



Introduction to the Animals (Scientific Procedures) Act 1986

Red Kite Veterinary Consultants

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Outline of the session

- Aim – overview of legislation
- Protected animals and regulated procedures
- System of Control
 - Licences
 - Named people
 - Additional controls
- Administration of the Act
- Other relevant legislation

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Legislation Exam Questions

- Recent change in exam to obtain personal licence
- Now 5 questions on Legislation which you must get right to progress to the rest of the exam
- Please pay attention and if anything is unclear during or after the presentation, just ask!

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Animals (Scientific Procedures) Act

- Based on Council of Europe Convention ETS 123
 - agreement between CoE member states
 - minimum standards for care and use of animals in research
- EU Directive 2010/63/EU
 - binding on EU member states. Requires members to implement provisions of ETS 123. Adopted Sept 2010
- Animals (Scientific Procedures) Act 1986
 - UK national legislation

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Sources of information

- Home office website:
 - <https://www.gov.uk/research-and-testing-using-animals>
 - Guidance on the operation of the Animals (Scientific Procedures) Act 1986
 - Codes of practice
 - EU directive 2010/63
- NC3Rs: <http://www.nc3rs.org.uk/>
- RSPCA:
 - <http://science.rspca.org.uk/sciencegroup/researchanimals>
- LASA <http://www.lasa.co.uk/> (record keeping, supervision)
- IAT <http://www.iat.org.uk/>
- Local – HOLC, NVS, NIO, NTCO

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- **Before applying for a licence under ASPA you must read the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986**

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LO: 1.1

7

ASPA 1986

ASPA controls the use of

Protected Animals in Regulated Procedures

- Aims
 - ensure animal research is original and justified, and no alternatives exist
 - ensure harms caused to animals are minimised (3Rs)
- Enabling Act
 - Can be amended by SoS
- ASPA allows activities which are otherwise prohibited by other legislation
- Other legislation still applies e.g. VSA, Veterinary Medicines Regulations

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LO: 1.10

8

What is a protected animal?

Any living vertebrate, other than man, and any living cephalopod

- Immature forms from certain stages of development
 - Mammals, birds and reptiles – last third of gestation or incubation
 - Fish, amphibia – stage of independent feeding
 - Cephalopods – end of embryonic stage
- Death = permanent cessation of the circulation or destruction of the brain

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LO: 1.8

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What is a Regulated Procedure?

- A procedure applied to a protected animal for an experimental or other scientific purpose which may have the effect of causing that animal pain, suffering, distress or lasting harm equivalent to or higher than the introduction of a needle in accordance with good veterinary practice.
- Scientific Purpose, and Protected animal, and potential for causing Pain



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LO: 2.1.8

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Regulated procedures ctd

- A procedure applied to an animal is also regulated if:
 - it is part of a combination of procedures which together cause pain suffering distress or lasting harm
 - the animal becomes a protected animal in the course of the procedure
- Examples
 - a combination of several individually innocuous procedures which together cause distress
 - a procedure started on an embryo which then develops to term

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LO: 1.8

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What is a scientific purpose?

- ASPA restricts the purposes for which use of animals may be authorised
- These are called qualifying purposes
- Research projects can not be authorised for purposes which fall outside these qualifying purposes

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LO: 2.1.8

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Qualifying Purposes

- Basic research
- Translational or applied research with one of the following aims
 - prevention, diagnosis or treatment of disease
 - physiological studies
 - animal welfare or production conditions
- Production and testing of drugs and foodstuffs
- Protection of the natural environment
- Preservation of the particular species of animal
- Education or training
- Forensic enquiries

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LO: 1.8

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Exemptions— these are not regulated

- marking
 - primarily for identification,
 - only momentary or transient pain
- humane killing
 - scientific purpose
 - Schedule 1 method
- recognised practice
 - veterinary, agricultural, or animal husbandry
 - veterinary clinical trials



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LO: 1.3

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System of Control

Three levels of control

- Person:
 - personal licence qualifying the holder to apply that procedure to that animal
 - Procedure Individual Licence or PIL
- Programme of work:
 - part of a programme of work in a project licence, authorising the application of that procedure to those animals as part of that programme
 - Procedure Project Licence or PPL
- Place:
 - specified in the project licence
 - usually a place licensed under ASPA Section 2C
 - Procedure Establishment Licence or PEL

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Recap

- ASPA controls Regulated Procedures
 - Protected Animals
 - Scientific Purpose
 - Pain, suffering, distress or lasting harm
- Control at 3 levels – person, project, place



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LO: 1.3

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The Personal Licence (PIL)

- The **personal licence** is concerned with the competence of the individual
- Must be over 18 with 'appropriate' training
- Qualifies the holder to perform categories of procedures
- Must be used in conjunction with project licence
- Responsibilities are defined in
 - ASPA, Standard Conditions, Guidance
- READ THEM!
- Personal licensees should be supervised by the PPL holder

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LO: 1.3

17

The Project Licence (PPL)

- Specifies a program of work with a single theme
- Authorises the application, **as part of that program**, of specified regulated procedures to specified animals at specified places
- Issued to someone who can take overall responsibility for the work
- i.e. specifies procedures to be performed on what types of animals, the place where they can be done and for what purpose.

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LO: 1.3

18

Project Licences ctd

- Scientific objectives and likely benefits
- How objectives are to be achieved
- Adverse effects to be caused
 - severity classification placed on each procedure
 - mild, moderate, severe, non-recovery
- Adverse effects weighed against likely benefit
- Require that benefit is maximised, and adverse effects minimised: 3R's
 - Replacement
 - Reduction
 - Refinement

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LO: 1.3

19

Responsibilities of PPLh

- Standard conditions
 - Implement 3 Rs
 - Ensure compliance
 - Plan of work and procedures are available to personal licence holders
 - Provide appropriate supervision for personal licensees
- i.e. you are entitled to know what it says in the project licence you are working under (*otherwise how can you fulfil your responsibilities?*)

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LO: 1.3/11

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Other PPL requirements

- Additional justification required for use of special species (cats, dogs, equidae, primates)
- Animals must be killed at end of procedures if they are likely to suffer
- PPLh must record actual severity experienced by animals undergoing procedures. This is reported as part of annual statistics.

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LO: 1.3

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The Establishment Licence (PEL)

- Procedures only performed at licensed scientific procedure establishments, unless scientifically necessary
- If scientifically necessary, project licences may specify other places, e.g. on farms, in the wild
 - Place Other than a Licensed Establishment or POLE



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LO: 1.3

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Establishment Licence

- Animals can only be held and used in rooms specifically licensed for the animal and procedure
- Rooms are coded on the schedule
 - Animals: SA, LA, Av, Aq, NHP etc
 - Holding: STH, LTH, NOH
 - Procedures: NSEP, SEP
- Facilities must be maintained according to standards in Code of Practice

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LO: 1.7

23

Establishment Licence Holder

- Establishment Licence holder has overall legal responsibility for facilities and procedures
 - Implementation of 3 Rs
 - Humane killing register
 - Maintenance of facilities and equipment
 - Staffing
 - Daily checking of animals and environment
 - Animal Welfare and Ethical Review Body
 - Prevention of unauthorised procedures
 - Records – source use and disposal

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LO: 1.6

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Animal Welfare and Ethical Review Body

- PELh must set up an AWERB
- Must include NACWO, NVS and a scientist (user establishment)
 - Other named people must be actively engaged with the AWERB
 - Inclusion of others (lay member, independent member) encouraged
- Role
 - Advise staff on matters relating to animal welfare
 - Advise on 3 Rs
 - Review management processes
 - Advise on project applications and review ongoing projects
 - Support named persons
 - Promote a 'culture of care'

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LO: 1.9

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PILh responsibilities

- Implement 3Rs
 - minimise number of animals, and intensity and duration of suffering
- Ensure appropriate authorities exist
- Check animals daily and make arrangements for absence
- Label cages or pens and maintain records of animals and procedures
- Ensure that veterinary advice and treatment are obtained whenever necessary
- Ensure that animals are killed promptly and humanely
 - if in severe pain or distress, which cannot be alleviated,
 - at the end of regulated procedures if they are suffering

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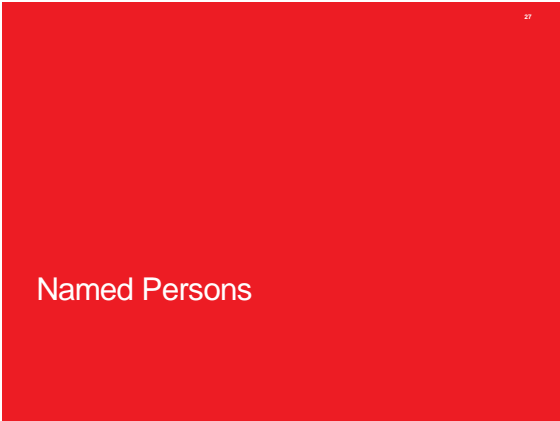
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Responsibilities of the PILh

- **The personal licence holder is primarily responsible for the animals on which they have performed regulated procedures**
- The competence of the PILh is key in maintaining animal welfare. They must be fully trained and competent before performing regulated procedures, and seek advice and assistance when necessary.

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Named Persons

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LO: 1.5

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Named persons

- PELh must nominate specific individuals to assist PELh fulfil his/her responsibilities.
- Actively involved with the AWERB.
- Licence holders and other staff dealing with animals should seek and follow their advice.
- Named persons must be given appropriate training and resources

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LO: 1.5

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Named Veterinary Surgeon (NVS)

- Statutory responsibility
 - to advise on animal health and welfare
 - notify the personal licence holder in charge of an animal if its health or welfare gives cause for concern.
 - If the licence holder is unavailable, make sure the animal is cared for and, if necessary, killed.
 - May also notify the HOI.
- Accountable to PELh and RCVS
- Safeguard the welfare of the protected animals at the establishment
- Advise licence holders and others on implementing the 3Rs
- Direct use of POMs and CDs

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LO: 1.5

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Named Animal Care and Welfare Officer (NACWO)

- Statutory responsibilities
 - to be responsible for the day to day care of animals
 - If the health or welfare of an animal gives cause for concern they must ensure that the animal is cared for, and, if necessary, that it is humanely killed.
- If the personal licence holder responsible for the welfare of an animal is unavailable, they must ensure that the animal is cared for, and, if necessary, that it is humanely killed.
- Accountable to the PELh, the NVS, or the HOI.
- Responsible for optimising the welfare of all animals used, kept for use or used at the establishment.



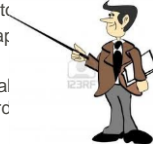
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LO: 1.5

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Named Training and Competence Officer (NTCO)

- 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 as needed.
- May or may not be directly involved in the provision of training; role is to assess.
- Endorse each applicant for a new or amended personal licence.
- Advise individual licence holders of any requirements they will need to have completed in order to obtain their licence(s).



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LO: 1.5

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Named Information Officer (NIO)

- To ensure staff working with animals have access to relevant information, including ASPA Guidance, biology and husbandry of the species used; animal welfare and implementing the 3Rs; good practice guides (e.g. reports produced by the ASC, LASA, LAVA, IAT, NC3Rs, RSPCA, etc).



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LO: 1.5

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Named Person Responsible for Compliance (NPRC)

- Where the establishment licence holder is a corporate entity, an individual must be named as NPRC.
- NPRC must be of similar standing and undertake similar training, to that required for an individual licence holder.
- Duties are the same as PELh.



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LO: 1.5

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Named people - summary

- Several pairs of eyes looking at animals
 - Personal licence holder
 - Project licence holder
 - Establishment licence holder
 - Named Veterinary surgeon
 - Named Animal Care and Welfare Officer
 - NIO, NTCO, NPRC
- Animal Welfare and Ethical Review Body
- All have specific responsibilities

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LO: 1.5

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Communication

- Many people are involved in maintaining animal welfare
 - Establishment licence holder, project licence holder, personal licence holder, veterinary surgeon, compliance officer, training officer, information officer, and animal care and welfare officer.
- Animals cannot speak for themselves: they rely on personnel to attend to their needs.
 - Effective communication between these key people is essential

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LO: 1.5

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Additional Controls

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LO: 1.11

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Humane killing of animals

- Animals may need to be killed: -
 - at the end of a series of regulated procedures.
 - at the end of their breeding life. Tissues or blood may be required
 - Animals must be killed at the end of procedures if they are suffering or likely to suffer
 - Animals must be killed if they are suffering severe pain or distress that is not temporary and cannot be alleviated
- There must be specific permission in the PPL if an animal is to remain alive after completing regulated procedures
- For an animal to remain alive, a veterinary surgeon must determine that it is not suffering or likely to suffer as a result of the regulated procedures carried out

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LO: 1.12

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Schedule 1 – methods of humane killing

- Killing an animal by particular methods for scientific purposes is not regulated
- Methods are listed in Schedule 1
- Schedule 1 is precise – methods are listed for particular types of animal with weight limits.
 - Make sure you are familiar with at least one method appropriate for your animals
- Only people listed on humane killing register at the establishment can conduct humane killing
 - This includes methods of killing not listed in Schedule 1 covered by PIL and PPL authority.

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LO: 1.10

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Schedule 2 – supply of animals

- Animals listed in schedule 2 must be purpose bred for use in procedures
- Places breeding/supplying Schedule 2 species must be licensed (PEL, vet and NACWO)
- Maintain standards of accommodation and care as specified in Code of Practice
- Exemptions must be authorised by the Home Office e.g. pet animals
- Establishments must also have a PEL if they breed non-schedule 2 animals primarily for use in research

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LO: 1.10

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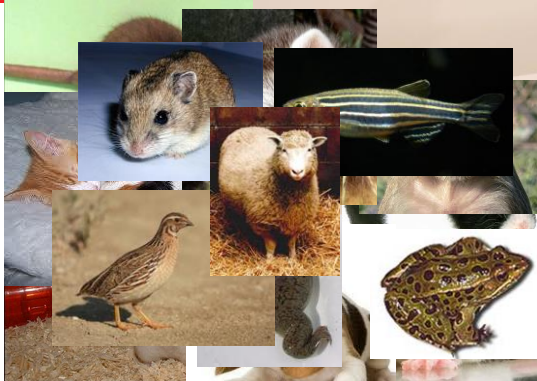
Schedule 2

- Rat, mouse, guinea pig, rabbit, hamster (Syrian and Chinese), gerbil,
- Cat, dog, ferret,
- Primates,
- Xenopus (laevis and tropicalis), Rana (temporaria and pipiens), zebra fish
- European quail
- Genetically modified sheep and pigs

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LO: 1.10

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LO: 5.6

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Anaesthesia

- ASPA requires that anaesthesia be used unless
 - The procedure will not cause severe pain
 - Analgesia (or other method) ensures adverse effects are minimal
 - It is more traumatic to the animal than the procedure itself, or would frustrate the purpose of the procedure
- The default position is that anaesthesia is used

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LO: 2.10

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Re-use

- Specific controls on re-use to limit the total suffering any animal may experience
- Conditions to be applied:
 - Permission from the Secretary of State
 - Not if animal has undergone a procedure classified as 'severe', unless exceptional justification
 - Further procedure is non-recovery, mild or moderate
 - Veterinary surgeon advises that state of health is fully restored

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LO: 2.10

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Re-Use criteria

- Permission from the Secretary of State? **Yes**
- Has animal has undergone a procedure classified as 'severe'? **No**
- Is further procedure non-recovery, mild or moderate? **Yes**
- Has veterinary surgeon advised that state of health is fully restored? **Yes**

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LO: 1.7

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Administration of the Act

- ASPA is administered by the Home Office
- Applications considered by Home Office Inspector but granted by the Secretary of State
- Inspector visits establishments to monitor compliance
- Inspectors investigate and report infringements
 - Penalties for non-compliance
- If in doubt, ask the Inspector!

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LO: 1.8

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Animals in Science Committee

- Independent body providing impartial advice to the Home Office on issues relating to the Act, e.g. best practice relating to the acquisition, breeding, accommodation, care and use of protected animals.
- The Chair and Members have a range of skills including lay members, scientists and welfarists.
- The Committee has no executive powers
 - provides advice to Ministers and AWERBs
 - shares information with committees in other EU Member States.
- SoS may refer project licence applications to the ASC
 - E.g. wild-caught non-human primates; severe procedures in 'special' species; use of endangered species; projects with major animal welfare or ethical implications.

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Summary

- ASPA covers regulated procedures on protected animals
- Control at 3 levels – person, project, place
- Named people – PILh, PPLh, PELh, NVS, NACWO, NIO, NTCO, NPRC
- PILh bears primary responsibility
- Additional controls on methods of killing, supply of animals, anaesthesia and re-use
- Administered by the Home Office
- If in doubt, ask!

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Summary

ASPA controls the use of Protected Animals in Regulated Procedures

Protected animals:

- Living vertebrate, other than man, and *Cephalopods*
- Immature forms from last third gestation/incubation or independent feeding

Regulated procedures:

- experimental or other scientific procedure
- protected animal
- may cause pain, suffering, distress or lasting harm

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Summary ctd

Control at 3 levels

- Person, project, place
- Personal, project and establishment licences
- PILh bears primary responsibility

• Named people

- PILh, PPLh, PELh, NVS, NACWO
- Information officer, training officer, compliance officer

• Additional controls

- killing, supply, anaesthesia and re-use

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Summary

ASPAs aim to ensure use of animals for research is original and justified, and that all opportunities are taken to minimise pain, suffering, distress and lasting harm.

The Three Rs of Reduction, Refinement and Replacement must be implemented at all times.

If in doubt, ask!

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Other UK Legislation for the Protection of Animals

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LO: 1.2

1) Animal Welfare

ASPAs are an enabling Act and allow the conduct of activities that would otherwise be prohibited under other animal welfare legislation:

- Animal Welfare Act 2006
- Veterinary Surgeons Act 1966
- Breeding of Dogs Act 1973

This protection is only effective if you are operating in compliance with the licences of ASPAs

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LO: 1.2

Animal Welfare Act 2006

Places a duty of care on an owner not to be cruel to an animal and to ensure its welfare needs are met.



Applies to "animals that are commonly domesticated in the UK, or that are under the control of man"



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LO: 1.2

Animal Welfare Laws

Now it's your
DUTY TO CARE



Client information regarding
The Animal Welfare Act
2006

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www.defra.gov.uk Helpline - 08459 335577

The animal welfare act makes owners responsible for ensuring that their animal's welfare needs are met.

- From 6 April 2007 (and in Wales from 27 March), animal welfare law is being improved.
- Not only is it still against the law to be cruel to an animal, you must now ensure that all animals' welfare needs are met.

These include the need:

- For a suitable environment (place to live)
 - For a suitable diet
 - To exhibit normal behaviour patterns
 - To be housed with or apart from other animals (if applicable)
 - To be protected from pain, suffering, injury and disease
- The new law also increases the minimum age a person can buy an animal to 16 and prohibits giving animals as prizes to unaccompanied children under this age.
- Anyone who is cruel to an animal or does not provide for its welfare needs may be banned from owning animals, fined up to £20,000 and/or sent to prison.

To find out how the new law affects you visit:
www.defra.gov.uk

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LO: 1.2

55

Veterinary Surgeons Act 1966



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LO: 1.2

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2) Animal Health

- Animal Health Act 1981
- a) Disease control
- b) Transport
- c) Import and export

56

LO: 1.2

57

a) Disease control

Diseases that present a serious
Health or economic threat

e.g.

- Rabies
- Bovine TB
- BSE / vCJD
- Bluetongue
- Swine Fever
- Foot and Mouth



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LO: 1.2

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b) Transport

Welfare of Animals (Transport) Order 2006

“No person shall transport animals .. in a way that is likely to cause injury or undue suffering to them”

Journey properly planned

Minimum travel time

Animals fit to travel

Container and vehicle design

Water, feed and rest for animals



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LO: 1.2

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c) Import of Animals

- Animals in Schedule 2 may now be acquired from abroad, providing they have been purpose-bred for research.
- You must obtain an IMPORT LICENCE from APHA to import any animals, or products of animal origin (POAO).
- Some animals may have to enter rabies quarantine
- APPLY TO: APHA Carlisle

Email: CentralOps.Carlisle@apha.gsi.gov.uk
LiveAnimalExports.Carlisle@apha.gsi.gov.uk

Telephone: 03000 200 301

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LO: 1.2

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d) Export of animals

The exact requirements of countries varies widely. Always check with the Defra trade centre in Carlisle.



Some countries require a veterinary examination and certification of animals prior to shipment.

Home Office permission to export any GA rodent, xenopus or zebrafish is given in all PPLs.

A veterinary surgeon must determine that these animals are not suffering, or likely to suffer, as a result of being released from the protection of ASPA.

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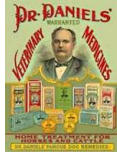
LO: 1.2

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3) Veterinary Medicines

• Veterinary Medicine Regulations

- Distribution categories
- GSL.....General sales list medicines
- NFA-VPS....Non-food producing animal medicines
- POM-VPS ...Food producing animal medicines
- POM-V.....Prescription Only Medicines



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LO: 1.2

62

4) Genetically Modified Organisms (contained use) Regulations 2014

- All activities involving GMOs must be assessed for the risk to humans and the environment (class 1 low to class 4 high)
- Must notify HSE of all premises using GMOs before they are used for the first time.
- Must notify HSE of individual activities of Class 2 (low risk) to Class 4 (high risk).
- Class 1 activities (no or negligible risk) are non notifiable.



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LO: 1.2

63

5) Wildlife

• a) Wildlife and Countryside Act 1981

Protects certain species from capture or killing

Regulation bodies:

Natural England
Natural Resources Wales
Scottish Natural Heritage



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SUMMARY

- Remember ASPA is not the only legislation concerning animals that you need to be aware of.
- ASPA will protect you from prosecution under some WELFARE legislation, but only if you are working under the authority of the 3 ASPA licences
- You still need to comply with other legislation in place to protect animals – Animal Health Act, Wildlife and Countryside Act, Veterinary Medicine Regulations, etc.

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LO: 1.2

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