BVA and LAVA response to Home Office consultation on draft guidance on the operation of the Animals (Scientific Procedures) Act 1986 (as amended) – continuation sheet

Introduction and background

1. The British Veterinary Association (BVA) and Laboratory Animals Veterinary Association (LAVA) welcome the opportunity to provide a joint response to the Home Office's consultation on draft guidance on the operation of the Animals (Scientific Procedures) Act (ASPA).

2. The British Veterinary Association (BVA) is the national representative body for the veterinary profession in the United Kingdom and has over 13,000 members. Its primary aim is to protect and promote the interests of the veterinary profession in this country, and it therefore takes a keen interest in all issues affecting the veterinary profession, be they animal health, animal welfare, public health, regulatory issues or employment concerns. This response has been prepared with particular involvement from the BVA’s Ethics and Welfare Group.

3. The Laboratory Animals Veterinary Association is a specialist division of the BVA. LAVA’s members are veterinary surgeons and students from the UK and elsewhere who are interested in laboratory animal medicine and science. Many members act as Named Veterinary Surgeons under the Animals (Scientific Procedures) Act 1986. LAVA promotes best practice and the dissemination of new technologies. It represents laboratory animal vets at national and international level when needed for discussions and decision making on laboratory animal law, welfare, ethics, transport, techniques and disease.

4. This response addresses the questions and issues which are relevant to the veterinary profession and has been put together based around the expertise of LAVA's membership.

Glossary of terms

Pain, suffering, distress and lasting harm

5. We would query whether “pain, suffering, distress or discomfort” (PIL standard condition 4) is to be interpreted the same or differently?
Background to the Animals (Scientific Procedures) Act 1986 (ASPA)

What procedures are not regulated?

Non-experimental clinical veterinary practices

6. Non-experimental clinical veterinary practices are not regulated procedures. There is no RCVS guidance on the interpretation of “non-experimental clinical veterinary practices” at present, only guidance on the obsolete term “recognised veterinary practice” from pre-amendment ASPA.

7. There is no mention of experimental clinical veterinary practices. LAVA believes that many if not most of these should not be brought under ASPA and would therefore consider clarification within the guidance notes as beneficial.

Non-experimental agricultural practices and practices undertaken for the purpose of recognised animal husbandry

8. Not all animal husbandry practices have associated welfare legislation and will not be performed as part of a scientific procedure. Also, LAVA believes that it is not desirable or advantageous to have all agricultural or husbandry practices if done for scientific purposes regulated as this may hinder progress of animal welfare. For example, nutritional and behavioural studies (e.g. comparing different methods of castration, farrowing systems etc) would under the proposed guidance require authorisations under A(SP)A.

Establishment licences

Named people

9. The previous HO Guidance (2000) suffers somewhat through a fragmented description of the role of the NVS. Thus the NVS has responsibility for the welfare of the animals (4.4), advises on animal welfare (4.48), and monitors animal welfare (4.62). It will be helpful if the full scope of, and expectations for, the role are presented comprehensively and consistently. In our suggestions relating to this section and the section “Named Veterinary Surgeon” we have attempted to do this. We have also suggested inserting appropriate guidance in relevant sections where other people with responsibilities under the Act have reciprocal responsibilities to interact with NVSs.

10. In the sub-paragraph relating to NVSs is a tautology and we suggest replacing “One or more” with “the” for consistency as with the descriptions of other named roles.

11. We note that ASPA section 2C says “a veterinary surgeon” and we suggest that the following text in relation to Named Veterinary Surgeons is added in this section:
“Establishment licences must name one or more people who are responsible for the following activities:

- the *Named Veterinary Surgeon* (NVS) with expertise in laboratory animal medicine to be responsible for, monitor and advise on the health, welfare and treatment of the animals and provide veterinary care. Exceptionally, you may be able to nominate another suitably qualified expert where you can show that they are more appropriate for this role.

All these named people should have regular contact with the holder of the establishment licence. They should help you fulfil your responsibilities. They should all be actively involved on a daily basis in safeguarding………and contribute actively to the work of the local animal welfare and ethical review body (AWERB) at your establishment.

You must entrust named people with the necessary authorities to carry out their role effectively.

The Named Veterinary Surgeon 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. Establishment licence holders may find these useful in helping to identify suitable nominees. There are training requirements for those taking up the Named Veterinary Surgeon role for the first time, whether on a full-time or part-time basis.

In addition to being accountable to the establishment licence holder for the performance of their duties, Named Veterinary Surgeons must 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*.

12. LAVA would welcome the opportunity to help define what training and expertise in laboratory animal medicine is appropriate.

**Installations and equipment**

13. Establishment licence holders should be required to ensure that appropriate facilities are available for adequate veterinary care of the protected animals at the establishment. This is a professional imperative that must be impressed upon establishment licence holders. We believe it must be included in the Guidance to bring this to PELHs attention.

**Your responsibilities as establishment licence holder**

**Conflicts of interest**

14. We believe that it is an unnecessary bureaucratic burden to require that Declaration Forms are sent to the Home Office with establishment licence applications and this would, in practice, compromise private confidential information.
**Animal care and accommodation**

15. We believe establishment licence holders should be explicitly required in this section to ensure that:
   - adequate veterinary cover and services are available at all times at establishments, under the supervision of the NVS; and
   - appropriate facilities are available for adequate veterinary care of the protected animals at establishments.

**Humane killing of animals**

16. We consider that the sections on humane killing are very unclear and difficult to understand and would benefit from complete rewriting.

**Disposing of animals**

17. The sections dealing with use and re-use of protected animals, end of procedures, release into the wild, re-homing and moving animals to another licenced establishment or for slaughter are confusing and difficult to understand and to interpret. Partly this is the fault of the guidance, but to at least an equal extent it is the fault of the muddled administrative arrangements in place. LAVA has previously provided guidance to NVSs on these issues, but clear and logical arrangements and guidance from the Home Office will be greatly appreciated. These comments apply equally to the sections of the guidance under “Project Licences” and “Establishment Licences”.

18. We hope that in any discussion of re-use, a clear distinction will be maintained between the use of animals, which have been used previously, and keeping animals, which might potentially be used again in the future. We have found that there is often confusion surrounding this distinction.

19. We also believe that clarification on the expectation of “full restoration of general health and wellbeing” is needed, in particular in cases of surgically prepared animals. Many of these will not be fully restored to their pre-surgical health status, however, re-use may still be considered desirable. There is also no discussion of the concept of “continued use” in the draft guidance.

**Personal licences**

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

20. In category B, further guidance on the interpretation of “minor/minimally invasive procedures” and “brief” are essential to maintain consistency between establishments. LAVA will be happy to assist in formulating guidance.
Your responsibilities

Animal welfare

21. We believe that there should be explicit guidance to PILs in this section that PILs must seek and follow advice from the NVS and NACWO on the health, welfare and use of animals, both at the planning stage and when work is in progress.

22. We also consider that if two or more personal licence holders are working with the same animal, this section should require that it is clear who is primarily responsible for that animal not only to the PILs involved but also to all others who may be involved in the care of the animal, including the project licence holder, the NVS, NACWO and HO inspectors.

Project licences

Preparing your project licence application

23. We believe that rather than “You must also consult your NVS and NACWO”, this section should include the more emphatic “You must consult your NVS and NACWO at an early stage to obtain their advice relating to your proposed application, or amendment to an existing licence, including advice on incorporating the 3Rs into the plan of the work.”

Applying the 3Rs in your project

24. We suggest that it would be preferable to replace “You should also consult ‘named people’ at your establishment, especially the NVSs and NACWOs” with “You must consult your NVS and NACWO at an early stage to obtain their advice relating to your proposed application, or amendment to an existing licence, including advice on incorporating the 3Rs into the plan of the work. You must seek and follow advice from the NVS and NACWO on the health, welfare and use of animals, both at the planning stage and when work is in progress.”

Disposition of animals

25. See Page 4, paragraph 18.

26. There is a particular problem relating to the conditions for re-use of animals. A veterinarian with knowledge of the lifetime experience of the animals must advise that their state of health and wellbeing has been fully restored. It is not at all clear what knowledge of the animals’ lifetime experience is required, or how that knowledge is to be applied. The Directive is clear that it should be taken into account, but ASPA is less clear. Further guidance to NVSs will be essential.

27. Unfortunately the draft guidance amends the wording in ASPA: a veterinary surgeon with knowledge of the lifetime experience of the animal or animals must have advised that their general state of health and wellbeing is likely to have been fully restored following the application of the previous procedure or
procedures. It is not clear what the effect of the words “general” and “likely to have been” are intended to have.

Your responsibilities as project licence holder

28. We suggest that it is appropriate to include the following text under “Responsibilities of the project licence holder”:

“You must seek and follow advice from the NVS and NACWO on the health, welfare and use of animals, both at the planning stage and when work is in progress.

You must 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 the personal licence holders working on the project, the NVS and the NACWO.”

Amending your project licence

We suggest that it is appropriate to include the following text in this section:

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

Severity categories

29. There is useful information and examples of severity assessment on the EU website. A reference to the title and location of the document would be helpful.

Humane killing of protected animals

30. We find the revised Schedule 1 and associated Guidance extremely difficult to interpret and feel that the whole section would benefit from being re-written. In particular LAVA feels that the current version lacks clarity in regards to its intention and the necessary controls, which should be put in place. We would appreciate if these could be clearly explained.

Care and accommodation of protected animals

31. Where an exemption from the requirements is necessary for animal welfare or animal health reasons it will be helpful if PELs can have standard authorities for this.

Named people:

32. We would suggest that the responsibilities of the Named people are insufficiently defined, which may lead to uncertainties about who carries the primary responsibility for the different activities performed by all named people.
Named Animal Care & Welfare Officer (NACWO)

Your role and responsibilities

33. In establishments with several NACWOs it will not be practical for all to be members of the AWERB. LAVA suggests NACWOs should “contribute actively to the work of the AWERB at your establishment; at least one NACWO at the establishment must be a member of the AWERB.”

Named Veterinary Surgeon (NVS)

34. As noted above, the previous HO Guidance (2000) suffers somewhat through a fragmented description of the role of the NVS. In our suggestions relating to this section we have attempted to consolidated all the expectations relating to the role of the NVS in this section. We therefore propose the following:

“Your role and responsibilities”
The Named Veterinary Surgeon (NVS) is responsible for, monitors and provides advice on the health, welfare and treatment of animals. You are accountable to the establishment licence holder for fulfilling your duties and responsibilities. You should help the establishment licence holder fulfil his/her responsibilities. You should expect that you will be entrusted with the necessary management authorities to carry out your role effectively, and that you will be seen to have senior management’s support. You should be provided with the necessary training and resources.

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 whenever necessary.

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 RCVS for your professional standards and conduct. There are training requirements for those taking up the Named Veterinary Surgeon role for the first time, whether on a full-time or part-time basis. Professional obligations also include continuing professional development relevant to the role being performed.

In addition to being accountable to the establishment licence holder for the performance of their duties, Named Veterinary Surgeons must 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.

You should:

- be actively involved, on a day to day basis, in safeguarding the welfare of the protected animals at the establishment;
- be familiar with the main provisions of ASPA;
• 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;

• 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, when requested by a personal licence holder;

• be familiar with relevant methods of humane killing listed in Schedule 1, together with any additional approved methods specified on the establishment licence;

• have a thorough knowledge of the husbandry and welfare needs of the species kept at your establishment, including the prevention, diagnosis and treatment of disease; and be able to advise on quarantine requirements and health screening, and the impact of housing and husbandry systems on the welfare and needs of 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; further guidance for establishment licence holders and Named Veterinary Surgeons has been issued by the Home Office and the Laboratory Animals Veterinary Association;

• keep animal health records for all the animals at your establishment, including advice or treatment given; and ensure that these records are available to the Named Animal Care & Welfare Officer, the establishment licence holder and the Home Office; records must be kept to a proper professional standard;

• 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 People; and

• be an active member of and play a central role in the AWERB at your establishment.

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 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 end-points.

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 applicant at an early stage to discuss and provide advice relating to a proposed application, or an amendment to an existing 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 or therapy is undertaken for the welfare of an animal being used for procedures but that data or other outputs from the work are not compromised as a result.

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, action has been taken to minimise the suffering of the animal.

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 there may be requirements for a veterinarian to certify that it will not suffer if it is no longer kept at the establishment.

If an animal is to be re-used you should be asked to confirm that its general state of health and wellbeing 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 which has been subjected to a regulated procedure the actual severity of which has been classified as “severe”, we will consult you to advise whether we should give consent for re-use. You must have examined the animal before you advise us.”

**Named Training and Competency Officer:**

35. In regards to the role and responsibilities of the NTCO, it would be useful if the persons, whose education and training have to be ensured by the NTCO could be named rather than the use of the more general term “everyone dealing with animals”.

**Animal Welfare and Ethical Review Bodies (AWERBs)**

**Membership**

36. We believe that ASPA requires the AWERB must comprise (as a minimum) the Named Veterinary Surgeon (NVS), at least one Named Animal Care and Welfare Officer (NACWO) and, in the case of a user establishment, a scientific member. Therefore this should be explicitly stated under membership, and the subsequent paragraph headed “Named Veterinary Surgeon” should be deleted.