registration in the UK. Likewise, an establishment which is part of government can only hold an establishment licence in the name of an individual, not as a corporate entity.

Where the holder is a corporate entity, the ultimate legal responsibility of the establishment licence holder will be carried by the individual legally accountable for the corporate entity (usually a Company Secretary). However, we recognise that this individual may be remote from work under ASPA and will therefore delegate responsibility for compliance to the *Named Person Responsible for Compliance* (NPRC) (see below and **Section 8 Named persons**) who, for all practical purposes, will fulfil the role and responsibilities of the establishment licence holder. Nevertheless, the ultimate legal responsibility lies with the corporate entity.

Standard Condition 3 of the establishment licence requires that the licence holder shall notify the Secretary of State of any proposed changes to the full name of the holder. In legal terms, such a change requires reconsideration of the suitability of the proposed new holder in terms of **section 2C(2)** and may require a new establishment licence (particularly where a corporate entity becomes a new company due to takeovers, mergers, etc.). However, provided that the Secretary of State is satisfied that the requirements of **section 2C(2)** are met, a pragmatic policy decision may be made to merely amend the existing licence.

Any changes to the name of the holder (whether individual or corporate) must take place simultaneously with the transfer of legal authority, i.e. on the day of replacement of the individual or change of the company status. In practical terms, this means that the licence change should take place within 24 hours of the organisational change. ASRU has the facility to post-date such changes so that they can come into effect on the expected date of the change of the legal authority at the establishment. For corporate entities, it is important to consider these implications as part of any corporate changes and commence discussions with ASRU well in advance. It is the responsibility of the establishment licence holder to put systems in place which ensure that appropriate authorities are in place at all times. See also **Section 3.6** in relation to the death of an establishment licence holder.

3.4 What training do I need to complete as an establishment licence holder or person responsible for ensuring compliance?

You are expected to have undertaken relevant ethical and legislative training or to already have equivalent knowledge (see Guidance on Training and Continuing Professional Development under ASPA, published on GOV.UK).

If you are a new establishment licence holder we recommend that you take additional training relevant to your role. Courses aimed at the establishment licence holders are arranged by the Laboratory Animal Science Association through their forum.

3.5 How long will my establishment licence last?

An establishment licence remains in force until it is revoked. Inspectors will normally review the establishment licence with PEL holders at least annually.

For further information, see **Section 3.15 What happens if your establishment licence is varied, revoked or suspended?**

3.6 Death or departure of an establishment licence holder

An establishment licence will cease to have effect in the event of the departure of the licence holder from the establishment. In practical terms, this means that the licence change should take place within 24 hours of such

an organisational change. In order to provide continuity, ASRU will require adequate notice to consider such an application for amendment or for a new licence.

ASRU cannot take a lenient view in the event of failing to promptly replace the name of the establishment licence holder. Only in very unusual circumstances, for example, in the event of sudden death of the holder or unexpected departure overseas, can ASRU react urgently to support steps taken to arrange continuity of authorities within 24 hours. It may be that a temporary nomination will be agreed upon in such an emergency situation, with a requirement to gain our agreement to a more permanent nomination within 28 days.

3.7 Before you apply for a new or amended establishment licence

Before you fill in your application form, you should collect all the necessary details including those of all the named persons at your establishment and of the area/s where animals are going to be held and/or used in procedures.

You will also need to request authorisation for any methods of killing you intend to use that are not specified in **Schedule 1** and for setting free or re-homing animals once procedures are complete. A method of killing specified in an establishment licence is an 'appropriate method' under **ASPA section 15A** (see **Section 6 Humane killing**) only when, on the basis of scientific evidence provided by you, it is considered at least as humane as a method listed in Schedule 1 as being appropriate for the type of animal.

You may find it helpful, at an early stage, to discuss your proposed application with the inspector assigned to your establishment. If applying for a new establishment licence, you may obtain contact details for the relevant inspector by emailing ASPA.London@homeoffice.gsi.gov.uk or by calling 020 7035 0477.

Application forms and details of where to send them are available from the Research and testing using animals page of the GOV.UK website.

3.8 Named Persons

Establishment licences must specify named individuals **[ASPA section 2C(5)]** who are responsible for the following activities:

- ensuring that the requirements of ASPA and conditions of the licence are complied with – *the Named Person Responsible for Compliance* (NPRC). This will normally be the holder of the establishment licence unless the licence is held by a corporate entity in which case it should be an individual with sufficient seniority to fulfil the role;
- overseeing the welfare and care of the animals – the *Named Animal Care and Welfare Officer* (NACWO);
- ensuring that those dealing with animals have access to any information they need about the species they are using – the *Named Information Officer* (NIO);
- ensuring that those dealing with animals are adequately educated, trained and supervised until they are competent and that appropriate further training continues – the *Named Training and Competency Officer* (NTCO);
- advising on the health, welfare and treatment of the animals – the *Named Veterinary Surgeon* (NVS) – who must be a member of the RCVS with expertise in laboratory animal medicine for the species being used in the establishment. Exceptionally, you may be able to nominate another suitably qualified expert where you can show that they are more appropriate for this role – for example, a specialist in fish health. We will normally consult the RCVS if you propose to nominate another suitably qualified expert to ensure no member of the RCVS is suitable.

In proposing the named persons for your establishment licence, you are also required to provide details of their qualifications (**Standard Condition 3**). By this we mean the combination of knowledge, skills and experience that qualifies them to be suitable for the proposed role. Whilst formal qualifications may be relevant, they should not be your sole consideration, and you do not need to routinely notify us when any of your named persons gain further qualifications.

A number of sources are available to help establishment licence holders identify appropriate individuals for some of these roles. For example, the RCVS maintains a Register of Members which can be searched by location on the RCVS website (http://findavet.rcvs.org.uk/check-the-registers/). Similarly, the Institute of Animal Technology (IAT) also maintains a Register of Laboratory Animal Technologists who may be appropriate to fill an NACWO post. Further details are available at www.iat.org.uk.

All the named persons should help you as the holder of the establishment licence (or NPRC in the case of a licensed corporate entity) to fulfill your responsibilities. They should all be actively involved in the local Animal Welfare and Ethical Review Body (AWERB) (see **Section 10**).

With the exception of the NPRC, it may be appropriate for more than one individual to fulfill the role of the named person in each category. Where this occurs, each person should have a clear understanding of their individual responsibilities. You must make arrangements for adequate care in the event any of the named persons is unavailable **[Standard Condition 16]**.

Named persons should be promptly replaced if their responsibilities change such that they are unable to continue in their named person role. Your establishment licence will need to be amended accordingly.

In addition, you may find it helpful to appoint one or several individuals to act as key contacts with the Home Office, liaising over licence applications and other matters. Such individuals are often called Home Office liaison contacts (HOLCs). However, there is no legal obligation to appoint HOLCs and they are not named on your establishment licence.

Example: Establishment A is a medium-sized academic establishment located on two geographical sites two miles apart. Mammalian work is done at both sites and aquatic work at just one. The establishment licence holder is a senior member of staff, an individual rather than a corporate entity, so she is also the NPRC. She has named the following on her establishment licence:

- one NIO;
- two NTCOs, one responsible for those working with mammals (who also happens to be the NIO), and the other for those doing aquatic work – the latter is also the NACWO for the aquatic unit;
- six NACWOs, each responsible for a different animal unit; and
- two NVSs, one for each site. They cover both sites on an out-of-hours duty rota.

She has also appointed one HOLC to assist licence applicants and to liaise with ASRU over licence applications. The HOLC is also the NTCO for those working with mammals and the NIO and provides administrative support to the AWERB. She has put in place arrangements to ensure that the HOLC receives all communications directed to her as an establishment licence holder and cascades those communications as appropriate to others in the establishment.

3.9 Schedule of Premises

Establishment licences contain a ‘Schedule of Premises’ listing the specific areas within the establishment where protected animals may be bred, held, used in regulated procedures and/or killed. These are referred to as ‘approved areas’ of an establishment, and the ‘Schedule of Premises’ provides a comprehensive list for inspectors (and your named persons) of those areas where animals may be bred, held, used and/or killed.

At a licensed establishment, you may carry out the following activities only in approved areas (subject to the nature of your licence – breeding, supplying and/or user):

- applying regulated procedures to protected animals;
- holding protected animals that are being, or have been used, in regulated procedures; or are being, or have been, kept for use in regulated procedures;
- breeding **ASPA Schedule 2** animals for use in regulated procedures, or the scientific use of their tissues or organs; or other protected animals (not listed in **ASPA Schedule 2**) *primarily* for the same purposes;
- holding **ASPA Schedule 2** animals which have been bred elsewhere and are to be supplied for use elsewhere in regulated procedures, or for the scientific use elsewhere of their tissues or organs;
- killing protected animals which:
    - are being or have been used in regulated procedures;
    - are being or have been kept for use in regulated procedures;
    - have been bred for use in regulated procedures; or
    - are being or have been kept for supply for use in regulated procedures;
- killing protected animals for the scientific use of their tissues or organs.

Your Schedule of Premises will specify the 'class or classes of use' for each area in your Schedule of Premises. By 'class of use', we mean the use to which the approved area or areas may be put, such as 'long-term animal holding', 'short-term animal holding', 'conducting non-sterile procedures' and 'conducting sterile procedures'.

You need to ensure that your staff are aware of what use is suitable for specific areas. For example, you may have a small area within a laboratory which might be suitable for killing animals but is not suitable for other regulated procedures, or for holding animals for more than a brief period. In such cases the Schedule of Premises may contain specific restrictions if we consider them appropriate. But you should ensure that you do not permit use which could negatively affect animal welfare without prior authorisation.

Your Schedule of Premises will also list the types of animal that may be held or used at your establishment, but it is not necessary to specify which of the approved areas may be used to hold each type of animal.

If your current Schedule of Premises is more detailed, you do not need to apply for an amendment and you may ignore the additional specifications which limit the use of approved areas to particular types of animal. You should, however, ensure that areas used are suitable for the species housed there, and be constantly aware that any change of use of your establishment which could negatively affect animal welfare must be authorised by us in advance.

3.10 Installations and equipment

You can find details of required installations and equipment in the Code of Practice on the care and accommodation of protected animals (which can be found on the Research and testing using animals page of the GOV.UK website).

3.11 How quickly will my application be decided?

We will aim to inform you of our decision within 40 working days of receiving your complete and correct application.

3.12 How we will assess your application for an establishment licence?

An inspector will assess your application against the requirements of **ASPA section 2C** and will advise the Secretary of State on whether, and on what terms an establishment licence should be granted. As part of that assessment the inspector will visit your establishment to verify that all of the requirements set out above have been met. Applications for amendment will be assessed in a similar manner, although a visit by the inspector may not always be necessary.

3.13 Your responsibilities as an establishment licence holder

3.13.1 Overview

Establishment licence holders (or, in the case of a corporate entity, the NPRC) have a number of responsibilities:

- providing leadership;
- ensuring compliance;
- ensuring the 3Rs are applied as fully as possible;
- ensuring your establishment has enough staff;
- setting up and running an Animal Welfare and Ethical Review Body;
- the performance and conduct of named persons;
- avoidance of conflicts of interest;
- ensuring animals have appropriate care and accommodation;
- countersigning project licence applications;
- record-keeping and ensuring appropriate identification of animals;
- maintaining a register of those competent (initially under supervision) to kill protected animals.

3.13.2 Leadership

You will need to be proactive and provide effective leadership. You will need good management and communication skills and the commitment to nurture a 'culture of care' in your establishment.

You should be representative of the governing authority of the establishment, for example, as the director of a research institute, a university registrar or the chief executive officer of a company.

You must be familiar with the provisions of ASPA and know what your responsibilities are under it. You should have sufficient seniority and authority to fulfill these responsibilities and, at the same time, take an active interest in the care and use of animals at your establishment.

3.13.3 Compliance

You are responsible for ensuring compliance at your establishment with all aspects of ASPA and with the terms and conditions of the establishment licence. You must put in place robust systems to prevent unauthorised procedures **[Standard Condition 20]** and to ensure compliance with the terms and conditions of any personal licences and project licences held at your establishment. You should be the best person in your establishment to do this.

You must put in place systems to ensure the appropriate personal and project licences are in place before any animals are used in regulated procedures. We strongly recommend that your management systems ensure that no one carries out procedures until you have received a copy (paper or electronic) of the relevant licence authorities. Also. that each personal and project licence holder knows that they have the appropriate authority before they perform any procedures.

You are responsible for putting in place systems to ensure those working at your establishment are competent, and your NTCO will assist you in achieving this. As people get older it is inevitable that general health and fitness will begin to deteriorate and this may impact an individual's ability to continue to fulfil their licence responsibilities.

Advice from the APC in 1991 recommended that particular attention should be given to licensees who are known to have retired or have reached the age of 70. For such licensees, you should ensure their performance is reviewed regularly with the following aims:

- to determine whether some or all of their licence authorities are still required;
- to review their training and competence records, particularly for personal licensees actively carrying out regulated procedures; and
- to ensure they continue to be appropriately supported by the general systems of control at your establishment.

You should keep records of such reviews and make them available to inspectors upon request.

3.13.4 The 3Rs

You must put in place systems which ensure that activities at your establishment follow the principles of the 3Rs – replacement, reduction and refinement. This applies to breeding protected animals, keeping them for supply and using them in procedures (see **Section 2**) **[Standard Condition 1]**.

3.13.5 Staffing

You must have enough trained and competent staff to maintain a high standard of all support functions, including animal husbandry, care and facility maintenance, at all appropriate times.

You are responsible, through your NTCO, for making sure that all staff are adequately educated and trained before they work with any protected animals or that they are supervised until they are competent **[Standard Condition 5]**.

You must also see that licensees, those applying for licences and anyone else who comes into contact with animals can access the education and training they need to do their job competently and that they take measures to maintain their competence.

3.13.6 Animal Welfare and Ethical Review Body

You must ensure that your establishment has an Animal Welfare and Ethical Review Body (AWERB) complying with the requirements of **Standard Condition 6** of the establishment licence (see **Section 10**).

You must keep records of the advice provided by the AWERB and decisions taken in response to that advice **[Standard Condition 6]**.

3.13.7 Performance and conduct of named persons

You are accountable to us for the performance and conduct of your named persons **[Standard Condition 15]**. When you nominate a new named person, you must provide sufficient information for us to judge their suitability. If we subsequently have good reason to believe that a named person is unsuitable, or not doing their job properly, we may vary, suspend or revoke your licence unless you can resolve the problem immediately or can nominate

someone else to take over their role through an appropriate amendment (see also **Section 3.16** regarding your right to appeal our decision).

You should ensure that named persons have the necessary authority to carry out their roles. All project and personal licence holders and other staff dealing with animals should seek and follow the named persons' advice on the health, welfare and use of animals, both at the planning stage and when work is in progress. They should also follow their advice on how to gain and maintain competence.

Named persons must be able to access licences and other documents about the production, care and use of animals at your establishment. They must be given appropriate training and resources.

You should put systems in place to ensure arrangements are made for the care and welfare of animals when the NVS or NACWO are unavailable **[Standard Condition 16]**.

3.13.8 Conflicts of interest

All those working under ASPA in your establishment should avoid conflicts of interest that may affect their judgement. It is recognised that minor conflicts of interest may be unavoidable, particularly in small establishments, in which case you should make certain that your AWERB is informed and ensures that appropriate attention is given to the development and outcome of the affected projects and programmes.

Given their role in providing independent advice on animal welfare, you must particularly avoid any scientific, financial or other conflicts of interest among those carrying out the role of NVS or NACWO. In order that we can be assured of this at the time of their nomination, the people proposed for these roles should provide you with a declaration detailing any relevant potential conflicts of interest, including:

- financial interests such as directorships and significant shareholdings;
- significant scientific and/or financial interests in the outcome of a programme of work;
- interests of close relations and/or friends which may be relevant, for example, if a partner or sibling is a director or major shareholder of the establishment; and
- any other relevant matters.

A suitable declaration form is available on the Research and testing using animals page of the GOV.UK website and you should ensure such a declaration is completed for each new NVS or NACWO. You will be required when nominating a new NVS or NACWO to assure us that you have done this. It follows that it would not normally be acceptable for you to fill the role of NVS or NACWO, given that you would be self-certifying.

You should regularly review these declarations for all your NVSs and NACWOs, and retain records which show that you have done so. These records should be available for inspectors to check. You should also require these named persons (NVS and NACWO) to inform you promptly about any significant changes to their declarations and you must then decide whether such changes render them no longer suitable for their role. In that event, you must nominate someone else to take over their role without delay.

In addition, for any protected animal undergoing regulated procedures, at least three people should fill the five key roles of: establishment licence holder, project licence holder, personal licence holder, NACWO and NVS. Furthermore, we will normally wish the establishment licence holder to *not* also hold a project licence.

Also, when an NVS or NACWO has a substantial interest in the scientific or financial outcome of a programme of work, you should arrange alternative provision such as nominating an alternative NVS or NACWO to be responsible for the veterinary or welfare oversight of the animals in question.

Your NTCO is required to endorse each application for a new or amended personal licence, which is requesting primary availability at your establishment. If your NTCO holds, or may wish to hold, a personal licence, you will need to nominate a second NTCO to independently endorse any applications made by the first NTCO.

Please ask us for advice if you are in any doubt about a potential conflict of interest.

3.13.9 Animal care and accommodation

You are responsible for making sure that all protected animals at your establishment have appropriate care and accommodation **[Standard Condition 4]**.

Unless your establishment licence or any relevant project licence provides a specific exemption, you must put systems in place which ensure that:

- the environment, housing, freedom of movement, food, water and care you provide for each animal, as well as its social structure, are appropriate for its health and well-being;
- the fabric, installations, equipment and environment of the approved areas meet, or are better than, the minimum standards set out in the Code of Practice on care and accommodation, 2013 (see **Section 7**);
- conditions for transporting an animal are appropriate for its health and well-being;
- any restrictions on an animal's physiological and behavioural needs are kept to an absolute minimum;
- the health and well-being of all protected animals and the environmental conditions in all areas of the establishment where protected animals are kept are checked at least daily by a competent person **[Standard Condition 4]**;
- any avoidable pain, suffering, distress or lasting harm is prevented in a timely way and, if this is discovered, is eliminated as quickly as possible;
- quarantine and acclimatisation facilities are provided and used when needed **[Standard Condition 18]**;
- there are adequate security measures to prevent animals from escaping and unauthorised intrusions **[Standard Condition 17]**;
- there are adequate fire precautions **[Standard Condition 19]**; you should also consider appropriate measures to deal with other disasters such as flooding and power cuts;
- the use of rooms or other areas is as described in the licence **[Standard Conditions 12 and 13]** and all those with responsibilities under ASPA have details of these approved areas.

Any changes to the use of the approved areas of your establishment which, in your judgement after taking advice from your AWERB and named persons, may have a negative effect on animal welfare must first be authorised by amending your licence **[Standard Condition 3]**.

If you wish to use types of animals not already specified in your licence, or to use areas not listed in the schedule to your licence, you must first be authorised by amending your licence **[Standard Condition 13]**.

3.13.10 Countersigning project licence applications

You, or someone you have designated, must countersign each request for a project licence or amendment involving work at your establishment, confirming that the application has completed local review by your AWERB.

3.13.11 Death or unexpected departure of a project licence holder

You must tell us about the death of a project licence holder within seven days of finding out about it. The project licence may remain in force for a further 28 days to allow you to complete work in progress or obtain a new licence. During this time, you are responsible for conducting the project **[Standard Condition 22]**. In the event of the unexpected departure of a project licence holder, you must similarly tell us about it within seven days of finding out about it, and if you wish to continue work under the project licence, a pragmatic policy decision may be made to allow the licence to remain in force for a further 28 days during which time you will be responsible for conducting the project.

3.13.12 Identifying animals

You should have processes in place that ensure that personal licence holders have properly labelled each cage and confinement area holding animals for which they are responsible (see **Section 4** on Personal licences for details). Cages or confinement areas containing animals that are not undergoing a regulated procedure must be labelled with a cage reference/area reference which identifies the animals held, by individual or batch.

Dogs, cats and primates housed at your establishment must be provided with a permanent means of identification **[Standard Condition 10]**. This does not necessarily need to be an external marking such as a tattoo but may instead involve a less painful method such as inserting a microchip.

For the purposes of this section, an *unmarked* animal is one that does not already have such a permanent means of identification. You must, therefore, put systems in place to make sure that:

- before any unmarked dog, cat or primate is weaned, it is given a permanent individual means of identification in the least painful way;
- before any unmarked dog, cat or primate that has not been weaned is transferred to another establishment, it is given a permanent individual means of identification unless it is impractical to do so;
- in the above case, a record of its mother is kept until the animal has been given a permanent individual means of identification; and
- where an unmarked dog, cat or primate is transferred to your establishment after being weaned, it is given a permanent individual means of identification as soon as possible.

If asked, you must provide a sound reason why any cat, dog or primate has not been given a permanent individual means of identification.

3.13.13 Keeping records

You are responsible for keeping records of the source, use and disposal of all protected animals used in procedures, bred or obtained for use, or supplied for use **[Standard Condition 8]**.

These records must account for each protected animal (i.e. every individual must be counted even though some animals, such as rodents, may be counted as batches of determinate size without being individually identified). By exception, immature forms (fetal, larval or embryonic), which have reached the stage of development where they become protected animals, and neonates can be recorded as batches of indeterminate size until they can be practically and safely handled and counted.

Your records must contain at least the following information:

- the number and the species of animals bred, acquired, supplied, used (and re-used) in procedures, or discharged from the control of ASPA;
- the origin of the animals, including whether they were bred for use in procedures;

- the dates on which the animals were acquired, supplied, or discharged from the control of ASPA;
- from whom the animals were acquired;
- the name and address of the recipient to whom animals have been supplied or re-homed;
- the number and species of animals which died or were killed in your establishment. For animals that have died, the cause of death must, when known, be noted; and
- if your establishment is authorised as a user establishment, the projects in which animals are used.

You must keep all these records for a minimum of five years from the date of final disposal of the animal, whether it has died, or been re-homed as a pet or to a sanctuary, or been discharged to a farm, a slaughter house or to the wild, or been supplied for export.

If requested, you must submit these records to us or make them available to an inspector. We may also require you to submit to us a summary report of the source, use and final disposal of all protected animals bred, kept, or used at your establishment for any regulated activities.

It is good practice for copies of relevant records to travel with animals of all species (e.g. mouse passports) when they are supplied to another establishment or transferred into subsequent care.

3.13.14 Individual history files

You must also keep individual history files for cats, dogs and primates **[Standard Condition 9]**.

These must contain:

- the animal's identity (for example, a microchip number);
- its place and date of birth, if known;
- for primates, whether it is the offspring of primates bred in captivity;
- a statement saying whether the animal was bred for use in procedures;
- any relevant reproductive, veterinary and social information;
- a record of the programmes of work involving the animal's use in regulated procedures (i.e. the project licences to which animals have been issued, if relevant).

At breeding establishments, you must start an individual history file as soon as possible after the animal is born.

At supplying and user establishments, where the animal has been obtained from an establishment in the UK or from an authorised breeder, supplier or user in another EU member state, an individual history file should accompany the animal.

Where the animal comes from a source outside the EU or where the individual history file is not available, you should start one as soon as possible.

When animals are moved from one establishment to another, you should provide the individual history file to the next establishment licence holder.

If the animal is re-homed, you must provide a copy of any veterinary or social information to the person with whom the animal is re-homed.

If the animal dies, is set free or re-homed, you should keep its individual history file for at least five years.

3.13.15 Other records

The NVS should supervise health records and make sure these are kept to a proper professional standard **[Standard Condition 14]**. You must ensure that these records are kept for a minimum of five years from the date of final disposal of the animal and, if requested, submit them to us or make them available to an inspector.

You must have processes in place that ensure that a daily record is kept of the environmental conditions in all areas of the establishment where protected animals are kept.

You should retain details of all project and personal licences currently authorised at your establishment. The personal licence records should cover at least the current and previous fee period (1 April to 31 March).

You must make all records available to us when asked to do so. Sometimes, we may ask for a summary of some or all of your records.

You should use the information in the records as tools to monitor and improve standards and practices at your establishment.

3.13.16 Origin of animals

Prior to 1 January 2013, ASPA prohibited the use in regulated procedures of cats and dogs that had not been bred at, and obtained from, a designated breeding establishment in the UK unless otherwise authorised in the project licence. (An establishment was previously 'designated' by a certificate issued under ASPA sections 6 or 7, which were removed when ASPA was amended in 2012.)

The use of other **Schedule 2** animals that had not been bred at or obtained from a designated breeding or supplying establishment in the UK was similarly restricted. Designated breeding and supplying establishments were also not permitted to obtain those animals from sources other than designated establishments without our authorisation.

Amended ASPA has discontinued those restrictions but, as required by **Directive Article 10**, prohibits the use in regulated procedures of any type of animal listed in **Schedule 2** that has not been 'bred for use in procedures' unless otherwise authorised in a project licence. The animal may, however, have been 'bred for use in procedures' somewhere else in the world.

The use in regulated procedures of certain other types of animal, including those taken from the wild, endangered species, stray and feral animals and non-human primates is subject to specific restrictions (**Section 5.18**). You should ensure that project licence holders at your establishment are aware of these restrictions and that you exercise due diligence when seeking to obtain a protected animal from sources other than licensed breeding or supplying establishments.

3.13.17 Breeding primates

If your establishment breeds primates which are not already second generation captive bred (F2), you must have a strategy, acceptable to us, for increasing the numbers bred from animals that were bred in captivity **[Standard Condition 7]**.

3.13.18 Humane killing of animals

You must keep a register of people at your establishment who are competent to kill protected animals, or undergoing training under supervision to attain competence, and have systems in place which ensure that only those people on the register carry out this task. The register must specify the types of animals and the methods of killing for each person registered. You must also be satisfied that, before anyone is added to this register, they have been educated and trained to kill animals, and once registered, they are supervised until they are competent (see **Section 6.2**).

Note that this requirement applies to *all* methods of killing, not just those listed in **ASPA Schedule 1 [Standard Condition 2]**.

The people on your register who use only methods listed in **ASPA Schedule 1**, or methods authorised in the establishment licence, do not need to have a personal or project licence for such killing, whether or not the animals are being killed for a scientific purpose. You should refer to **Section 6** to put systems in place to ensure people at your establishment have any necessary authorisations for other methods.

You must make sure that you have enough registered people available at all times so that someone is available to expediently kill an animal if necessary. You should check that any equipment needed is on hand and well maintained.

We recommend that you display a copy of **Schedule 1** and details of any other methods authorised in your licence together with **Section 6** of this guidance in all areas used for killing animals.

At times it may be necessary to kill animals that have not been used, or supplied for use, in procedures, for example those that are surplus to stock (see **Section 2.4**). You must make sure this is done competently. They must be culled by an appropriate **Schedule 1** method or another method authorised in your licence.

A copy of **Schedule 1** is provided at **Appendix D**.

3.13.19 Disposing of animals

You must put systems in place to ensure that any animal still living after undergoing a series of procedures is kept at your establishment under the supervision of a veterinary surgeon. This is the case until or unless we have authorised the animal's transfer to another establishment, its setting free or re-homing, or its re-use in another series of regulated procedures **[Standard Condition 23]**.

Our permission to release animals from the controls of ASPA, for example, for setting free to the wild at the end of procedures, may alternatively be specified in the relevant project licence (see **Section 5**).

3.13.20 Paying fees

You need to pay us fees to cover the costs of operating ASPA. This includes the costs of inspecting, licensing and of the Animals in Science Committee.

Currently, we charge annual fees for the establishment licence and for each personal licensee working at your establishment with 'primary availability'. If the 'primary availability' changes, we will charge the establishment licence holder at each establishment holding 'primary availability' for that personal licensee during that year (1 April to 31 March). We do not currently charge for project licences.

We issue an invoice each year for fees payable for the previous year. This must be paid within 28 days. If unpaid, we may revoke your establishment licence, subject to your right to make representations.

We can vary these fees and will give you notice of any changes.

3.14 Amending your establishment licence

You can ask us to amend your establishment licence at any time. You must *notify* us if there are to be changes to:

- the title of your establishment (including a change of company name, registration, or legal entity);
- any of the named persons.

You must *apply for an amendment* of your licence if you are planning to change:

- the holder of the establishment licence;
- the class of licensed activity (breeding, supplying and/or user);

or you are adding:

- a new type of animal not already listed in your licence schedule; or
- a new area for breeding or holding not already listed in your licence schedule **[Standard Condition 13]**.

The licence must also be amended before an approved area is used for a regulated activity that is not currently permitted in the licence schedule and which, in your judgement, after taking advice from your AWERB and named persons, could negatively affect animal welfare **[Standard Condition 12]**.

The new authorities will not come into force until we have granted an amended licence. You can find an application form for amendments to your licence on our website. In addition, if you propose making any significant changes to the structure and/or functions of your AWERB, including a proposed change of the person who chairs your AWERB, you should discuss and agree these with your inspector.

3.15 What happens if your establishment licence is varied, revoked or suspended?

An establishment licence may be revoked at any time at your request.

Under **ASPA section 11**, we may also suspend, vary or revoke your licence if you have failed to comply with a condition of your licence or with a provision of ASPA, and the circumstances justify it. For example, we may suspend, vary or revoke your licence in the event of:

- failure to ensure that the establishment is appropriately staffed **[Standard Condition 5]**;
- failure of any named person to be able to meet their responsibilities where you have not identified a suitable replacement **[Standard Conditions 3 and 15]**;
- failure to pay fees **[ASPA section 8]**;
- breeding Schedule 2 animals for use in regulated procedures when your licence authorises only the applying of regulated procedures **[ASPA section 2B]**.

We can also revoke your licence if you have failed to comply with a compliance notice issued under **ASPA section 11**. For further information about compliance notices, see **Section 12.10**.

If there is an urgent need to safeguard animal welfare, we may suspend your licence under **ASPA section 13**.

Suspending or revoking a licence immediately invalidates all personal and project licences at your establishment and means that all procedures must stop immediately and that you may no longer breed or keep animals for supply.

We may require you to take action to safeguard the welfare of your animals or, if you are not willing or able to do so, we may take that action. For example, we may appoint another individual to be responsible for the welfare of those animals.

3.16 Your right to make representations

Under **ASPA section 12**, you have the right to make representations if we intend to suspend, vary or revoke your licence under **ASPA section 11** other than at your request. We are required to notify you of any such intention, and will provide you with guidance on your right to appeal. See **Appendix E** for more information.

If we suspend an establishment licence to urgently safeguard animal welfare under **ASPA section 13**, we are not required to give notice of our intention to do so and the licence holder has no right of appeal against that suspension.

3.17 Standard and additional conditions for establishment licences

We grant establishment licences subject to standard conditions. These are set out at **Appendix A**.

Sometimes, we may include additional conditions, for example:

- to further restrict the use of specified areas of the establishment;
- to set specific requirements at your establishment for managing the work; or
- to require you to submit a report on the environmental conditions maintained within a specific part of the premises.

We may also authorise you to use a method of humane killing which is not included in **ASPA Schedule 1** if you have applied and provided scientific justification that is acceptable to us (see **Section 6.6**). Such authorisation will be given in the schedule of your licence, not as an additional condition.

4. PERSONAL LICENCES

4.1 What does a personal licence cover?

Your personal licence shows that we have authorised you to carry out specified regulated procedures, under supervision if necessary.

Under ASPA, you are not allowed to apply a regulated procedure to an animal unless all three of the following requirements are met:

- you hold a *personal licence* authorising you to apply a procedure of that description to an animal of that type;
- the procedure is applied as part of an authorised programme of work specified in a project licence; *and*
- the place where the procedure is carried out is specified in that project licence.

4.2 Who can hold a personal licence?

To become a personal licence holder, you must:

- be at least 18 years old;
- have met minimum educational standards;
- have satisfactorily completed the appropriate training modules; and
- have appropriate experience of handling protected animals and looking after their welfare.

4.3 What training do I need to complete?

As a personal licence holder, we expect you to have at least five GCSEs or Standard Grade passes (including a biological science) or equivalent academic, professional or vocational qualifications.

You must also complete the relevant formal modular training to qualify for the specific categories of procedure you require. You may be exempt from these requirements if you can supply evidence of equivalent relevant education, training, experience and competence. See Guidance on Training and Continuing Professional Development under ASPA, published on GOV.UK.

As a personal licence holder, you will have to undertake practical training under supervision until confirmed as competent in each technique at your place(s) of work. You should review your training and supervision needs regularly with your NTCO, at a minimum every five years but generally more frequently. Many factors will influence your ongoing training and supervision needs. For example, if you are planning to start a new technique, work with a new species or implement new knowledge such as new anaesthetic or analgesic agents or methods, you will need to review your training needs with your NTCO before commencing.

Note that regulated procedures may only be conducted on living protected animals for a purpose authorised by a project licence.

If English is not your first language, your NTCO will seek reassurance that you understand the provisions of ASPA and any local rules relating to the use of animals.

4.4 How long will my personal licence last?

Although your personal licence will remain in force indefinitely or until revoked, we will review it at least every five years. You may be asked for information to assist this review. This may include similar details to those you provided for your initial application and confirmation that this information is still correct. You may also be asked to provide your records of animal use.

4.5 Death or departure of a personal licence holder

Your personal licence will end on your death. In that event, the establishment licence holder will assume responsibility for animals on which you have performed procedures. If you leave the establishment, you must ensure that another personal licence holder assumes responsibility for the animals on which you have performed procedures. If you fail to do so, the establishment licence holder must assume responsibility.

4.6 Before you apply for a personal licence

Before you apply for a personal licence you must complete all the training relevant to the licence category or categories you want us to authorise. In particular, as a personal licensee you have primary responsibility for the welfare of animals, and it is important that you fully understand that responsibility.

Application forms are available on the Research and testing using animals page of the GOV.UK website.

4.7 What information is needed in a personal licence application?

Your application must include:

- your personal information for identification;
- details of the establishment specified as your primary availability;
- the type(s) of animal(s) on which you wish to work;
- the category(ies) of personal licence you are requesting;
- evidence of successful completion of formal accredited module training, as appropriate.

Your application must be endorsed by the Named Training and Competency Officer (NTCO) at the establishment you are naming as your primary availability.

4.8 What is covered by the different categories of personal licence?

The categories of personal licence permit you to carry out procedures of the descriptions specified and are as follows:

A. Minor/minimally invasive procedures not requiring sedation, analgesia or general anaesthesia.

B. Minor/minimally invasive procedures involving sedation, analgesia or brief general anaesthesia; surgical procedures conducted under brief non-recovery general anaesthesia.

C. Surgical procedures involving general anaesthesia; administration and maintenance of balanced or prolonged[2] general anaesthesia.

D. Use of neuromuscular blocking agents (see also **Section 5.18.3** and **Appendix H**).

E. Procedures conducted in accordance with a specified education or training project licence.

F. Other.

Category E is for applicants who intend to attend an education and training course conducted under a single project licence. You should consult your course provider for details of pre-course formal training requirements and which species to request (see also **Section 5.18.10**). If you intend to conduct work under other project licence authorities, you will need to apply for the relevant categories and species and supply copies of the necessary formal training certificates.

Category F is for the rare occasions where the regulated procedures you wish to conduct do not fall within the scope of one of the preceding categories or formal training requirements. You *must* consult us for advice before making such an application.

Examples are provided on the Research and testing using animals page on the GOV.UK website, and you should consult these if you are unsure whether a particular regulated procedure falls within a particular category. If you are still unsure, you should then consult an inspector.

4.9 Where can I use my personal licence?

Your licence must specify your primary place of work. This will be the establishment where you are based – called the 'primary availability'. This establishment is responsible for paying a fee for your licence and will oversee the maintenance of your training and competence record.

Your licence is not normally restricted to working only at your primary place of work. In most cases you may work under your personal licence at any licensed establishment in the UK but you must contact the NTCO at any additional establishments before starting any work there. Note that you may only work with the relevant project licence holder's permission.

You may also work at places that are not included in an establishment licence (POLEs) but this can only be as part of an authorised programme of work.

4.10 Which project licences can I work on?

For categories A, B, C and D, you can work on any projects as long as the classes of techniques and species you are using are authorised in your licence and on the project licence, you are competent to perform the techniques on those species (or supervised until you have demonstrated competence), and the project licence holder and NTCO at the establishment are aware of your work.

Category E or F licences may limit you to working on a specific project licence.

4.11 How quickly will my application be decided?

We aim to process all applications for personal licences within 20 working days.

[2] Prolonged is defined as any duration greater than 15 minutes which may require additional or continuous dosing (including anaesthesia for imaging).

We provide a fast-track service for a limited range of applications – essentially personal licence applications for overseas scientists and some students planning short-term studies in the UK. We aim to process these applications within five days of receipt.

You should contact us (by email to ASPA.London@homeoffice.gsi.gov.uk or by telephone on 020 7035 0477) if you believe your application is eligible for the fast-track service to ensure we process it appropriately upon receipt.

4.12 How we will assess your application for a personal licence

We will check that you are old enough to hold a licence and that you satisfy the educational requirements and/or have satisfactorily completed training appropriate to the category of licence you have requested. We will also check that your application has been endorsed by the NTCO for the establishment at which you will be working. In some cases, you might be asked for further information, for example, relating to your experience or qualifications, and your application may be referred to an inspector for advice.

4.13 Your responsibilities

4.13.1 Checking your authorities

You must comply with the terms and conditions of your licence.

Before you carry out a regulated procedure, you must check that it is authorised by a project licence, being carried out as part of the programme of work specified in that licence and that it is being carried out at a place named in that project licence. You should also check that the required categories or descriptions of techniques and animals are listed in your personal licence **[Standard Condition 19]**.

You should be familiar with the details of the licences for projects you are working on, including their objectives, plans of work and protocols.

You must only perform regulated procedures with the permission and in the full knowledge of the project licence holder. You must also understand the tasks the project licence holder asks you to perform, including any end-points you need to apply.

You must be trained and competent to carry out the procedure so that you cause the minimum pain, suffering, distress or lasting harm, with supervision as necessary until such competence is attained.

4.13.2 Supervision

Until the project licence holder and NTCO where you are working are satisfied that you have achieved competence in a particular technique and species, you must not apply regulated procedures unless given the appropriate level of supervision by the project licence holder or an experienced personal licence holder assigned by him or her. This is to ensure that regulated procedures are performed competently **[Standard Condition 17]**.

4.13.3 Animal welfare

You must not allow an animal to experience severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated **[Standard Condition 3]**.

You should act at all times in a manner that is consistent with the principles of the 3Rs – replacement, reduction and refinement **[Standard Condition 1]**.

You are responsible for the welfare of the animals you work on. This involves:

- being responsible for the welfare of the animals you have performed procedures on and ensuring that they are properly monitored and cared for **[Standard Condition 2]**;
- knowing the techniques and species involved, what the consequences of performing procedures on them will be and the signs of pain, suffering, distress or lasting harm in that species;
- taking precautions to prevent, or reduce to a minimum consistent with the purposes of the procedure, any pain, suffering, distress, or discomfort to the animal which may or may not lead to lasting harm. This may include using medication where appropriate, such as sedatives, tranquillisers, analgesics or anaesthetics, as well as other appropriate methods, such as husbandry measures, which increase animal comfort or improve access to food and water **[Standard Conditions 4 and 12]**;
- telling the project licence holder immediately if you think that the severity limit of any procedure, or other limitations (constraints) upon adverse effects, have been or are likely to be exceeded and agreed humane end-points have not or cannot be applied **[Standard Condition 13]**;
- getting and following veterinary advice and treatment, where needed **[Standard Condition 15]**;
- arranging for the care and welfare of an animal when you are away **[Standard Condition 14]**;
- making sure that any animal that is in severe pain or severe distress, which cannot be alleviated, is painlessly killed using an appropriate method **[Standard Condition 8]**;
- ensuring that neuromuscular blocking agents (if authorised to be used) are used in combination with anaesthesia and analgesia as required by the project licence **[Section 5.18.3]**;
- ensuring animals are killed by an appropriate method at the end of the procedures if the animal is suffering or is likely to suffer adverse effects **[Section 5.20]**.

If two or more personal licence holders are working with the same animal, you must be clear who is primarily responsible for that animal and it must also be clear to others involved in the care of the animal, including the care staff, the project licence holder, the named persons and inspectors.

4.13.4 Record keeping and cage labelling

You must keep records of all the regulated procedures you perform and note whether you were supervised. You should record any adverse reactions including morbidity and mortality resulting from those procedures, to enable your project licence holder to decide if you need further training or supervision **[Standard Condition 20]**.

Your records should be retained for at least five years and should be available to the NTCO and project licence holder(s) where you work and, on request, to our inspectors **[Standard Condition 20]**.

You must clearly label cages, pens and other enclosures. The label should include details of:

- the project licence number;
- the protocol;
- the date the protocol was started; and
- the responsible personal licensee **[Standard Condition 16]**.

You can use a coding system as long as this can be easily decoded by others caring for the animals or with responsibilities under ASPA, including our inspectors.

We also recommend that the number of animals is included on the label to assist with monitoring, recording and compliance.

4.13.5 Delegating tasks

You can delegate tasks that form an integral part of the regulated procedures that you are authorised to perform to assistants under your control who do not themselves possess the requisite personal licence authority. The tasks must not require technical knowledge or skill. Any such assistant must be trained, instructed and supervised as necessary. You remain responsible for the conduct of the tasks and the consequent effects on the animals.

For example, you could use an assistant to:

- fill food hoppers and water bottles with previously mixed diets or liquids of altered constitution or to which test substances have already been added;
- in your presence, put an animal in a predefined altered environment, such as a pressure chamber;
- press the exposure button to deliver predetermined doses of irradiation to an animal;
- pair animals for breeding animals with harmful genetic defects as instructed;
- operate automated machinery for inoculating eggs;
- competently place animals into restraining devices that do not require special skill to apply or operate, as defined by the project licence;
- withdraw food or water, as defined by the project licence;
- place avian eggs into pre-set chillers at the end of a procedure;
- manipulate the controls of anaesthetic apparatus only under your direct instruction.

You may delegate other tasks, but only in your presence and when the animal has been rendered insentient by decerebration or general anaesthesia that will continue until it dies. This might include administering substances through a catheter, or administering electrical stimuli through electrodes. If you consider other tasks are suitable for delegation, you should discuss this with an inspector on a case-by-case basis.

During surgery, unlicensed assistants can only perform simple duties under your instruction. This may include cutting of sutures or ligatures. They may not make or close surgical incisions or perform any other intervention that requires knowledge or technical skill.

You should consult us if you are unsure whether or not a task can be delegated.

4.14 Conflicts of interest

Conflicts of interest must be avoided. For any group of protected animals, there should be at least three people filling the five key roles of: establishment licence holder/NPRC, project licence holder, personal licence holder, NACWO and NVS (see **Section 3.13.8**).

Please ask us for advice if you are in any doubt about a potential conflict of interest.

4.15 Amending your personal licence

You can ask us at any time to add categories of techniques or species or to change the primary availability on your licence. Your application will need to be endorsed by your NTCO, who will confirm:

- when adding categories of techniques or species that you have undertaken any necessary additional accredited training; and
- that the primary availability supports your request.

Do not start using any new categories of techniques etc. until you have received your amended licence. We have to reissue your licence before any amendments can come into force.

4.16 Suspending your personal licence

Where necessary, we can suspend your licence to safeguard an animal's welfare. If this happens, you must immediately stop all procedures. We may require you to take action to safeguard the welfare of your animals, or we may take that action.

4.17 Revoking or varying your personal licence

You can return your licence to us at any time for it to be revoked, for example, when you leave your job.

In addition, we may revoke, suspend or vary personal licences:

- as a result of a breach of a condition – for example, if you can no longer be entrusted with the responsibilities of a licensee, or we might vary a licence to add new conditions; or
- where it is appropriate to do so – for example, if the establishment licence holder named on your licence asks us to revoke the availability at that establishment or is no longer willing to endorse you as having that establishment as your primary place of work.

4.18 Your right to make representations

Under **ASPA section 12**, you have the right to make representations (appeal) to us if we intend to vary, suspend or revoke your licence other than at your request or at the request of the establishment licence holder should that establishment cease to be your sole or primary place of work. If we notify you of such an intention, we will provide you with guidance on your right to appeal (see **Appendix E** for more information).

4.19 Standard conditions for personal licences

We grant personal licences subject to standard conditions. These are set out at **Appendix B**. These apply to all personal licences and you should ensure that you understand the obligations they place on you. In particular, you should note the requirement that you maintain up-to-date records of work you do under your licence and make these available to our inspectors on request.

Sometimes we may include additional conditions, for example to restrict the authorities on your licence when using neuromuscular blocking agents or working under an education or training project licence.

5. PROJECT LICENCES

5.1 What does a project licence cover?

A project licence is a licence granted by the Secretary of State which specifies a programme of work and authorises the application, as part of that programme, of specified regulated procedures to animals of specified descriptions at a specified place or places.

The place or places specified in a project licence must be either:

a) a licensed user establishment; or

b) a place other than a licensed establishment (POLE).

You must have a project licence before regulated procedures are carried out on animals.

5.2 Who can hold a project licence?

Each project licence is granted to a single, named individual. We do not grant project licences to organisations or research groups, nor does ASPA recognise deputies on project licences. The holder of the licence should be the most suitable person in the research group or department to manage the project and have the appropriate level of authority to do so. It is not essential that a project licence holder is also a personal licence holder.

You may appoint individuals with whom you agree local arrangements to assist you in your duties as a project licence holder, for example if your project is being performed on more than one site within the same establishment, or if you are absent from time to time. However, this does not take away from you your legal responsibility for compliance with your licence and conditions at all times. See also **Section 5.7.6** regarding additional availability at other establishments.

5.3 What training do I need to complete?

You must have completed the relevant training for project licence holders before applying for your licence. Your establishment NTCO will be able to advise you, and further details are given in the Guidance on Training and Continuing Professional Development under ASPA, published on GOV.UK.

5.4 How long does a project licence last?

A project licence may last for up to five years. You must apply for a new licence when the licence expires if you wish to continue the work. If your project licence was granted for less than five years, you may apply to have it extended to a maximum of five years from the original date of issue.

5.5 Death or sudden departure of a project licence holder

A project licence terminates if the licence holder dies. If the establishment licence holder wishes work to continue under a project licence following the death or sudden departure of the project licence holder, he/she must let us know within seven days and request a temporary extension. Assuming the request is approved, the licence can continue for a further 28 days to allow work in progress to be completed or a new licence to be obtained. During this time, the establishment licence holder is responsible for conducting the project.

5.6 Preparing your project licence application

It may take you some time to prepare your complete application, especially if it describes a novel or complex programme of work, involves using specially protected species (cats, dogs, primates or equidae, endangered species or feral animals) or raises matters of significant public interest.

You may find it helpful, at an early stage, to discuss your proposed application or amendment to an existing licence with the inspector assigned to your establishment as well as with other, experienced project licence holders. You should consult your NVS, NACWO and NIO at an early stage to obtain their advice relating to your proposed application, including advice on incorporating the 3Rs into the plan of work.

You may need to revise your original draft before we consider that it is a complete and correct application. We will be as clear and as prompt as possible in advising you of any revisions required.

All applications for a new project licence must also be evaluated by the local Animal Welfare and Ethical Review Body (AWERB) at the establishment where the work is going to take place. If you plan to work at more than one establishment, you will need to arrange for this review at each establishment.

The AWERB will advise you of any local issues or policies relevant to your proposal and will consider, amongst other things, how effectively you are applying the 3Rs in your work. Their conclusions will assist the decision by the establishment licence holder whether to support your application to work at their establishment. Your complete application needs to be signed by the establishment licence holder (or, in the case of a corporate entity, the NPRC) at each establishment named in the project licence before you send it to us.

Application forms and details of where to send them are available on the Research and testing using animals page of the GOV.UK website [https://www.gov.uk/research-and-testing-using-animals].

5.7 What information is needed in a project licence application?

5.7.1 Overview

Your application must:

- describe the programme of work (see below);
- specify the regulated procedures, the descriptions of animals and the place or places you want to be specified in the project licence;
- include information on the matters set out in **Annex 6 of the Directive** (see below and **Appendix F**);
- describe the realistic likely benefits;
- include such other information as we may reasonably require; and
- be accompanied by a project summary written in non-technical terms.

5.7.2 Programme of work

A project licence covers a single programme of work. It must describe the programme, state its purpose and specific objectives, specify the regulated procedures to be applied and identify the adverse effects (harms) likely to be experienced by the animals and how you will avoid, recognise and alleviate them.

A project licence might cover an entire programme of work to develop a new drug involving many animals of various species, numerous protocols and a large team of personal licence holders. Or it might cover the work of one scientist researching just one part of a process using a few animals of a single species.

5.7.3 Regulated procedures to be applied and expected adverse effects

Your application must describe the experimental or other scientific protocols you propose to follow and specify the regulated procedures you may apply within each protocol. You must describe the expected adverse effects of these procedures on the animals, their likely incidence, the control measures you will adopt to minimise their severity, and the humane end-points that will be applied as specific limits on severity. We will confirm the severity classification in your granted licence (see **Section 5.12**).

5.7.4 Description of the animals to be used

Your application must specify the type (e.g. species, strain, health status) of animals you plan to use.

5.7.5 Number of animals to be used

Your application must provide a realistic estimate of the number of animals of each species or type that you intend to use in each protocol.

5.7.6 Place or places you want to be specified in the project licence

You must specify the place where the work will be carried out. In most cases, this will be a licensed establishment. We call this the 'primary availability'. The licence may also name other licensed establishments where the work can take place. These are called 'additional availabilities' and we require you to identify an individual as a 'point of contact' for your project at each of these establishments.

Exceptionally, when required by the nature of the programme or the regulated procedures, you may be authorised to carry out procedures at a place other than a licensed establishment (known as a POLE) – for example, an inland waterway or a farm. In this case, you must notify us when the work is to be carried out so that an inspector can choose whether to be there. We may also put extra safeguards in place to protect the welfare of any animals that are to be left unattended or released into the wild (set free) once you have completed the procedures.

The manner in which a POLE is specified needs to be sufficiently detailed to allow inspection. For example, a full address of the site with grid references, post code (for a farm) or other ways of identifying it, contact names and telephone numbers (and mobiles, if appropriate). However, general information (e.g. "Farms in England and Wales where cattle have been diagnosed as suffering from tuberculosis", "Sites where pied flycatchers are nesting", "Tributaries of the River Dee in North Wales", "Fish farms on West Coast of Scotland") can be sufficient if details are to be given on notification.

5.7.7 Information on the matters set out in Annex 6 of the Directive

Your application must explain or provide details of:

- the relevance of and justification for (a) the use of animals, including their likely origin (i.e. animal born in the UK or rest of the EU and whether at an authorised breeder; animal born in the rest of Europe or in the rest of the world), estimated numbers, species and life stages; and (b) procedures;
- the application of the 3Rs;
- the planned use of anaesthesia, analgesia and other pain-relieving methods;
- measures proposed to reduce, avoid and alleviate any animal suffering, from birth to death where appropriate;
- the use of humane end-points;
- the experimental or observational strategy and statistical design to minimise animal numbers, pain, suffering, distress and environmental impact;

- the proposed re-use of animals and the cumulative effect on the animals;
- the proposed severity classification of procedures;
- measures proposed to avoid unjustified duplication of procedures;
- the housing, husbandry and care conditions for the animals including appropriate environmental enrichment (if those conditions will not meet in full the minimum standards set by Annex 3 or, where higher, those of the Code of Practice);
- the proposed methods of killing; and
- the competence of the persons involved in the project.

Annex 6 is reproduced in full in **Appendix F** of this guidance.

5.7.8 Other information

There may be other information that you will need to include in your application. For example, in an application for an education and training project licence, we would expect the programme of work to include information about how learning outcomes would be monitored. We will advise you of this on a case-by-case basis.

5.7.9 Project summary

Your application must be accompanied by a project summary written in non-technical terms and which can be understood by a non-scientist. You should complete the project summary template, which is available on the Research and testing using animals page of the GOV.UK website.

We expect that, for all but the most complex of projects, you will be able to provide a satisfactory project summary using between 500 and 1,000 words. The project summary must:

- describe the proposed programme of work and state the objectives of the programme;
- state the types of animal and the estimated number of each type that you will use;
- predict all of the likely harms to the animals that will be caused and the likely benefits that will be gained by carrying out the programme of work; and
- demonstrate how you will comply with the principles of replacement, reduction and refinement throughout the project.

Your project summary must ***not*** contain any of the following:

- information of a confidential nature;
- information the publication of which may lead to the infringement of any person's intellectual property rights;
- your name or address nor that of any other person.

5.8 How quickly will my application be decided?

5.8.1 Timescales

We will acknowledge receipt of your application when we receive it. We will not start assessment until we receive a complete and correct application, including a satisfactory non-technical project summary.

Unless the application involves a complex or multidisciplinary programme, we will complete our assessment within 40 working days (about eight weeks) of receiving your correct and complete application. We will either grant your project licence or notify you of our intention to refuse your application.

For applications describing a complex or multidisciplinary programme, we may extend this period by up to 15 working days (about three weeks) and will notify you accordingly.

5.8.2 Incomplete or incorrect applications

If your application contains any errors or lacks essential information necessary for us to evaluate it, we will tell you as soon as we can and set out the additional information that needs to be provided to complete or correct it. Provided the additional information submitted to us completes or corrects the application, we will complete the assessment and grant process as described above.

5.9 Permissible purposes

We cannot grant a project licence unless the programme of work is to be carried out entirely for one or more of the following purposes:

a) basic research;

b) translational or applied research with one of the following aims:

(i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in humans, animals or plants;

(ii) the assessment, detection, regulation or modification of physiological conditions in humans, animals or plants; or

(iii) the improvement of the welfare of animals or of the production conditions for animals reared for agricultural purposes;

c) the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feedstuffs or any other substances or products, with one of the aims mentioned in paragraph (b);

d) the protection of the natural environment in the interests of the health or welfare of humans or animals;

e) research aimed at preserving the species of animal subjected to regulated procedures as part of the programme of work;

f) higher education or training for the acquisition, maintenance or improvement of vocational skills;

g) forensic inquiries.

Under the previous ASPA (before the 2012 amendments), we authorised licences for the breeding of genetically altered animals. This is no longer a permissible purpose in its own right. Therefore the purpose for which genetically altered animals are being bred must be one or more of the above, and must be specified in the licence.

5.10 How we will assess your application for a project licence

The purpose of our evaluation is to verify that:

- carrying out the programme of work is justified from a scientific or educational point of view, or is required by law;
- the purposes of the programme of work justify the use of protected animals; and
- the programme of work is designed so as to enable the regulated procedures involved to be applied in the most humane manner possible and to comply with any relevant environmental legislation or regulations.

In carrying out the evaluation, we must:

- evaluate the objectives of the programme of work and its predicted scientific benefits or educational value;
- assess the compliance of the programme of work with the principles of replacement, reduction and refinement;
- classify prospectively as 'non-recovery', 'mild', 'moderate' or 'severe' the likely severity of each series of regulated procedures that would be applied as part of the programme of work and confirm or revise the proposed severity category for each protocol;
- carry out a harm–benefit analysis of the programme of work to assess whether the harm that would be caused to protected animals in terms of suffering, pain and distress is justified by the expected outcome, taking into account ethical considerations and the expected benefit to human beings, animals or the environment (guidance on how we carry out this harm–benefit analysis is provided in **Appendix I**);
- assess any scientific justification relating to the following:
    - use of animals at a POLE (ASPA 5(3));
    - methods of killing (ASPA 15A(7)); or
    - use of neuromuscular blocking agents (ASPA 17(2));
    - use of endangered primates (ASPA Schedule 2B, para 1(4));
    - use of non-endangered primates (ASPA Schedule 2B, para 2(4)); or
    - use of other endangered species (ASPA Schedule 2B, para 3(3));
    - use of feral animals (ASPA Schedule 2C, para 25 (2));
    - use of wild-caught and purpose-bred animals (ASPA Schedule 2C para 25(3));
- assess whether carrying out the programme of work would give rise to any scientific reason for an exemption under paragraph 11(5) of Schedule 2C relating to the care and accommodation of animals; and
- on the assumption that a project licence is granted in respect of the programme of work, determine whether and (if so) when the programme should be retrospectively assessed under section 5F (see **Section 5.17** for further information).

Inspectors will exercise their professional skills and judgement to try to ensure that they are fair to licensees and other individuals. They work collaboratively with other inspectors to try to achieve consistency in their advice and decisions. This does not mean that the same decision will be made in two apparently similar, yet subtly different, circumstances. However, all their judgements should be defensible. A process exists for individuals to seek a

second opinion on any matter. Information on this is contained in the document "Dealing with disagreements between inspectors and individuals at establishments" which is available on the Research and testing using animals page of the GOV.UK website.

5.11 Applying the 3Rs in your project

Your licence will require you to ensure, to the greatest extent, that you use non-animal (replacement) methods to achieve your scientific objectives wherever possible and that the specified regulated procedures:

- use the minimum number of animals;
- involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;
- cause the least pain, suffering, distress or lasting harm; and
- are most likely to produce satisfactory scientific results **[Standard Condition 4]**.

In assessing the harms and benefits of a programme of work and its individual protocols, we follow the principles of the 3Rs. **See Section 2**.

We must be satisfied that the work is justified from a scientific or educational point of view, or is required by law, and that the objectives justify using animals.

You must also show us that you will apply the regulated procedures in the most humane way and comply with any relevant environmental legislation or regulations.

It is the responsibility of the project licence holder to put systems in place which ensure that the 3Rs are applied effectively throughout the life of the project, taking into consideration any scientific or technical developments which may permit greater replacement, reduction or refinement than was possible at the time the project was authorised. This principle is particularly relevant for multiple generic projects.

We may review your project licence and may require it to be amended if suitable replacement, reduction or refinement alternatives become available during its lifetime.

If you wish to use endangered species, primates, cats, dogs or equidae (e.g. horses), you will have to make the case as to why other species cannot be used instead. If you wish to use animals taken from the wild or feral animals of a domestic species, you will need to explain why captive-bred animals cannot be used instead. If you wish to use any of the animals listed in **Schedule 2** of the Act when they haven't been bred for use in procedures you will need to explain why purpose-bred animals cannot be used. You may not use great apes or stray animals of domestic species.

We recognise that sometimes it is possible to reduce the number of animals used by increasing the severity of the adverse effects caused to each animal or, conversely, to reduce the severity of the adverse effects in each animal by increasing the number of animals used. We will judge this on a case-by-case basis to reflect the most appropriate balance between reduction and refinement.

All procedures must be carried out under general or local anaesthesia unless administering the anaesthetic would cause more suffering for the animal than the procedure itself or would be incompatible with the purposes of the procedures **[Standard Condition 17]**.

If anaesthesia is not used, analgesics or another appropriate way of minimising any pain, suffering, distress or harm caused must be used. You must make sure that no animal is subjected to severe pain, distress or suffering that is likely to be long-lasting and cannot be ameliorated **[Standard Condition 7]**.

You should seek the advice of the NVS on appropriate methods of anaesthesia and analgesia or when considering appropriate ways of minimising pain, suffering distress or harm in circumstances when anaesthetics or analgesics are not used.

We must be satisfied that you are using good practices and that the work will be carried out competently. In your application you must describe how you intend to prevent or minimise the extent, duration and incidence of adverse effects. This includes specifying humane end-points and control measures such as observation schedules.

Once granted, your licence will require you to ensure, throughout the life of the licence, that the purpose of the programme of work cannot be achieved by using a scientifically satisfactory method or testing strategy which does not involve protected animals and which, where appropriate, satisfies the relevant EU regulatory requirement **[Standard Condition 2]**.

You will also have to ensure that you do not perform procedures for which the results are already available in a Member State using procedures which satisfy the relevant EU regulatory requirement **[Standard Condition 3]**.

5.12 Severity categories

5.12.1 How are severity categories defined?

Before we grant a project licence, we have to classify how severe the series of procedures specified in each protocol is expected to be. We use the severity categories – 'mild', 'moderate', 'severe' and 'non-recovery' – which are defined in **Appendix G** together with examples of each category. There is useful information and examples of severity assessment on the EU website at: http://ec.europa.eu/environment/chemicals/lab_animals/pdf/examples.pdf and http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Consensus%20doc%20on%20severity%20assessment.pdf

5.12.2 How we determine the severity category of a protocol

We determine the severity category of a protocol by assessing the pain, suffering, distress or lasting harm that an animal is likely to experience in that protocol after applying all the appropriate refinement techniques.

We look at the types of procedures you are going to use considering particularly:

- the type of manipulation and handling;
- the nature of the pain, suffering, distress or lasting harm likely to be caused by the procedure;
- its intensity, duration, frequency and the number of techniques being used in each animal;
- any cumulative suffering within a protocol;
- if the animal is prevented from behaving naturally by restricting its housing, husbandry and standards of care;
- methods used to reduce or eliminate pain, suffering and distress, including refining housing, husbandry and care; and
- humane end-points and how they will be applied.

Besides looking at the procedures involved, we also consider:

- type of species, strain and genotype;
- the maturity, age and gender of the animal;
- training experience of the animal with respect to the procedure; and

- if the animal is to be re-used, the actual severity of the previous procedures.

In carrying out this assessment, we use the criteria set out in **Annex 8** of the Directive (**Appendix G**), which requires that the severity category assigned to a protocol should be based on the most severe effects likely to be experienced by an individual animal.

5.12.3 Expected adverse effects

To enable us to determine the severity category, you will be required, in your project licence application, to provide for each protocol:

- a clear and accurate description of the expected adverse effects likely to be experienced by the animals;
- a prediction of the incidence of those effects among the different animals used in the protocol;
- the refinement measures and other controls you will adopt to prevent or minimise suffering associated with those effects; and
- the humane end-points you will apply as severity-limiting measures.

Example: Adverse effects description for a protocol covering the surgical transfer of genetically altered mouse embryos.

- All animals are likely to experience some post-operative discomfort but are otherwise expected to make a rapid and unremarkable recovery from the implantation procedure. **[Expected adverse effects and likely incidence]**
- Surgical procedures will be carried out according to the *LASA Guiding Principles for Preparing for and Undertaking Aseptic Surgery (2010).* Analgesic agents will be administered. **[Refinement control measures]**
- In the unlikely event of post-operative complications, animals will be killed unless, in the opinion of the Named Veterinary Surgeon, such complications can be remedied promptly and successfully using no more than minor interventions. In the case of wound dehiscence, uninfected wounds may be re-closed on one occasion. **[Humane end-points and specific limits on severity]**
- Rarely (<1%), genetic modifications may affect gestation or parturition. Expected birth dates will be recorded and any female not giving birth within two days of the expected date will be killed. **[Consequential adverse effect, incidence, controls and humane end-point]**

In the example above, the expected adverse effects following the surgical procedure and their likely incidence indicate that a prospective severity category of 'moderate' would be applied to the protocol. The potential for post-operative complications, while not expected, is recognised and appropriate remedial measures are described. A clear limit on severity is imposed in the case of any animal in which post-operative complications are not promptly remedied.

Your description of the expected adverse effects of the procedures on the animals and their likely incidence, together with the refinement control measures and humane end-points that will be applied, will help inform our assessment of whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome in determining whether the proposed project should be authorised (see **Section 5.13**).

In some protocols, a small proportion of animals may be expected to experience adverse effects that are more severe than those experienced by the majority of animals. For example, when carrying out vaccine batch safety studies involving simple inoculation, the substances administered may be expected to cause no more than mild and transient discomfort, but a small minority of studies may result in more significant adverse effects. The expected adverse effects you describe in your project licence application should include any such effects which are reasonably likely

to occur, their likely incidence and the humane end-points you propose to implement. This will ensure that the protocol is properly assessed in a harm–benefit analysis and is assigned the correct severity category.

5.12.4 Severity conditions on your licence

Your project licence requires you to ensure that no unnecessary pain, suffering, distress or lasting harm is caused **[Standard Condition 4]**. You should not allow an animal's condition to approach the severity limits specified in the protocol except where absolutely necessary in order to meet the project's objectives.

You must adhere to the control measures and rigorously apply the humane end-points stated in your project licence, taking all reasonable steps to ensure that animals do not exceed these limits on severity. If the severity limits or expected adverse effects specified in the licence have been, or look likely to be exceeded, you must contact us as soon as possible (typically via your assigned inspector but alternatively, if your assigned inspector is unavailable, by sending an email to ASPA.London@homeoffice.gsi.gov.uk). We may authorise a temporary higher severity category or vary other limits and controls on the project licence for up to 14 days, but *only if you can justify this*. This is to give us time to review the likely harms and benefits and consider amending your project licence **[Standard Condition 18]**.

The conditions of your licence will be breached if you do not notify us promptly when an animal suffers, or is likely to suffer, more than is permitted by the severity limits or other constraints on adverse effects set out in your licence. This will also be the case if the end-points you apply result in more suffering than is necessary to achieve the project's objectives.

We recognise this is a complex area and propose to develop additional advice and case studies. These will be available in an Advice Note on the 'Research and testing using animals' page on the GOV.UK website.

If an animal suffers for an unforeseen reason unrelated to regulated procedures, such as intercurrent disease or injury, you may not be in breach of your licence conditions provided that you have taken steps immediately on discovery to alleviate that suffering and you notify us promptly.

However, on no account may you allow an animal to experience severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

5.13 Assessing harms and benefits

Before granting a project licence, we have to weigh the likely harm to the animals, after taking into consideration the optimal implementation of the 3Rs against the benefits that are likely to be gained from the work. We have to ensure that the harms are minimised and the benefits are maximised. In **Appendix I**, we describe how we carry out a harm–benefit analysis on each application for a project licence.

By 'likely harm' we mean the adverse effects that the animals are likely to experience in terms of pain, suffering, distress or lasting harm. By 'likely benefit' we mean how far humans, animals, plants or the environment may potentially benefit if the project meets its objectives. It relates to the value that may be placed directly on the outcomes of the programme of work, both in the short term and taking account of possible longer-term impact.

We assess the harms and benefits at the start of a programme of work but you must continue this throughout the life of your licence to make sure that the original assumptions and assessment are still sound. For example, the 'actual severity' reported (see **Section 5.23.3**) may be different from that predicted, or research directions may change.

5.14 Multiple generic projects

Article 40(4) of the Directive provides that Member States may authorise multiple generic projects if they are to satisfy regulatory requirements or are using animals for production or diagnostic purposes with established methods.

'Generic' is best understood by reference to the breeding of genetically altered mice, the production of antibodies or the conduct of a safety evaluation test – within each of which the particular production process, experiment or study is the same irrespective of the actual genotype, specific antibody or substance concerned. If in doubt, you should consult an inspector.

5.15 When will applications be referred to the Animals in Science Committee?

See **Section 13.5.**

5.16 External assessors

Where we need additional expert advice on a particular project licence application, we may appoint an independent external assessor to evaluate that application. If we intend to do this, we will let you know and also take account of your views in selecting the assessor. Usually, you will be told who they are and the questions we have asked them to address. For more information, see **Section 14**.

5.17 Retrospective assessment

In relation to projects authorised after 1 January 2013, all those using non-human primates, cats, dogs and equidae and all those involving procedures classified as severe must be assessed retrospectively. In addition, it is our policy that all project licences for education and training (see **Section 5.18.10**) and those authorising the use of endangered animals (see **Section 5.18.7**) will normally be assessed retrospectively.

We will consider whether other projects should be assessed retrospectively and, if so, when on a case-by-case basis when we assess the application. We will inform you of our decision when the project licence is granted. We may also reconsider this during the life of your project. In considering whether to require a retrospective assessment, we will take account of:

- the number and type of procedures to be used;
- the number and species of animals to be used;
- the nature of the programme of work and its objectives; and
- whether the project raises any important animal welfare or ethical concerns, novel or contentious issues, or societal concerns.

If your project is to be retrospectively assessed, we will require you to provide information to your AWERB at the time the retrospective assessment is due to be carried out. The information you provide must include an updated non-technical summary and enable the AWERB to consider:

- whether the programme of work has been carried out;
- whether the objectives of the programme of work have been achieved;
- the amount of harm caused to animals by the carrying out of the programme of work (including the number of animals subjected to regulated procedures as part of the programme of work, the species of animals subjected to those procedures and the severity of those procedures); and

- whether any lessons can be learnt from the programme of work which may contribute to the further implementation of the principles of replacement, reduction and refinement.

This will enable your AWERB to retrospectively assess your project, including the harms and benefits. As soon as your AWERB has completed its retrospective assessment (normally within three months of the due date), we will require you to submit to us the AWERB's conclusions, together with the updated non-technical summary agreed with the AWERB, in order that an inspector can complete the assessment on behalf of the Secretary of State.

5.18 Restrictions on programmes of work

5.18.1 Overview

Additional restrictions apply to programmes of work involving the following:

- animals containing human material;
- neuromuscular blocking agents;
- primates (including endangered primates);
- endangered species (other than primates);
- cats, dogs and the equidae;
- feral domestic animals; or
- education and training.

Project licences will not be granted for programmes of work involving the following:

- testing cosmetics;
- developing or testing alcohol or tobacco products (however, we may consider the use of alcohol or tobacco as research tools for investigating disease or novel treatments);
- developing or testing offensive weapons (but we may consider licences for developing and testing ways of protecting or treating service men and women, or the population as a whole);
- using great apes (chimpanzees, pygmy chimpanzees, gorillas and orang-utans); or
- using stray animals of a domestic species.

5.18.2 Animals containing human material

Projects involving the use of animals containing human material (ACHM) may raise significant ethical issues and societal concerns. In addition to regulation under ASPA, they may also require regulation under other legislation, for example, the Human Fertilisation and Embryology Act 1990 and the Human Tissue Act 2004. You should, therefore, seek the earliest possible advice from us and the other regulators to confirm the authorities you will require.

As part of their assessment, we may refer project licence applications made under ASPA for work involving the use of human material to the Animals in Science Committee for independent advice. We will publish further detailed guidance, in association with the Department of Health, in due course.

5.18.3 Neuromuscular blocking agents

Neuromuscular blocking agents (NMBAs) may be used only with explicit authority in the project licence. We will not permit their use without appropriate anaesthesia or analgesia in accordance with the project licence. You must ensure that personal licensees using NMBAs on your project licence have explicit personal licence authority.

You should comply with our guidance on the use of neuromuscular blocking agents which you can find in **Appendix H** in this guidance.

5.18.4 Project licences authorising the use of non-endangered primates

A project licence for a programme of work using primates of non-endangered species may be granted only if the work is to be carried out for:

- basic research;
- translational or applied research; or
- research aimed at preserving the species of primate being used.

Translational or applied research must be for the avoidance, prevention, diagnosis or treatment of debilitating[3] or potentially life-threatening clinical conditions or their effects in humans, or the development, manufacture or testing of the quality, effectiveness and safety of drugs for the same purposes.

You must also provide scientific justification showing that the purpose of the programme of work cannot be achieved by the use of animals that are not primates.

5.18.5 Project licences authorising the use of endangered primates

A project licence for a programme of work using primates of endangered species may be granted only if the work is to be carried out for:

- translational or applied research; or
- research aimed at preserving the species of primate being used.

As in **Section 5.18.4**, translational or applied research must be for the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions or their effects in humans, or the development, manufacture or testing of the quality, effectiveness and safety of drugs for the same purposes.

You must also provide scientific justification showing that the purpose of the programme of work cannot be achieved by the use of animals which are not primates; and are not of a species listed in **Annex A to Council Regulation (EC) No 338/97** on the protection of species of wild fauna and flora by regulating trade therein [http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1997R0338:20080411:EN:PDF].

5.18.6 Use of purpose-bred primates

Non-human primates, like other species listed in **Schedule 2**, may be used only in procedures where they have been bred for use in procedures. In addition, unless an exemption has been granted, marmosets may be used in procedures only if they are the offspring of marmosets bred in captivity or have been obtained from a self-sustaining colony of marmosets.

Other species of primate may, in due course, be subject to the same additional restrictions as marmosets.

[3] Debilitating is defined in Recital 17 of Directive 2010/63 as having a substantial impact on a person's day-to-day functioning.

You will need to provide scientific justification showing that the purpose of the programme of work cannot be achieved without using such animals to obtain an exemption from these requirements.

A 'self-sustaining colony' is one kept in a way that ensures the animals are accustomed to humans and which consists only of animals that have been bred in captivity, either within the colony or in another self-sustaining colony.

5.18.7 Project licences authorising the use of endangered animals that are not primates

A project licence for a programme of work using other endangered species may be granted only if the work is to be carried out for:

- translational or applied research; or
- research aimed at preserving the species of animal being used.

As in **Section 5.18.4**, translational or applied research must be for the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in humans, animals or plants; or the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feedstuffs or any other substances or products, for the same purposes.

You must also provide scientific justification showing that the purpose of the programme of work to be specified in the licence cannot be achieved by the use of animals which are not of a species listed in **Annex A to Council Regulation (EC) No 338/97** on the protection of species of wild fauna and flora by regulating trade therein [http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1997R0338:20080411:EN:PDF].

5.18.8 Project licences authorising the use of cats, dogs and equidae

We will grant a project licence for a programme of work using cats, dogs and equidae only where the purpose of the programme of work specified in the licence can be achieved only by their use or where it is not practicable to obtain other suitable animals.

5.18.9 Feral domestic animals

A feral animal is an animal living in the wild but descended from domesticated individuals. A project licence for a programme of work using feral animals of domestic species may be granted where the purpose of the programme of work can be achieved only by the use of such feral animals, and the study is essential to protect the health or welfare of that species or to avoid a serious threat to human or animal health or the environment.

5.18.10 Licences for education and training

Project licences will not be granted for education or training in primary or secondary schools. We will consider applications for higher education or for training to acquire, maintain or improve vocational skills.

Projects will normally be limited to training individuals who will eventually be carrying out scientific work using living animals and who therefore need an understanding of *in vivo* biological phenomena that cannot be ascertained using non-animal alternative methods. We will rigorously apply the principles of the 3Rs – replacement, reduction and refinement – and the harm–benefit analysis in assessing applications for such work. The severity classification of any protocols in such projects should normally be either non-recovery or mild.

We will require you to review your project's objectives regularly (at least once a year) to consider the latest alternatives for replacing, reducing and refining the use of animals. You must also provide a critical evaluation of the learning objectives as part of the assessment of benefit for our harm–benefit analysis of your application, and we will require ongoing assessment of these benefits throughout the duration of the project as well as a retrospective assessment at the end of the project (see **Section 5.17**).

Further, we currently issue licences for the training of practising surgeons with a demonstrable career commitment to a surgical discipline requiring the use of micro-vascular techniques. The training authorised in such licences must ensure appropriate staging with the use of artificial materials before progressing to the use of cadavers and then, finally, to training in terminally anaesthetised animals. Given the physiological characteristics of the blood and its circulation, coupled with the anatomy and physiology of the blood vessel walls, the impact of surgical intervention cannot currently be accurately replicated *in vitro* or *ex vivo*.

5.19 Use and re-use of protected animals

The 'use' of an animal lasts from the time you carry out the first regulated procedure on that animal until you have completed any observations or collection of data for your experiment or test.

The use of the animal will involve one or more regulated procedures being applied for a particular purpose. Typically, but not exclusively, this 'series of regulated procedures for a particular purpose' will be specified in a single project licence protocol. Re-use means using an animal that has completed one series of regulated procedures for a particular purpose in a second or subsequent series of procedures for a particular purpose when to satisfy your scientific, regulatory or educational objective, you could have used a naïve (i.e. previously unused) animal for the second or subsequent series.

In this context, a 'series of regulated procedures for a particular purpose' could include the repetition of one or more steps with an intervening 'rest' or 'maintenance' period within one protocol where the repeated steps are being performed to address a common scientific objective.

We must give our consent to the re-use of an animal and specifically authorise it in your project licence(s). In addition, the following conditions must be met before an animal may be re-used.

Firstly, the severity classification of the protocol in which the animal is to be re-used must be 'non-recovery', 'mild' or 'moderate'. Re-use in a protocol classified as 'severe' will not be permitted under any circumstances.

Secondly, a veterinary surgeon with knowledge of the lifetime experience of the animal or animals must have advised that their general state of health and well-being is likely to have been fully restored following the application of the previous series of regulated procedures. In this respect, a user would normally be expected to know the conditions under which animals have been bred and to exercise due diligence in advising the veterinary surgeon.

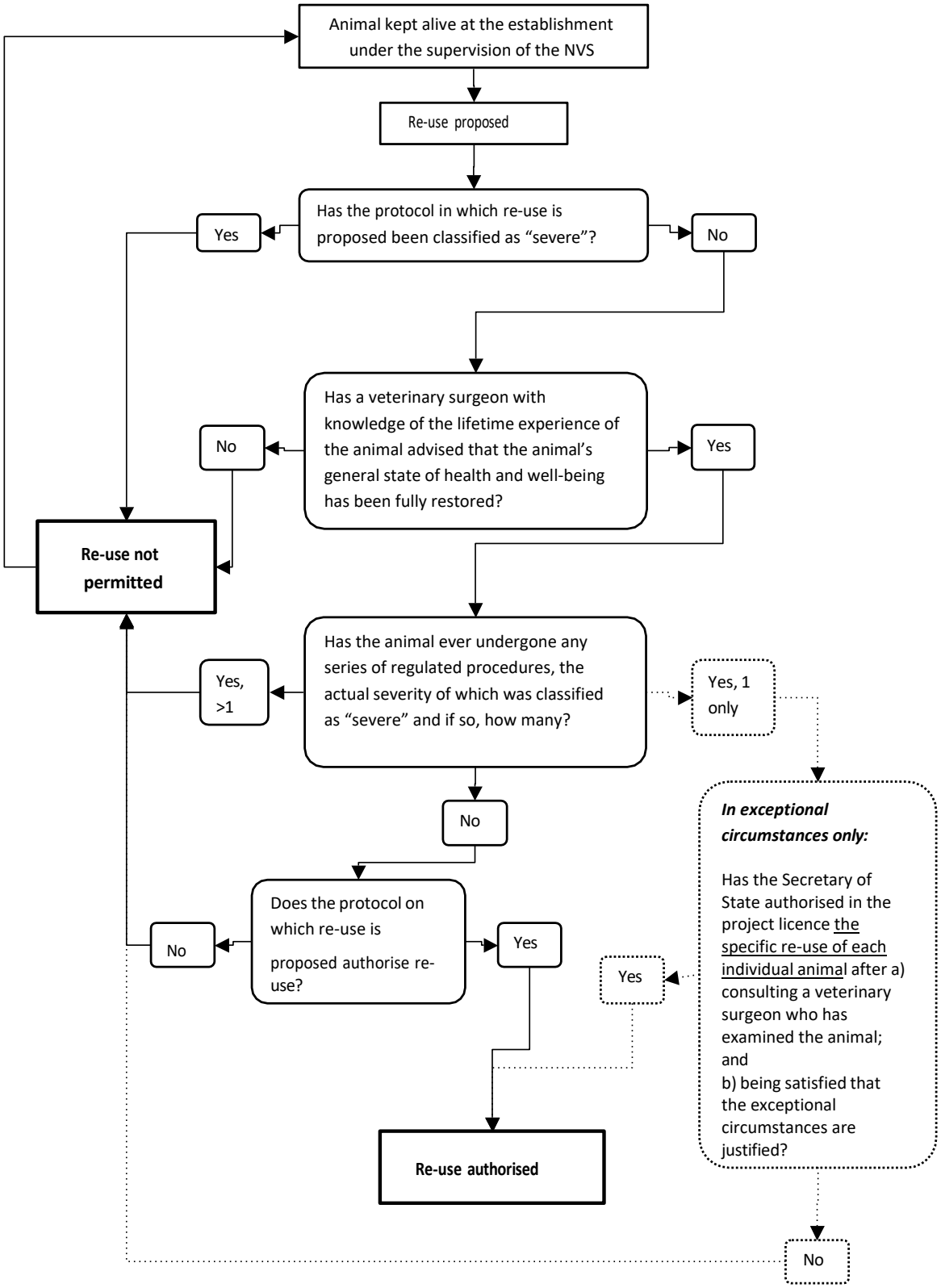
In practical terms, restoration of general health and well-being means that the animal must be free of adverse effects arising from the previous regulated procedures that would be above the lower threshold (see **Section 1.6**). If, as a consequence of any previous regulated procedures, maintaining an animal's state of health and well-being were to require interventions or measures that would themselves cross the lower threshold, the animal could not have been kept alive for prospective re-use (see **Section 5.20**).

Thirdly, where more than one series of regulated procedures has previously been applied to the animal, the actual severity of no more than one of those series has been classified as 'severe'.

Our consent may relate to the specific animal concerned or to animals used in specified procedures or specified circumstances. But in the case of an animal that has been subjected to a series of regulated procedures, the actual severity of which has been classified as 'severe', our consent must relate to the specific animal concerned, and we will give consent only after we have consulted a veterinary surgeon who has examined the animal to advise whether consent should be given. Furthermore, we must be satisfied that there are exceptional circumstances that justify the particular animal being used for the further series of regulated procedures.

These conditions are further illustrated in Figure 1.

Figure 1: Re-use of animals (section 14)



5.20 End of the procedure

At the end of procedures **ASPA section 15** requires that any animal that is suffering, or likely to suffer, adverse effects as a result of the procedures you have applied is humanely killed (see **Section 6**) **[Standard Condition 11]**.

If the animal is not suffering, a veterinary surgeon or other competent person must decide whether the animal can be kept alive. The test for determining whether an animal may be kept alive is that it is not suffering and is not likely to suffer adverse effects as a result of the regulated procedures. In practical terms, this means that the animal's general state of health and well-being has been fully restored. It must be free of residual adverse effects that would be above the lower threshold (see **Section 1.6**). If, as a consequence of any previous regulated procedures, maintaining an animal's state of health or well-being requires interventions or measures that would themselves cross the lower threshold the animal cannot be kept alive.

The animal must continue to be kept at your establishment under the supervision of the Named Veterinary Surgeon unless your project licence authorises the setting free or re-homing of the animal (see **Section 5.21** below) **[ASPA section 17A]**.

5.21 Setting free and re-homing

You must have our prior consent to release an animal into the wild or to re-home an animal either during the course of, or at the end of, a series of procedures. Consent for setting an animal free during the course of procedures will be incorporated into the project licence protocol. Typically, consent for setting free an animal at the end of procedures will be incorporated in your project licence where animals are re-homed or set free immediately after the procedures have ended, or in the establishment licence, where animals have been kept under the supervision of the NVS after completing procedures.

We must be satisfied that you have taken the maximum possible care to safeguard the animal's well-being. You will need to have explained in your project licence application how you will decide that the animal is fit to be set free and that it will be at no biological (or competitive) disadvantage because of the procedures it is undergoing or has undergone or because of its time in captivity.

Adequate schemes for ensuring the socialisation of an animal before being set free or re-homed should be in place. These might include rehabilitation for wild animals or socialisation and training programmes for animals being re-homed as domestic companion animals. In all schemes, the primary aim should be to ensure the animals being set free or re-homed have been well prepared to adapt to their new environment.

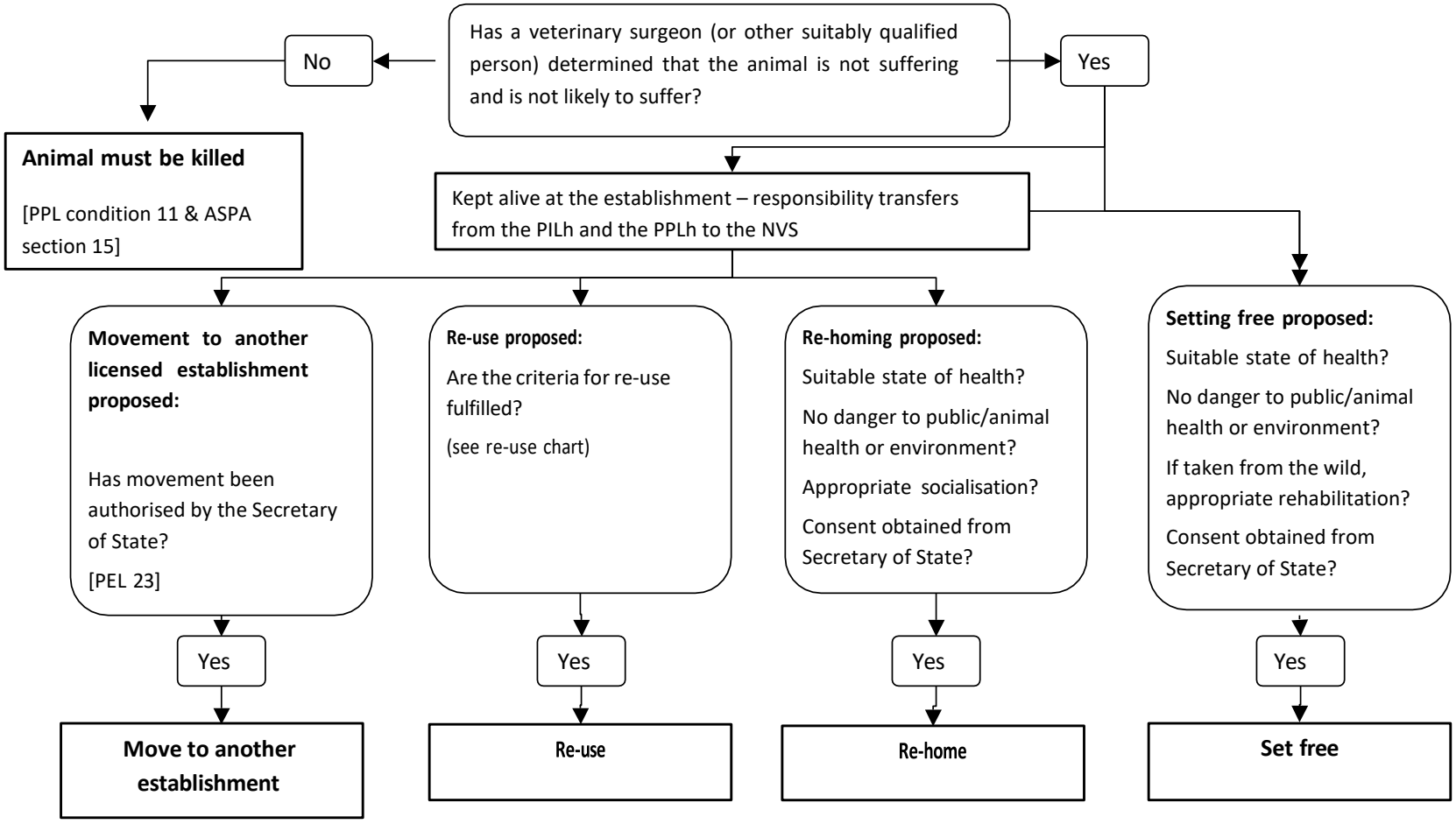
For an animal being re-homed, you must be satisfied that it is likely to settle into that home, including having confidence in the ability of the new owners to manage the animal and provide proper facilities for its care, exercise, etc. If the animal being re-homed is a cat, dog or primate, the new owner must be given a copy of any veterinary or social information about the animal that is included in its individual history file **[Standard Condition 9(4) of the Establishment Licence]**.

We must also be satisfied that the release or re-homing of the animal does not pose a danger to public health, animal health or the environment additional to that existing prior to the capture of the animal. You must also ensure that you have met the requirements of other relevant legislation and, where appropriate, you have implemented an agreed rehabilitation programme.

5.22 Moving an animal to another licensed establishment

You must not move an animal that is undergoing regulated procedures under your project licence from one licensed establishment to another without our prior consent **[Standard Condition 24]**. Typically, such consent will be incorporated into your project licence.

Figure 2: Fate of animals at the END of a series of regulated procedures



5.23 Your responsibilities as a project licence holder

5.23.1 Main responsibilities

As the project licence holder you are responsible for the overall implementation of the programme of work and for ensuring that regulated procedures are carried out strictly in accordance with your project licence, and in compliance with all the conditions of the licence **[Standard Condition 1]**.

You are expected to direct and manage the work of all of the personal licensees carrying out regulated procedures under the authority of your project licence and to ensure that such procedures are carried out only at the place or places specified in the licence **[ASPA section 3(c)]**. Personal licensees may apply regulated procedures to protected animals only as specified in the relevant protocol and in accordance with the programme of work specified in your project licence **[ASPA section 3(b)]**.

You would be committing an offence if you allow someone under your control to carry out a regulated procedure that is not in accordance with your programme of work **[ASPA section 22(2)(a)]**.

You would also be committing an offence if you allow someone without the requisite personal licence authority to carry out regulated procedures on your project **[ASPA section 22(2)(b)]**.

As the project licence holder, you must ensure that the programme of work is carried out in accordance with the 3Rs. You and others working on the project should seek and follow advice from the NVS, NACWO and NIO on the health, welfare and use of animals and on implementation of the 3Rs, both at the planning stage and when work is in progress. Specifically, you must ensure that:

- regulated procedures are not carried out if a satisfactory alternative (i.e. one which achieves the scientific outcome) to the use of protected animals is available **[Standard Condition 2]**;
- regulated procedures are not carried out if the data to be obtained are already available in an EU Member State and have been obtained using procedures which satisfy relevant EU regulatory requirements **[Standard Condition 3]**;
- the regulated procedures carried out are those which use the minimum number of animals; animals with the lowest capacity to experience pain, suffering distress or lasting harm; cause the least pain, suffering distress or lasting harm; and are most likely to provide satisfactory results **[Standard Condition 4]**;
- the regulated procedures carried out are designed so as to result in the death of as few protected animals as possible; and to reduce to the minimum possible the duration and intensity of suffering caused to those animals that die and, as far as possible, ensure a painless death **[Standard Condition 5]**;
- a regulated procedure is not applied to an animal if it may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated **[Standard Condition 7]**;
- any unnecessary pain, suffering, distress or lasting harm that is being caused by a regulated procedure is stopped **[Standard Condition 8]**;
- death as the end-point of any regulated procedure is avoided as far as possible and is replaced by an early and humane end-point; and as soon as the purpose of the procedure has been achieved, the procedure is stopped and appropriate action is taken to minimise the suffering of the animal **[Standard Condition 9]**;
- an animal is killed at the end of a series of regulated procedures unless a veterinary surgeon or other competent person has determined that the animal is not suffering and is not likely to suffer adverse effects, as a result of the regulated procedures **[Standard Condition 11]**;

- regulated procedures are carried out under general or local anaesthesia unless anaesthesia would be more traumatic to the animal than the procedures or incompatible with the purposes of the work **[Standard Condition 17]**.

You must ensure that those carrying out regulated procedures under your project licence adhere to the severity limits specified and observe any other controls described in the licence. If these constraints appear to have been, or are likely to be, breached, you must ensure that the Secretary of State is notified as soon as possible **[Standard Condition 18]**.

In addition, in accordance with **Article 24.2(b)** of the Directive, if you become aware of a failure to comply with any conditions of your licence, you must take steps to rectify that failure (if it is capable of being rectified) and you must keep a record of the steps you have taken **[Standard Condition 16]**.

As the project licence holder you are also responsible for ensuring that:

- the appropriate level of supervision is provided for all personal licensees carrying out regulated procedures under the authority of your licence **[Standard Condition 6]**. Note that while the NTCO is responsible for ensuring that, within the establishment, personal licensees are adequately educated, trained and supervised (see **Section 8 Named Persons**) their supervision when performing regulated procedures under your project licence is your responsibility and you should liaise with the NTCO regarding the maintenance of training, competence and supervision records;

- when an animal completes a series of regulated procedures for a particular purpose, you, or a suitably qualified personal licensee deputed by you, must classify the severity of the series as 'non-recovery', 'mild', 'moderate' or 'severe' using the criteria in **Appendix G [Standard Condition 10]**;

- if you, or a suitably qualified personal licensee deputed by you, consider the animal experienced a level of pain, suffering, distress or lasting harm that did not reach the lower threshold for regulation (see **Section 1.6** of this guidance) you should classify the severity as 'sub-threshold' in your records and for the annual statistical returns;

- regulated procedures are not carried out on any stray animal of a domestic species **[Standard Condition 12]**;

- regulated procedures are not carried out on:

  (a) any feral animal of a domestic species;

  (b) any animal taken from the wild;

  (c) a marmoset that is not the offspring of animals bred in captivity or has been obtained from a self-sustaining colony; or

  (d) any animal specified in Schedule 2 to the Act that has not been bred for use in procedures;

  unless specifically authorised in the project licence **[Standard Condition 13]**.

If your project licence authorises the use of animals taken from the wild, you must ensure that such animals are captured by a competent person using a method which does not cause the animal avoidable pain, suffering, distress or lasting harm. You must also endeavour to ensure that an animal taken from the wild which is found to be injured or in poor health is not subjected to a regulated procedure unless and until it has been examined by a veterinary surgeon or other competent person; and, unless the Secretary of State has agreed otherwise, action has been taken to minimise the suffering of the animal **[Standard Condition 14]**.

As the project licence holder, you must also ensure that:

- details of the programme of work and regulated procedures specified in the licence, and any additional conditions applied to the licence, are known to the personal licence holders working on the project and the NACWO, and to the NVS, NTCO, NIO and the establishment licence holder or Named Person Responsible for Compliance on request **[Standard Condition 23]**;
- the required records are maintained **[Standard Condition 19]**;
- annual statistical returns are provided when requested **[Standard Condition 20]**.

5.23.2 Keeping records

You are also responsible for keeping contemporaneous records of the procedures carried out under the project licence. We may ask to look at these at any time **[Standard Condition 19]**. The required information should be kept up to date.

Your records should include the names of the personal licence holders performing procedures authorised by the licence. They should record details of the procedures and protocols you and they apply, including:

- the species of protected animals used;
- a running tally of the numbers of each species used in each protocol;
- the sex and approximate age of the animals at the start of the protocols;
- the identification of the animals used (where appropriate);
- the start and end dates of the protocols;
- a brief description of the procedures you apply;
- adverse reactions including morbidity or mortality;
- the fate of the animals at the end of procedures (e.g. killed at the establishment, re-homed, set free);
- actual severity classification recorded at the end of the procedure;
- details of any continued use or re-use; and
- copies of any veterinary or other advice you have received.

5.23.3 Classification of actual severity

At the end of a series of regulated procedures for a particular purpose, you, or a suitably qualified person (typically a personal licensee) deputed by you, must classify the actual severity of the series of procedures carried out as ‘sub-threshold’, ‘mild’, ‘moderate’, ‘severe’ or ‘non-recovery’ using the observations taken from the animals during day-to-day monitoring. The criteria set out in **Appendix G** to this guidance describe severity which may be classified as ‘mild’, ‘moderate’, ‘severe’ or ‘non-recovery’.

In addition, when the actual severity experienced by animals is recorded at the end of a procedure, it may be that some animals have experienced severity which is below the lower threshold for regulation, i.e. below the level of pain, suffering, distress or lasting harm equivalent to that caused by inserting a hypodermic needle according to good veterinary practice (**Section 1.6**). We will require you to record this severity as ‘sub-threshold’.

The actual severity to be reported for the individual animal should be the highest level experienced at any point for that individual, including any cumulative effects, during the course of the procedure or series of procedures. It is not an average over the duration of the study, nor should it be based on the residual severity at the end of the series of procedures.

The requirement to classify actual severity in this way is intended to improve transparency and provide a focus for the refinement of procedures and applies from 1 January 2013 **[Standard Condition 10]**. You will need to submit data on actual severity to us for all procedures completed under your licence after 1 January 2014. The first time you will need to submit those data to us will be in January 2015 for all procedures completed during 2014.

The death of an animal whilst undergoing regulated procedures is regarded as being severe in terms of actual severity classification, provided it complies with two conditions:

- an 'informed decision' cannot be made that the animal did not experience severe suffering prior to death; and
- the death must be procedure-related.

Factors allowing an informed decision to be made will vary case by case but include frequency of monitoring, use of anaesthesia and analgesia, information on the cause of death and knowledge of what each means in terms of the likely experience of the animal. If it is unlikely that death was preceded by severe suffering, the actual severity classification should reflect the known experience prior to death. If an animal dies whilst under effective general anaesthesia such a death would not be regarded as severe.

For the purposes of statistical reporting of actual severity, the severity allocated should primarily relate to the severity of the experimental procedures and not unrelated incidents and non-procedural harms.

Unrelated causes might be disasters such as failed environmental controls, fire or floods, as well as disease outbreaks and cage flooding. These scenarios are over-arching incidents, affecting more than one particular study. However, they must be recorded, investigated further and followed up to prevent recurrence. They should be separately reported to us under the responsibilities of the Establishment Licence holder.

Furthermore, a death should not be considered to be procedure-related if the death might be expected to have occurred in the normal course of time in the absence of the specific procedure being performed. For example, deaths which are within a predicted level of mortality associated with a background strain in a GAA colony should not be considered to be procedure-related.

We recognise this is a complex area and propose to develop additional advice and case studies during the introduction of actual severity reporting. These will be available in an Advice Note on the 'Research and testing using animals' page on the GOV.UK website. Meanwhile, some useful information and examples can be found here: http://ec.europa.eu/environment/chemicals/lab_animals/pdf/examples.pdf and http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Consensus%20doc%20on%20severity%20assessment.pdf

Actual severity assessments should be used to identify further opportunities to implement the 3Rs in future studies, including the potential to improve protocols for assessing animal suffering and severity.

5.23.4 Annual statistical returns

You are responsible for supplying data to the Home Office on the procedures you carry out for publication in the *Statistics of Scientific Procedures using Living Animals*. This information must be provided by 31 January each year on the 'return of procedures' form. If you fail to submit the data by the required date or supply inaccurate data, we may revoke your licence **[Standard Condition 20]**. If your project licence either expires or is revoked during the year, you must make the return within 28 days of the date of expiry or revocation.

We issue code lists and explanatory notes to help you complete the form.

5.24 Avoiding duplication in projects

You must take steps to ensure that you do not carry out procedures on an animal if the data you want to obtain are already available **[Standard Condition 3]**. In the case of genetically altered animals, you must not undertake regulated procedures to create a genetically altered line if suitable animals of the same or equivalent line are available. You may be justified in replicating work in order to validate the study under your own conditions or if you have reasonable doubts as to the veracity of the data, and this should be clearly stated in the programme of work specified in your project licence (see also **Sections 2.5** and **2.6**).

5.25 Conflicts of interest

Conflicts of interest must be avoided. For any group of protected animals, there should be at least three people filling the five key roles of establishment licence holder, project licence holder, personal licence holder, NACWO and NVS. (See **Section 3.13.8** for more information.)

Please ask us for advice if you are in any doubt about a potential conflict of interest.

5.26 Amending your project licence

You might need to amend your project licence as the work evolves. This may be because:

- there are material discrepancies between the predicted and actual adverse effects;
- you want to add new objectives;
- you want to introduce new or revised protocols to help meet your objectives or incorporate new reduction, refinement or replacement strategies;
- you need to revise the estimated number of animals to be used;
- your details need to be updated;
- specified places need to be added or deleted.

The estimated number of animals to be used in each protocol forms part of the specified programme of work. Your licence should be submitted for amendment if a change to the estimated numbers represents a significant change to the programme and/or would have a bearing on the harm–benefit analysis.

An increase of more than ten per cent of the estimate in non-recovery, mild or moderate severity protocols is likely to be regarded as significant in this respect. We would expect the estimated numbers in protocols classified as severe, and all protocols involving the specially protected species (primates, cats, dogs and equidae), not to be exceeded without an amendment being authorised.

You should consult your NVS, NACWO and NIO at an early stage to obtain their advice relating to your proposed amendment, including their advice on incorporating the 3Rs.

Your amendment request must also be evaluated by your AWERB before it is sent to us. If your proposed amendment involves work at more than one establishment, you will need to arrange for this review at each establishment.

Our inspectors will advise us whether and on what terms we should grant the amended authorities. They will perform a harm–benefit analysis of the requested amendment but also will consider whether the original harm–benefit analysis has been overtaken by scientific or technical advances since the licence was previously authorised. We may refer your request to an external assessor or to the Animals in Science Committee.

Amendments only take effect once we have issued your revised licence. You should wait until you have your amended licence document before you carry out any work under the revised authorities.

You must make sure that personal licence holders are familiar with the amended terms and conditions. You must also supply a copy of the amended licence authorities to the establishment licence holder and named persons.

5.27 Revoking your project licence

You may request that your licence be revoked at any time.

If you want to relinquish responsibility for the programme of work or can no longer comply with the terms and conditions of your licence, we will need a fresh application from the new applicant if the programme of work is to continue. However, where no significant changes are made to the programme of work, and the new applicant is deemed suitable, we may issue a licence specifying the same programme of work and with the same expiry date, licence number and conditions as the original.

5.28 Revoking, suspending or varying your project licence other than at your request

A project licence becomes invalid on its expiry date. We may also revoke, suspend or vary project licences at other times. These include:

- as a result of non-compliance with the requirements of ASPA – for example, if the holder can no longer be entrusted to manage the programme of work; or we might vary a licence to add new conditions;
- where it is appropriate to do so – for example, where advances in science, animal welfare, the 3Rs or views on ethics alter the balance between the likely harms and the likely benefits.

5.29 Suspending your project licence to safeguard animal welfare

We may suspend a project licence if there is an urgent need to safeguard the welfare of a protected animal. If this happens, all procedures authorised by that licence must stop immediately. We may require you to take action to safeguard the welfare of your animals or if you are unable to do so, we may take that action.

There is no right of appeal against this suspension. However, such suspension would only be in force for three months in the first instance, with subsequent similar periods applied only if a formal decision to vary or revoke your licence has not been made by the end of the suspension period.

5.30 Your right to make representations

Under **ASPA section 12**, you have the right to make representations (appeal) if we intend to vary or revoke your licence other than at your request or at the request of the establishment licence holder should that establishment cease to be your sole or primary place of work. If we notify you of such an intention, we will provide you with guidance on your right to appeal (see **Appendix E** for more information).

5.31 Standard conditions for project licences

We grant project licences subject to standard conditions. These are set out in **Appendix C**.

The requirements for meeting these responsibilities, where these are not entirely self-evident, have been set out above or elsewhere in this guidance.

Sometimes we may include additional conditions, for example:

- to ask you for a report after first using a novel procedure; or
- to require you to notify us before regulated procedures are carried out at a POLE so that the inspector may attend to observe the conduct of the procedures if he or she wishes. The requirements for meeting these additional responsibilities will usually have been explained to you by either an inspector or other ASRU officials.

6. HUMANE KILLING OF PROTECTED ANIMALS

The principle of refinement set out in **ASPA section 2A** requires that animals are killed with a minimum of pain, suffering and distress.

6.1 How is the killing of animals regulated by ASPA?

Details regarding who may kill protected animals, the methods that may be used under different circumstances and any penalties, should these requirements not be met, are set out in ASPA section 15A. This section also refers to other requirements expanded in ASPA section 2(7), and **Schedule 1**.

ASPA section 15A permits relevant protected animals to be killed intentionally only by a competent person using a method that is defined as appropriate. Note that killing an animal in breach of this requirement could be a criminal offence. The terms 'relevant protected animal' and 'intentionally' are used in **ASPA section 15A** for the purpose of setting out the law. It is not necessary to use them in general parlance with regard to the requirements of ASPA. The way in which **ASPA section 15A** applies is described in the remainder of this section.

ASPA Schedule 1 lists killing methods appropriate for different types of animals, which are considered to be reasonably straightforward and can be performed consistently in a humane manner by someone who has received appropriate training and supervision.

ASPA section 2(7) defines the circumstances under which humane killing is a regulated procedure.

6.2 Who may kill a protected animal?

You must be registered as competent to kill animals in the register kept by the establishment licence holder. This registration will clarify the species and types of animals, and the killing methods, which are linked to the training and supervision you have undergone.

If you are to kill protected animals at a place other than a licensed establishment (POLE), you must be registered by the licence holder for the establishment named as the 'primary availability' for the project licence concerned.

There are no legal constraints under ASPA for a person killing an animal in emergency circumstances. However, in such an emergency, where it is necessary for an animal to be killed as a matter of urgency, it is good practice to ensure an appropriate method of killing is carried out by a competent person whenever possible.

In addition to being registered at your establishment, you must hold appropriate personal licence authority to kill animals by methods authorised in a project licence, including a project licence which may specify places other than licensed establishments (POLEs).

You will need to have been adequately educated and trained in the killing of animals before your name can be entered in the register. You can receive theoretical training in the killing of animals, and can observe killing and can practise methods on dead animals (e.g. physical methods) prior to being entered in the register. However, you may not kill an animal until you are registered. Once registered, you must be supervised when killing animals until you have demonstrated that you are competent to kill animals of the type in question by the specific methods used.

6.3 Where may protected animals be killed?

Within a licensed breeding supplying or user establishment protected animals may be killed only in an area listed in the Schedule of Premises (**Section 3.9**).

Protected animals may also be killed at a place other than a licensed establishment (POLE) only if that place is authorised for the conduct of regulated procedures by project licence authority and the animal is being or has been subjected to a regulated procedure under the authority of that project licence.

There are no legal constraints under ASPA for a person killing an animal at a place other than a licensed establishment solely for the scientific use of its organs or tissues.

6.4 What methods may be used to kill protected animals?

See Figure 3, which summarises this information.

For protected animals kept at *licensed breeding, supplying or user establishments*, including those killed for scientific use of their tissues or organs, one of the following methods should be used, as appropriate:

- a method listed in **Schedule 1** of ASPA;
- a method specified in the establishment licence;
- a method specified in a project licence, under which authority the animal has been used in regulated procedures;
- a method complying with Article 4 of **Council Regulation (EC) No 1099/2009** when used to kill an animal used in an agricultural research project requiring animals to be kept under commercial farm conditions, the process of killing being completed by one of the methods listed in paragraph 1 of **Schedule 1**; or
- any method if an animal is already deeply anaesthetised (or at an equivalent level of unconsciousness in the course of a series of regulated procedures) and will not regain consciousness, and the process of killing is completed by one of the methods listed in paragraph 1 of **Schedule 1**.

For licensed work at a POLE, a protected animal may be killed by a method specified in the project licence, by a **Schedule 1** listed method, or by a method specified as appropriate to that type of animal in the establishment licence where the project is primarily authorised. In the case of a method specified in the establishment licence, both project licence and personal licence authority will be required.

If an animal, which has *not* been subject to regulated procedures under licence authority, is killed at a POLE for the post-mortem collection of organs or tissues for scientific use, ASPA does not regulate the process of killing. In such cases, the method of killing should be humane such that the sanctions of other animal welfare legislation would not come into play.

Similarly, there are no ASPA requirements for killing a protected animal that has been set free or re-homed after completing regulated procedures, because it is no longer subject to the controls of the Act. In such cases, the method of killing should be humane such that the sanctions of other animal welfare legislation would not come into play.

Where it is necessary for a protected animal to be killed as a *matter of urgency* for animal welfare, public health, public security or environmental reasons, the method of killing is not specified by ASPA, nor is there a requirement for the person carrying out the killing to be on the establishment register. In practice, where the welfare of an individual animal at a licensed establishment is at stake, the person killing the animal would usually be registered and use a method which they were competent to apply.

6.5 Schedule 1 (Appendix D)

Schedule 1 to the Act lists killing methods appropriate for different types of animals, which are considered to be reasonably straightforward and can be performed consistently in a humane manner by someone with appropriate training and supervision. **Schedule 1** largely reproduces **Annex 4** to the Directive but, with the intention of retaining more extensive protection of animals, omits certain methods of killing and retains some other limitations and controls that were in force before the Directive was adopted.

The killing of a protected animal in accordance with **Schedule 1** is not a regulated procedure, either at a licensed establishment or at a POLE, and personal and project licence authorities are not required.

The methods of humane killing listed in **Schedule 1** are appropriate for the particular types of animal (and therefore legally permissible) only if the process of killing is completed by one of the six methods set out in paragraph 1 of Schedule 1. **Use of one of these methods to confirm death is mandatory in every case where an animal is killed by a Schedule 1 method.**

The use of a confirmatory method is intended to ensure the completion of the process of killing and that an animal is dead before either conducting post-mortem procedures or disposing of the cadaver. When an animal is killed using a method of killing that is also listed as a 'completion method' in paragraph 1, a different method must be used to complete the process of killing. For example, if a mouse is killed by dislocation of the neck, the process of killing must be completed using another method, such as exsanguination. If, for example, an animal is killed within an isolator with restricted access, it should be removed from the isolator as soon as possible after killing in order that completion of killing can be carried out before any risk of recovering consciousness. Where the use of such methods, including the confirmatory procedure, does not meet the scientific requirements for killing the animal, consideration should be given to either seeking project licence authorities or requesting the addition of another method of killing to the establishment licence (**Section 6.6**).

When it is in the welfare interests of the animal, any Schedule 1 method of humane killing may be carried out with prior sedation or anaesthesia. Dislocation of the neck in larger rodents, rabbits and birds should be carried out with prior use of a sedative or anaesthetic unless to do so would be likely to cause greater distress than using the same method of killing without sedative or anaesthetic. You should obtain advice from a suitably competent person such as the NVS or an NACWO.

The administration of a sedative or anaesthetic for this purpose is regarded as an integral part of the process of killing authorised by Schedule 1; it is not a regulated procedure and does not require personal or project licence authorities. The competence of the individual administering the sedative or anaesthetic will be assured through their registration by the establishment licence holder to use this specific Schedule 1 method to kill the type of animal in question.

For the purpose of limiting the use of carbon dioxide as described in **Schedule 1**, the age of neonatal rodents is up to and including day 10 where the day of birth is day 1.

6.6 Appropriate killing methods other than Schedule 1

6.6.1 a) Humane killing methods specified in an establishment licence

An establishment licence may specify a method of killing as being appropriate to a particular type of animal but only when the Secretary of State is satisfied, on the basis of scientific evidence, that the method is at least as humane as one of the Schedule 1 methods of killing that are appropriate to the type of animal in question. We will report those methods which have been so approved to the Commission on an annual basis.

In requesting the addition of such a method, the establishment licence holder should provide the scientific evidence to support the claim that the method is at least as humane as other methods listed in Schedule 1 for the particular type of animal. The rationale for requesting the additional method should be explained. The detail of the method,

including the provision and maintenance of necessary equipment, should be clarified. Any individual carrying out such a method must be registered in the establishment register of those authorised to kill animals. Such registration requires that individuals are adequately educated, trained, and supervised to ensure competence.

At a licensed establishment, a method of killing specified in the establishment licence may be used to kill any relevant protected animal for a scientific purpose as well as for a non-scientific reason, whether or not they have undergone or are undergoing regulated procedures. This includes those killed for scientific use of their tissues or organs. Killing animals in this way at a licensed establishment is not a regulated procedure. Where a method of killing specified in an establishment licence is used to kill animals undergoing regulated procedures, the method of killing will not need to be specified in the project licence.

6.6.2 b) Humane killing methods specified in the project licence

A project licence may specify a method of killing as being appropriate to a particular type of animal but only when the Secretary of State is satisfied, on the basis of a scientific justification, that the purposes of the programme of work cannot be achieved if a Schedule 1 method of killing appropriate to the type of animal in question is used.

A method complying with Article 4 of **Council Regulation (EC) No 1099/2009** may be used to kill an animal in an agricultural research project requiring animals to be kept under commercial farm conditions. The process of killing must be completed by one of the methods listed in paragraph 1 of Schedule 1. The use of such a method to kill protected animals is a regulated procedure and, therefore, requires personal and project licence authorities but no specific justification is required for its use.

An animal that has been rendered unconscious, for example, by general anaesthesia or decerebration for other regulated procedures, may be killed by any other method provided that the animal does not regain consciousness before death. The process of killing must be completed by one of the methods listed in paragraph 1 of Schedule 1. Killing an unconscious animal in this way is a regulated procedure and, therefore, requires personal and project licence authorities but no specific justification is required for its use.

Methods of humane killing specified in the project licence may be carried out both at licensed establishments and at POLEs.

6.7 Use of prior sedation or anaesthesia for methods other than Schedule 1

Unless carried out as non-experimental clinical veterinary practice, the administration of a sedative or anaesthetic prior to the use of a method of killing other than one listed in Schedule 1 is a regulated procedure.

6.8 What is meant by ‘killed intentionally’?

The controls set out in **ASPA section 15A** apply only to animals that are killed intentionally, i.e. where the purpose of the procedure is primarily to cause the death of the animal. The controls and sanctions for non-compliance described in this section of the guidance do not apply where a regulated procedure will, or is likely to, result in the consequential death of the animal. For example, such deaths may occur in severe procedures such as severe disease models or some safety testing, whether or not death is a prescribed end-point to that procedure. Similarly, the controls set out in **section 15A** do not apply in cases where death occurs as an unexpected adverse effect during the course of a regulated procedure.

Figure 3: Regulation of Humane Killing by the Animals (Scientific Procedures) Act 1986
Section 15A applies to all shaded cells

Location:	**Licensed Establishment**				**Place Other than a Licensed Establishment (POLE)**			
	User	**Breeding, Supplying or User**						
Purpose:	During/end of regulated procedures	For scientific use of tissues or organs	Surplus stock (no regulated procedures performed)	Emergency	During/end of regulated procedures	For scientific use of tissues or organs	Surplus stock (no regulated procedures performed)	Emergency
Section15A applies? (Appropriate method & registered person)	**YES**	**YES**	**YES**	**NO**	**YES**	**NO**	**YES**	**NO**
Permissible methods:	**Green = not a regulated procedure; Orange = a regulated procedure; Red = method not permitted.**							
Schedule 1	Not a regulated procedure	Not a regulated procedure	Not a regulated procedure	Not a regulated procedure	Not a regulated procedure	Not a regulated procedure	Not a regulated procedure	Not a regulated procedure
Specified in establishment licence	Not a regulated procedure	Not a regulated procedure	Not a regulated procedure	Not a regulated procedure	Regulated procedure	Not a regulated procedure	Not a regulated procedure	Not a regulated procedure
Specified in project licence	Regulated procedure	Regulated procedure	N/A	Not a regulated procedure	Regulated procedure	N/A	N/A	Not a regulated procedure
Slaughter method (EC 1099/2009) + Sch1 completion	Regulated procedure	N/A	N/A	Not a regulated procedure	Regulated procedure	N/A	N/A	Not a regulated procedure
Any method in an unconscious animal + Sch1 completion	Regulated procedure	N/A	N/A	Not a regulated procedure	Regulated procedure	N/A	N/A	Not a regulated procedure
Any other humane method	Not permitted	Not permitted	Not permitted	Not a regulated procedure	Not permitted	Not a regulated procedure	Not permitted	Not a regulated procedure

7. CODE OF PRACTICE ON THE CARE AND ACCOMMODATION OF PROTECTED ANIMALS

7.1 Introduction

The draft Code of Practice setting out the mandatory requirements for establishments relating to the care and accommodation of animals is available on the Research and testing using animals page of the GOV.UK website. The definitive Code of Practice will be laid before Parliament in accordance with **ASPA section 21** after consulting the Animals in Science Committee and will then replace the draft Code of Practice on the GOV.UK website.

The draft Code of Practice dated 15 February 2013 confirms the mandatory accommodation and care requirements, which must be met with effect from the amended legislation coming into force on 1 January 2013. This draft is based on **Annex 3** of the Directive and also includes details of additional or higher UK standards retained under **Article 2** of the Directive. Section A of the code describes general requirements. Section B describes the requirements for specific species of animals. This code is applicable until 31 December 2016. Before that time, we will issue a revised code to be applicable from 1 January 2017.

7.2 What does ASPA require?

It must be ensured that, at licensed establishments:

(a) the environment, housing, freedom of movement, food, water and care provided for each such animal is appropriate for the animal's health and well-being;

(b) the conditions under which any such animal is transported are appropriate for the animal's health and well-being;

(c) any restrictions on the extent to which each such animal can satisfy its physiological and ethological needs are kept to the absolute minimum;

(d) the environmental conditions in which such animals are kept are checked daily;

(e) the well-being and state of health of such animals is monitored by a suitably qualified person in order to prevent pain or avoidable suffering, distress or lasting harm; and

(f) arrangements are made to ensure that any defect discovered and any avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible.

7.3 What standards apply?

In most cases, establishments must, as a minimum, meet the standards concerning the care and accommodation of animals set out in **Annex 3** of the Directive. However, where an additional or higher standard concerning the care and accommodation of animals is set out in our Code of Practice, establishments must meet those standards, as a minimum, instead. Details are provided in the Code.

7.4 When do the standards have to be implemented?

Most of the standards must be applied from 1 January 2013. Where standards apply from a different date, this is explained in the Code.

7.5 Can I apply for an exemption from the requirements?

We may allow exemptions from the requirements where compliance with them would:

- prevent a programme of work specified in a project licence being carried out; or
- prevent the objectives of a programme of work specified in a project licence from being achieved; or
- in any other cases where an exemption is necessary for scientific, animal welfare or animal health reasons.

7.6 Where can I get more detailed advice on the housing and care of animals?

Questions relating to the care and accommodation of animals not covered by the Code should be referred to an inspector.

8. NAMED PERSONS

8.1 What does ASPA require?

Under **ASPA section 2C(5)**, establishment licences must specify named individuals who are responsible for the following activities:

- ensuring that the requirements of ASPA and the conditions of the establishment licence are complied with – the *Named Person Responsible for Compliance*. This will usually be the holder of the establishment licence;
- advising on the health, welfare and treatment of the animals – the *Named Veterinary Surgeon* (NVS) with expertise in laboratory animal medicine. Exceptionally, you may be able to nominate other suitably qualified experts where you can show that they are more appropriate for this role;
- overseeing the welfare and care of the animals – the *Named Animal Care and Welfare Officer* (NACWO);
- ensuring that those dealing with animals are adequately educated, trained and supervised until they are competent and that they continue to undertake appropriate further training – the *Named Training and Competency Officer* (NTCO); and
- ensuring that those dealing with animals have access to information they need about the species they are using – the *Named Information Officer* (NIO).

8.2 Named persons have an important role

Named persons have an important role and should help the holder of the establishment licence to fulfil their responsibilities. They should be actively involved with the local Animal Welfare and Ethical Review Body (AWERB). At least one NACWO and one NVS must be full members of your AWERB.

All project and personal licence holders and other staff dealing with animals should seek and follow their advice.

Named persons must be given appropriate training and resources and be able to access licences and other documents about the production, care and use of animals at the establishment.

8.3 Performance and conduct of named persons

Establishment licence holders are accountable for the performance and conduct of their named persons **[Standard Condition 15]**. They should ensure that named persons have the necessary authority to carry out their roles effectively.

If we think that a named person is unsuitable, or not doing his/her job properly, we will inform the establishment licence holder of our concerns so that the problem can be resolved.

8.4 Conflicts of interest

Given their role in providing independent advice on animal health and welfare, named persons carrying out the roles of NVS or NACWO must avoid perceived or real scientific, financial or other conflicts of interest. The people nominated for these roles should provide a declaration detailing any potential conflicts of interest. See **Section 3.13.8** for further details.

8.5 Named Person Responsible for Compliance (NPRC)

8.5.1 Who should be appointed NPRC?

Where the establishment licence holder is a corporate entity, it will be necessary to appoint an individual to serve as the NPRC. In all other circumstances, we expect that the individual named as the establishment licence holder will be the same as the NPRC. The NPRC should therefore be of similar standing in terms of authority and seniority, and undertake similar training, to that required for an individual who is an establishment licence holder (see Guidance on Training and Continuing Professional Development under ASPA, published on GOV.UK).

8.5.2 NPRC role and responsibilities

The responsibilities of the NPRC are the same as those of an individual serving as establishment licence holder. Please refer to **Section 3.13** regarding the responsibilities of establishment licence holders.

8.6 Named Veterinary Surgeon (NVS)

8.6.1 What is expected of the NVS?

The NVS is responsible for, monitors and provides advice on the health, welfare and treatment of animals and should help the establishment licence holder fulfil their responsibilities.

As the NVS you should be entrusted with the necessary management authorities to carry out your role effectively, and be seen to have senior management's support. You should be provided with appropriate training.

You should expect that appropriate facilities and resources are made available for adequate veterinary care of the protected animals at the establishment, including adequate support to ensure that veterinary care can be provided at all times.

You must be a member of the Royal College of Veterinary Surgeons (RCVS) with expertise in the species being used in the establishment.

You are accountable to the establishment licence holder for fulfilling your duties and responsibilities. In addition, NVSs should also observe their professional responsibilities to the animals under their care, to other veterinary surgeons, to the public and to the Royal College of Veterinary Surgeons, as set out in the RCVS *Code of Professional Conduct for Veterinary Surgeons*.

8.6.2 NVS role and responsibilities

The RCVS, in consultation with the Home Office and the Laboratory Animals Veterinary Association (a division of the British Veterinary Association), has produced guidance on the role and responsibilities of the NVS under ASPA, which was last updated in April 2012. The RCVS has committed to revising this guidance to reflect changes brought in under the 2012 amendments to ASPA. However, in the meantime, the current guidance will continue to apply.

The NVS should:

- be familiar with the main provisions of ASPA;
- establish a programme of veterinary care and health monitoring;

- be actively involved, on a day-to-day basis, in safeguarding the welfare of the protected animals at the establishment;
- ensure that adequate veterinary cover and services are available at all times at your establishment and that those caring for animals have your contact details;
- monitor the health and welfare of the animals under your care by regularly visiting all parts of your establishment specified in the establishment licence;
- advise on biosecurity issues and be able to advise on quarantine requirements and health screening;
- notify the personal licence holder in charge of an animal if its health or welfare is giving cause for concern. If the licence holder is unavailable, you must make sure the animal is cared for and, if necessary, killed humanely using a **Schedule 1** method, or another method approved in the establishment licence;
- provide veterinary advice and treatment, where needed and when requested by a personal licence holder;
- be familiar with relevant methods of humane killing listed in **ASPA Schedule 1**, together with any additional approved methods specified on the establishment licence;
- have a thorough knowledge of the husbandry, housing and welfare needs of the species kept at your establishment, including the prevention, diagnosis and treatment of disease; and the impact of housing and husbandry systems on the welfare and needs of an animal;
- comply with the requirements of the Veterinary Medicines Regulations relating to the supply and use of controlled drugs, prescription-only medicines and other therapeutic substances used on animals;
- maintain animal health records for all of the animals at your establishment, including of advice or treatment given; and ensure that these records are available to the Named Animal Care and Welfare Officer, the establishment licence holder and the Home Office; records must be kept to a proper professional standard;
- advise on breeding programmes, recognition of well-being and environmental enrichment;
- advise on the welfare of animals to be transported to another place and provide any necessary certification;
- have regular contact with the establishment licence holder and the other named persons; and
- be an active member of, and play a central role in, the AWERB at your establishment. (Note: At least one NVS at the establishment must be a full member of the AWERB.)

At a user establishment, you should advise licence holders and others on implementing the 3Rs. In particular, you should advise on:

- the impact of procedures on animals;
- recognising signs of pain, suffering, distress or lasting harm;
- general and experimental surgical techniques, and post-operative care;
- the scientific use of controlled drugs, prescription-only medicines and other therapeutic substances used on animals;
- appropriate methods of general anaesthesia, analgesia and euthanasia;
- strategies for minimising the severity of protocols, including recognising and implementing suitable humane end-points and other refinements; and

- factors causing bias, e.g. seasonal rhythms, chronobiological effects, stress due to husbandry restrictions and transport between facilities or within the facility.

You should be familiar with the main provisions of the project licences in use at your establishment. You should be aware of the adverse effects for each protocol and how they can be avoided, recognised and alleviated, and also of the humane end-points to be applied. The project licence holder should ensure that details of the programme of work and regulated procedures specified in the licence, and any additional conditions imposed on those procedures, are known to you. You should have access to licences and other relevant documentation.

You should expect to be consulted by the project licence holder, or project licence applicant, at an early stage to discuss and provide advice relating to a proposed application, or an amendment to an existing project licence, including advising on incorporating the 3Rs into the plan of the work.

You should expect your advice on the welfare of animals to be sought and followed by project and personal licence holders, and other staff dealing with animals, of whatever seniority, both at the planning stage and whilst work is in progress. Project licence holders will keep copies of any veterinary advice or certification you have given them.

You should make sure that an appropriate clinical investigation is undertaken, and therapy provided where appropriate, for the welfare of an animal being used for procedures, but you should also be aware of the possible compromising effects your recommended actions may have on data or other outputs from the work.

If an animal taken from the wild is found to be injured or in poor health, you should be asked to examine it before it is subjected to a regulated procedure and, unless the Secretary of State has agreed otherwise, take action to minimise the suffering of the animal **[PPL Standard Condition 14]**.

If an animal is to remain alive after a series of procedures, you should be asked to determine that the animal is not suffering and is not likely to suffer adverse effects, as a result of the regulated procedures.

Any animal still living after undergoing a series of procedures should be kept at the establishment under your supervision.

If an animal is to be removed from the establishment, you may be asked to advise whether the animal's state of health allows it to leave the establishment (whether to be set free or re-homed) and whether appropriate measures have been taken to safeguard its well-being.

If an animal is to be re-used, you should be asked to confirm that its general state of health and well-being has been fully restored following the application of the previous procedure or procedures. In making your assessment you should ensure you have knowledge of the lifetime experience of the animal.

If an animal is to be re-used that has been subjected to a regulated procedure, the actual severity of which has been classified as 'severe', you should be consulted to advise on whether consent can be given for re-use of that individual animal. You must have examined the animal before you provide this advice.

8.6.3 Your training

See Guidance on Training and Continuing Professional Development under ASPA, published on GOV.UK.

8.7 Other suitably qualified person

The NVS must be a member of the Royal College of Veterinary Surgeons. The RCVS maintains a register of veterinary surgeons holding specialist and other higher qualifications and maintains a Register of Members which can be searched by location on the RCVS website (http://findavet.rcvs.org.uk/check- the-registers/). Establishment licence holders may find these useful in helping to identify suitable nominees.

Nevertheless, under ASPA, a person other than a veterinary surgeon may be named on the establishment licence in place of an NVS. We will only permit this in exceptional circumstances where no suitable veterinary surgeon is available and the 'other suitably qualified person' has proven expertise relevant to the health and welfare of the particular types of protected animal held at the establishment and the range of regulated procedures performed there. To date, it has been deemed appropriate only when the protected animals involved were fish or embryonated avian eggs. We will normally consult the RCVS before approving such an appointment to ensure no suitable veterinarian is available.

With regard to providing advice on health and welfare, and ensuring action is taken to protect animals where there is concern for their health or welfare, the responsibilities of the 'other suitably qualified person' are equivalent to those of a NVS. Special arrangements may be necessary in relation to the supply and use of controlled drugs, prescription-only medicines and other therapeutic substances.

8.8 Named Animal Care and Welfare Officer (NACWO)

8.8.1 Who can become an NACWO?

NACWOs are responsible for overseeing the day-to-day husbandry, care and welfare of the protected animals held at their establishment. They should be a source of independent advice on welfare and care to minimise suffering and optimise the welfare of all animals that are bred, kept for use or used at the establishment.

A suitable person might, for example, be a senior animal technician with an animal technology qualification or an experienced stockperson with a qualification in agricultural science. The IAT maintains a *Register of Animal Technologists* who may be appropriate to fill an NACWO post. Further details are available at www.iat.org.uk.

NACWOs should have appropriate personal authority to promote high standards and will need good communication and diplomacy skills to champion a culture of care amongst both scientific and husbandry staff.

We expect NACWOs to have appropriate managerial authority to enable them to ensure that high standards of husbandry and care are practised, meeting or exceeding the minimum standards set out in the Code of Practice. This responsibility extends into all areas named on the establishment licence.

8.8.2 NACWO role and responsibilities

The NACWO should:

- be familiar with the main provisions of ASPA;
- have up-to-date knowledge and experience of relevant animal technology and a thorough knowledge of the husbandry and welfare needs of the species kept in the establishment;
- be aware of the standards of care, accommodation, husbandry and welfare set out in the **Code of Practice** and take appropriate steps to develop and maintain high standards of care and husbandry appropriate to the species;
- know about relevant methods of humane killing listed in **ASPA Schedule 1** and any additional approved methods specified on the establishment licence, and either be competent in their use or be able to contact others who are named on your establishment's register of qualified persons;
- be able to recognise the signs of pain, suffering, distress or lasting harm in the species for which you care and ensure that there is available expertise to monitor all animals to recognise any variation from normal health and behaviour;

- know which areas of your establishment are listed in the 'Schedule of Premises' on the establishment licence;
- establish a system to ensure that a competent person sees and checks every animal kept in an approved holding area at least once daily;
- know how to contact, at any time, the NVS or their deputy, and the establishment licence holder or their nominee. At user establishments, you should also know how to contact project and personal licence holders;
- pro-actively, working with the NVS as appropriate, promote implementation of refinements in animal care, husbandry and use;
- be familiar with the main provisions of project licences, particularly the adverse effects expected for each protocol, the control measures and humane end-points specified and the methods of killing specified in licences;
- champion a culture of care at your establishment acting as a role model for all those who care for, and use, animals;
- help the establishment licence holder to keep suitable records of the health of the animals (under the supervision of the NVS); of the environmental conditions in the approved areas in which animals are held; and of the source and disposal of animals; and
- be an active member of the AWERB at your establishment, and advise applicants for licences and licence holders on practical opportunities for implementing the 3Rs. (Note: At least one NACWO at the establishment must be a full member of the AWERB.)

If the health or welfare of an animal is giving cause for concern you must tell the personal licence holder who is responsible for the welfare of that animal. If that person is unavailable, you must ensure that the animal is cared for and, if necessary, that it is humanely killed using a **Schedule 1** method or another method approved in the establishment licence as per **ASPA section 2C(7)**. If you have any doubt about what you should do, you should contact the NVS or your assigned inspector as per **ASPA section 2C(8)**.

Where a NACWO is also a project licence holder or a personal licence holder, another person should be nominated to fulfill the role of NACWO for providing advice on the welfare of animals being used under that project or personal licence. Alternatively, the arrangement may be overseen by the AWERB, on behalf of the establishment licence holder, to ensure there is no conflict of interest.

8.8.3 Your training

See Guidance on Training and Continuing Professional Development under ASPA, published on GOV.UK.

8.9 Named Training and Competency Officer (NTCO)

8.9.1 Who can become an NTCO?

The NTCO is responsible for ensuring that all those dealing with animals are adequately educated, trained and supervised until they are competent and that they continue to undertake appropriate further training to maintain their expertise. The role may be undertaken by a single person or by a number of people at a large establishment. It is important that all tasked with this role at an establishment should work to the same principles and standards and that, where more than one person in an establishment is an NTCO, each understands their own individual responsibilities, e.g. for a particular animal unit, species or type of work.

The NTCO needs to be sufficiently senior to influence others and make decisions on training issues. It is likely that this role will require significant resource and the support of senior management.

As NTCO, you may or may not be directly involved in the provision of training; your role is to oversee the process, making sure that training is taking place, that standards are acceptable and that a consistent approach is being adopted and delivered. You will require good communication, management and organisational skills.

As NTCO, you are required to endorse each application for a new or amended personal licence which is requesting primary availability at the establishment. However, you may not endorse your own application for a personal licence or amendment. If you hold or wish to hold a personal licence, the establishment licence holder must nominate a second NTCO to independently endorse any applications made by you.

8.9.2 NTCO role and responsibilities

The NTCO should:

- be familiar with the main provisions of ASPA;
- be familiar with relevant training courses available either in-house or commercially;
- ensure everyone planning to work with animals under ASPA (including non-licensed people such as study directors, people undertaking **Schedule 1** killing, and those caring for animals) at your establishment is made known to you at an early stage in order that you can discuss their training needs with them;
- advise individuals on the training they will need to have completed in order to be issued with the licence(s) they seek and on any practical training and supervision they will need after they have received their licence;
- advise individuals on how supervision and assessment of competence are managed in the establishment;
- ensure provision is made for appropriate supervision to support formal training as a means to achieve competence;
- identify trainers for specialist procedures or techniques;
- ensure assessment of competence is conscientiously performed and properly recorded;
- ensure records, including certification, are maintained of training provided and competence assessments for all individuals working with animals under ASPA;
- set local standards for training, supervision, competence and continuing professional development for those carrying out procedures, designing projects and studies, taking care of and killing animals in line with national expectations;
- communicate local requirements and expectations to all relevant staff;
- endorse personal licence applications and applications for amendment to a personal licence;
- ensure that individuals working with animals under ASPA participate in appropriate continuous training to supplement their basic training and that this is recorded as evidence that their competence is maintained;
- be familiar with the species used and types of research performed at the establishment so that you can recommend appropriate basic and further training courses and identify appropriate supervisors;
- develop local training and assessment records and ensure that they are kept up to date;

- ensure that competence is maintained and establish mechanisms to identify refresher training requirements; and
- be actively involved with and provide advice to the AWERB at your establishment on matters related to education and training.

8.9.3 Your training

See Guidance on Training and Continuing Professional Development under ASPA, published on GOV.UK.

8.10 Named Information Officer (NIO)

8.10.1 What is an NIO?

The NIO is responsible for ensuring that those dealing with animals in the establishment have access to information they need about the species held there and procedures being performed. You will have good communication and networking skills.

8.10.2 NIO role and responsibilities

You must put in place systems to ensure that up-to-date information relevant to the needs of those dealing with animals is readily available. The information that you provide may be in hard copy or electronic format. This should include information relating to:

- guidance on the Act and local rules and information;
- biology of the species used at the establishment;
- provision of appropriate animal care and husbandry;
- animal welfare and implementing the 3Rs;
- relevant guiding principles for good practice (e.g. reports and other publications produced by organisations such as the ASC (and its predecessor, the APC), LASA, LAVA, IAT, NC3Rs, RSPCA, etc.);
- new scientific initiatives, technical advances and good practice relevant to types of work and species at the establishment;
- implementing the 3Rs in ways which may encourage replacement, reduction and refinement of the use of animals throughout the establishment; and
- sources of further information on any of these topics.

The NIO should establish and maintain a network within and outside the establishment to gather relevant information and to be able to target its dissemination to appropriate individuals.

The NIO should:

- be familiar with the main provisions of ASPA;
- be familiar with the species used and the types of research performed in the establishment;
- proactively search for and disseminate relevant, up-to-date information, including information on implementing the 3Rs;

- be actively involved with and provide advice to the AWERB at your establishment, in particular relating to the gathering and dissemination of information;
- maintain contacts for information sharing (e.g. with the Home Office and specialist groups and bodies such as the ASC, LASA, NC3Rs and animal welfare organisations);
- maintain local contacts based, for example, on function, role and research interests in order to be able to direct information proactively and towards relevant individuals;
- assist project licence holders to secure information relevant to their projects; and
- provide guidance on where and how to search for relevant information.

8.10.3 Your training

See Guidance on Training and Continuing Professional Development under ASPA, published on GOV.UK.

9. TRAINING

This chapter has been replaced by the Guidance on Training and Continuous Professional Development under ASPA, published on GOV.UK.

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10. ANIMAL WELFARE AND ETHICAL REVIEW BODIES (AWERBs)

Animal Welfare and Ethical Review Bodies (AWERBs) should, in most respects, continue and develop the work of the local Ethical Review Processes (ERPs) they replaced on 1 January 2013. For further information, see the joint RSPCA/LASA report "Guiding principles on good practice for Ethical Review Processes" (2010)

10.1 The requirement

Under **Article 26** of the Directive, the Home Office, must ensure that each breeding, supplying and user establishment sets up an animal welfare body. **Article 26** also stipulates the minimum membership of the animal welfare body and **Article 27** sets out its minimum tasks.

These requirements are implemented by **ASPA Schedule 2C** and **Schedule 3**.

ASPA Schedule 2C, **Part 1**, **paragraph 6**, stipulates that a section 2C establishment licence must include a condition requiring the holder to establish and maintain an AWERB. **ASPA Schedule 3**, **Part 2**, **paragraph 6**, sets out the relevant standard condition, including membership requirements.

10.2 Minimum membership

ASPA Schedule 3, **Part 2**, **paragraph 6** specifies that the AWERB must have, as full members, at least one of your establishment's Named Animal Care and Welfare Officers (NACWO) and at least one of your Named Veterinary Surgeons (NVS). If yours is a user establishment, your AWERB must also include a scientific member. Under **ASPA Schedule 3**, **Part 2**, **paragraph 6(2)(b)**, the required credentials for this member must be acceptable to the Secretary of State. In general, we are likely to accept a nomination of an individual who is actively engaged in science using animals and who is willing to commit time to the work of the AWERB. You should also ensure that your other named persons, including NIOs and NTCOs, are actively engaged with the AWERB, given the breadth of its tasks (see **Section 10.4**).

10.3 Additional members

Under **ASPA Schedule 3**, **Part 2**, **paragraph 6(2)(c)**, it is also open to the Secretary of State to specify, through this guidance, requirements for other people to be members of the AWERB. Accordingly, in order to help ensure the integrity of the process, we expect establishment licence holders to arrange for their AWERBs to actively seek a wider membership, taking into account, in a transparent manner, the views of people who do not have responsibilities under ASPA, as well as one or more persons who are independent of the establishment. Inspectors may also attend meetings of the AWERB from time to time as part of their responsibilities for monitoring compliance with the legislation.

10.4 Minimum tasks of the AWERB

ASPA Schedule 3, **Part 2**, **paragraph 6(3)** stipulates that the AWERB must carry out the tasks set out in **Article 27** of the Directive. These are to:

(a) advise staff dealing with animals in the licensed establishment on matters related to the welfare of the animals, in relation to their acquisition, accommodation, care and use;

(b) advise on the application of the 3Rs (see **Section 2**), and keep it informed of relevant technical and scientific developments;

(c) establish and review management and operational processes for monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the licensed establishment;

(d) follow the development and outcome (retrospective review) of projects carried out in the establishment, taking into account the effect on the animals used; and to identify and advise on elements that could further contribute to the 3Rs; and

(e) advise on re-homing schemes, including the appropriate socialisation of the animals to be re-homed.

10.5 Additional tasks

ASPA Schedule 3, **Part 2**, **paragraph 6(3)** also provides for AWERBs to be allocated other advisory and reviewing tasks, either through the relevant establishment licence or in guidance issued by the Secretary of State.

Accordingly, AWERBs should also:

- advise the establishment licence holder whether to support project proposals, primarily considering such proposals from a local perspective and bringing local knowledge and local expertise to bear;
- assist with the retrospective assessment of relevant projects carried out at their establishment (see **Section 5.17**); and
- respond to enquiries, and consider advice received, from the Animals in Science Committee (see **Section 13**).

More generally, AWERBs should:

- promote awareness of animal welfare and the 3Rs;
- provide a forum for discussion and development of ethical advice to the establishment licence holder on all matters related to animal welfare, care and use at their establishment;
- support named persons and other staff dealing with animals on animal welfare, ethical issues and provision of appropriate training;
- help to promote a 'culture of care' within the establishment and, as appropriate, in the wider community.

Whilst protecting confidentiality, it may be appropriate to share some of the outputs from the AWERB with colleagues in the establishment and the wider community to promote awareness of the AWERB's activities.

10.6 Record keeping

ASPA Schedule 3, **Part 2**, **paragraph 6(4)** requires the establishment licence holder to ensure a record is kept of any advice given by the AWERB and any decisions taken as a result. These records must be kept for at least three years and must be made available to an inspector or to the Secretary of State on request.

11. ABOUT HOME OFFICE INSPECTIONS

11.1 What do inspectors do?

Home Office (ASRU) inspectors are appointed under **ASPA section 18**. Their role is to:

- advise the Secretary of State on applications for ASPA licences and on requests for their variation or revocation;
- advise on the periodic review of licences, including retrospective assessments;
- visit licensed breeding, supplying and user establishments, and other places where work under ASPA is carried out (POLEs) to monitor standards and practices and compliance with ASPA and the conditions of any licences;
- report all non-compliance and recommend the action to be taken; and
- encourage good practices.

Inspectors have no powers to grant, refuse, vary or revoke licences. They provide advice to the Secretary of State. Granting and amending licences, and other actions, are carried out by administrative staff acting on behalf of the Secretary of State.

11.2 What powers does an inspector have?

If an inspector considers that a protected animal is undergoing excessive suffering he/she has the power under **ASPA section 18(3)** to require the animal to be immediately killed using an appropriate method.

These cases are individual and require the inspector to use their professional judgement. In determining what constitutes excessive suffering, an inspector evaluates:

- the level and nature of harm;
- the severity classification and adverse effects, refinement control measures and humane end-points specified in the protocol of the licence;
- the duration;
- the response to any treatment or control methods already given, and potential for alleviation;
- the ability of that animal to cope with that harm (e.g. stressed animals cope less well);
- the extent to which further data from that animal are necessary for the authorised programme of work; and
- any other factors which seem relevant.

Such considerations would be made in the context of a specific harm–benefit analysis relating to that individual animal.

11.3 What qualifications do inspectors have?

Inspectors are all fully registered medical or veterinary practitioners and usually have higher scientific or clinical postgraduate qualifications and first-hand experience of biomedical research.

11.4 How often do inspectors visit establishments?

Under ASPA, we are required to follow a risk-based approach when deciding how often to visit an establishment.

We use the following factors to make the risk assessment:

- the number and type of procedures, if any, you undertake;
- the severity classification and records of actual severity of those procedures;
- the number and species of animals housed and used at your establishment;
- your history of compliance with ASPA and the conditions of your licence(s);
- the general culture of your establishment in relation both to animal care and to structures and communication which encourage compliance; and
- any information which might indicate the likelihood of non-compliance and the likely impact.

All establishments are assessed in terms of whether they are low, medium or high risk. 'High risk' does not necessarily imply poor performance or a high likelihood of non-compliance; it may be associated with your use of sensitive species or severe procedures.

In addition to the requirement for a risk-based approach, ASPA also requires that at least one-third of user establishments and all establishments keeping non-human primates are inspected every year. In practice, we aim to inspect *all establishments* at least once a year. The majority will be visited more frequently.

11.5 How many inspectors are there?

The number of inspectors is determined primarily by the Secretary of State. This number is determined according to the overall risk at all establishments and the amount of work (including inspection, assessment and contributing to policy development) that needs to be done. The number is reported in the ASRU Annual Report together with data on the number and duration of inspections and the number of licence assessments performed.

11.6 What happens during an inspection?

Inspectors' visits will often be unannounced. You must allow an inspector access to all parts of the establishment listed in the schedule to your establishment licence and to visit other parts of the establishment so that they can:

- inspect areas you are using or are proposing to include in the schedule to your establishment licence to ensure that they comply with the **Code of Practice**;
- determine whether animals are being or have been used in procedures, or for breeding or supply, in areas not listed on the schedule;
- determine whether the breeding, supply and/or use of animals in procedures is compliant with licence authorities and conditions on licences;
- visit licence holders or applicants for licences to determine compliance or to advise on compliance with legal requirements;
- visit people named in the establishment licence to determine whether they understand and are fulfilling their required duties, and to advise on these roles.

You must provide any necessary assistance to inspectors to facilitate effective inspections, including access to records and facilities for meeting relevant personnel. You must advise us if you have local controls or precautions in place to minimise the risks of transmitting disease, as this may affect how we carry out inspections.

After an inspection, your inspector will prepare a report for the Chief Inspector of their findings. This is used as the basis to advise the Secretary of State, including whether you are breaching the conditions of your licence even if this is a minor matter (see **Section 12**).

These reports are not made available to you, but the inspector will inform you or your staff, usually during the course of the visit, of any issues which give cause for concern or indicate a risk of future non-compliance. Issues of non-compliance will always be reported to you formally.

We will keep inspection reports for at least five years.

The inspector reviews your risk status following each visit, noting any changes to the relevant risk factors. These changes, and recommendations, will be discussed with the establishment licence holder at least annually, including exploring options for reducing the risks. The Inspectorate reviews the risks of all establishments at least once a year to enable the Chief Inspector and the Secretary of State to agree on a suitable programme of inspections for the subsequent year.

11.7 Encouraging good practice

When you apply for a project licence, your inspector is likely to discuss your proposals with you in detail to ensure that you have done everything possible to follow the principles of the 3Rs.

During inspections your inspector is likely to inform you of best practice which has been seen in other establishments and encourage you to adopt this where appropriate.

11.8 Consistency and challenge

Inspectors will exercise their professional skills and judgement to try to ensure that they are fair to licensees and other individuals. They work collaboratively with other inspectors to try to achieve consistency. This does not mean that the same decision will be made in two apparently similar, yet subtly different, circumstances. However, all their judgements should be defensible. A process exists for individuals to seek a second opinion on any matter. Information on this is contained in the document “Dealing with disagreements between inspectors and individuals at establishments” which is available on the Research and testing using animals page of the GOV.UK website.

11.9 EU inspections

Article 35 of the Directive provides for the European Commission to examine the infrastructure and operation of national inspections in Member States where there is reason for concern, for example, about the proportion of inspections being carried out without prior warning. Should this occur, you must assist experts from the European Commission in carrying out their duties under Article 35.

12. NON-COMPLIANCE

12.1 What is non-compliance?

'Non-compliance' refers to a failure to comply with:

- a condition of a licence granted under ASPA; or
- a provision of ASPA.

12.2 Reporting non-compliance

12.2.1 During direct inspection by your assigned inspector

The inspector may witness a procedure(s) which is non-compliant with licence authorities, or they may identify non-compliance through examination of records, cage labelling or other data available during routine inspections. Inspectors may also see evidence which suggests that you may be at risk of non-compliance. In such cases they may give verbal or written advice with a view to helping you to ensure continued compliance (see **Section 12.9**).

12.2.2 Reported by the personal or project licensee or via the establishment

Incidents of non-compliance, especially those impacting animal welfare, may be reported promptly by telephone to the inspector assigned to your establishment. If the inspector is not available, a report to our central email address must be made without delay.

12.2.3 Other sources of information available to us

Information may come to our notice from a wide range of sources such as intelligence gathered by any inspector in the course of their duties, information published in the literature or via other media formats or information provided directly to us by stakeholders.

12.3 Offences

Whilst non-compliance covers a wide range of issues as noted above, the following are also criminal offences under **ASPA sections 22** and **23**:

a) operating a user, breeding or supplying establishment without a section 2C establishment licence (**ASPA s2B**);

b) applying regulated procedures to protected animals without a personal licence (**ASPA s3**)[4];

c) applying regulated procedures to protected animals that are not authorised in a project licence (**ASPA s3**)[4];

d) applying regulated procedures to protected animals at a place which is not specified in the relevant project licence (**ASPA s3**)[4];

e) failing to provide the information required to assist the retrospective assessment of a project (**ASPA s5F(4)**);

f) failing to comply with the ASPA provisions relating to:

- re-use (**ASPA s14**);

[4] You will not be guilty of this offence if you can show that you reasonably believed, after making due enquiry, that you had the necessary authority.

- the action to be taken at the end of a series of regulated procedures (**ASPA s15**);
- methods of killing (**ASPA s15A**)[5];
- the prohibition of public exhibitions (**ASPA s16**);
- the use of neuromuscular blocking agents (**ASPA s17**)[4];
- setting free and re-homing (**ASPA s17A**);

g) failing to comply with a requirement imposed by an inspector under **ASPA s18(3)** to kill an animal immediately to alleviate excessive suffering;

h) providing false or misleading information or recklessly providing such information to obtain, or assisting another person to obtain, a licence (**ASPA s23**).

In addition:

i) a project licence holder is guilty of an offence who procures or knowingly permits a person under his control to carry out a regulated procedure otherwise than as part of the programme specified in the licence; or otherwise than in accordance with that person's personal licence.

12.4 What can I do to avoid non-compliance?

A common cause of non-compliance is the inclusion of over-prescriptive detail in project licences, for example, stating unnecessarily precise volumes for fluid administration, or a specific age or weight range in which procedures will be performed.

In addition, many breaches of licence conditions, or ASPA, occur because the details of the authorities granted in the relevant personal and project licences have not been adequately checked. Failure to check licence authorities will not be accepted as a mitigating circumstance. Make sure you check your licence(s) carefully and understand what you are authorised to do. If in doubt, after seeking local guidance at your place of work, ask your inspector.

Do not start new work until you have received and personally checked your licence(s) and conditions.

Do not assume or accept the word of others, that authorities have been granted. You must check for yourself.

Check the detail of your licence(s) and remind yourself of the requirements of ASPA regularly, particularly before starting any new procedure.

Ensure that your licence(s) are available to anyone with relevant responsibilities under ASPA.

Take particular care if you work under more than one project licence to ensure that the necessary authorities exist in the *relevant* project licence.

The standard conditions of issue require establishment licence holders to take all reasonable steps to prevent the performance of unauthorised procedures in their establishment. Establishment licence holders should, therefore, also be mindful of the common causes of non-compliance and the measures that can be taken to prevent them.

[5] If you fail to comply with ASPA section 15A relating to methods of killing you will not be guilty of an offence if you can show that you did not know and had no reason to believe that the animal was a relevant protected animal (within the meaning of section 15A).

12.5 Compliance advice

Should you require it, your inspector will advise on a case-by-case basis on how to ensure compliance with licence conditions and the requirements of ASPA. They will also advise on how to avoid non-compliance on a case-by- case basis.

12.6 How we will deal with non-compliance

It is a requirement of **ASPA section 18(2A)(c)** that inspectors report to the Secretary of State on compliance with the provisions of the Act and with the conditions of licences. Where there is non-compliance, under **ASPA section 18(2A)(d)**, the inspector must advise on the action to be taken by the Secretary of State.

Inspectors will normally provide initial details of a non-compliance case to the ASRU Licensing Team within *five working days* of its discovery or notification. The ASRU Licensing Team will write to those who appear to be involved, notifying them of the ongoing investigation.

Assuming the non-compliance case does not obviously merit referral for prosecution (see **Section 12.7**), inspectors will investigate the circumstances of the case to establish what happened and why, who was involved, and what needs to be done to prevent it happening again (both within the establishment involved and, if appropriate, in other establishments). They will normally submit their full investigation report and recommendation to the ASRU Licensing Team within *30 working days* of its discovery or notification.

At this point, those involved in the case, either directly or as the relevant project licence holder or establishment licence holder, will be informed in writing by the ASRU Licensing Team about the nature of the non-compliance reported by the inspector. They will also be invited to provide, *within 28 calendar days*, any information they wish to be considered before a decision is taken regarding the appropriate sanction.

The ASRU Licensing Team will then consider the inspector's full report and recommendations, together with any information which may have been provided by those involved in the case. They will normally notify those involved, within a *further 15 working days*, of the sanction the Secretary of State proposes to apply. If this includes variation or revocation of licence authorities, the right to appeal under **ASPA section 12** will be explained.

The number of non-compliances and a summary of each case are published each year in an anonymised form in the ASRU Annual Report.

12.7 Cases referred for possible prosecution

At an early stage in the investigation of suspected non-compliance, inspectors will take a view on whether an offence has been committed that is sufficiently serious to justify referral for prosecution. In such cases, the inspector will normally suspend investigations pending referral of the matter to the prosecuting authorities. The inspector will also caution the person(s) involved.

Prosecution is reserved for the most serious cases,yg78 vv meriting referral to the prosecuting authorities. In England and Wales, this is the Crown Prosecution Service and, in Scotland, the Procurator Fiscal.

Examples may include:

- abuse of animals;
- severe and sustained neglect of animal care or welfare.

12.8 Criminal sanctions

The criminal sanctions applicable to the offences listed above are set out in **ASPA sections 22** and **23**. Any breach of ASPA sections 22 and 23 which is punishable by a criminal sanction, but is not accepted by the prosecuting authorities for prosecution, will nevertheless require immediate resolution and is likely to result in suspension or revocation of the relevant licence(s).

12.9 Other sanctions

Most non-compliance cases do not merit referral for prosecution. In these cases, inspectors will investigate the circumstances of the non-compliance to establish what happened and why, who was involved, and what needs to be done to prevent it from happening again (either within the establishment involved or, if necessary, in other establishments).

A range of other sanctions is available to the Secretary of State, including measures aimed at deterring or otherwise preventing a recurrence of non-compliance. These include:

- issuing a formal, written reprimand;
- issuing a compliance notice;
- requiring additional formal training or re-training;
- applying additional, special conditions to licences; and
- revoking, suspending or varying (amending) licences.

12.10 Written reprimands and compliance notices

If you have breached a condition of a licence you hold, or a provision of ASPA, we may issue you with a written reprimand or, if we require you to take action to prevent further non-compliance within a specified period, we will issue you with a 'compliance notice'. A written reprimand or a compliance notice will specify the licence condition(s) or ASPA provision(s) with which you have failed to comply.

In addition, a compliance notice specifies:

a) the action you must take to ensure that the failure is not continued or repeated;

b) any action you must take to eliminate or reduce any consequences of the failure.

It requires you to take that action within a specified time and explains what will happen if you fail to comply with the notice, including possible revocation of your licence.

12.11 Revoking, suspending or varying (amending) licences

If you have not complied with a condition of a licence you hold, or a provision of ASPA and the circumstances justify it, we may suspend, revoke or vary (amend) your licence either for a specified period or until further notice.

We may also suspend a project licence if there is an urgent need to safeguard the welfare of one or several protected animals. If this happens, all procedures authorised by that licence must stop immediately. We may require you to take action to safeguard the welfare of those animals or, if you are not willing or able to take that action, we may take action. For example, we may appoint another individual to be responsible for the welfare of those animals.

12.12 Suspension of licences on welfare grounds (ASPA section 13)

If there is an urgent need to safeguard the welfare of one or several protected animals, and you are not willing or able to take that action, we may take action (whether or not a compliance notice has already been issued). For example, we may suspend a licence for up to a maximum period of three months and may appoint another individual to be responsible for the welfare of those animals. If this happens, we may inform you that all work requiring the authorisation of that licence(s) must stop immediately.

12.13 Right of appeal

Under **ASPA section 12**, you have the right to make representations (appeal) to us if we intend to vary or revoke your licence other than at your request. If we notify you of such an intention, we will explain your right to make representations and how to do it.

12.14 Severity of non-compliance

We classify non-compliance cases according to their severity. It is a general principle that the severity of the sanctions imposed will escalate in line with the severity of the non-compliance. However, in determining the relevant sanction, each case is considered on its own merits, including taking account of both aggravating and mitigating circumstances.

The treatment of non-compliance will depend on how it came about, its scale and any consequential animal suffering. Deliberate or reckless non-compliance, causing unnecessary animal suffering or attempting to conceal the facts, will significantly increase the perceived gravity of non-compliance and hence the severity of the sanctions imposed. Repeated failures will generally be viewed more seriously than single incidents.

13. THE ANIMALS IN SCIENCE COMMITTEE

13.1 Introduction

The Animals in Science Committee (ASC) is an independent, non-departmental, public body set up under **ASPA sections 19** and **20**.

The ASC is responsible for providing impartial, balanced and objective advice to the Home Office, and the Department of Health , Social Services and Public Safety for Northern Ireland (DHSSPSNI), on issues relating to the 1986 Act (as amended).

The Committee is commissioned for advice by Home Office Ministers and can consider issues of its own volition. Issues may also be referred to the Committee by Northern Ireland Ministers.

The Committee has no executive powers and cannot grant, revoke or vary (amend) licences granted under ASPA.

13.2 Membership of the Committee

The Chair and Members of the Committee are appointed by the Secretary of State according to their skills, expertise and experience. They do not represent any organisation or interest group. The Committee includes lay members with an interest in the ethical issues related to the use of animals in scientific research.

The ASC will draw from a diverse range of expertise to meet its obligations under ASPA and can co-opt additional expertise where necessary.

13.3 Functions of the Committee

The Committee is convened to provide advice to Ministers, Animal Welfare and Ethical Review Bodies and to share best practice on matters relating to the acquisition, breeding, accommodation, care and use of protected animals.

The Committee is also convened to share information with national committees in other EU Member States on the evaluation of project licences and on the operation of Animal Welfare and Ethical Review Bodies.

The Committee, in its considerations, must have regard to both the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

Members of the Committee are expected to work in the public interest in accordance with the seven principles of public life.

13.4 Working protocol

The Home Office Ministers, the Northern Ireland Assembly Minister and the Committee are developing a ‘working protocol’ providing a framework under which the Committee and Ministers will work together. The working protocol, when finalised, will be published on the Committee’s website.

13.5 When will project licence applications be referred to the Animals in Science Committee?

Under **ASPA section 9(1)**, the Secretary of State may refer project licence applications to the Animals in Science Committee for advice.

In particular, we will seek specific or general advice, as appropriate, on applications involving:

- the use of wild-caught non-human primates;
- the use of cats, dogs, equidae or non-human primates in severe procedures;
- use of endangered species;
- projects with major animal welfare or ethical implications;
- projects involving the use of admixed embryos falling into category 3 of the AMS report on ACHM and category 2 where the predominance of an admixed embryo is unclear or uncertain (see **Section 5.18.2**);
- projects which may invoke any of the 'safeguard clauses' in the Directive with respect to the purpose of primate use, proposals for the use of a great ape, or proposals to cause long-lasting pain, suffering or distress that cannot be ameliorated[6]; or
- projects of any kind raising novel or contentious issues, or giving rise to serious societal concerns.

13.6 Contact details

You can contact the Animals in Science Committee through its secretariat by emailing asc.secretariat@homeoffice.gsi.gov.uk.

[6] Applications that may invoke one of the 'safeguard clauses' in Directive 2010/63 will require amended legislation e.g. according to ASPA section 5C for the use of great apes.

14. OTHER ADVISERS TO THE SECRETARY OF STATE

14.1 External assessors

Under **ASPA section 9(1)**, the Secretary of State may consult an independent assessor on project licence applications.

We may do so in a variety of circumstances. Advice may be sought when the issues raised require specific, expert knowledge not available to the inspectorate, or when there is a debate within the scientific or welfare communities, or between the inspectorate and an applicant, about:

- the scientific validity of the proposed methodology;
- the scope for further refinement of the work;
- the likely benefits arising from the programme of work; or
- the welfare costs to animals.

If we intend to refer your application to an external assessor, we will let you know and also take account of your views in selecting them. Usually, you will be told who the assessor is and the questions we have asked them to address.

The assessor's advice will be taken into account in the Secretary of State's decision but is not binding.

14.2 People who consider representations

ASPA section 12 sets out the actions we must take if we propose to refuse an application for a licence, or to vary or revoke an existing licence without your consent. Section 12 also provides for a right of appeal against our decision.

Where there is an appeal, we will appoint a person who is legally qualified to consider your representations. The appointed person's report will be taken into account when we make our final decision, but it is not binding.

APPENDIX A

STANDARD CONDITIONS IN SECTION 2C (ESTABLISHMENT) LICENCES

In these conditions, references to the 'Animals Directive' means Directive 2010/63/EU on the protection of animals used for scientific purposes. Section 2C licences are also known as establishment licences.

1. The licence holder shall ensure that the regulated activities carried on at the establishment are carried on in a manner that is consistent with the principles of replacement, reduction and refinement.

2. (1) The licence holder shall ensure that a register is maintained of those who are competent to kill protected animals. A person's name shall not be included in the register unless the person has been adequately educated and trained in the killing of animals.

(2) The register must specify, in relation to each person named, the descriptions of animals that the person is competent to kill and the methods of killing that the person is competent to use to kill each such animal.

(3) The licence holder shall ensure that each person so registered is supervised when killing animals at the establishment until he or she has demonstrated the requisite competence.

(4) The licence holder shall ensure that at all times the number of persons who are so registered and are present at the establishment is sufficient to enable any protected animal being kept at that place that needs to be killed to be killed expeditiously.

(5) The register shall, on request, be submitted to the Secretary of State or made available to an inspector.

3. The licence holder shall notify the Secretary of State of any proposed change in:

(a) the full name of the holder; or

(b) the full name and qualifications of the named person Responsible for Compliance; or

(c) the full name and qualifications of the named Animal Care and Welfare Officer; or

(d) the full name and qualifications of the named Veterinary Surgeon or other suitably qualified person; or

(e) the full name and qualifications of the named information Officer; or

(f) the full name and qualifications of the named Training and Competency Officer; or

(g) the areas appearing on the Schedule of premises for the establishment or the class of use within those areas; or

(h) the types of protected animals to be held and/or used in regulated activities at the establishment.

4. (1) All protected animals must at all times be provided with adequate care and accommodation appropriate to their type or species.

(2) Any restrictions on the extent to which such an animal can satisfy its physiological and ethological needs shall be kept to the absolute minimum.

(3) Unless otherwise authorised by the Secretary of State an environment, housing, freedom of movement, food and water appropriate for the health and well-being of each protected animal shall be provided.

(4) The licence holder shall ensure that the installations and equipment at the establishment are suitable for the species of protected animals kept at the establishment and for the regulated procedures, if any, carried out at the establishment. The design, construction and method of functioning of the installations and equipment must be such as to enable regulated procedures to be performed in a manner that provides reliable results, uses the minimum number of animals and causes the minimum degree of pain, suffering, distress and lasting harm to the animals used.

(5) The health and well-being of protected animals, and the environmental conditions in all parts of the establishment where protected animals are kept, shall be checked at least once daily by competent persons. Arrangements shall be made to ensure that any defect discovered and any avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible.

(6) The holder shall ensure that the conditions under which any protected animal is transported are appropriate for the animal's health and well-being.

(7) Unless otherwise authorised by the Secretary of State the licence holder shall ensure that at least the following standards are met:

(a) any applicable standard concerning the care and accommodation of animals or installations and equipment, which is set out in Annex 3 of the Animals Directive;

(b) any additional or higher standard concerning the care and accommodation of animals which is set out in any code of practice issued or approved under section 21 that was in force on 9 November 2010.

(8) For the purposes of subparagraph (7)(a) a standard set out in Annex 3 of the Animals Directive is not to be treated as being an "applicable standard" if the Annex specifies a date from which the standard is to have effect and that date has not been reached.

5. The licence holder shall ensure that the establishment shall be appropriately staffed at all times to ensure the well-being of the protected animals. Staff shall be adequately educated and trained before they perform any function relating to the care of the protected animals and shall be supervised when performing any such function until they have demonstrated the requisite competence.

6. (1) The licence holder is required to have established, and to maintain, an Animal Welfare and Ethical Review Body.

(2) The Animal Welfare and Ethical Review Body must consist at least of:

(a) one Named Animal Care and Welfare Officer and one named Veterinary Surgeon;

(b) if this licence authorises the application of regulated procedures to protected animals at the establishment, the holder of a project licence which specifies the establishment as a place where regulated procedures may be carried out, or another person with suitable scientific credentials acceptable to the Secretary of State; and

(c) such other persons as may be specified in guidance issued by the Secretary of State.

(3) The Animal Welfare and Ethical Review Body must carry out the tasks mentioned in Article 27.1 of the Animals Directive and any other advisory and reviewing tasks specified in this licence or in guidance issued by the Secretary of State.

(4) The licence holder shall ensure that whenever the Animal Welfare and Ethical Review Body provides advice a record is made of the advice and of any decisions taken in response to the advice. Such records shall be kept for a minimum period of three years and shall, on request, be submitted to the Secretary of State or made available to an inspector.

7. If this licence authorises the breeding of protected animals, the holder is not authorised to breed, at the establishment, non-human primates from any animal not bred in captivity unless the holder has in place a strategy acceptable to the Secretary of State for increasing the proportion of primates bred from animals bred in captivity. Any substantial changes to the strategy that are proposed shall be submitted to the Secretary of State for approval.

8. (1) Records shall be maintained, in a format acceptable to the Secretary of State, of the source, use and final disposal of all protected animals bred, kept or used at the establishment for any regulated activities.

(2) Such records shall include at least the following information:

(a) the number and the species of animals bred, acquired, supplied, used in procedures, or discharged from the control of the Act;

(b) the origin of the animals, including whether they are bred for use in procedures;

(c) the dates on which the animals are acquired, supplied, or discharged from the control of the Act;

(d) from whom the animals are acquired;

(e) the name and address of the recipient of animals;

(f) the number and species of animals which died or were killed in each establishment. For animals that have died, the cause of death shall, when known, be noted; and

(g) where this licence authorises the applying of regulated procedures to protected animals, the projects in which animals are used.

(3) Such records shall be kept for a minimum of five years from the date of final disposal of the animal and, on request, be submitted to the Secretary of State or made available to an inspector.

(4) The licence holder shall, on request, submit to the Secretary of State a summary report, in a form specified by the Secretary of State, of the source, use and final disposal of all protected animals bred, kept, or used at the establishment for any regulated activities.

9. (1) For the purposes of this condition, an "individual history file" is a file kept in relation to a dog, cat or non-human primate which contains particulars of the animal's identity; particulars of the animal's date and place of birth (if known); a statement as to whether the animal was bred for use in regulated procedures; any relevant reproductive, veterinary and social information about the animal; a record of the programmes of work, if any, which have involved the use of the animal in regulated procedures; and in the case of a primate, a statement as to whether the animal is the offspring of primates bred in captivity.

(2) The licence holder shall ensure that for each dog, cat and non-human primate held at the establishment an individual history file is established and kept up to date. In the case of such an animal bred at the establishment the individual history file shall be established as soon as is reasonably practicable after the animal's birth. Where such an animal is transferred to the establishment an individual history file shall be established in relation to the animal as soon as is reasonably practicable after its transfer (unless the animal is transferred from a place specified in another section 2C licence and an individual history file previously established in relation to the animal is provided in accordance with conditions included in that other licence).

(3) The licence holder shall ensure that if a dog, cat or non-human primate kept at the establishment is transferred to a place specified in another section 2C licence, the individual history file kept in relation to the animal is provided to the holder of that other licence.

(4) The licence holder shall ensure that if a dog, cat or non-human primate kept at the establishment is transferred otherwise than to a place specified in another section 2C licence, the person to whom the animal is

transferred is provided with a copy of any veterinary and social information about the animal that is included in the animal's individual history file.

(5) The licence holder shall ensure that if a dog, cat or non-human primate kept at the establishment dies at that place, is set free from that place or is transferred otherwise than to a place specified in another section 2C licence, the individual history file for the animal is kept for a period of three years following its death, setting free or transfer.

(6) A copy of any individual history file required to be kept by this condition shall, on request, be submitted to the Secretary of State or made available to an inspector.

10. (1) The licence holder shall ensure that before any unmarked dog, cat or non-human primate is weaned at the place specified in the licence the animal is marked. The licence holder shall ensure that before any unmarked dog, cat or non-human primate that has not been weaned is transferred from the establishment to a place specified in another section 2C licence, the animal is marked unless it would not be reasonably practicable to do so. Where an unmarked dog, cat or non-human primate that has not been weaned is transferred to the establishment, the establishment shall maintain records attesting to the identity and origin of the animal's mother until the animal is marked.

(2) The holder shall ensure that any unmarked cat, dog or non-human primate which is taken into the establishment after weaning shall be marked as soon as possible.

(3) The holder shall ensure that where a dog, cat or primate at the establishment is marked it is done in the least painful manner possible.

(4) The holder shall comply with any request made by the Secretary of State for an explanation of why any dog, cat or primate at the establishment has not been marked.

(5) For the purpose of this condition, "marked" means provided with a permanent means of individual identification and "unmarked" refers to an animal that has not been provided with a permanent individual identification mark.

11. (1) inspectors shall be provided with access at all reasonable times to all parts of the establishment which are concerned with the use, holding, breeding or care of protected animals.

(2) The licence holder must give any necessary assistance to inspectors carrying out visits by virtue of section 18(2A)(b); and to experts of the European Commission carrying out duties under Article 35 of the Animals Directive.

12. Unless authorised by the Secretary of State, there shall be no variation of the use of the approved areas of the establishment in the licence that may have adverse consequences for the welfare of the protected animals held.

13. Unless otherwise authorised by the Secretary of State:

(a) only the types of protected animals specified in the licence may be kept in the place or places specified in the licence for the purpose of the regulated activities specified in the licence; and

(b) for the purpose of the regulated activities specified in the licence, these animals may only be kept, bred and used in the areas listed in the schedule to the licence.

14. Records shall be maintained, in a format acceptable to the Secretary of State and under the supervision of the named Veterinary Surgeon, relating to the health of all protected animals bred, kept or used at the establishment for any regulated activities. Records shall, on request, be submitted to the Secretary of State or made available to an inspector.

15. The licence holder shall nominate and be responsible for the performance of named persons, acceptable to the Secretary of State, as required by section 2C(5).

16. Arrangements to ensure that animals are given adequate care must be made in the event that the named persons referred to in condition 15 above are not available for any reason.

17. Adequate security measures shall be maintained to prevent the escape of protected animals and to prevent intrusions by unauthorised persons.

18. Quarantine and acclimatisation facilities shall be provided and used as necessary.

19. Adequate precautions against fire shall be maintained at all times.

20. If this licence authorises the applying of regulated procedures to protected animals, the holder shall take all reasonable steps to prevent the performance of unauthorised procedures in the establishment.

21. The licence holder shall make adequate and effective provision for regular and effective liaison with and between those entrusted with responsibilities under the Act and with others who have responsibility for the welfare of the protected animals kept at the establishment.

22. Where this licence authorises the applying of regulated procedures to protected animals, the licence holder shall notify the Secretary of State of the death of a project licence holder within seven days of its coming to his or her knowledge when, unless the Secretary of State directs otherwise, the project licence shall continue in force for 28 days from the date of notification. The section 2C licence holder will, during that period, assume responsibility for ensuring compliance with the terms and conditions of the project licence.

23. (1) This condition applies where this licence authorises the applying of regulated procedures to protected animals.

(2) A protected animal which, having been subjected to a completed series of regulated procedures, is kept alive shall continue to be kept at the establishment under the supervision of a veterinary surgeon or other suitably qualified person unless:

(a) it is moved, with the authority of the Secretary of State, to another establishment;

(b) the Secretary of State consents under section 17A to the animal no longer being kept at the establishment; or

(c) its re-use in another procedure is authorised by the Secretary of State.

24. A copy of these conditions shall be readily available for consultation by all licence holders and named persons in the establishment.

25. The licence remains the property of the Secretary of State, and shall be surrendered to him on request.

APPENDIX B

STANDARD CONDITIONS IN PERSONAL LICENCES

In these conditions, references to the 'Animals Directive' means Directive 2010/63/EU on the protection of animals used for scientific purposes.

1. In exercising his or her responsibilities, the licence holder shall act at all times in a manner that is consistent with the principles of replacement, reduction and refinement.

2. The licence holder is entrusted with primary responsibility for the welfare of the animals on which he or she has performed regulated procedures; the licence holder must ensure that animals are properly monitored and cared for.

3. The licence holder must not apply a regulated procedure to an animal if the procedure may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

4. The licence holder must not apply a regulated procedure to an animal unless the holder has taken precautions to prevent or reduce to the minimum consistent with the purposes of the procedure any pain, suffering, distress or discomfort that may be caused to the animal.

5. Where the licence holder is applying a regulated procedure to an animal the holder must ensure that any unnecessary pain, suffering, distress or lasting harm that is being caused to the animal is stopped.

6. Where the licence holder is applying or has applied a regulated procedure which is causing the animal severe pain, suffering or distress the holder must take steps to ameliorate that pain, suffering or distress.

7. The licence holder shall ensure that where the holder applies a regulated procedure death as the end-point of the procedure is avoided as far as possible and is replaced by an early and humane end-point.

8. in all circumstances where an animal which is being, or has been, subjected to a regulated procedure is in severe pain, suffering or distress which is likely to be long-lasting and cannot be ameliorated, the licence holder must ensure that the animal is immediately killed in accordance with section 15A.

9. The licence holder may apply a regulated procedure without the use of general or local anaesthesia only if the holder is satisfied that:

(a) the procedure will not inflict serious injuries capable of causing severe pain; and

(b) the use of general or local anaesthesia would be more traumatic to the animal than the procedure itself or would frustrate the purposes of the procedure.

10. When anaesthesia (whether general or local) is used, it shall be of sufficient depth to prevent the animal from being aware of pain arising during the procedure.

11. If the licence holder applies a regulated procedure to an animal with the use of general or local anaesthesia the holder must, unless it would frustrate the purpose of the procedure, use such analgesics or other pain-relieving methods as may be necessary to reduce any pain that the animal may experience once the anaesthesia wears off.

12. The licence holder must use analgesia or another appropriate method to ensure that the pain, suffering and distress caused by regulated procedures are kept to a minimum.

13. It is the responsibility of the personal licence holder to notify the project licence holder as soon as possible when it appears either that the severity limit of any procedure listed in the project licence or that the constraints upon adverse effects described in the project licence have been, or are likely to be, exceeded.

14. The licence holder shall ensure that suitable arrangements exist for the care and welfare of animals during any period when the personal licence holder is not in attendance.

15. The licence holder shall ensure that, whenever necessary, veterinary advice and treatment are obtained for the animals in his or her care.

16. The licence holder shall ensure that all cages, pens or other enclosures are clearly labelled. The labelling must be such as to enable inspectors, named Veterinary Surgeons and named Animal Care and Welfare Officers to identify the number of the project licence authorising the procedures, the project licence protocol in which the animals are being used, the date the protocol was started, and the responsible personal licence holder.

17. In order to ensure that regulated procedures are performed competently, the licence holder shall not apply regulated procedures unless given the appropriate level of supervision by the project licence holder or an experienced personal licence holder deputed by him/her for such time as may be needed to achieve competence.

18. The licence holder is authorised to delegate to assistants, who do not themselves possess the requisite personal licence authority but are under his or her control, the delegable tasks which form an integral part of the regulated procedures the licence holder is authorised to perform by this licence. The tasks must not require technical knowledge or skill, and delegation shall be in accordance with any relevant guidance published by the Secretary of State under section 21.

19. The licence holder must take all reasonable steps to ensure appropriate personal and project licence authorities exist before performing regulated procedures. The licence holder must be aware of the nature of the authorities given by this licence and the project licence, and of the conditions of issue attached to the licences.

20. The licence holder shall maintain a record of all animals on which procedures have been carried out, including details of supervision and declarations of competence by the project licence holder as appropriate. This record shall be retained for at least five years and shall, on request, be submitted to the Secretary of State or made available to an inspector.

21. The licence holder must give any necessary assistance to inspectors carrying out visits by virtue of section 18(2A)(b); and to experts of the European Commission carrying out duties under Article 35 of the Animals Directive.

22. The licence remains the property of the Secretary of State, and shall be surrendered to him on request.

APPENDIX C

STANDARD CONDITIONS IN PROJECT LICENCES

In these conditions, references to the 'Animals Directive' means Directive 2010/63/EU on the protection of animals used for scientific purposes.

1. The licence holder is responsible for the overall implementation of the programme of work specified in this licence and for ensuring that the programme of work is carried out in compliance with the conditions of the licence.

2. The licence holder shall ensure that the specified programme of work does not involve the application of any regulated procedure to which there is a scientifically satisfactory alternative method or testing strategy not entailing the use of a protected animal.

3. The licence holder shall ensure that regulated procedures are not applied to an animal as part of the specified programme of work if the data to be obtained from the application of those procedures is already available in a Member State and has been obtained there by procedures which satisfy any relevant regulatory requirements of the EU.

4. The licence holder shall ensure that the regulated procedures applied as part of the programme of work specified in this licence are those which to the greatest extent use the minimum number of animals; involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm; cause the least pain, suffering, distress or lasting harm; and are most likely to provide satisfactory results.

5. The licence holder shall ensure that the regulated procedures applied as part of the programme of work specified in this licence are designed so as to result in the death of as few protected animals as possible; and to reduce to the minimum possible the duration and intensity of suffering caused to those animals that die and, as far as possible, ensure a painless death.

6. The licence holder shall ensure that the appropriate level of supervision is provided for all personal licensees carrying out regulated procedures under the authority of this licence.

7. The licence holder shall ensure that a regulated procedure is not applied to an animal as part of the programme of work specified in this licence if the procedure may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

8. The licence holder shall ensure that where a regulated procedure is being applied to an animal as part of the programme of work specified in this licence, any unnecessary pain, suffering, distress or lasting harm that is being caused to the animal shall be stopped.

9. The licence holder shall ensure that where a regulated procedure is applied to an animal as part of the specified programme of work, death as the end-point of the procedure is avoided as far as possible and is replaced by an early and humane end-point; and as soon as the purpose of the procedure has been achieved, the procedure is stopped and appropriate action is taken to minimise the suffering of the animal.

10. The licence holder shall ensure that where a regulated procedure has been applied to an animal as part of the programme of work specified in this licence, a suitably qualified person classifies the severity of the procedure as "non-recovery", "mild", "moderate" or "severe" using the criteria in Annex 8 of the Animals Directive. For the purposes of this condition, a series of regulated procedures applied to an animal for a particular purpose is to be treated as constituting a single regulated procedure.

11. Where a series of regulated procedures are applied to an animal for a particular purpose the licence holder shall ensure that the animal is killed at the end of the series unless a veterinary surgeon or other competent person has determined that the animal is not suffering and is not likely to suffer adverse effects, as a result of the regulated procedures.

12. Regulated procedures shall not be carried out on any stray animal of a domestic species as part of the programme of work specified in this licence.

13. Except with the authorisation of the Secretary of State, regulated procedures shall not be carried out as part of the programme of work specified in this licence on any of the following types of animal:

(a) any feral animal of a domestic species;

(b) any animal taken from the wild;

(c) a marmoset unless it is the offspring of marmosets bred in captivity or has been obtained from a self-sustaining colony of marmosets;

(d) any animal of a description specified in Schedule 2 to the Act unless it has been bred for use in procedures.

14. If the application of regulated procedures to animals taken from the wild is authorised in this licence the holder shall ensure:

(a) that animals taken from the wild are captured by a competent person using a method which does not cause the animal avoidable pain, suffering, distress or lasting harm; and

(b) that an animal taken from the wild which is found to be injured or in poor health is not subjected to a regulated procedure unless and until it has been examined by a veterinary surgeon or other competent person; and, unless the Secretary of State has agreed otherwise, action has been taken to minimise the suffering of the animal.

15. The licence holder must give any necessary assistance to inspectors carrying out visits by virtue of section 18(2A)(b); and to experts of the European Commission carrying out duties under Article 35 of the Animals Directive.

16. if the licence holder becomes aware of a failure to comply with any conditions of the licence the holder must take appropriate steps to rectify the failure (if it is capable of being rectified); and keep a record of the steps taken.

17. All authorised procedures shall be carried out under general or local anaesthesia unless:

(a) anaesthesia would be more traumatic to the animal concerned than the procedures themselves; or

(b) anaesthesia would be incompatible with the purposes of the procedures.

18. The licence holder shall ensure adherence to the severity limits as specified in the project licence and observance of any other controls described in the licence. If these constraints appear to have been, or are likely to be, breached, the holder shall ensure that the Secretary of State is notified as soon as possible.

19. The licence holder shall maintain a contemporaneous record of all animals on which procedures have been carried out under the authority of the project licence. This record shall show the procedures used and the names of personal licensees who have carried out the procedures. The record shall, on request, be submitted to the Secretary of State or made available to an inspector.

20. The licence holder shall send to the Secretary of State, before 31 January each year (and within 28 days of the licence having expired or been revoked), a report in a form specified by the Secretary of State, giving details

of the number of procedures and animals used, and the nature and purpose of the procedures performed under the authority of the project licence during the calendar year.

21. The licence holder shall maintain a list of publications resulting from the licensed programme of work and a copy of any such publication shall be made available to the Secretary of State on request. The list shall, on request, be submitted to the Secretary of State or made available to an inspector, and it shall be submitted to the Secretary of State when the licence is returned to him on expiry or for revocation.

22. The project licence holder shall submit such other reports as the Secretary of State may from time to time require.

23. The project licence holder shall ensure that details of the programme of work and regulated procedures specified in the licence, and any additional conditions imposed on those procedures, are known to:

(a) all personal licensees performing those procedures;

(b) the named person Responsible for Compliance;

(c) the named Animal Care and Welfare Officers responsible for the day-to-day care of the animals;

(d) the named Veterinary Surgeon, on request; and

(e) the named information Officer and named Training and Competency Officer, on request.

24. The licence holder must obtain the permission of the Secretary of State before:

(a) any animal undergoing regulated procedures is moved from a place specified in one section 2C licence to a place specified in another section 2C licence; or

(b) any animal is released for slaughter, unless this is already explicitly authorised by the project licence.

25. The licence remains the property of the Secretary of State, and shall be surrendered to him on request.

APPENDIX D

SCHEDULE 1 – APPROPRIATE METHODS OF HUMANE KILLING

See also **Section 6** and **ASPA sections 2** and **15A.**

1. The methods of humane killing listed in **Tables A** and **B** below are appropriate for the animals listed in the corresponding entries in those tables only if the process of killing is completed by one of the methods listed in sub-paragraphs (a) to (f) below:

(a) confirmation of permanent cessation of the circulation

(b) destruction of the brain

(c) dislocation of the neck

(d) exsanguination

(e) confirming the onset of rigor mortis

(f) instantaneous destruction of the body in a macerator.

2. [deleted]

3. (1) A requirement in Table A for prior use of a sedative or anaesthetic:

(a) is subject to sub-paragraph (2); and

(b) is not to be read as prohibiting the prior use of sedative or anaesthetic in any cases where it is not required by that Table.

(2) Nothing in this Schedule requires or permits the prior use of sedative or anaesthetic where the distress likely to be caused by administering it is greater than the distress likely to be caused by using the appropriate method of killing without sedative or anaesthetic.

A. Methods for animals other than fetal, larval and embryonic forms	**Animals for which appropriate**
1. Overdose of an anaesthetic using a route and an anaesthetic agent appropriate for the size and species of animal	All animals.
2. Exposure to carbon dioxide gas in a rising concentration	Birds and Rodents up to 1.5 kg (but not neonatal rodents).
3. Dislocation of the neck (with the prior use of a sedative or anaesthetic in the case of rodents and rabbits over 150 g and birds over 250 g)	Rodents up to 500 g; Rabbits up to 1 kg; Birds up to 1 kg.
4. Concussion of the brain by striking the cranium	Rodents and Rabbits up to 1 kg; Birds up to 250 g; Amphibians and reptiles (with destruction of the brain before the return of consciousness) up to 1 kg; Fishes (with destruction of the brain before the return of consciousness).
5. One of the recognised methods of slaughter set out below which is appropriate to the animal and is performed by a registered veterinary surgeon, or, in the case of the methods described in paragraph (ii) below, performed by the holder of a current licence granted under the Welfare of Animals (Slaughter or Killing) Regulations 1995 **(a)** i) destruction of the brain by free bullet using appropriate rifles, guns and ammunition, or ii) captive bolt or electrical stunning followed by destruction of the brain or exsanguination before return of consciousness.	Ungulates.
B. Methods for fetal, larval and embryonic forms	**Animals for which appropriate**
1. Overdose of an anaesthetic using a route and anaesthetic agent appropriate for the size, stage of development and species of animal	All animals.
2. Refrigeration, or disruption of membranes, or maceration in apparatus approved under appropriate slaughter legislation, or exposure to carbon dioxide in near 100% concentration until they are dead	Birds; Reptiles.
3. Cooling of fetuses followed by immersion in cold tissue fixative	Mice, Rats and Rabbits.
4. Decapitation	Mammals and Birds up to 50 g.

(a) S.i. 1995/731

APPENDIX E

PROCEDURE FOR REPRESENTATIONS UNDER THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

Explanatory note issued to those who may wish to make representations

Introduction

1. This note describes the procedure to be followed if you intend to exercise your right under the Animals (Scientific Procedures) Act 1986 to make written and, if you wish, oral representations against the Secretary of State's proposal to revoke, or vary, or not to vary the conditions of any licence issued to you under the Act, or to refuse your application for a licence under the Act.

2. Section 12 of the Act provides that if you make representations, a legally qualified person (who must be a person who holds, or has held, judicial office in the United Kingdom, or a barrister, solicitor or advocate of at least seven years' standing) will be appointed to consider them and report to the Secretary of State. The Secretary of State will take the report into account when making a final decision upon your licence or application.

Notification

3. You must notify the Secretary of State of your wish to make representations and say whether you wish to make oral or written representations or both, by the date shown in the notice. This will not be less than 28 days from the date of service of the notice. Once your notification has been received, the Secretary of State will inform you of the name of the legally qualified person appointed to consider the matter and the address to which you may send any written representations.

Documents

4. At the same time, the Secretary of State will send to you and to the person appointed to consider your representations, a copy of the list of documents he considers relevant to the consideration of your case, together with a copy of each document.

Time limit for written representations

5. You must submit your written representations to the person appointed to consider your case within 21 days of the date you are notified of his appointment and sent the relevant documents. This period may be extended at the discretion of the person appointed.

Notice of hearing of oral representations

6. If you have asked to make oral representations, you will be given at least 28 days' notice in writing of the date, time and place of the hearing. At the same time you will be asked to state whether you wish the hearing to be in public. In addition, if you wish to dispute any fact contained in a report from the inspector, you must give notice of this to the Secretary of State and provided you give at least seven days' notice, the inspector will attend the hearing and you will be entitled to question him or her about any matter of fact contained in the report.

Procedure at hearings or oral representations

7. The person appointed to hear your representations will determine the procedure to be followed at the hearing. You may attend the hearing if you wish. You may also be represented at the hearing by another person who may or may not be a lawyer. You have a right to call witnesses and to address the person appointed. The hearing will only be held in public if you have asked for this, but any hearing may be attended by a member of the Council on Tribunals or of its Scottish Committee.

Decision

8. The person appointed will provide a written report and recommendation to the Secretary of State. The Secretary of State will send you a copy with his final decision.

Note: the Annex to Appendix E sets out the Rules for the procedure for representation.

ANNEX TO APPENDIX E

1986 no. 1911

ANIMALS

The Animals (Scientific Procedures) (Procedure for Representations) Rules 1986

Made	*7th November 1986*
Laid before Parliament	*18th November 1986*
Coming into Operation	*10th December 1986*

In exercise of the powers conferred on me by Section 12(7) of the Animals (Scientific procedures) Act 1986, I hereby make the following Rules:–

Citation, commencement and extent

1. These Rules may be cited as the Animals (Scientific Procedures) (Procedure for Representations) Rules 1986 and shall come into operation on 10th December 1986.

2. These Rules shall apply to England and Wales and Scotland.

Interpretation, etc.

3. (1) In these Rules–

"the Act" means the Animals (Scientific procedures) Act 1986;

"applicant" means

under the Act, or the holder of such a licence, who wishes to make written or oral representations under section 12(3) or (4) of the Act in respect of –

(a) a proposal to refuse, revoke, vary or suspend the licence; or

(b) the inclusion of any condition in the licence.

and

"person appointed" means a person appointed to receive such representations under section 12 of the Act.

(2) Any notification, notice, written representations or other document given or sent in pursuance of these Rules may be given or sent by post.

Notification of appointment

4. Where the applicant has notified the Secretary of State of his wish to make representations under section 12(3) or (4) of the Act, the Secretary of State shall notify the applicant in writing of the name of the person appointed and of the address to which his written representations are to be sent.

Documents

5. The Secretary of State shall prepare a list of the documents which he considers relevant to the consideration of representations by the person appointed and shall send a copy of such list, together with a copy of each of the documents included in it, to the applicant with the notification sent in pursuance of the preceding Rule, and to the person appointed.

Time limit for written representations

6. The applicant shall submit his written representations under section 12(3) or (4) to the person appointed not later than 21 days after the date on which he is notified of the appointment of the person appointed in pursuance of Rule 4 of these Rules; but the person appointed may, if he thinks fit, extend the period during which such representations are to be submitted to him.

Notice of hearing of oral representations

7. (1) Where the applicant has notified the Secretary of State of his wish to make oral representations under section 12(3) or (4) of the Act, the Secretary of State shall give him at least 28 days' notice in writing of the date, time and place of the hearing by the person appointed.

(2) Such notice shall request the applicant to state whether he wishes the hearing to be in public.

(3) Such notice shall, where the documents sent in pursuance of Rule 5 of these Rules include a report by an inspector appointed under section 18 of the Act, invite the applicant to notify the Secretary of State whether he intends to dispute any fact contained in that report; and where the applicant has given the Secretary of State at least seven days' notice of his intention to dispute any such fact, the inspector shall attend the hearing and the applicant shall be entitled to question him about any matter of fact contained in the report.

Procedure at hearings of oral representations

8. (1) Subject to the provisions of the Act and the other provisions of these Rules the person appointed shall, in his discretion, determine the procedure at the hearing of oral representations.

(2) The applicant may appear in person at such a hearing, or may be represented by any other person, and shall be entitled to call witnesses and to address the person appointed.

(3) If the applicant so requests, the hearing by the person appointed shall be in public.

(4) Any member of the Council on Tribunals or of the Scottish Committee of the Council in his capacity as such may attend any hearing by a person appointed.

Postponement or adjournment

9. The person appointed may, if he thinks fit, postpone or adjourn any hearing of oral representations pending before him, and shall give the applicant reasonable notice of the date, time and place of the subsequent hearing.

Appointed person's report

10. Following his consideration of representations, the person appointed shall prepare a written report of his findings and recommendation and send it to the Secretary of State who shall furnish a copy of it to the applicant.

Home Office. 7th November 1986.
Douglas Hurd,
One of Her Majesty's principal Secretaries of State.

APPENDIX F

ANNEX 6 TO DIRECTIVE 2010/63/EU: LIST OF ELEMENTS REFERRED TO IN ARTICLE 37(1)(c)

1. Relevance and justification of the following:

   (a) use of animals including their origin, estimated numbers, species and life stages;

   (b) procedures.

2. Application of methods to replace, reduce and refine the use of animals in procedures.

3. The planned use of anaesthesia, analgesia and other pain-relieving methods.

4. Reduction, avoidance and alleviation of any form of animal suffering, from birth to death where appropriate.

5. Use of humane end-points.

6. Experimental or observational strategy and statistical design to minimise animal numbers, pain, suffering, distress and environmental impact where appropriate.

7. Re-use of animals and the accumulative effect thereof on the animals.

8. The proposed severity classification of procedures.

9. Avoidance of unjustified duplication of procedures where appropriate.

10. Housing, husbandry and care conditions for the animals.

11. Methods of killing.

12. Competence of persons involved in the project.

APPENDIX G

ANNEX 8 OF DIRECTIVE 2010/63/EU: SEVERITY CLASSIFICATION OF PROCEDURES

The severity of a procedure shall be determined by the degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of the procedure.

Section I: Severity categories

Non-recovery:

Procedures which are performed entirely under general anaesthesia from which the animal shall not recover consciousness shall be classified as 'non-recovery'.

Mild:

Procedures on animals as a result of which the animals are likely to experience short-term mild pain, suffering or distress, as well as procedures with no significant impairment of the well-being or general condition of the animals shall be classified as 'mild'.

Moderate:

Procedures on animals as a result of which the animals are likely to experience short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as procedures that are likely to cause moderate impairment of the well-being or general condition of the animals shall be classified as 'moderate'.

Severe:

Procedures on animals as a result of which the animals are likely to experience severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress, as well as procedures that are likely to cause severe impairment of the well-being or general condition of the animals, shall be classified as 'severe'.

Section II: Assignment criteria

The assignment of the severity category shall take into account any intervention or manipulation of an animal within a defined procedure. it shall be based on the most severe effects likely to be experienced by an individual animal after applying all appropriate refinement techniques.

When assigning a procedure to a particular category, the type of procedure and a number of other factors shall be taken into account. All these factors shall be considered on a case-by-case basis.

The factors related to the procedure shall include:

- type of manipulation, handling;
- nature of pain, suffering, distress or lasting harm caused by (all elements of) the procedure, and its intensity, the duration, frequency and multiplicity of techniques employed;
- cumulative suffering within a procedure;

- prevention from expressing natural behaviour including restrictions on the housing, husbandry and care standards.

Examples are given in Section III of procedures assigned to each of the severity categories on the basis of factors related to the type of the procedure alone. They shall provide the first indication as to what classification would be the most appropriate for a certain type of procedure.

However, for the purposes of the final severity classification of the procedure, the following additional factors, assessed on a case-by-case basis, shall also be taken into account:

- type of species and genotype;
- maturity, age and gender of the animal;
- training experience of the animal with respect to the procedure;
- if the animal is to be re-used, the actual severity of the previous procedures;
- the methods used to reduce or eliminate pain, suffering and distress, including refinement of housing, husbandry and care conditions;
- humane end-points.

Section III:

Examples of different types of procedure assigned to each of the severity categories on the basis of factors related to the type of the procedure.

1. Mild:

(a) administration of anaesthesia except for the sole purpose of killing;

(b) pharmacokinetic study where a single dose is administered and a limited number of blood samples are taken (totalling < 10% of circulating volume) and the substance is not expected to cause any detectable adverse effect;

(c) non-invasive imaging of animals (e.g. MRI) with appropriate sedation or anaesthesia;

(d) superficial procedures, e.g. ear and tail biopsies, non-surgical subcutaneous implantation of mini-pumps and transponders;

(e) application of external telemetry devices that cause only minor impairment to the animals or minor interference with normal activity and behaviour;

(f) administration of substances by subcutaneous, intramuscular, intraperitoneal routes, gavage and intravenously via superficial blood vessels, where the substance has no more than mild impact on the animal, and the volumes are within appropriate limits for the size and species of the animal;

(g) induction of tumours, or spontaneous tumours, that cause no detectable clinical adverse effects (e.g. small, subcutaneous, non-invasive nodules);

(h) breeding of genetically altered animals, which is expected to result in a phenotype with mild effects;

(i) feeding of modified diets, that do not meet all of the animals' nutritional needs and are expected to cause mild clinical abnormality within the time-scale of the study;

(j) short-term (< 24h) restraint in metabolic cages;

(k) studies involving short-term deprivation of social partners, short-term solitary caging of adult rats or mice of sociable strains;

(l) models which expose animals to noxious stimuli which are briefly associated with mild pain, suffering or distress, and which the animals can successfully avoid;

(m) a combination or accumulation of the following examples may result in classification as 'mild':

(i) assessing body composition by non-invasive measures and with minimal restraint;

(ii) monitoring ECG with non-invasive techniques with minimal or no restraint of habituated animals;

(iii) application of external telemetry devices that are expected to cause no impairment to socially adapted animals and do not interfere with normal activity and behaviour;

(iv) breeding genetically altered animals which are expected to have no clinically detectable adverse phenotype;

(v) adding inert markers in the diet to follow passage of digesta;

(vi) withdrawal of food for < 24h in adult rats;

(vii) open field testing.

2. Moderate:

(a) frequent application of test substances which produce moderate clinical effects, and withdrawal of blood samples (> 10% of circulating volume) in a conscious animal within a few days without volume replacement;

(b) acute dose-range finding studies, chronic toxicity/carcinogenicity tests, with non-lethal end-points;

(c) surgery under general anaesthesia and appropriate analgesia, associated with post-surgical pain, suffering or impairment of general condition. Examples include: thoracotomy, craniotomy, laparotomy, orchidectomy, lymphadenectomy, thyroidectomy, orthopaedic surgery with effective stabilisation and wound management, organ transplantation with effective management of rejection, surgical implantation of catheters, or biomedical devices (e.g. telemetry transmitters, minipumps etc.);

(d) models of induction of tumours, or spontaneous tumours, that are expected to cause moderate pain or distress or moderate interference with normal behaviour;

(e) irradiation or chemotherapy with a sublethal dose, or with an otherwise lethal dose but with reconstitution of the immune system. Adverse effects would be expected to be mild or moderate and would be short-lived (< 5 days);

(f) breeding of genetically altered animals which are expected to result in a phenotype with moderate effects;

(g) creation of genetically altered animals through surgical procedures;

(h) use of metabolic cages involving moderate restriction of movement over a prolonged period (up to five days);

(i) studies with modified diets that do not meet all of the animals' nutritional needs and are expected to cause moderate clinical abnormality within the time-scale of the study;

(j) withdrawal of food for 48 hours in adult rats;

(k) evoking escape and avoidance reactions where the animal is unable to escape or avoid the stimulus, and are expected to result in moderate distress.

3. Severe:

(a) toxicity testing where death is the end-point, or fatalities are to be expected and severe pathophysiological states are induced. For example, single dose acute toxicity testing (see relevant OECD testing guidelines);

(b) testing of device where failure may cause severe pain, distress or death of the animal (e.g. cardiac assist devices);

(c) vaccine potency testing characterised by persistent impairment of the animal's condition, progressive disease leading to death, associated with long-lasting moderate pain, distress or suffering;

(d) irradiation or chemotherapy with a lethal dose without reconstitution of the immune system, or reconstitution with production of graft versus host disease;

(e) models with induction of tumours, or with spontaneous tumours, that are expected to cause progressive lethal disease associated with long-lasting moderate pain, distress or suffering. For example tumours causing cachexia, invasive bone tumours, tumours resulting in metastatic spread, and tumours that are allowed to ulcerate;

(f) surgical and other interventions in animals under general anaesthesia which are expected to result in severe or persistent moderate post-operative pain, suffering or distress or severe and persistent impairment of the general condition of the animals. Production of unstable fractures, thoracotomy without adequate analgesia, or trauma to produce multiple organ failure;

(g) organ transplantation where organ rejection is likely to lead to severe distress or impairment of the general condition of the animals (e.g. xenotransplantation);

(h) breeding animals with genetic disorders that are expected to experience severe and persistent impairment of general condition, for example Huntington's disease, Muscular dystrophy, chronic relapsing neuritis models;

(i) use of metabolic cages involving severe restriction of movement over a prolonged period;

(j) inescapable electric shock (e.g. to produce learned helplessness);

(k) complete isolation for prolonged periods of social species e.g. dogs and non-human primates;

(l) immobilisation stress to induce gastric ulcers or cardiac failure in rats;

(m) forced swim or exercise tests with exhaustion as the end-point.

Further guidance on this can be found within the EU Guidance on severity assessment[1] and its associated worked examples[2].

[1] http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Consensus%20doc%20on%20severity%20assessment.pdf

[2] http://ec.europa.eu/environment/chemicals/lab_animals/pdf/examples.pdf

APPENDIX H

GUIDANCE ON THE USE OF NEUROMUSCULAR BLOCKING AGENTS (NMBAs)

This Appendix revises and replaces Appendix K of the Guidance on the Operation of the Animals (Scientific procedures) Act 1986 dated 23 March 2000.

Introduction

1. Section 17 of the Animals (Scientific procedures) Act 1986 as amended in 2012 (the Act), states that "A person must not use a neuromuscular blocking agent in the course of a regulated procedure unless:

(a) the person is expressly authorised to do so by the personal licence and the project licence under which the procedure is carried out; and

(b) the agent is used in combination with such level of anaesthesia or analgesia as is determined in accordance with the project licence."

if use does not comply with these requirements, it would constitute an offence under the Act. But should a person be able to show that he reasonably believed, after making due enquiry, that he had complied he would not be guilty of the offence.

2. Curare and other agents that block neuromuscular transmission are used to abolish muscle tone during anaesthesia in humans and animals. Special care is necessary when such pharmacological compounds are used systemically because they specifically block neuromuscular transmission causing paralysis, yet have no significant central effects and will not therefore induce analgesia, unconsciousness or even sedation.

3. Neuromuscular blocking agents (NMBAs) may be classified according to their action at the motor endplate:

(a) depolarising – including suxamethonium. These agents depolarise the motor endplate causing muscle fasciculation and then prevent further, normal, depolarisation;

(b) non-depolarising – including tubocurarine, gallamine, alcuronium, pancuronium, atracurium and vecuronium. These agents occupy motor endplate receptors and prevent normal depolarisation. Their effects can be antagonised by anti-cholinesterase compounds.

There are other naturally occurring biological compounds, such as venoms (e.g. Black Widow Spider) and toxins (e.g. Clostridium botulinum toxin) which, when used systemically, block neuromuscular transmission. There are also other agents (e.g. neomycin, high concentrations of magnesium ions) which have non-specific effects at the motor endplate. Such agents are not used clinically as neuromuscular blockers. They will not be regarded specifically as neuromuscular blocking agents for the purposes of the Act; however, they must not be administered to living animals for an experimental or other scientific purpose unless authorised by a project licence.

4. NMBAs must not be used without an appropriate level of anaesthesia and/or analgesia as determined in the project licence. If administered to a conscious animal they would not prevent it feeling pain and the animal would be in a state of paralysis.

NMBAs cause paralysis of the respiratory muscles unless the dose is small. This means that animals given an NMBA almost always need mechanical ventilation. However, this is not the case for early life stages of certain species such as amphibia that can respire without the use of respiratory muscles.

Full and effective anaesthesia and analgesia is required when using an NMBA for any animal unless a specific case has been agreed by the Secretary of State that this is not required. However, the use of NMBAs without anaesthesia or analgesia, other than with decerebrated animals, is expected to be justified only rarely. Such justification is likely to be based on an assessment that even in the absence of anaesthesia or analgesia there will be no appreciable pain or distress.

5. In some circumstances pain, suffering, distress or lasting harm will not be caused by the administration of NMBAs. For example:

(a) where used for restraint purposes for non-painful procedures in some immature forms of non-mammalian species; or

(b) where animals have been rendered permanently insentient by mechanical means, such as decerebration, and are not able to feel pain or suffer and therefore there is no requirement for anaesthesia and analgesia.

6. Project licence applications and amendments to use NMBAs in circumstances such as those described in paragraphs 5a and 5b above will need to be considered on a case-by-case basis based on information provided by the applicant and may need to be referred to internal or external experts. Not all requirements under paragraphs 7 to 10 below may be applicable.

The administration of neuromuscular blocking agents

7. The following are minimum requirements for the use of NMBAs administered to protected animals under all circumstances, whether or not it is intended that the animal should recover from anaesthesia.

(a) They must be used in conjunction with an established anaesthetic regime known to produce a stable level of anaesthesia for the duration of neuromuscular blockade in the species of animal used. Suitable provision must be made to ensure that the correct level of anaesthesia is maintained throughout.

(b) They must be administered by an experienced licensee who is competent in animal anaesthesia and aware of the actions and interactions of the compounds to be used. Care should be taken in procedures in which autonomic function is blocked because this will interfere with the normal cardiovascular response during light anaesthesia.

(c) An emergency routine should be agreed in advance to cater for hazardous events such as power failure (which could interrupt the operation of mechanical ventilators and infusion pumps, for example). The aim must be to ensure that in such circumstances the interests of the animal are safeguarded.

8. In addition, the following special conditions will apply:

(a) Animals should be attended at all times by a person competent to administer NMBAs and monitor anaesthesia, pain and distress, and analgesia effects. This includes monitoring during the recovery period until there is no risk that there could be a return to neuromuscular paralysis. Where surgical intervention is involved, a second person must be present at all times to ensure the maintenance of anaesthesia.

(b) In lengthy procedures (greater than eight hours), additional competent personal licensees with authority to use NMBAs must be available to provide assistance and take over responsibility in the event of fatigue.

(c) There should be continuous monitoring of heart rate and/or blood pressure, so as to indicate any lightening of the level of anaesthesia which may require prompt action. It may sometimes be appropriate to assess the depth of anaesthesia by continuous recording of the electroencephalogram, provided the recording is not invalidated by agents such as atropine, or by a rise in carbon dioxide tension which should be measured and maintained within the normal range.

(d) Where anaesthesia is used, provision should be made for prompt administration of a narcotic or anaesthetic agent in the event of return to consciousness e.g. by maintaining access to a vein at all times. Adequate reserves of anaesthetic agents must be available.

(e) Facilities should be available to measure and maintain body temperature.

(f) In the case of animals allowed to recover from anaesthesia, appropriate compounds (e.g. neostigmine) should be used to reverse any residual neuromuscular blockade brought about by non-depolarising agents and an assessment should be made of neuromuscular function before return of consciousness is allowed to occur. If a depolarising agent is used, the full effects must have worn off before the return to consciousness.

Licensing requirements

9. **Personal licence:** Applicants will have to provide evidence from their training records that they are competent in the procedures for achieving and maintaining anaesthesia in the animal species with which they propose to work and they understand the use of NMBAs as set out in this note for guidance. They will normally be required to have witnessed the use of these agents and to be familiar with the monitoring required under such regimes. Where a licensee has been given permission to use NMBAs, he or she may be required (by addition of a condition to the personal or project licence) to give an inspector 72 hours' notice of the performance of any procedure using these agents until informed by an inspector that this notification is no longer required.

10. **Project licence:** Applicants who wish to use NMBAs in their project will have to:

(a) justify their use;

(b) provide details of the anaesthetic and analgesic and/or decerebration regimens to show that they are sufficient to ensure the welfare of the animal, or to justify why such methods are not required;

(c) describe the methods available to ensure adequate ventilation and/or gaseous exchange where appropriate;

(d) provide details of the methods used to assist in monitoring the depth of anaesthesia; and

(e) show evidence of competence of staff or how such competence will be obtained.

APPENDIX I

GUIDANCE ON THE HARM-BENEFIT ANALYSIS OF PROJECT LICENCE APPLICATIONS

Introduction

When you prepare your project licence application, you must specify the required regulated procedures for the programme of work, the likely adverse effects that may occur as a result of the regulated procedures, and the humane end-points that will be applied. You must also explain what benefits are likely to accrue as a result of the project.

The harm–benefit analysis must be undertaken by the inspectorate, based on the information you provide, as part of the project evaluation process. inspectors provide advice to the Secretary of State based on the harm–benefit analysis of project licence applications. To do this we utilise a number of processes to ensure a consistent approach amongst inspectors: good communication, continued professional development, precedent cases, and utilising external views (e.g. the Animals in Science Committee (ASC), external expert reviews and other stakeholders).

This guidance explains how inspectors carry out the harm–benefit analysis and the main factors they take into consideration. it will be of particular interest to project licence applicants and to AWERBs considering applications from a local perspective.

What is a harm–benefit analysis?

The likely harms that the animals will experience as a consequence of the project are assessed by analysing the information you provide in the project licence application. The extent to which you have applied the 3Rs (replacement, reduction and refinement) will be evaluated in considering whether the proposed harms are minimised in relation to the particular purpose of the requested animal use. We will advise you if we consider you have not adequately explained how the proposed harms are minimised as much as possible.

Inspectors may also use additional information to assess the likely harms such as evidence from inspection of your work or that of others, the scientific literature and their own specialist knowledge of science, animal welfare, veterinary and human medicine. During this process the inspector will also confirm the severity categories of each of your protocols by using the descriptors in Annex 8 of 2010/63/EU (see **Appendix G**), other relevant guidance, literature evidence, knowledge of similar work authorised under ASPA and their own professional judgement.

The benefits that may result and the likelihood of their delivery are also assessed from the information you provide in the application. Inspectors may seek further information either from you, from the scientific literature or from specialist knowledge within the inspectorate to understand the context and the value of those benefits.

Once the benefits have been clearly defined and understood, the likelihood of delivery of those benefits is considered. Inspectors use criteria such as the proposed scientific methodology, the resources available to you and your track record with regard to publications and animal use, to determine how likely the benefits are to be delivered.

Only once the harms, benefits and likelihood of delivery have been fully explored by the inspector, including the extent to which the effective implementation of the 3Rs has been addressed, is a judgement made as to whether the likely harms are justified by the likely benefits. This judgement is fundamental to the recommendation provided to the Secretary of State with regard to granting or rejection of the application and reflects the scale and significance of the proposed harms and benefits.

The balance between harm and benefit may be further analysed throughout the life of the project for a number of reasons, and should be considered to be a continuous process. For example, unexpected adverse effects may increase the level of suffering during a project, and the inspectorate will need to reconsider the analysis.

On 1 January 2013, the recording of actual severity experienced by each animal became a legal requirement. This will facilitate continuous analysis of actual harm throughout and at the end of the project, providing a mechanism to review the predictions made at the beginning of the project. In addition, some categories of applications are subject to retrospective assessment, which in part involves reconsideration of actual harms and benefits. This will facilitate regular harm–benefit review which will inform our decisions regarding whether ongoing project authorities are still appropriate and whether new project applications have predicted harm appropriately.

BENEFITS

What information is taken into account?

The benefits that are weighed against the harms are the specific likely outcomes of the programme of work, and not the non-specific benefits of the area of research.

Projects may both deliver direct and indirect benefits, and/or short-term and long-term benefits.

Inspectors weigh the importance of benefits by considering:

What will be the benefits of the work?

What data or product(s) may be acquired from the work? What scientific questions will be answered? What are the knowledge gaps that will be filled by the work?

Who and how many will benefit from the work?

For example, other researchers in the field or other fields, patients or clinicians.

How will they benefit – impact?

For example, further understanding of normal brain function, better diagnostic tools, better therapy or monitoring the success of therapy, improvements to quality of life, or knowledge to inform drug development.

When will the benefits be achieved?

For example, within the life of the project or in 20 years' time.

Explaining benefits in the project application

It can be useful to address some or all of the following points in your application to provide detailed information about the benefits of your project:

1. Clarify the current state of knowledge on which your project intends to build.

2. Explain the way in which the project will help to advance knowledge through filling a knowledge/ information gap.

3. Wherever possible, "increased knowledge" as the primary benefit should be linked to a more tangible strategic goal, even though any wider benefits may be much further in the future and less predictable.

4. Explain why the benefits go beyond "it would be nice to know".

5. Scale of improvement (for humans, animals or the environment); numbers; size and quality (need informed judgement – orphan drugs may be used in a few people but high impact on individuals) and

burden to society of the problem (both in basic and applied research).

6. Basic research driven by hypotheses needs to confirm that the hypothesis is scientifically sound and realistic.

7. In some areas of basic research expanding knowledge can be a suitable objective in its own right – but ***should always be linked to dissemination*** of results, whether positive or negative (having regard to intellectual property), and potential longer-term benefits.

Evaluating benefits

It is often more straightforward to judge the severity of harms to be applied than to place specific value on benefits. Projects that directly benefit human health tend to be considered of high value but basic research is also a permissible purpose under ASPA and is not necessarily considered to be less valuable. The seriousness of a human disease and number of patients affected may be taken into account. However, if there are existing efficacious drugs for the disease in question already, the benefit may be considered to be lower. The benefits of regulatory testing can be difficult to determine beyond that of safety and efficacy, but there are legal requirements that these be conducted.

It should be recognised that the value of particular benefits to society are dynamic and influenced by social factors and by health, economic and political issues. These will vary over time. Finally, the perceived value of a particular benefit is affected by an individual's own personal values and will therefore vary amongst individuals. In order to avoid significant inconsistency of decision-making within the inspectorate, we use a number of mechanisms:

- internal referral of specified cases;
- inspector review panels;
- regular discussion groups;
- advice from the ASC;
- external assessors.

HARMS

Each protocol has a severity category applied but of itself does not provide sufficient information for the harm–benefit analysis to be undertaken.

The key issues for consideration of harms include:

1. Procedures being applied to animals:
    - frequency/duration of procedures;
    - likelihood of each adverse effect, percentage of animals predicted to be affected;
    - severity level and methodology to minimise severity;
    - monitoring regime; welfare assessment protocols;
    - humane end-points and triggers for interventions.
2. Species/strain/age of animals being used.
3. Number of animals.

4. Fate of animals:

    - death – intrinsic value of animal; "quality" of death impacts on animal's experience and on severity;
    - criteria for re-use or rehoming.

5. Contingent harms – husbandry and care practices; transportation.

Consideration should also be given to the cumulative effects of techniques considered to be 'lower than' or 'below threshold' which when used in combination or on more than one occasion (multiple) may lead to a 'higher' or above 'minimum threshold' severity when repeated.

LIKELIHOOD OF ACHIEVEMENT

After the harms and benefits have been assessed, the final key consideration in the harm–benefit analysis is the likelihood that the benefits might be realised. The following factors are taken into account when determining the likelihood that benefits will be achieved.

1. The appropriateness of animal models and the extrapolation of results to the human condition if relevant.
2. Clarity, reliability and convincing arguments by the applicant.
3. Trust and confidence in culture at establishment where work will be conducted.
4. Are the objectives realistic?
5. Is the work timely?
6. Is the work scientifically sound?
7. Is it deliverable in the timeframe outlined?
8. Is it adequately resourced? (financial, appropriate facilities, personnel – scientific and care staff).
9. What is the experience/track record of the applicant or the research group in field and in the specific area of planned work?
10. Is there a clearly defined plan of work – choice of methods/design/species/animal model?
11. What is the publication plan?

COMMON PROBLEMS

The following are common problems with harms and benefits encountered in project applications:

- Failing to adequately explain benefits:
    - often lacking the wider context of the research programme (and potential benefits of the specific project to the overall research programme);
    - benefits not sufficiently described or translated – especially in the area of basic research; unsubstantiated/unrealistic claims of potential benefits;
    - benefits not linked to the objectives set out in the application;

- not indicating the timescale when benefits may be expected (when feasible).

- Failing to sufficiently address likelihood of success i.e. likelihood of attaining the objectives set for the project:
  - no information on group's (or establishment's) track record (for example, previous experience; relevant publications; resource availability, including animal facilities and funding) to help assess likelihood of success;
  - justification for the work not well structured, lack of key indicators of success, insufficient focus and relevance;
  - insufficient details to allow evaluation of the likelihood of achieving success;
  - insufficient details on animal models (and where applicable, the use of Genetically Altered Animals [GAs]) and why they were chosen;
  - insufficient information on how the procedures contribute to the objectives of the project.
- Failing to sufficiently address the application of the 3Rs:
  - omission of, or incomplete, information necessary to consider whether or not all 3Rs have been addressed – for example, missing information on how harms are reduced to a minimum consistent with scientific objectives and no justification given for circumstances where recognised good practices are not employed e.g. use of analgesia; social housing.
- Failing to adequately estimate harms:
  - procedures on animals not sufficiently detailed to estimate harms to individual animals;
  - no information on nature and level of harms or information on welfare assessment or humane end-points.

WHAT DOES THE LAW REQUIRE?

EU Directive 2010/63/EU requires a harm–benefit analysis as part of the project evaluation process (Article 38):

> *a **harm–benefit analysis** of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account **ethical considerations**, and may ultimately benefit human beings, animals or the environment.*

Section 2a of ASPA introduces the principles of the 3Rs. These must be used to minimise the harms required to achieve the scientific objectives.

> **2a Principles of replacement, reduction and refinement**
>
> (1) The Secretary of State must exercise his or her functions under this Act with a view to ensuring compliance with the principles of replacement, reduction and refinement.
>
> (2) For the purposes of this Act:
>
> (a) the principle of replacement is the principle that, wherever possible, a scientifically satisfactory method or testing strategy not entailing the use of protected animals must be used instead of a regulated procedure;

(b) the principle of reduction is the principle that whenever a programme of work involving the use of protected animals is carried out the number of protected animals used must be reduced to a minimum without compromising the objectives of the programme;

(c) the principle of refinement is the principle that the breeding, accommodation and care of protected animals and the methods used in regulated procedures applied to such animals must be refined so as to eliminate or reduce to the minimum any possible pain, suffering, distress or lasting harm to those animals.

Section 5 of ASPA requires that a harm–benefit analysis is undertaken.

5 (1) A project licence is a licence granted by the Secretary of State which specifies a programme of work and authorises the application, as part of that programme, of specified regulated procedures to animals of specified descriptions at a specified place or specified places.

5B (2) … the evaluation of a programme of work is favourable only if it verifies:

(a) that carrying out the programme of work is justified from a scientific or educational point of view or is required by law;

(b) that the purposes of the programme of work justify the use of protected animals; and

(c) that the programme of work is designed so as to enable the regulated procedures applied as part of it to be applied in the most humane and environmentally sensitive manner possible.

(3) (d) … a harm–benefit analysis of the programme of work to assess whether the harm that would be caused to protected animals in terms of suffering, pain and distress is justified by the expected outcome, taking into account ethical considerations and the expected benefit to human beings, animals or the environment.

INDEX

Figures are in **bold**. Tables are in *italics*.