

5 September 2011

CONSULTATION ON OPTIONS FOR THE TRANSPOSITION OF EUROPEAN DIRECTIVE 2010/63/EU ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES

Joint response from the British Veterinary Association and Laboratory Animals Veterinary Association

i) The BVA is the national representative body for the veterinary profession in the United Kingdom and has over 12,000 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.

ii) The Laboratory Animals Veterinary Association (LAVA) is a non-territorial 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 through its biannual meetings and other avenues.

iii) The BVA and LAVA have worked closely together in preparing this response, with particular involvement from the BVA's Ethics and Welfare Group. The wider membership of both organisations has also been consulted through BVA's divisions and LAVA's regional meetings.

iv) We are grateful for the opportunity to respond to the Home Office's consultation on options for the transposition of European Directive 2010/63/EU on the protection of animals used for scientific purposes.

v) In principle, we are supportive of both A(SP)A (Animals (Scientific Procedures) Act) 1986 as a proven working system in the UK and the new EU directive as an instrument towards European harmonisation and the improvement of standards, in particular the transposition of the directive as outlined in the Home Office consultation document under *Option 3: Retain current higher UK standards and requirements*. However we have a number of general comments as well as specific comments on the questions raised in the consultation paper on how the directive may best be implemented in the UK, which are outlined below:

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Comments

vi) The BVA and LAVA agree that the responsible use of animals in research has improved human and animal welfare through the advancement of scientific knowledge and the development of safer and more effective medicines. However, animals should only be used in research when no non-animal alternative is available and the work is justified through independent ethical scrutiny. It is generally reported that the UK has the most robust system of regulation in the world under A(SP)A, which maintains a high level of public confidence in the regulation of scientific procedures using animals in the UK. This high level of public confidence should not be compromised by the reduction of UK requirements without evidence that it will not result in potential reductions in animal welfare standards.

vii) The UK must transpose the provisions of the EU Directive 2010/63/EU into UK legislation by 10 November 2012 with the majority of the provisions of the Directive being implemented in UK legislation from 1 January 2013. Article 2 of the Directive allows Member States to retain current, more stringent national provisions in place on 9 November 2010 provided they are not used to inhibit the free market. The Home Office has outlined three options for the transposition:

- *Option 1: No Change* is not a viable option as parts of the current UK legislation (A(SP)A) do not meet the minimum requirements of the Directive.
- *Option 2: Transpose the minimum requirements of the Directive* is not supported by the BVA or LAVA as this would reduce the welfare standards of many animals currently used in scientific procedures across the UK.
- *Option 3: Retain current higher UK standards and requirements* is broadly supported by the BVA and LAVA. However, the Home Office has suggested that the more stringent measures in A(SP)A should be retained where there are clear benefits to science, welfare and/or the conduct of research. We agree that where there are clear benefits to welfare, the more stringent measures should certainly be maintained. However, we also strongly believe that as a precautionary principle, these higher standards should be retained even without clear evidence of benefit to animal welfare, unless there is evidence to show that no reduction in welfare will be caused by the lowering of UK standards to meet the Directive's minimum requirements. It is true that this may have some impact on harmonisation but this should only be marginal. The UK is currently a world leader in high quality scientific research in general, and in scientific research using animals, even though it has more stringent measures than elsewhere.

viii) The veterinary profession has a legal and ethical duty to care for animals used in research and we strongly endorse the requirements under the current regulations for researchers to seek and act upon veterinary advice in the planning and conduct of procedures on animals; 'Named Veterinary Surgeons' operate in every research facility in the UK to ensure the highest possible

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standards of care and welfare for all animals used in research. We believe that it should be written into the primary legislation that the Designated Veterinarian (DV) is a full and central member of the proposed Animal Welfare Body (AWB). The DV must be a statutory member of the AWB. The current role, responsibilities and authority of the Named Veterinary Surgeon (NVS) are almost entirely laid down in HO Guidance and RCVS Guidance. The role of the NVS must not be diminished, and the ability to carry out that role must not be reduced. Retention of the key roles and responsibilities of the NVS as required under A(SP)A, current Home Office Guidance and RCVS Guidance to NVSs is critical.

- ix) The existing Guidance on the Operation of A(SP)A and the Codes of Practice for housing and husbandry of laboratory animals have been invaluable tools for 'hands on' implementation of UK law. A key part of the transposition process must be the drafting of a new set of equivalent documents. LAVA and the BVA are willing to assist in this process.
- x) We respect the intrinsic value and sentience of animals and continue to support the traditional principles of the "Three Rs" – that living animals are **Replaced** with non-sentient alternatives whenever possible, scientific procedures are **Refined** so as to reduce the pain, suffering, distress or lasting harm caused to the absolute minimum consistent with achieving the scientific objectives, and the number of animals used is **Reduced** to the minimum needed for scientific validity.

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Answers to questions

3: SUBJECT MATTER AND SCOPE

Article 2: Stricter national measures

Limit on protection of foetal forms of mammals to the last third of the gestation period

Question 1: Is our analysis of the impact of this provision correct? Is there scientific evidence that suggests that the UK should continue to protect mammals from half way through gestation using Article 2 to the Directive?

We agree that the scientific evidence suggests that changing the limit on protection of foetal forms of mammals to the last third of the gestation period is acceptable.

Exclusion of foetal forms of birds and reptiles from protection

Question 2: Is there scientific evidence to support the continued protection of foetal forms of birds and egg laying reptiles using Article 2 to the Directive?

This is an extremely complex question owing to the vast range of variation in incubation periods (reptiles) and the degree of maturity on hatching (birds). We do not believe there is sufficiently robust scientific evidence to remove protection from all foetal forms of birds and reptiles and would support the EFSA recommendation for protection during the last third of incubation¹.

Inclusion of cephalopods

Question 3: Are our assumptions correct? Do you have any further information of the current use of cephalopods?

We are satisfied that there is sufficient evidence that cephalopods are sentient and should be included within the scope of this legislation.

Inclusion of animals specifically bred for organs and tissues

Question 4: Are our assumptions correct? Do you have any further relevant information of the current breeding and use of animals bred for organs and tissues?

¹ The EFSA Journal (2005) 292, 1-46 - Opinion on the "Aspects of the biology and welfare of animals used for experimental and other scientific purposes"

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We support the Home Office analysis of this issue that although not necessarily counted, these animals are already bred and used at designated UK establishments and subject to the same care and accommodation standards as animals used in procedures; and therefore that their inclusion is not expected to have any significant regulatory or animal welfare impact.

Absence of special protection for cats, dogs and equidae

Question 5: Is loss of special protection likely to lead to increased use of cats, dogs and equids? Should the UK retain its current special protection for dogs, cats and equids using Article 2 to the Directive?

The provision of special protection for cats, dogs and equids is not based on scientific evidence or animal welfare benefit, and scientific evidence shows there are other species with a similar capacity to experience pain, suffering or distress (for example pigs and ferrets). With the application of the “3 R’s”, researchers currently required to use of the lowest species that can be scientifically justified. We believe that transposing the requirement to use only scientifically justified species with the lowest capacity to experience pain, suffering or distress would not lead to an increase in the numbers of cats, dogs and equids used in scientific procedures in the UK. However, we recognise that the domesticated status of cats, dogs and equids in the UK means that these species are the subject of particular public concern, and this was the reason for providing them with special protection under ASPA. There is a case for retaining this protection based on maintaining public confidence in the regulatory system.

Practices to which the Directive does not apply

Question 6: Is our assessment of the impact of this omission correct? Should we retain our current requirements exempting only those methods of marking (used for scientific purposes) which cause no more than momentary pain or distress, and no lasting harm?

We believe that without express permission within the project, only methods for the primary purpose of identification causing no more than momentary pain should be permitted. We also support the replacement of “sole” (from A(SP)A 2.5) by “primary”, which would allow, for example, the use of tissue from ear marking for DNA analysis or dual purpose microchips for identification and temperature monitoring.

4. PROVISIONS ON THE USE OF CERTAIN ANIMALS IN PROCEDURES

Article 7: Endangered species

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Question 7: Should the UK retain its current restrictions on the use of endangered species using Article 2? What implications would adoption of the provisions of Article 7 of the Directive have for the use of endangered species in the UK?

We believe that the provision of Article 7 provides sufficient controls on the use of endangered species and that the present UK text need not be retained.

Article 8: Non-human primates

Permissible uses and the definition of 'debilitating condition'

Question 8: Do you agree with our analysis of the likely impact of Article 8 on work involving non-human primates? Are there any further issues we should consider when transposing these provisions relating to the use of non-human primates?

We believe that the use of non-human primates should be minimised, and they should only be used with exceptional justification.

Question 9: Are there any further issues we should consider when transposing these provisions relating to the use of endangered species of non-human primate?

Great apes

Question 10: Do you agree that the UK should continue to operate a policy ban on the use of great apes? Are there any further issues we should consider relating to the use of great apes?

We believe that the current policy ban on the use of great apes should be maintained.

Article 9: Animals taken from the wild

Question 11: Are there any issues we should consider relating to the prohibition on the use of animals taken from the wild? What impact will the more limited derogation provided in Article 9 have on the conduct of research in the UK?

We support the implementation of this article.

New requirements relating to trapping and capture

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Question 12: What criteria should be applied to ensure the competence of persons capturing animals in the wild?

If animals are to be captured as part of a scientific research programme it is important that the persons carrying this out are properly trained and supervised until competence is achieved. Responsibility for ensuring this is implemented should remain with the project licence holder.

Article 10: Animals bred for use in procedures

Question 13: Are our assumptions regarding the impact of Article 10 correct? Is there a case for retaining the current UK requirement that common quail and ferrets should be purpose bred, as permitted by Article 2?

We believe that ferrets should be purpose bred to ensure suitable health status, and care and accommodation standards. As common quail are rarely used in scientific procedures in the UK there is no need to retain the requirement for this species.

Question: What impact will this have on UK breeders, suppliers and users? Will opening up the ability to supply animals have any animal welfare impact?

We believe that opening up supply to the UK from other European breeders has the potential for negative welfare impacts. Transport may be longer, and must be carefully managed to reduce any negative welfare impact. Scientists obtaining animals from overseas establishments should seek guarantees for standards of welfare and care in transit, and also in the breeding establishments themselves. This is likely to prove difficult, so there should be clear guidance on how research establishments can monitor the standards in supplying organisations, and guidance should also strongly encourage the acceptance of suppliers only where the welfare standards would match those provided in the UK, in order to maintain levels of public confidence.

We believe that the distances/durations that animals are transported for should always be as low as possible and that this should be the primary concern when considering suppliers. With regards to animals slaughtered for food, the BVA believes that animals should not be transported long distances to the abattoir but should be slaughtered as near to the point of production as possible, and that no animal should be exported and then raised in systems previously banned in this country due to welfare considerations (neither should the meat from such animals be re-imported). Opening up the supply could reduce the transportation times in some instances due to the proximity of the UK's south coast to mainland Europe, and we would welcome this, however we oppose the opening up of the ability to supply animals where cost becomes the primary concern rather than welfare considerations.

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Non-human primates

Question 14: What impact will these requirements have on UK breeders, suppliers and users? What impact, if any, is there likely to be on animal welfare?

We support the principle of moving to self-sustaining colonies, but recognise that there could be significant welfare issues if this were progressed too rapidly. We support the Commission's view that any decision on the timetable for implementation should be based on the outcome of the proposed feasibility study, which should include animal health and welfare assessments.

We support the current Home Office policy of assessing overseas breeding centre of non-human primates and believe it should continue in the future.

Article 11: Stray and feral animals of domestic species

Question 15: Is there a case on animal welfare grounds for retaining the current UK prohibition on the use of stray and feral animals, as permitted by Article 2?

We believe that stray and feral animals should only be used in scientific research relating to the health and welfare of these populations, where there may be a public or animal health or welfare benefit.

5. PROCEDURES

Article 3: Definition of 'procedure'

67. ... under the new Directive ... the use of a method of killing of animals not listed in Annex IV (Methods of Killing Animals) solely for the use of their organs and tissues is not a procedure and will not require project authorisation. However, exemption from using an Annex IV method of killing will be needed. A system will be required to enable exemption to be granted to individuals who are not licence holders and are outside the regulatory system.

Question 16: Do you have any proposals as to how this might be achieved?

We believe that the use of methods other than those listed in Annex 4 (see specific comments on Annex 4) should be subject to a cost-benefit analysis as there may be significant welfare costs involved. We believe the current UK requirement should be maintained using Article 2 and should still be part of the project evaluation. This would be consistent with the requirements of Article 37 (c) and Annex 6 (para 11) that methods of killing are included as part of the project proposal.

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Article 5: Purposes of procedures

Question 17: Are there any further issues we should consider in relation to the 'permissible purposes' set out in Article 5?

The competence of personnel undertaking procedures for 'permissible purposes' needs to be appropriate and ensured, in order to maximise animal welfare. The current situation is inadequate – for example many scientists obtain skills by attending overseas training courses. We believe that the development of manual skills in non-recovery procedures has the potential to improve animal welfare. Any such use should be in the context of a project authorisation to ensure live animals are only used when they are essential to developing a specific manual skill such as laparoscopic surgery.

We believe that current policy restrictions on the use of animals for research into tobacco, alcohol, offensive weapons and cosmetics testing should be maintained.

Article 12: Procedures

Question 18: Are there any further issues we should consider in relation to the provisions on procedures set out in Article 12?

We believe that there should be additional formal Guidance as to what constitutes a procedure (similar to 2.13 to 2.23 of the current Home Office Guidance). Otherwise there are no further issues.

Article 14: Anaesthesia (and the use of neuromuscular blocking agents)

Question 19: We propose to transpose these provisions relating to the use of anaesthesia as they stand. Are there any further issues we should consider relating to the use of anaesthesia?

We support the direct transposition of these provisions. Additionally, in any future Guidance we would suggest that there is a clear requirement that post-surgical analgesia should only be withheld when there is clear scientific evidence that this will compromise the scientific outcomes.

Neuromuscular blocking agents

Question 20: Should current UK provisions relating to the use of neuromuscular blocking agents in mammals be retained? Should we continue to apply the same provisions to other animals?

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We believe that NMBs should only ever be used with full general anaesthesia for all protected animals.

Article 16: Re-use

Question 21: We propose to transpose the provisions of Article 16 relating to re-use as they stand. Are there any further issues relating to re-use we should consider?

We believe that project authorisation, including a broad framework of acceptable re-use, should be required for any re-use to ensure a proper cost-benefit assessment can take place. The phrase "taking into account the lifetime experience of the animal" is extremely vague and potentially impossible to assess. Detailed Guidance is required to assist Designated Veterinarians with the implementation of this requirement.

We do not agree that any animal that has undergone severe pain, distress or equivalent suffering should be re-used in anything other than an anaesthetised, non-recovery procedure.

Article 17: End of the procedure

Question 22: Should we retain current stricter UK requirements relating to the welfare of animals at the end of a regulated procedure? What issues may arise if animals suffering mild effects are released?

We strongly believe that current requirements should be maintained and only animals that are not suffering or likely to suffer adverse effects are kept alive at the end of procedure.

We believe that Designated Veterinarians would not be able to certify or even determine the potential consequences of an animal staying alive whilst currently demonstrating any adverse effects.

We believe that it should be clearly defined who is responsible for the animals that are kept alive at the end of the procedure.

Article 18: Sharing organs and tissues

Question 23: How should we facilitate the sharing of organs and tissues? Are there any further issues relating to the sharing of organs and tissues we should consider?

We strongly support maximising the use of animal tissues.

6. METHODS OF KILLING

Article 6 and Annex IV: Methods of killing

Question 24: Do you agree with our analysis of Article 6 and Annex IV? Should the UK retain some methods listed in ASPA Schedule 1 using Article 2? Which methods should be retained?

We support only the use of methods of euthanasia that have been demonstrated as humane, and we are concerned that there is insufficient scientific evidence to support the inclusion of a number of methods listed in Annex 4 (for example the use of inert gases in rodents).

We believe that an expert panel should be convened as soon as possible to review the scientific evidence, humaneness and public acceptability of methods of euthanasia. For farm species, standardisation with national slaughter regulations would be beneficial. Only methods identified by this expert group should be included in UK legislation.

We would also strongly support the development of a code of practice to ensure that these methods are always applied in a humane manner.

7. CHOICE OF METHODS

Article 4: Principle of replacement, reduction and refinement

Question 25: We propose to transpose the requirements of Article 4 as they stand. Are there any further issues relating to replacement, reduction and refinement we should consider?

We support the transposition the requirements of Article 4 as they stand.

Article 13: Choice of methods

Question 26: Is our analysis of the impact of Article 13 correct? Are there any further issues relating to the choice of methods we should consider? Are there any currently permitted testing methods which will be prohibited?

We agree that the Article 13 is consistent with current UK requirements and should be transposed as it stands

Question 27: We propose to transpose the provisions of Article 13 as they stand. Are there any further issues we should consider relating to the use of death as an endpoint?

We agree that death as an endpoint is almost never essential and should be avoided.

8. AVOIDANCE OF DUPLICATION OF PROCEDURES AND ALTERNATIVE APPROACHES

Article 46: Avoidance of duplication of procedures

Question 28: We propose to transpose the provisions of Article 46 as they stand. Are there any further issues we should consider relating to avoidance of duplication of procedures?

We welcome this position.

Article 47: Alternative approaches

Question 29: Are there any further issues we should consider in relation to the provisions for alternative approaches set out in Article 47?

There are no further issues.

Article 48 and Annex VII: Union reference laboratory

Question 30: Are there any further issues we should consider in relation to the Union reference laboratory?

There are no further issues.

9. SEVERITY OF PROCEDURES

Article 15 and Annex VIII: Classification of severity of procedures

Question 31: Are there any areas in which the Annex VIII severity classification is unclear? Are there any additional examples of severity that might be included in guidance on the application of the proposed severity classification system? [See also questions relating to Article 55 below.]

We are concerned that Article 15 does not explicitly require that animals should not exceed the authorised procedure severity classification, nor does it describe what action should be taken should this happen. We believe that the current UK requirements (for example project licence standard condition 8) should be maintained so action can be taken in these circumstances.

Additional examples of severity in a variety of procedures should be generated, and in particular for those potentially in the severe category (for example models of pain, arthritis and sepsis).

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We would also like additional explanation provided on lower thresholds such as very short term restraint in a metabolic cage, short-term water withdrawal, short term single housing of social rodent strains.

We cannot envisage any situation where safeguard clause 55(3) would need to be invoked, so believe it should not be enshrined in UK law.

We believe that the current inviolable termination condition, requiring euthanasia for animals experiencing severe pain or distress that cannot be alleviated, should be retained.

10. BREEDERS, SUPPLIERS AND USERS

Article 20: Authorisation of breeders, suppliers and users

Question 32: Are the changes to the requirements for authorisation of breeders, suppliers and users and the need to notify changes likely to raise any problems? Are there any further issues we should consider in relation to the requirements set out in Article 20?

There are no further issues.

Article 21: Suspension and withdrawal of authorisation

Question 33: We propose to transpose the provisions of Article 21 as they stand. Are there any further issues we should consider relating to the suspension and withdrawal of authorisations?

There are no further issues.

Article 22: Requirements for installations and equipment

Question 34: Are there any further issues we should consider in relation to the requirements for installations and equipment set out in Article 22?

There are no further issues.

Article 28: Breeding strategy for non-human primates

Question 35: Are our assumptions relating to Article 28 correct? Are there any further issues we should consider in relation to the requirements for a breeding strategy for non-human primates set out in Article 28?

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There are no further issues.

Article 19: Setting free of animals and re-homing

Question 36: We propose to transpose the provisions of Article 19 as they stand. Are there any further issues relating to the setting free and re-homing of animals we should consider?

We believe in principle that animals can be rehomed, but animals should not be rehomed if exhibiting or likely to exhibit any adverse effects – the concerns raised in response to Q22 are applicable here.

The responsibilities of those involved in the rehoming of animals should be clearly defined in any Home Office Guidance: veterinary certification is vital to this process and should be retained.

Article 29: Scheme for re-homing or setting free of animals

Question 37: We propose to transpose the provisions of Articles 28 and 29 as they stand. Are there any further issues we should consider relating to these issues?

We welcome this position. It should be emphasised that the quality of socialisation is key for the long-term welfare of any rehomed animals.

Article 30: Animal records

Article 31: Information on dogs, cats and non-human primates

Article 32: Marking

Question 38: We propose to transpose the provisions of Article 30, 31 and 32 as they stand. Are there any further issues we should consider relating to these Articles?

There are no further issues.

11. CARE AND ACCOMMODATION

Article 33: Care and accommodation

Question 39: We propose to transpose the provisions of Article 33 as they stand. Are there any further issues we should consider relating to the issues covered by Article 33?

Annex III: Care and accommodation standards referred to in Article 33

Question 40: Are there any specific issues we should consider when preparing guidance and codes of practice on accommodation and care?

Some aspects of Annex III are lower than current UK requirements. We strongly believe that UK standards should only be reduced where there is scientific evidence that there are no demonstrable adverse consequences for the animals. Additionally, we would support the provision of detailed guidance using the Commission recommendation 2007/526/EC as the basis of such guidance. This guidance should focus on performance standards rather than engineering standards.

Please see Appendix II for detailed questions on Annex III.

12. COMPETENCE AND AUTHORISATION OF PERSONNEL

Article 23 and Annex V: Competence of personnel

Impact on the UK personal licensing system

Question 41: Should the UK: (a) retain its current system of personal licensing using Article 2, as necessary; or (b) adopt a simplified version of that system with greater local accountability? What might be the features of a system involving greater local accountability? What risks might be associated with such a system and how might these be mitigated? What will be the cost to individual breeders, suppliers and users of implementing such a system?

We welcome the focus on training and competence of persons working with and performing scientific procedures on animals. The current individual responsibility for health and welfare of animals undergoing procedures is the responsibility of the personal licence holder. This individual responsibility should remain in any new legislation.

We believe that some form of simple licence or registration allied to individual responsibility should be maintained by the Home Office, which can be withdrawn should individuals prove unsuitable.

Education and training

Question 42: What specific features would you like to see in a UK or European training system? What elements of current UK training could be omitted whilst still complying with Annex V? How should the quality of individual training and supervision be assured so that new employers are confident about training and competence and to facilitate the transfer of individuals within the UK

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and across Europe? Would such a system result in any additional costs? If so, please specify. How might the requirement for continuous professional development best be met?

We believe that a common base-level syllabus, set of teaching outcomes and quality assurance/accreditation process should be maintained within the UK. The Home Office should then work within the EU to ensure a common framework for training across Europe.

We believe that the relative responsibilities of project licence holders and training and competence officers should be very clearly defined within formal Guidance. Ultimate responsibility for ensuring regulated procedures are performed competently should remain with the project licence holder.

We believe that Certificate Holders should be responsible for ensuring that appropriate CPD for all staff working with animals is provided and undertaken. The Home Office should provide details on expected levels and amount of CPD within their guidance.

Article 24: Specific requirements for personnel

Question 43: Are there any further issues we need to consider regarding the requirements for personnel?

See previous question and answer.

Article 25: Designated veterinarian

Question 44: Are there any further issues we need to consider regarding the requirement for a designated veterinarian or other suitably qualified person?

The current role, responsibilities and authority of the Named Veterinary Surgeon (NVS) are almost entirely laid down in HO Guidance and RCVS Guidance. The role of NVS must not be diminished, and the ability to carry out that role must not be reduced. Retention of the key roles and responsibilities of the NVS as required under A(SP)A, current Home Office Guidance and RCVS Guidance to NVSs is critical.

For the purposes of the Veterinary Surgeons Act 1966, the protected animals at the designated establishment will be under the care of the designated veterinarian. The designated veterinarian must be a member of the RCVS and accountable to the RCVS for their professional standards and conduct. We believe that the DV should always be a member of the RCVS (as all veterinarians are members) unless the RCVS specifically agrees to the appointment of another "suitably qualified expert".

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A detailed description of role, responsibilities and authority (particularly HO Guidance 4.48-4.54 and 4.59-4.64) must be retained for DVs to be effective.

Current HO Guidance states that NVS advice must be both “sought and taken by project and personal licence holders, of whatever seniority, both at the planning stage and once work is in progress.” This must be carried forward and reinforced; stronger support for this requirement from the Home Office would be welcome.

There should remain a requirement that the DV is consulted during the drafting of project licence applications.

We believe that it should be written into the primary legislation that the DV is a full and central member of the Animal Welfare Body (AWB). The DV must be a statutory member of the AWB to:

- (1) Enable the DV to fully discharge his/her professional responsibilities
- (2) Maintain public confidence that appropriate levels of care are in place
- (3) Ensure that the fullest advice is available to licensees and others at every stage of the consideration of animal care and use
- (4) Help ensure the maximum scientific benefit from the use of animals
- (5) Help ensure the fullest implementation of the 3Rs, best practice in animal welfare and the highest standards of animal care

The designated veterinarian must be actively involved on a day to day basis in safeguarding the welfare of the protected animals bred, kept and used at designated establishments. They should help certificate holders fulfil their responsibilities, and should play a central role in the animal welfare body.

To discharge their responsibilities DVs should have access to licences and other relevant documentation relating to the production, care and use of animals within the establishment.

Training requirements for DVs should remain, and continuing professional development and training should be actively encouraged by the Home Office and the RCVS. Access to the necessary training and resources must be provided by the Certificate Holder.

If there are changes in responsibility of the DV, we believe LAVA/BVA should work with the Home Office and RCVS to develop updated Home Office Guidance and an updated appendix to the RCVS Guide to Professional Conduct.

13. PROJECTS

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Article 36: Project authorisation

Article 37 and Annex VI: Application for project authorisation

Article 38: Project evaluation

Question 45: We propose to transpose the provisions of Article 36, 37 and 38 as they stand. What type of information should be placed in the public domain about the project evaluation process to ensure transparency of the process? Under what circumstances would you expect project applications to be referred to external experts and/or the new national committee required under Article 49? Are there any further issues we should consider relating to project authorisation and evaluation?

We believe that Designated Veterinarians should be involved in the development of project applications to ensure the 3Rs (and in particular refinements) are adequately addressed.

Article 39: Retrospective assessment

Question 46: Should we extend the requirement for retrospective assessment to some or all projects involving procedures classified as "mild" or "non-recovery"? What should be the process for retrospective review and should this involve the animal welfare body?

We believe that all projects should be subject to retrospective review to ensure all opportunities to implement the 3Rs are taken. We believe that the Animal Welfare Body is the most appropriate group to take responsibility for this review.

Article 40: Granting of project authorisation

Multiple generic projects

Question 47: Are there any other categories of project that should be covered by these provisions?

Article 41: Authorisation decisions

Question 48: How should 'complex and multidisciplinary projects' be defined for the purposes of Article 41?

Article 42: Simplified administrative procedure

Question 49: Should the UK adopt a simplified administrative procedure for relevant categories of project? What form should the simplified administrative procedure take?

Article 43: Non-technical project summaries

Question 50: Should we waive the requirement for non-technical summaries for some projects involving only mild or moderate procedures? Or, should we continue to aim to publish non-technical summaries for all authorised projects? What details should be included in non-technical summaries?

We believe that non-technical summaries should be provided for all projects as this gives a more balanced view of the nature of research being undertaken within the UK.

Article 44: Amendment, renewal and withdrawal of a project authorisation

Question 51: Are there any risks involved in limiting the requirement to amend or renew project authorisations to changes that may have a negative impact on animal welfare? If so, how might the risks be mitigated?

We have concerns that amending licences within an establishment has the potential for significant difficulties. As a minimum any such decision should rest with the full AWB (including DV). More detailed Guidance and practical examples from the Home Office would be essential as part of the introduction of such a process. This would need to clearly define how amendments could be written into a project licence by internal systems and hence become legally binding without the Competent Authority knowing or agreeing to it.

14. ANIMAL WELFARE BODIES

Article 26 and Article 27: Animal Welfare Body and Tasks of the Animal Welfare Body

Question 52: Is there a case for animal welfare bodies to have more extensive membership and functions than the minimum requirement set out in Articles 26 and 27? If so, what additional members and functions should be required or recommended in guidance? Might animal welfare bodies play a role in advising on training and competence? How might 'small' establishments be defined and how might they meet the requirements for animal welfare bodies 'by other means'?

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We strongly believe that the DV should be a full member of the animal welfare body, and this should be recognised in the primary legislation.

It is essential that the designated veterinarian is a full member of the AWB to:

- (1) Enable the DV to properly discharge his/her professional responsibilities
- (2) Maintain public confidence that appropriate levels of care are in place
- (3) Ensure that the fullest advice is available to licensees and others at every stage of the consideration of animal care and use
- (4) Help ensure the maximum scientific benefit from the use of animals
- (5) Help ensure the fullest implementation of the 3Rs, best practice in animal welfare and the highest standards of animal care

As the introduction of the ERP into the UK around 10 years ago has had an immense beneficial effect for animals, we believe that the composition and function of the ERP should largely be retained within the new AWBs.

We believe that all designated establishments must have an animal welfare body, regardless of size.

15. NATIONAL COMMITTEE FOR THE PROTECTION OF ANIMALS USED IN SCIENTIFIC PROCEDURES

Article 49: National committees for the protection of animals used for scientific purposes

Question 53: Should the Animal Procedures Committee form the basis for the new National Committee? Are there any models other than the APC on which the National Committee might be based? What should be its membership and what range of expertise will the National Committee require to enable it to meet the requirements set out in Article 49? How might this expertise be accessed?

16. INSPECTIONS

Article 34: Inspections by the Member State

Question 54: What system of inspection would best meet UK needs? What impact would adoption of a detailed and more formal, but less frequent audit-style approach to inspection have on (a) establishments; (b) public confidence? What aspects of the current UK inspection system should be retained? How might it be improved?

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Although the Directive does not require a professional Inspectorate, we strongly believe a professional expert, specialist Inspectorate with veterinary or medical qualifications and experience of various forms of research in the life sciences should be retained.

The Directive requires a minimum inspection regime far less frequent than is currently the case. If such a regime were adopted, the present inspection system would necessarily be replaced by a regime with less frequent, more intensive audit-style inspections which would be treated in a very different way to the current programme which is based on both announced and unannounced visits from inspectors. This may result in a more adversarial, less co-operative, more rule-driven approach to compliance which is likely to be detrimental to animal welfare and good regulation. The less contact with an inspector the more likely it is that the inspectors will be viewed as auditors and the additional benefits for animal welfare improvements will be lost.

We do not support the audit approach with a much reduced frequency as the retrospective nature is problematic. It is also likely to be confrontational and any welfare problems identified are likely to be historical and beyond correction. An important role for Inspectors is to advise potential applicants, licensees and others about the Act and its implementation and encourage best practise. This means licensees can seek continuous improvements and prevent issues before they arise. The Inspectorate plays an important role in identifying and disseminating best welfare and scientific practice, and provides operational and professional insights into policy development, implementation, maintenance and review. This should be retained.

The present inspection system has had very favourable feedback from the Hampton Review; it promotes good practice, promotes consistency, and assists prevention of problems.

We believe that the current system of routine, unannounced inspections is a major asset in maintaining public confidence so should be retained in a largely similar regime.

17. REPORTING

Article 54: Reporting

Question 55: Should the UK continue to publish a full range of statistics as in the current annual statistics report? Is there scope for streamlining UK statistics? Are there additional statistics it would be useful to publish?

18. SAFEGUARD CLAUSES

Article 55: Safeguard clauses

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Question 56: Is our analysis of the likely need to invoke the provisions of Article 55 correct? Are there any areas of work currently authorised that you believe may require reference to the Commission under Article 55?

This derogation in Article 55 allows otherwise unacceptable procedures to be performed on animals, or the use of Great Apes in extreme circumstances. It is hard to imagine any justification for such a requirement.

19. PENALTIES

Article 60: Penalties

Question 57: Should the UK incorporate the penalties from Part 3 of RESA into transposing legislation? Should they include provision for monetary penalties?

20. OTHER PROVISIONS

Article 50: Adaptation of annexes to technical progress

Article 56: Committee

Article 59: Competent authorities

Article 63: Amendment of Regulation (EC) No 1069/2009

Article 64: Transitional provisions

Question 58: Are there any issues we should consider in relation to Articles 50, 56, 59, 63 and 64?

21. CONFIDENTIALITY (ASPA SECTION 24)

Question 59: How might ASPA 24 be amended to provide greater flexibility regarding disclosure of information while protecting proprietary rights and intellectual property?

22: ASPA PROVISIONS NOT COVERED BY THE DIRECTIVE

Definition of 'death'

Question 60: Should ASPA section 1(4) be retained? What would be the effect if it were not retained?

We agree that this definition should be retained.

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Use of animals in public exhibitions

Question 61: Should restriction on public exhibition be retained?

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APPENDIX I: COMPARISON OF ANNEX IV AND ASPA SCHEDULE 1

Birds, rodents and rabbits: Cervical Dislocation

Question 62: Should sedation be used where it is in the welfare interests of the animal?

Rodents: Inert Gases

Question 63: Concerns have been expressed that there is currently insufficient evidence of humaneness for this method: should it require specific justification?

APPENDIX II: COMPARISON OF ANNEX III AND THE CURRENT UK USER AND BREEDER CODES OF PRACTICE

Table 1.2: Rats

Question 64: Is there a welfare need/benefit for retaining 20cm cage height for rats that are >250g and that are post-weaned stock or being used?

Table 1.4: Hamsters

Question 65: Is there a welfare need/benefit for retaining 15cm cage height?

Tables 2.1 to 2.4: Rabbits

Question 66: Is there a welfare need/benefit for retaining current UK CoP minimum floor areas for some weights of rabbits over 10 weeks of age? Is there a welfare need/benefit for retaining current UK CoP minimum enclosure sizes for does without litters?

Tables 4.1 and 4.2: Dogs

Question 67: Is there a welfare need/benefit for retaining the larger minimum enclosure size? Is there a welfare need/benefit for retaining the larger minimum enclosure size?

Tables 6.1 to 6.4: Non-Human Primates

Question 68: Is there a welfare need/benefit to retaining the slightly larger minimum floor area for breeding pairs of marmosets?

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Table 7.1: Cattle

Question 69: Is there a welfare need/benefit to retaining current minimum trough space allocations for ad libitum feeding of individual polled cattle?

Table 7.2: Sheep and goats

Question 70: Is there a welfare need/benefit to retaining current space allocations for most weights of sheep and goats?

Table 7.3: Pigs and minipigs

Question 71: Is there a welfare need/benefit to retaining the current minimum floor area per animals and are there likely to be welfare issues if minimum water flow rates and trough space allowances are not specified?

Table 7.4: Equines

Question 72: Is there a welfare need/benefit to retaining the current space allocations for equines?

PART II: IMPACT ASSESSMENT

73: Respondents are invited to submit estimated costs and other details to help refine the Impact Assessment and ensure that decisions on options are taken in the light of full and accurate information.

Competitiveness

74: We would particularly welcome data enabling the impact of the proposal on UK competitiveness to be assessed more fully. This has been identified by the Regulatory Policy Committee as a weak area in the impact assessment.

Different impacts on establishments and sectors

75: There are a number of areas in which the requirements of the Directive may have different impacts depending on the sector implementing them (for example, industry or higher education institutions). Some of these different impacts have been identified in the impact assessment at Part II. We would, however, welcome further and better information on such effects both in general and as they relate to specific provisions in the Directive.

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Summary

The BVA and LAVA agree that the responsible use of animals in research has improved human and animal welfare through the advancement of scientific knowledge and the development of safer and more effective medicines. However, animals should only be used in research when no alternative is available and the work is justified through independent ethical scrutiny, and we continue to support the traditional principles of the “Three Rs”. We strongly believe that higher standards should be retained under Article 2 of the Directive even without clear evidence of benefit to animal welfare, unless there is evidence to show that no reduction in welfare will result. The high level of public confidence in the robust regulation of scientific procedures using animals in the UK should not be compromised by the reduction of requirements without this evidence. We strongly endorse the requirements under the current regulations for researchers to seek and act upon veterinary advice in the planning and conduct of procedures on animals, as the veterinary profession has a legal and ethical duty to care for animals used in research. The existing Guidance on the Operation of A(SP)A and Codes of Practice are invaluable tools and a new set of equivalent documents must be drafted. LAVA and the BVA are willing to assist in this process.