Home Office

Consultation on EU proposals for a new directive on the protection of animals used for scientific purposes

ISBN 978 1 84726 906 5

Foreword by Shahid Malik

Parliamentary under secretary of state

The UK has had legislation to regulate animal experiments since 1876. The Cruelty to Animals Act 1876 controlled 'painful experiments' on animals and was the first legislation of its kind in the world. Although not without its critics, the 1876 Act proved adaptable to the developments in biomedical research for over a century.

Fundamental reform was inevitable and it arrived in the 1980s with the passing of the Animals (Scientific Procedures) Act 1986 into UK legislation and the adoption of the Council of Europe Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Procedures, closely followed by EEC Directive 86/609 covering much of the same ground. All three remain in force today.

The publication in November 2008 of the European Commission's proposal for a new European Directive to replace Directive 86/609 provides another opportunity to look at how best to regulate the use of animals in scientific procedures and to ensure that their welfare is safeguarded effectively.

The Government welcomes this. To quote the second White Paper on Scientific Procedures on Living Animals[1] published prior to the enactment of the 1986 Act, one of the tests of a civilised society is its treatment of animals. This is particularly true of animals used in scientific experiments and testing and we firmly believe that it is essential for Europe to set high standards for their welfare, to minimise suffering and support high quality science. At the same time, we also remain convinced that animal experimentation continues to be necessary if we are to make improvements in healthcare, and to protect people and the environment from other hazards.

These considerations require that we strike a balance in our approach to the legislation in this area. Our key priority in negotiating the revised directive will be to develop practical, proportionate and enforceable legislation that makes proper provision for the welfare of experimental animals, facilitates their responsible use, and can adapt to further technical progress. We will also work hard to ensure that the new directive does not impose inflexible measures which add disproportionate or unjustified regulatory burdens and undermine the success and sustainability of European research.

I hope this consultation provides the basis for a lively debate about how we should achieve these objectives, shape future regulation of animal experiments and testing and protect laboratory animals. I look forward to your responses and thank you for taking the time to respond to this consultation.

SHAHID MALIK

1 Cmnd 9521: May 1985

Contents

Page

Summary

Scope of the consultation

Topic of this consultation	The European Commission's proposal for a new Directive on the protection of animals used for scientific purposes published on 10 November 2008.
Scope of this consultation	The UK Government will use the responses to develop its negotiating position during discussions on the draft Directive.
Geographical scope	United Kingdom
Impact assessment	A partial impact assessment is attached.

Basic Information

To	This consultation is open to everyone, but we would particularly like to hear from individuals and organisations with a direct knowledge of the relevant issues.
Duration	8 May 2009 to 3 July 2009 (8 weeks)
Enquiries	Animals Scientific Procedures Division Home Office 4th Floor, South West Seacole Building 2, Marsham Street London SW1P 4DF Tel: 020 7035 4848 Email: aspd-brp@homeoffice.gsi.gov.uk
How to respond	To the postal or e-mail address above.
Additional ways to become involved	This is a written consultation. Please contact Animals Scientific Procedures Division (at the address above) if you require a copy of this paper in any other format such as Braille, large font or audio.
After the consultation	A summary of responses will be published before or alongside any further action.

.

Background

Getting to this stage	The Commission first indicated its intention to revise Directive 86/609/EEC in late 2001. In June 2003, technical expert working groups met to collect background information. The Commission sponsored a public and an 'expert' consultation in July and August 2006. A 'working document' was circulated by the Commission for comment in January 2007.
Previous engagement	Preliminary discussions have been held across Government and with a number of stakeholder groups and the European Commission. The House of Commons European Scrutiny Committee debated the proposal on 3 February 2009. The proposal was also discussed in an adjournment debate on 24 February 2009.

Section A: General Information

Introduction

1. This consultation document seeks your comments on the European Commission proposal for a new Directive on the protection of animals used for scientific purposes and on the estimated costs and benefits of the proposal identified in our partial impact assessment (Section C). Your views will inform the UK Government's ongoing negotiation.

2. The Commission's proposal was published on 10 November 2008 and is available at: <http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm>.

How to respond

3. When responding please state whether you are responding as an individual or whether you are representing the views of an organisation. If responding on behalf of an organisation, please make it clear who the organisation represents and, where applicable, how the views of members were assembled.

4. The consultation will run for 8 weeks. The closing date for responses is 3 July 2009. However, we would welcome early initial responses from consultees. A shortened consultation period has been agreed by Ministers so that we can take account of views before detailed consideration of the draft directive starts under the Swedish Presidency in July. A list of consultation questions can be found on pages 3 to 7.

5. A response can be submitted by letter or email to:
Animals Scientific Procedures Division
Home Office
4th Floor, South West
Seacole Building
2, Marsham Street
London
SW1P 4DF
Email: aspd-brp@homeoffice.gsi.gov.uk

6. This consultation is open to everyone, but we would particularly like to hear from individuals and organisations with a direct knowledge of the relevant issues.

Additional copies

7. This consultation can be found at: <http://www.homeoffice.gov.uk/about-us/haveyoursay/> and is also available from the Animals Scientific Procedures Division at the address above. You may make additional copies without seeking permission.

Responses: Confidentiality & Disclaimer

8. The information you send us may be passed to colleagues within the Home Office, the Government or related agencies.

9. Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 [FOIA], the Data Protection Act 1998 [DPA] and the Environmental Information Regulations 2004).

10. If you want other information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

11. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

12. The Department will process your personal data in accordance with the DPA - in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

Help with queries

13. Questions about the policy issues raised in the document can be addressed to the Animals Scientific Procedures Division, Home Office (contact details as above).

14. You should also contact the Animals Scientific Procedures Division should you require a copy of this consultation paper in any other format, e.g. Braille, Large Font, or Audio.

Consultation Criteria

15. This consultation follows the Government's Code of Practice on Consultation - the criteria for which are set below:

- Criterion 1 – When to consult – Formal consultation should take place at a stage when there is scope to influence the policy outcome.
- Criterion 2 – Duration of consultation exercises – Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible[2].
- Criterion 3 – Clarity of scope and impact – Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.
- Criterion 4 – Accessibility of consultation exercises – Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.
- Criterion 5 – The burden of consultation – Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.
- Criterion 6 – Responsiveness of consultation exercises – Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.
- Criterion 7 – Capacity to consult – Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

16. The full Code of Practice on Consultation is available at:
<http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44420.html>

Consultation Coordinator

17. If you have a complaint or comment about the Home Office's approach to consultation, you should contact the Home Office Consultation Co-ordinator, Nigel Lawrence. Please DO NOT send your response to this consultation to Nigel Lawrence. The Co-ordinator works to promote best practice standards set by the Government's Code of Practice, advises policy teams on how to conduct consultations and investigates complaints made against the Home Office. He does not process your response to this consultation.

18. The Home Office consultation co-ordinator can be emailed at:

<Nigel.Lawrence@homeoffice.gsi.gov.uk>

or alternatively write to him at:

Nigel Lawrence, Consultation Co-ordinator
Home Office
Performance and Delivery Unit
Better Regulation Team
3rd Floor Seacole
2 Marsham Street
London
SW1P 4DF

2 See paragraph 4, above

What happens next?

19. A summary of the responses received will be published before or alongside the next significant action in the development of the policy-making process.

20. The UK Government will use the responses to help inform its negotiating position during discussions on the draft Directive. The text of the proposed Directive can undergo major changes during negotiations and the timetable and progress of discussion can change very quickly.

21. Decisions taken in light of the consultation will be publicised along with a summary of the responses received.

22. Stakeholders will be able to follow developments on this Directive on the Home Office website at <http://scienceandresearch.homeoffice.gov.uk/animal-research/legislation/>.

23. As negotiations on the Directive progress, it may be necessary to hold a further consultation. This may be done via a similarly wide exercise or using a more targeted approach.

Consultation questions

Chapter I: General Provisions

Q1: What are your views on the proposed inclusion of animals bred for their tissues and organs within the scope of the proposal and our estimate of its impact?

Q2: What are your views on the provisions regarding the protection of immature forms?

Q3: What are your views on the inclusion of cyclostomes, cephalopods and crustacean decapods within the scope of the proposal? Can you provide any information on their current use in the UK for experimental or other scientific purposes?

Q4: Do you have any views on the proposed exemption affecting veterinary clinical trials?

Q5: Do you have any views on the proposed “marking” exemption? Do you support the proposition that the most appropriate humane methods should be used?

Q6: Do you have any comments on our approach to the proposed exemption of non-invasive practices?

Q7: Do you have any comments on any of the proposed definitions set out in Article 3 and their implications? Are there any other terms used in the proposal that should be defined in this article? How would you define those terms?

Q8: Do you have any comments on the provisions of Article 4 relating to replacement, reduction and refinement?

Q9: Do you have any comments on the proposed permissible purposes?

Q10: What are your views on the implications of the requirements relating to humane killing? Is there evidence-based alternative provision you believe should be considered?

Chapter II: Provisions on the use of certain animals in procedures

Q11: What are your views on the provisions protecting endangered species? Are you aware of any current classes of animal use in the UK that would be affected?

Q12: What are your views on the provisions limiting the use of non-human primates?

Q13: What are your views on the provisions relating to great apes?

Q14: What are your views on the provisions limiting the use of animals taken from the wild? Would there ever be justification for the use of such animals on the grounds that suitable purpose-bred animals were not available?

Q15: Do you have any comments on the proposed requirements regarding the use of purpose-bred animals? Are you aware of any potential problems with the likely availability of sufficient, suitable, purpose-bred animals?

Q16: What are your views on the proposed timetable(s) for the switch to the use of F2+ non-human primates? Do you agree that a feasiblity study should be carried out to identify the best way forward?

Q17: Do you have any comments on the proposed prohibition of the use of stray and feral domestic animals?

Chapter III: Procedures

Q18: Do you have any comments on the provisions of Article 12 relating to the conduct of procedures?

Q19: Do you have any comments on the proposed requirements regarding the selection of methods to be used in procedures?

Q20: Do you have any comments on the proposed requirements regarding death as an endpoint?

Q21: Do you have any comments on the proposed requirements regarding anaesthesia? Or our concerns about the inadequate provision made for post-operative animals?

Q22: Do you have any comments on the proposed severity classification requirements? Or our belief that fuller details must be agreed before a new directive is adopted?

Q23: Do you have any comments on the proposed limitation on the performance of “severe” procedures? Or our belief that it may prohibit important areas of research?

Q24: Do you have any comments on the provisions for re-use or the impact it would have on current UK practice?

Q25: Do you have any comments on the provisions regarding the end of procedures?

Q26: Do you have any comments on the proposed requirement regarding the sharing of organs and tissues and how it might be implemented in practice?

Q27: Do you have any comments on the proposed requirement regarding the setting free and re-homing of animals?

Chapter IV: Authorisation

Q.28: What are your views on the proposed provisions for personal authorisation? And the specific issues highlighted in our analysis?

Q29: Do you have any comments on the proposed requirement for authorisation of establishments? Or our analysis of their impact?

Q.30: What are your views on the proposed provisions for the mandatory suspension and withdrawal of authorisation for non-compliance with the provisions of the directive and on our preference for a more proportionate approach?

Q31: Do you have any comments on the proposed requirement for installations and equipment?

Q32: Do you have any comments on the proposed requirement for personnel in establishments?

Q33: Do you have any comments on the roles proposed for the animal welfare and care person and designated veterinarian?

Q34: Do you have any comments on the proposed requirement for permanent ethical review bodies (PERBs)? What are your views on their proposed membership? Is there a need to involve lay or external members?

Q35: What are your views on the proposed tasks of permanent ethical review bodies?

Q36: What are your views on the proposed requirement that establishments breeding and supplying non-human primates shall have a strategy for increasing the supply of F2 animals.?

Q37: What are your views on the requirement for re-homing schemes?

Q38: Do you have any comments on the requirements for records on animals?

Q39: Do you have any comments on the requirements for information on dogs, cats and non-human primates?

Q40 Do you have any comments on the requirements for marking?

Q41: What are your views on the requirements for care and accommodation? Should the UK retain present standards where they exceed the recommendations in Annex IV?

Q42: Do you have any comments on the requirements for national inspections?

Q43: Do you have any comments on the provisions for audit of the operation of national inspections?

Q44: What are your views on the proposal for authorisation of projects and on possible provision for notification of projects?

Q45: Do you have any comments on the proposed content of applications for project authorisation?

Q46: Do you have any comments on the proposals for ethical evaluation of projects?

Q47: Do you have any comments on the provisions for retrospective assessment of projects? Or our belief that further clarification is required?

Q48: Do you have any comments on the provisions relating to records of ethical evaluation?

Q49: Do you have any comments on the requirement for project summaries and its impact on current UK practice?

Q50: Do you have any comments on the provisions for granting of project authorisations? Or our preference for retaining a five-year maximum duration for project authorisations?

Q51: Do you have any comments on the provisions for the amendment, renewal and withdrawal of project authorisations?

Q52: Do you have any comments on the proposed provisions relating to authorisation decisions?

Chapter V: Avoidance of duplication and alternative approaches

Q53: Do you have any comments on the provisions relating to the sharing of data and any practical suggestions how data sharing might be implemented in practice?

Q54: Do you have any comments on the provisions to encourage the development of alternative approaches?

Q55: What are your views on the proposed requirements for the designation and functions of national reference laboratories?

Q56: What are your views on the proposed requirement for a national animal welfare and ethics committee and how it might be staffed and resourced?

Chapter VI: Final provisions

Q57: What are your views on the proposed arrangements for updating the technical annexes?

Q58: Do you have any comments on the proposed reporting requirements?

Q59: Do you have any views on the safeguard clause? And its likely impact on current practice in the UK?

Q60: Do you have any views on the proposal for the Commission to be assisted by a committee and of the need for the directive to contain more information on its terms of reference and composition?

Q61: Do you have any views on the requirements for an implementation report?

Q62: Do you have any views on the proposal for review of the directive?

Q63: What are your views on the provisions for competent authorities and the best option for the UK?

Q64: Do you have any views on the provisions for penalties?

Q65: Do you have any views on Articles 56, 57, 58, 59 or 60?

Annexes

Q66: Do you have any views on Annex I (invertebrate species)?

Q67: Do you have any views on Annex II (list of animals referred to in Art. 10)?

Q68: Do you have any views on Annex III (list of non-human primates referred to in Art, 10(1))?

Q69: Do you have any comments on the accommodation and care standards set out in Annex IV?

Q70: Do you have any comments on the humane killing methods set out in Annex V?

Q71: Do you have any comments on Annex VI (education and training)?

Q72: Do you have any comments on Annex VII (project authorisation)?

Section C: impact assessment

Evidence base

Option 1 (Retain current EU and UK legislation)

Q73: Do you agree that the retention of Directive 86/609/EEC and current UK legislation (Option 1) is not a viable option? If not, please explain your reasons.

Annex A

Q74: Do you have any comments on the functional headings and grouping of articles used for this impact assessment?

Annex B

Option 2 (Accept the European Commission's proposal as drafted)

Q75: Can you suggest any additional sources of evidence to supplement those used in developing this impact assessment?

Q76: Can you suggest how we might estimate the monetary value of increased transparency, improved animal welfare, or increased development and use of alternative methods? Can you suggest any sources of evidence to enable such an estimate to be made?

Scope and definitions

Q77: Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the extended scope of the proposed new directive?

Q78: Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the extended scope? Can you suggest any sources of evidence to enable such an estimate to be made?

Authorisation, enforcement and information requirements

Q79: Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the authorisation, enforcement and information requirements under the proposed new directive?

Q80: Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of those authorisation, enforcement and information requirements? Can you suggest any sources of evidence to enable such an estimate to be made?

Animal welfare and alternatives

Q81: Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to animal welfare and alternatives?

Q82: Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to animal welfare and alternatives? Can you suggest any sources of evidence to enable such an estimate to be made?

Non-human primates

Q83: Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to non-human primates?

Q84: Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to non-human primates? Can you suggest any sources of evidence to enable such an estimate to be made?

Procedures

Q85: Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to procedures?

Q86: Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to procedures? Can you suggest any sources of evidence to enable such an estimate to be made?

Personnel and training

Q87: Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to personnel and training?

Q88: Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to personnel and training? Can you suggest any sources of evidence to enable such an estimate to be made?

Places

Q89: Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to places?

Q90: Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to places? Can you suggest any sources of evidence to enable such an estimate to be made?

Compliance

Q91: Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to compliance?

Q92: Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to compliance? Can you suggest any sources of evidence to enable such an estimate to be made?

Transitional costs

Q93: Do you have any comments on the assumptions we have made about the timing of transitional costs and benefits?

Annex C

Small firms impact test

Q94: Do you have any comments on the small impact test?

Section B: The Commission Proposal

Executive summary

The European Commission's proposal

24. The Commission's proposal seeks to establish revised measures for the protection of animals used for scientific purposes to replace those currently set out in Directive 86/609/EEC.

25. The revised measures are intended to achieve three high-level objectives.

26. First, the draft directive aims to rectify wide variations in the implementation of Directive 86/609 by Member States. Second, the draft directive is intended to strengthen the protection of animals used in scientific procedures - for example by making special provision for non-human primates, and by making the ethical evaluation of proposed animal use a mandatory requirement. Third, the draft directive seeks to promote the Three Rs – the development, validation, acceptance and implementation of methods and strategies that Replace, Reduce and Refine the scientific use of animals.

27. The UK Government supports the Commission's high-level objectives.

28. Harmonisation is essential if we are to create a level playing field in Europe for the research community in industry and the academic sector.

29. It is also right that the European Community should set high welfare standards for laboratory animals. Good animal welfare and good science are inextricably linked and high standards of animal welfare are essential if we are to maintain public support for the vitally important research that still requires animal use.

30. It is also timely and important to promote the development and use of alternatives more effectively – an area in which the UK already plays a leading role. The Three Rs framework was developed in the UK, is a key component of the harm-benefit assessment in our current legislation - the Animals (Scientific Procedures) Act 1986 - and is supported by our National Centre for the Three Rs.

Main provisions

31. The Commission's proposal:

- creates a regulatory framework in which individuals, places and projects using animals in scientific procedures must be authorised in advance;
- requires Member States to establish an inspection system to monitor and enforce compliance by establishments with the requirements of the Directive;
- requires each establishment to have a permanent ethical review body to advise on the ethical treatment and welfare of animals and the Three Rs; and to carry out annual reviews of certain projects;
- requires procedures to be classified according to their severity (in terms of the pain, suffering, distress and lasting harm to the animals);
- places restrictions on the use, breeding and acquisition of non-human primates;
- requires Member States to promote the Three Rs; and
- requires Member States to apply prescribed minimum standards of care and accommodation.

32. The proposal also:

- extends the scope of the directive to include some invertebrates and animals bred for tissue and organs;
- extends protection to immature and larval forms;
- specifies the circumstances in which animals may be re-used in procedures;
- requires Member States to:
  - establish a national animal welfare and ethics committee to advise on issues relating to the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practices;

- ❏ nominate a national reference laboratory to assist in the validation of alternative methods;
- ❏ publish non-technical project summaries to aid transparency;
- ❏ avoid unnecessary duplication of procedures by accepting regulatory testing data from other Member States and by ensuring the sharing of data generated for other experimental purposes, subject to safeguarding confidential information;

UK overview

33. Many provisions similar to those set out in the draft directive are already implemented in the UK. For example, the UK already:

- requires three levels of authorisation (individuals, places and projects);
- provides for a national inspection programme;
- extends protection to some immature and invertebrate animals;
- has a system of local ethical review;
- places restrictions on the use of non-purpose bred animals;
- limits the re-use of animals;
- publishes project summaries (abstracts); and
- has a severity classification system.

34. There are, however, some significant differences. We are particularly concerned that:

- a number of the provisions will add to the UK administrative burden and costs without benefiting animal welfare, and may damage the success, sustainability and competitiveness of the UK and EU research base;
- the proposed restriction of non-human primate use to research into life-threatening or debilitating clinical conditions in human beings may rule out a number of important areas of work involving unmet clinical needs, such as vision research and research into infertility;
- the provisions limiting the use of non-human primates to those which are the offspring of animals which have been bred in captivity lack a delivery strategy and risk driving important areas of research out of Europe if overseas producers are unable, or unwilling, to adapt. This would seriously damage the UK and EU research base;
- the framework provided in the draft directive for the re-use of animals would increase the number of animals used in the UK and increase the overall welfare costs of some studies where additional animals are used;
- the addition of classes of invertebrates and provision for animals bred for tissues and organs would significantly increase the administrative burden with little evidence provided to support their inclusion or of any scientific or welfare benefit likely to accrue;
- a number of requirements in the annexes on standards of care and accommodation (Annex IV) and humane methods of killing animals (Annex V) would compromise animal welfare and hinder scientific outcomes.

35. We would welcome views on these and the other issues identified in the following sections of this consultation paper.

Chapter I: General Provisions

Article 1: Subject matter

36. Article 1 sets out the areas in which the directive lays down rules. These are the replacement and reduction of the use of animals in procedures and the refinement of the breeding, accommodation, care and use of animals in procedures; the origin, breeding, marking, care and accommodation of animals; the functioning of breeding, supplying and user establishments; and the evaluation and authorisation of projects involving the use of animals in procedures.

37. These areas are similar to those covered in the UK by the Animals (Scientific Procedures) Act 1986 (ASPA) which transposes the current directive (86/609/EEC). Differences in detail are dealt with below under the relevant articles.

Article 2: Scope

38. The draft directive applies where animals are used, or intended to be used, in scientific procedures. In some respects, its scope is significantly different to that of Directive 86/609 and current UK legislation.

Animals bred for organs and tissues

39. The directive will extend cover to animals bred specifically so that their tissues and organs may be used for scientific purposes. This will, we believe, affect about one million animals a year. These animals are largely bred, kept and used at places already regulated under ASPA, but their welfare is currently protected under general UK animal welfare legislation. We estimate that this provision is likely to require about 250 additional project authorisations and a small number of additional establishment authorisations. We are minded to oppose this proposal on the grounds that it will create a significant administrative overhead without a clear welfare or scientific gain in the UK.

Q1: What are your views on the proposed inclusion of animals bred for their tissues and organs within the scope of the proposal and our estimate of its impact?

Immature forms

40. Article 2(2)(a) provides for the directive to apply to live non-human vertebrate animals, including independently feeding larval forms and embryonic or foetal forms from the last third of their normal development. Article 2(3) extends protection to animals at an earlier stage if they are to be allowed to live beyond the specified stage of development and are likely to experience pain, suffering, distress or lasting harm after they have reached that stage.

41. In support of the provision, recital 7 of the draft directive cites scientific evidence showing that such forms in the last third of their development may have an increased risk of experiencing pain, suffering and distress, which may also affect negatively their subsequent development; and that procedures on embryonic and foetal forms at an earlier stage of development could result in pain, suffering, distress or lasting harm should the developmental forms be allowed to live beyond the first two thirds of their development.

42. Section 1(2) of the Animals (Scientific Procedures) Act 1986 provides similar protection to foetal, larval or embryonic forms of vertebrate mammals, birds or reptiles, but from half way through the gestation or incubation period for the relevant species and also provides for their protection at an earlier stage if that is warranted.

43. Given the similarities in the provisions of the draft directive and current UK legislation in this area we are minded to accept this element of the proposal. If adopted, it may result in some work currently licensed in the UK falling outside the scope of regulation, for example, on embryonated avian eggs, but the impact on welfare is likely to be negligible.

Q2: What are your views on the provisions regarding the protection of immature forms?

Invertebrate forms

44. Article 2(2)(b) extends coverage to classes of live invertebrate animals listed in Annex I - cyclostomes, cephalopods and crustacean decapods. The inclusion of this provision in the draft directive reflects advice provided to the Commission by the Scientific Committee of the European Food Standards Agency (EFSA). The only invertebrate form protected under ASPA is the common octopus (Octopus vulgaris).

45. We intend to oppose the inclusion of these animals. In our view, the EFSA advice on which it is based is not robust. In the absence of satisfactory evidence that these animals have the capacity to suffer, the provision has the potential to increase the regulatory burden significantly without achieving any animal welfare benefit. It will also be impractical to count immature forms of these animals for statistical returns.

Q3: What are your views on the inclusion of cyclostomes, cephalopods and crustacean decapods within the scope of the proposal? Can you provide any information on their current use in the UK for experimental or other scientific purposes?

46. Article 2(4) identifies the practices and classes of animal use to which the Directive will not apply. These are non-experimental, agricultural or clinical veterinary practices and trials; practices undertaken for the purposes of recognised animal husbandry; practices undertaken for the primary purpose of marking an animal; and practices that are not invasive.

Veterinary clinical trials

47. The proposed exemption of the use of animals for veterinary clinical trials extends well beyond those currently exempted from ASPA. It would, for example, appear to exempt any surgery or sampling, or any withholding of treatment from control groups performed as an integral part of the veterinary clinical trial. Although few UK licences would be affected, it is not clear what other regulatory framework would make provision for the welfare of the animals involved, or even if such studies would be permissible under general UK animal welfare legislation. We are, therefore, minded to oppose the exemption of veterinary clinical trials unless alternative provision can be made to protect the welfare of the animals affected.

Q4: Do you have any views on the proposed exemption affecting veterinary clinical trials?

Marking of animals

48. The proposed exemption of practices undertaken for the purpose of marking animals refers to the primary rather than the sole purpose of the procedure and sets no upper limit on the harm that can be caused. Under ASPA, the ringing, tagging or marking of an animal for the sole purpose of identification is not regulated if it causes only momentary pain, suffering, distress and no lasting harm. We propose to support this exemption but will seek to include a stipulation that the most appropriate humane method should be used.

Q5: Do you have any views on the proposed "marking" exemption? Do you support the proposition that the most appropriate humane methods should be used?

Non-invasive practices

49. The proposal exempts practices that are not invasive. As drafted, this could exclude over one third of animal use currently regulated in the UK, including the breeding of established lines of genetically altered animals (30% of currently licensed animal use), many psychology studies and some oral toxicity tests. However, we understand that this provision was intended to exempt only non-manipulative, observational studies and we will seek to amend the proposal to reflect this objective.

Q6: Do you have any comments on our approach to the proposed exemption of non-invasive practices?

Article 3: Definitions

Procedure

50. The proposal defines a 'procedure' as "any use of an animal for experimental or other scientific purposes, with known or unknown outcome, which may cause the animal pain, suffering, distress or lasting harm, including any course of action intended, or liable, to result in the birth of an animal in any such condition or the creation of a new genetically modified animal line".

Project

51. 'Project' is defined as a programme of work having a defined scientific objective and involving one or more procedures. This is similar to the definition that can be taken from ASPA.

Establishment

52. 'Establishment' is defined as any installation, building, group of buildings or other premises and may include a place that is not wholly enclosed or covered and mobile facilities.

Breeding and Supplying Establishments

53. 'Breeding establishment' is defined as any establishment where animals are bred with a view to their use in procedures or for the use of their tissue or organs for scientific purposes. 'Supplying establishment' is any establishment, other than a breeding establishment, from which animals are supplied with a view to their use in procedures or for the use of their tissue or organs for scientific purposes.

54. The equivalent terms under ASPA only apply to establishments breeding and/or supplying commonly used laboratory animals listed in Schedule 2 to the Act. This proposal is not similarly qualified and potentially applies to places breeding and supplying any species of animal for scientific use. This will increase the range of places which will need to be authorised and inspected.

55. Such places will be required to comply with the care and accommodation requirements set out elsewhere in the proposal. It is likely that many such places do not currently do so and will incur additional costs if they are to put in place the required infrastructure, standards and processes. This may increase the cost of animals and, in some cases, may reduce supply if breeders or suppliers choose not to make the required investment.

56. The number of establishments potentially requiring authorisation is also increased by the inclusion of the killing of animals to provide tissue and organs. This may include places which at present have no infrastructure to implement the required controls. However, regulation is probably not required when the tissue retrieved is a by-product of another process, for example, at a slaughterhouse.

57. We welcome the inclusion of definitions of key terms and believe they are essential for clarity and the consistent implementation of the proposal. We will seek to ensure that other essential terms are also defined in the text. We will also seek ensure that the definitions of breeding establishment and supplying establishment apply only to those places breeding and/or supplying species listed in Annex III to the directive.

Q7: Do you have any comments on any of the proposed definitions set out in Article 3 and their implications? Are there any other terms used in the proposal that should be defined in this article? How would you define those terms?

Article 4: Replacement, reduction and refinement

58. Article 4 requires that Member States ensure that animal use is not authorised where alternative methods of testing exist not involving the use of animals. Member States must also ensure that the number of animals used in projects is minimised consistent with the objectives of the project. They must also ensure procedures, breeding, and accommodation and care are refined to eliminate or minimise pain, suffering, distress or lasting harm to animals. These provisions reflect closely the current requirements of ASPA. However, they do not limit replacement alternatives to those which are reasonably and practically available. This is addressed in Article 13.1.

Q8: Do you have any comments on the provisions of Article 4 relating to replacement, reduction and refinement?

Article 5: Purposes of procedures

59. Article 5 specifies that procedures may only be carried out for one of the following purposes:

- basic research for the advancement of knowledge in biological or behavioural sciences;
- translational or applied research with either of the following aims:
  - the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants;
  - the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants;
- the development, manufacture or testing of the quality, effectiveness and safety of drugs, food- and feed-stuffs and other substances or products having either of the aims referred to in point (2);
- the protection of the natural environment in the interests of the health or welfare of human beings or animals;
- research aimed at preservation of the species;
- higher education or training;
- forensic inquiries.

60. These are broadly similar to the permissible purposes set out ASPA section 5(3), but, unlike ASPA, do not separately identify the breeding of animals as a permissible purpose. However, in practice, as in the case of breeding genetically altered animals or animals with other harmful genetic defects, there should always be a link to another of the permissible purposes. We will, however, seek to ensure this is clarified in the text.

Q9: Do you have any comments on the proposed permissible purposes?

Article 6: Humane methods of killing

61. Subject to exemptions based on scientific justification and relating to killing in an emergency, the proposal requires that animals produced or used for experimental or other scientific purposes are killed in an authorised establishment, by an authorised person, with a minimum of pain suffering and distress using a humane method appropriate to the species as specified in Annex V.

62. At present ASPA does not apply when animals are killed outside designated establishments for experimental or other scientific purposes by methods not listed in ASPA Schedule 1 (which is similar to, but less extensive than, Annex V) . This may occur in a number of contexts, for example, gathering tissue after death to look at toxin or residue levels or disease prevalence (and epidemiological studies). In such circumstances, other animal welfare legislation currently applies. The proposal would regulate this class of animal use. Furthermore it would seem to require only Annex V methods be used.

63. We support the principle that appropriate evidence-based humane methods should be used. However, we believe that as drafted Article 6 will cause serious practical problems. Many UK stakeholders have commented that Annex V has a number of significant shortcomings.

64. For example, some commonly used humane killing methods are omitted (such as, anaesthetic overdose for birds), and some unproven (inert gases for rodents) and unsuitable methods (simultaneous administration of general anaesthetics and paralysing agents) are listed. Also, the use of many methods is impractical for many field studies and there are no methods listed for some classes of protected animals, for example many of the invertebrate forms.

65. We are of the view that Annex V should not be incorporated in its current form and will seek substantial amendments to better reflect the current state of knowledge in this area and to make better provision for animal welfare. We also have concerns that it may prove difficult to keep the list of humane methods up to date as technical progress is made and that this will not make best provision for animal welfare.

Q10: What are your views on the implications of the requirements relating to humane killing? Is there evidence-based alternative provision you believe should be considered?

Chapter II: Provisions on the use of certain animals in procedures

Article 7: Endangered species other than non-human primates

66. To protect biodiversity, the proposal prohibits the use of the endangered species listed in Annex A to Council Regulation (EC) No 338/97[3] except where no other species not listed can be used to achieve the purpose of the procedure and the procedure is for translational or applied research for the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants; the development, manufacture or testing of the quality, effectiveness and safety of drugs, food- and feed-stuffs and other substances or products having either of the aims referred to in point (2); or research aimed at the preservation of the species.

67. The proposed list of endangered species and purposes for which they may be used is slightly longer than is presently provided for under ASPA, although we believe this is unlikely in practice to impact on their use for experimental or other scientific purposes. We will seek confirmation that evidence gathering by a veterinary surgeon under the Police and Criminal Evidence Act relating to wildlife crime would be unaffected. This is currently deemed to be recognised veterinary practice and is not regulated under ASPA.

3 The most recent consolidated version of the EU reference document can be found at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1997R0338:20080411:EN:PDF>

Q11: What are your views on the provisions protecting endangered species? Are you aware of any current classes of animal use in the UK that would be affected?

Article 8: Non-human primates

68. The Commission recognises that the use of non-human primates is still necessary in biomedical research and also that their use raises specific ethical and practical problems in terms of their behavioural, environmental and social needs in a laboratory environment.

69. The proposal restricts the use of non-human primates to basic research for the advancement of knowledge in biological or behavioural sciences; translational or applied research; and the development, manufacture or testing of the quality, effectiveness and safety of drugs, food- and feed-stuffs and other substances or products with a view to the avoidance, prevention, diagnosis or treatment of clinical conditions having "a substantial impact on patients' day-to-day functioning being either life-threatening or debilitating"; and to research aimed at the preservation of the species.

70. We are concerned that the proposal has the potential to prohibit some important current lines of research using non-human primates, for example, fundamental and applied studies into vision and fertility. We believe that the proposed directive's approach of defining in advance the detailed circumstances in which they may be used should be replaced with something closer to the UK approach. In the UK, we already apply stringent controls on non-human primate use authorising it only when there is sufficient justification, no alternative, and when purpose bred animals are used.

Q12: What are your views on the provisions limiting the use of non-human primates?

71. The proposal also prohibits the use of great apes, except in research aimed at the preservation of those species and where action is warranted in relation to a life-threatening or debilitating condition endangering human beings and no other species or alternative method would suffice (see 'safeguard clause' at Article 50).

72. Great apes have never been used as laboratory animals under ASPA and in 1997 we gave a commitment that we will not allow their use in the future. This remains our position. Although these provisions appear weaker than our current position, we support the proposal in principle. The exemptions allowed could only be invoked in genuinely exceptional circumstances and in practice we believe the provision would be an effective ban on the use of great apes consistent with UK policy.

Q13: What are your views on the provisions relating to great apes?

Article 9: Animals taken from the wild

73. The proposal prohibits the use of animals taken from the wild, subject to exemption based on scientific justification. This is generally consistent with current practice in the UK.

Q14: What are your views on the provisions limiting the use of animals taken from the wild? Would there ever be justification for the use of such animals on the grounds that suitable purpose-bred animals were not available?

Article 10: Animals bred for use in procedures

74. Subject to exemption on the basis of scientific justification, the proposal limits the use of the following species (listed in Annex II) to those which have been bred for use in procedures:

- Frog (Xenopus (laevis, tropicalis, Rana (temporaria, pipiens)),
- Mouse (Mus musculus),
- Rat (Rattus norvegicus),
- Guinea Pig (Cavia porcellus),
- Syrian (Golden) Hamster (Mesocricetus auratus),
- Chinese Hamster (Cricetulus griseus),
- Mongolian gerbil (Meriones unguiculatus),
- Rabbit (Oryctolagus cuniculus),
- Dog (Canis familiaris),

- Cat (Felis catus),
- Non-human primate (all species)

75. ASPA already makes similar provision for mice, rats, hamsters, gerbils, guinea pigs, rabbits, cats, dogs and non-human primates. Under ASPA, common quail and genetically modified sheep and pigs must also be purpose bred. There will be no significant savings, or welfare costs, resulting from their omission from the list. The addition of frog species can also be accommodated with little resource cost to users. However there may be some instances where purpose-bred animals will not be available and research would be delayed and we will seek to ensure that the allowed exemption on the basis scientific justification will include such cases.

Q15: Do you have any comments on the proposed requirements regarding the use of purpose-bred animals? Are you aware of any potential problems with the likely availability of sufficient, suitable, purpose-bred animals?

76. Article 10 also specifies the dates from which Member States must ensure that only non-human primates which are the offspring of animals bred in captivity (F2+) may be used. The aim of the provision is to "gradually end the capturing of non-human primates from the wild for breeding purposes". The dates are:

New World Primates

- Marmosets (Callithrix jacchus), 18 months from the entry into force of the directive;

Old World Primates

- Cynomolgus monkeys (Macaca fascicularis) 7 years after transposition of the Directive;
- Rhesus monkeys (Macaca mulatta), 7 years after transposition of the Directive;
- Other species, 10 years after transposition of Directive.

77. Marmosets (which are New World Primates) have been purpose-bred for many years and the supply of F2+ animals is not an issue in the UK. However, world-wide, there are currently insufficient F2+ Old World primates to sustain the UK science-base (where they are used primarily for pharmaceutical research and development).

78. Although it is proposed to encourage overseas breeders to produce more F2+ animals it is arguable that this will not be achieved within seven years or without considerable investment and ongoing costs. The EU is a relatively small user of non-human primates in global terms and without some incentives to meet F2+ requirements, progress towards F2 populations will be slow.

79. We are concerned also that the proposal identifies no clear funding or strategy to meet the target and in particular that there is no planned EU investment to make it happen. In addition, although the timetable can be changed by comitology, the proposal offers no commitment to review at critical points whether the target is likely to be achieved; or to change the timetable if it is not.

80. Furthermore, we are not convinced that the proposal will have any significant impact in terms of achieving its objective to reduce the trapping and taking of wild animals. In many primate-producing countries with indigenous populations, the trapping and taking of wild animals is the alternative to killing the animals as agricultural pests, and the majority of other user countries continue to use F1 and, in some cases, wild-caught animals.

81. Whilst in principle we support limitations on the use of non-human primates to those which have been purpose-bred, before firm commitments are made we believe a study should be undertaken to consider the feasibility of moving to the exclusive use of F2+ animals and the timescale over which it could be achieved.

82. We also believe that progress in F2 supply would need to be carefully monitored to ensure that no prohibition is imposed which would prevent the use of animals in vital research programmes.

Q16: What are your views on the proposed timetable(s) for the switch to the use of F2+ non-human primates? Do you agree that a feasiblity study should be carried out to identify the best way forward?

Article 11: Stray and feral animals of domestic species

83. The proposal prohibits the use of stray and feral animals of domestic species. This would require no change to current UK legislation.

Q17: Do you have any comments on the proposed prohibition of the use of stray and feral domestic animals?

Chapter III: Procedures

Article 12: Procedures

84. The proposal requires that procedures are always carried out in authorised user establishments unless an exemption is granted on the basis of scientific justification. This derogation would, we believe, apply to field studies. Article 12 further requires that procedures are only carried out within the framework of a project. These provisions would require no change to current UK legislation.

Q18: Do you have any comments on the provisions of Article 12 relating to the conduct of procedures?

Article 13: Methods used in procedures

85. The proposal prohibits the use of animals in a procedure if a scientifically satisfactory, non-animal method, or testing strategy, is reasonably and practicably available. Where more than one animal method is available, the method to be used is that which: uses the minimum number of animals; involves the lowest degree of neuro-physiological sensitivity; causes the least pain, suffering, distress and lasting harm; and is most likely to provide satisfactory results. These requirements closely resemble those of current UK legislation.

Q19: Do you have any comments on the proposed requirements regarding the selection of methods to be used in procedures?

86. Article 13 also requires that death as an endpoint to a procedure should be avoided as far as possible and, where it is unavoidable, procedures should be designed to result in the minimum number of deaths. This is current UK practice. We will seek confirmation that the killing of animals for tissue and organs will be considered to meet these requirements.

Q20: Do you have any comments on the proposed requirements regarding death as an endpoint?

Article 14: Anaesthesia

87. Article 14 requires that all procedures are carried out under general or local anaesthesia except where anaesthesia would be more traumatic than the procedure itself; or is incompatible with the purpose of the procedure (other than where the procedure involves serious injuries that may cause severe pain).

88. The proposal also requires that where a procedure is carried out without anaesthesia, analgesia or other appropriate methods are used to ensure that unavoidable pain, suffering and distress is minimised. Also, that analgesics, or other appropriate pain-relieving methods, are administered to animals which may suffer considerable pain when anaesthesia has worn off and that animals must be immediately killed by a humane method where such treatment is not possible.

89. The proposal also makes provision regarding the use of neuromuscular blocking agents, requiring that appropriate anaesthesia or analgesia is used in conjunction with such agents.

90. These requirements are generally consistent with current UK legislation. The Commission's objective is to minimise pain and suffering by requiring the responsible and appropriate use of anaesthetics and analgesics – a proposition we fully support and strive to implement through the current UK system of controls[4]. All animals should receive appropriate treatment to prevent or remedy pain and distress.

4 At present in the UK over 60% of animal use under ASPA does not require the use of anaesthesia or analgesia as the regulated procedures applied (for example, simple dosing or sampling) are less traumatic than their administration.

91. However, the provision requiring pain relief or humane killing only if there may be considerable pain after anaesthesia has worn off is not best practice. The majority of post-operative animals require appropriate analgesia even though they are not at risk of considerable pain. We will, therefore, seek an amendment to reflect this.

Q21: Do you have any comments on the proposed requirements regarding anaesthesia? Or our concerns about the inadequate provision made for post-operative animals?

Article 15: Classification of severity of procedures

92. The proposal introduces a requirement for procedures to be classified in one of four severity categories: "up to mild[5]", "moderate", "severe" and "non-recovery[6]". The proposal provides for the criteria for this classification to be established within 18 months from the entry into force of the Directive "with stakeholder input using existing severity classification schemes in place in Member States as well as those promoted by international organisations". However, we understand that the Commission may seek to complete this work more quickly following early representations from stakeholder groups and Member States.

93. The objective of the provision is to provide a common framework for the classification of the severity of procedures to "enhance transparency, facilitate project authorisation and provide tools for monitoring compliance". The basis of the classification will be the duration and intensity of potential pain, suffering, distress and lasting harm, the frequency of intervention, the deprivation of ethological needs and the use of anaesthesia or analgesia or both.

94. We recognise this as one of the key provisions of the draft directive. We support severity classification and the UK already has such a system in place. However, we believe that it is essential that the detail of the severity classification system is developed and agreed before the directive is finalised and adopted. This is necessary to enable the impact of other provisions to be fully assessed, to ensure that potential unintended consequences are identified, and to ensure the timely transposition and implementation of any new requirements.

95. It is also not clear if the prospective categorisation will relate to the "likely or typical" or the "worst possible" outcome for the animals. This is crucial to determining the meaning and impact of other key provisions. In addition, it is unclear if the re-use requirements for individual animals (in article 16) relate to the prospective assessment or to the actual welfare outcomes. We believe it should be the latter and will seek to have this made clear in the directive.

Q22: Do you have any comments on the proposed severity classification requirements? Or our belief that fuller details must be agreed before a new directive is adopted?

96. Article 15 also prohibits the performance of "severe" procedures if the pain, suffering or distress is to be prolonged (even if it is not severe). Our initial assessment is that some non-human primate models of Parkinson's disease which cause prolonged, severe distress (for the period the animals are symptomatic) may be prohibited by this provision, as it currently stands. We propose to seek drafting changes to permit the continuation of such research.

Q23: Do you have any comments on the proposed limitation on the performance of "severe" procedures? Or our belief that it may prohibit important areas of research?

Article 16: Re-use

97. The Commission recognises that the number of animals used in procedures could be reduced by allowing the re-use of animals where this does not detract from the scientific objective or result in poor animal welfare.

98. The proposal limits the re-use of animals to circumstances in which the previous procedure was classified "up to mild"; the animal's health and well-being has been fully restored; and

5 We believe that the 'up to mild' category is intended to be broadly equivalent to 'mild' in the current UK classification system.

6 Procedures performed under general anaesthesia where the animal will be killed by a humane method without recovering consciousness will be classified as "non-recovery".

the further procedure is classified “up to mild” or “non-recovery”. Where there is scientific justification, re-use may also be allowed where animals have previously been used in more severe procedures, provided the further procedure is “mild” or “non-recovery”.

99. Under these provisions the re-use of surgically prepared animals may not be permissible (assuming that such surgical procedures are likely to be classified as of moderate severity). This would result in a significant increase in the number of dogs and non-human primates used and the total suffering caused.This is unacceptable. We will seek drafting changes to permit the continuation of responsible re-use and to ensure that the intended welfare gains from this provision are realised.

Q24: Do you have any comments on the provisions for re-use or the impact it would have on current UK practice?

Article 17: End of the procedure

100. The proposal defines the end of a procedure as the point at which no further observations are to be made or, for new genetically modified lines, when lack of adverse effects can be scientifically demonstrated. It requires a decision to be taken by a veterinarian or other competent person at the end of a procedure whether the animal is to be kept alive or killed by a humane method and specifies that an animal must be killed when it is likely to remain in lasting pain or distress. Where an animal is to be kept alive, it is to receive the care and accommodation appropriate to its state of health and be placed under the supervision of a veterinarian or another competent person.

101. In broad terms these requirements are consistent with current UK practice. However, we consider that lasting harm and suffering should also be included as relevant considerations regarding the fate of animals, as they are already under ASPA. It is also worth recording that the majority of animals are usually killed because tissues are needed to complete the scientific study or because they are surplus to requirements, not because they are suffering. It is not clear what veterinary determination would add in these cases.

Q25: Do you have any comments on the provisions regarding the end of procedures?

Article 18: Sharing of organs and tissues

102. Article 18 requires that Member States establish programmes for the sharing of organs and tissues of animals killed by a humane method.

103. We support the aim to minimise animal production and use by encouraging the sharing of organs and tissues. Although this is not a current UK requirement, it is encouraged and many breeding establishments already provide this service, particularly for cats, dogs and non-human primates. There are, however, potential logistical problems associated with more prescriptive measures relating to continuity and timeliness of supply, and potentially high costs of shipping viable tissues. In practice we believe it is unlikely there would be any significant reductions in animal production, or savings to users, as a result.

Q26: Do you have any comments on the proposed requirement regarding the sharing of organs and tissues and how it might be implemented in practice?

Article 19: Setting free of animals and re-homing

104. The proposal permits Member States to allow the setting free or re-homing of animals used, or intended for use, in procedures providing they are healthy, present no danger to the public, and the “maximum possible care” has been taken to safeguard the well-being of the animal.

105. This is already the UK requirement with respect to animals released during the course of authorised procedures and occasionally non-human primates are ‘retired’ to animal sanctuaries. However, in the UK, relatively few laboratory animals (generally cats and dogs) are re-homed. Animal shelters already have more animals from other sources than can be re-homed, and those which are not are humanely killed as a result.

Q27: Do you have any comments on the proposed requirement regarding the setting free and re-homing of animals?

Chapter IV: Authorisation

Section 1: Authorisation of persons

Article 20: Authorisation of persons

106. The Commission recognises that the welfare of animals used in procedures is highly dependent upon the quality and professional competence of the personnel performing and supervising procedures and taking care of the animals. The proposal requires that individuals must be authorised before they carry out procedures on animals, kill animals by a humane method, supervise or design procedures and projects, or supervise those taking care of animals.

107. To be authorised, they must have the appropriate training and have demonstrated competence and those supervising or designing procedures or projects must have received instruction in a relevant scientific discipline and be capable of handling and taking care of the species concerned.

108. Authorisations will be for no longer than five years and may only be renewed on demonstration of the requisite competence.

109. Member States will be required to publish minimum education and training requirements relating to a range of issues, including relevant national legislation, ethics, biology, animal behaviour, animal health management, recognition of pain, suffering and distress in common laboratory species, anaesthesia, pain relief and euthanasia, use of humane end-points and the Three Rs. They must also publish their requirements for obtaining, maintaining and demonstrating relevant competences.

110. We support the proposition that key personnel must be properly trained, technically competent, and authorised and the 5 year maximum authorisation period is, we believe, workable. We also support the main training requirements.

111 We will seek to remove the requirement that those authorised for the supervision or design or projects must be able to handle animals, which, we believe, may lead to authorisations being delegated to more junior staff than is desirable. We will also challenge the requirement for prospective licensees to “demonstrate” competence as it is hard to see how someone new to animal use could satisfy it. In our view, a better approach would be to require effective supervision of personal licensees until they can demonstrate competence.

112. At a strategic level, a key Commission objective is to encourage the free movement of skilled labour in this sector. We believe this would be better achieved by a common EU training framework, rather than different national systems.

Q.28: What are your views on the proposed provisions for personal authorisation? And the specific issues highlighted in our analysis?

Section 2: Requirements for establishments

Article 21: Authorisation of establishments

113. The proposal requires that all breeding, supplying and user establishments must be authorised by and registered with the competent authority. In addition, authorisations shall only be given to an establishment if it has been inspected by the competent authority and found to comply with the requirements of the Directive (set out in Articles 23 to 32, below). The authorisation must also specify the person responsible for the establishment and for compliance with the Directive.

114. Under ASPA, the requirement for authorisation of breeding and supplying establishments is limited to those breeding and supplying animals of the species listed in ASPA Schedule 2. The Commission’s proposal does not limit the species to which the proposed requirement for authorisation will apply. A wider range of establishments may, therefore, require authorisation under the proposed Directive. There are likely to be resource implications for breeding/ supplying establishments authorised for the first time, with costs passed on to users.

115. While we support the principle that the commonly used laboratory species should be purpose-bred, with authorisation and oversight of the breeders and suppliers, we question whether there are additional, proportionate benefits in the case of other types of animal (such as farm animals) which are commonly bred in other places and are protected by other animal welfare legislation. Our full impact assessment will consider how many places are likely to be affected and the associated resource costs.

Q29: Do you have any comments on the proposed requirement for authorisation of establishments? Or our analysis of their impact?

Article 22: Suspension and withdrawal of authorisation

116. The proposal requires competent authorities to withdraw authorisation where an establishment ceases to comply with the requirements of the Directive. Where authorisations are withdrawn or suspended, Member States will be required to ensure the welfare of animals housed at an establishment is not adversely affected.

117. The proposal makes no distinction between minor and major compliance failures and strictly interpreted allows no flexibility in the terms of the disciplinary action allowed. The effect of withdrawal or suspension of authorisation will be to stop all work requiring animals to be killed. It is not clear that this has been taken into account in the drafting of this provision.

118. In the UK, most non-compliance is minor and technical, for example, involving minor defects in record keeping. Disciplinary action is tailored to individual cases to be effective, dissuasive and proportionate. We believe this is the right approach and that it is essential that competent authorities can respond proportionately to cases of non-compliance, in particular to prevent the needless killing of animals. We consider Article 55 (which requires that penalties for infringement of legislation are provided) is sufficient on its own to ensure penalties fit the circumstances.

Q.30: What are your views on the proposed provisions for the the mandatory suspension and withdrawal of authorisation for non-compliance with the provisions of the directive and on our preference for a more proportionate approach?

Article 23: Requirements for installations and equipment

119. The proposal requires Member States to ensure that all breeding, supplying and user establishments have installations and equipment suited to the species housed and, where relevant, to the performance of procedures, and that their design, construction and method of functioning is such that the procedures are carried out as effectively as possible and obtain consistent results using the minimum number of animals and causing the minimum pain, suffering, distress or lasting harm. The aim is to ensure that authorised places are properly equipped for the proposed production, keeping and use of animals. This is consistent with current UK requirements.

Q31: Do you have any comments on the proposed requirement for installations and equipment?

Article 24: Requirements for personnel in establishments

120. The proposal requires that breeding, supplying and user establishments have sufficient trained staff including, as a minimum, persons responsible for the welfare and care of the animals bred, kept or used and a designated veterinarian with expertise in laboratory animal medicine to advise on the well-being and treatment of the animals. No provision is made for the use of “other suitably qualified experts” where appropriate, rather than a veterinarian. This is relevant where only embryonated eggs, fish or protected invertebrates are used, where there may be no veterinarians with relevant “experience in laboratory animal medicine” for these types of animal. We will seek to have them included.

Q32: Do you have any comments on the proposed requirement for personnel in establishments?

121. The proposal further specifies that the animal welfare and care person shall ensure that staff dealing with animals have access to information relevant to the species housed in the establishment; projects are carried out in accordance with the relevant authorisation;

procedures causing unnecessary pain, suffering, distress or lasting harm are stopped; and appropriate measures are taken to rectify non-compliance with project authorisations and are recorded and reported to the permanent ethical review body (see Articles 25 and 26). The proposal does not require non-compliance with project authorisations to be reported to the relevant national body conducting inspections under Article 33.

122. The roles of the animal welfare and care person and designated veterinarian are similar to those of the Named Animal Care and Welfare Officer (NACWO) and Named Veterinary Surgeon (NVS) under ASPA. However, NACWOs do not currently have responsibility for identifying and rectifying non-compliance. This need not require additional resource, but it will change the relationship between the scientists and those who support their activities. We would particularly welcome views on whether this is desirable.

Q33: Do you have any comments on the roles proposed for the animal welfare and care person and designated veterinarian?

Article 25: Permanent ethical review body

123. The proposal requires that each breeding, supplying and user establishment has a permanent ethical review body (PERB) and specifies that its members must include the designated veterinarian, the person responsible for the welfare and care of animals and, in user establishments, a scientific member.

124. The Commission considers that animal welfare considerations should be given the highest priority in the context of animal keeping, breeding and use and identifies the primary task of the PERB as "focusing on ethical debate at establishment level, fostering a climate of care and providing tools for the practical application and timely implementation of developments in the Three Rs to enhance the life-time experience of the animals". Although Article 26 (see below) sets a slightly broader list of tasks, this is similar to the current UK requirement for local ethical review processes. We, therefore, support the proposal. We would, however, welcome views on the appropriate membership and composition of these bodies.

Q34: Do you have any comments on the proposed requirement for permanent ethical review bodies (PERBs)? What are your views on their proposed membership? Is there a need to involve lay or external members?

Article 26: Tasks of permanent ethical review body

125. Article 26 sets out the functions of permanent ethical review bodies. These are to provide advice on the ethical treatment and welfare of animals in respect of their accommodation, care and use; on the application of, and technical developments in, the Three Rs; and on re-homing schemes.

126. They are also to be required to establish and review operational processes for the monitoring, reporting and follow-up of animal welfare issues in establishments; to carry out annual reviews of projects lasting longer than a year, focusing on the number, species and life stages of animals used the preceding year, the justification for the animal use proposed for the following year, and the use of humane killing and how developments in relation to the use of animals have been taken into account in projects. Based on their reviews, PERBs are also to consider whether project authorisations need to be amended or renewed.

127. Establishments will be required to keep records of the advice received from their PERB, and of any decisions taken as a result. Such records must be submitted to the relevant competent authority on request.

128. Although some of these requirements go beyond the current minimum requirements for local ethical review processes in the UK, we broadly support them. None of the requirements are excessive and they correspond quite closely to current UK good practice. The requirements to review projects annually and consider compliance issues may add to compliance costs.

Q35: What are your views on the proposed tasks of permanent ethical review bodies?

Article 27: Breeding strategy for non-human primates

129. The proposal requires establishments breeding and supplying non-human primates to have a strategy for increasing the supply of F2 animals. Establishments will be required to provide proof to the competent authority, on request, that the establishments from which they have acquired non-human primates have such a strategy in place. These are new requirements.

130. We support the objective of this provision, but have concerns about how it will work in practice. World-wide, demand for non-human primates for scientific use exceeds supply. Purpose bred Old World animals are in short-supply, and F2+ animals are in particularly short supply and expensive. In addition, we understand that this provision can only apply to breeders and suppliers located within the EU and has no extra-territorial application. As most breeders are located outside the EU and EU users are not their major customers, it may prove difficult to persuade non-EU breeders to make the necessary investment without guarantees that they will be able to charge a large premium for the resulting F2+ animals. This may significantly increase the costs of undertaking this type of research in the EU. Competition within the EU for such animals may also reduce supply and increase costs for individual Member States.

Q36: What are your views on the proposed requirement that establishments breeding and supplying non-human primates shall have a strategy for increasing the supply of F2 animals.?

Article 28: Re-homing scheme

131. Under Article 19 above, Member States may allow the setting free or re-homing of animals used or intended for use in procedures. Where they do so, relevant establishments will be required to have a re-homing scheme that ensures socialisation of the animals to be re-homed. We broadly support this provision. Experience has shown that ex-laboratory cats and dogs make better companion animals if socialised, and socialisation programmes are increasingly part of their husbandry and care in the UK.

Q37: What are your views on the requirement for re-homing schemes?

Article 29: Records on animals

132. Article 29 sets out the records to be kept by establishments on animals. These are the number and species of animals bred, acquired, supplied, re-homed. humanely-killed or that have died; the dates on which animals were acquired, supplied, released or re-homed; and the name and address of the supplying establishment, or recipient, and date of arrival. These records are to be kept for three years and submitted to the competetent authority on request. The objective is to set common, minimum information requirements for animal record keeping by establishments. (Article 30 goes on to make special provision for cats, dogs and non-human primates.) These requirements are broadly consistent with current UK requirements.

Q38: Do you have any comments on the requirements for records on animals?

Article 30: Information on dogs, cats and non-human primates

133. Under the proposal, all establishments will be required to keep the following information on each dog, cat and non-human primate: identity; place of birth, whether purpose-bred for use in procedures; and, for non-human primates, whether they are the offspring of captive-bred animals. In addition each non-human primate must have an individual history file to accompany the animal throughout its life. These records are to be kept for three years and submitted to the competetent authority on request.

134. These requirements are broadly consistent with current UK requirements. The requirement to keep “social information” for individual non-human primates is new, but where it is not already practised the resource implications are, we believe, low.

Q39: Do you have any comments on the requirements for information on dogs, cats and non-human primates?

Article 31: Marking

135. The proposal requires that dogs, cats and non-human primates are given an individual identification mark, before weaning, in the least painful manner possible. Unmarked animals taken into establishments must be marked as soon as possible after first receipt. If a dog, cat or non-human primate is moved to another establishment before weaning, and it is not practical to mark it beforehand, a full documentary record must be maintained by the receiving establishment until it is marked. If asked, establishments must explain why an animal is unmarked.

136. These requirements are broadly consistent with current UK requirements.

Q40 Do you have any comments on the requirements for marking?

Article 32: Care and accommodation

137. Article 32 sets out the requirements for the care and accommodation of animals kept in establishments. These are that:

a) all animals are provided with accommodation, an environment, at least some freedom of movement, food, water and care which are appropriate to their health and well-being;

b) any restrictions on the extent to which an animal can satisfy its physiological and ethological needs are limited to a minimum;

c) the environmental conditions in which animals are bred, kept or used are checked daily;

d) the well-being and state of health of animals are observed by a competent person to prevent pain or avoidable suffering, distress or lasting harm;

e) arrangements are made to ensure that any defect or suffering discovered is eliminated as quickly as possible.

138. Regarding points a) and b), Member States must apply the standards set out in Annex IV as from the dates specified in it. However, Member States may allow exemptions to this requirement for animal welfare reasons. No exemption is currently provided on grounds of scientific justification. We understand this may be an oversight, which we will seek to remedy. Unlike the equivalent Annex to Directive 86/609, which is guidance, Annex IV sets mandatory minimum standards, reflecting current European legislative practice. These can be revised by comitology.

139. This article is a major concern. Although many elements in Annex IV reflect current UK good practice, and the proposed transitional arrangements are generally sensible, its lack of flexibility will increase compliance costs, decrease capacity, and increase the cost of purpose-bred animals without improving UK welfare or scientific outputs. Indeed, the apparent reduction in control of the animal environment may in some circumstances have adverse welfare and scientific consequences and result in an unnecessary increase in animal numbers as a consequence.

140. We believe more flexibility is required to make best provision for animal welfare and science at local level. This could be achieved by incorporating more material, particularly the narrative sections, from Appendix A to Council of Europe Convention ETS 123, which sets minimum requirements for the accommodation and care of animals in terms of performance standards and output measures, rather than engineering standards and input measures, and allows flexibility to make best provision for local needs and to adapt to technical progress.

141. There are aspects of Annex IV which we believe to be detrimental to animal welfare and will seek to have these corrected. Others appear to have no scientific or welfare benefit. In addition, there are a few requirements for enclosure size and space allowances which fall below those set out in present UK codes of practice.

Q41: What are your views on the requirements for care and accommodation? Should the UK retain present standards where they exceed the recommendations in Annex IV?

Section 3: Inspections

Article 33: National inspections

142. The proposal requires Member States to ensure that establishments are inspected for compliance with the requirements of the Directive. Inspections are to be carried out at least twice a year. One inspection must be unannounced. The frequency and extent of inspections must be adequate to the number and species of animals housed, the compliance record of the establishment, and the number and types of projects carried out. Records of inspections must be kept for at least five years. Member States must ensure that it has sufficient trained inspectors and appropriate infrastructure to ensure inspections are carried out. They must also establish programmes for joint inspections by Member States to share best practice.

143. We support this proposal. Compliance monitoring is currently one of the functions of the Home Office Inspectorate and their frequency and extent is typically determined using similar criteria to those listed. Informal joint visits with other relevant inspectorates, both within and outside the EU, already take place.

Q42: Do you have any comments on the requirements for national inspections?

Article 34: Controls of national inspections

144. Article 34 provides for the Commission to audit the organisation and operation of national inspections and to report their findings to Member States. It is likely that this role will be allocated to the EU Food and Veterinary Office (FVO). Member States must provide all necessary assistance to the Commission when such audits are conducted and to act upon the resulting report.

145. This is a new requirement, but the resource costs to the UK should not be high. There may be some handling issues to be resolved relating to biosecurity and the control of information that would not normally be disclosed to third-parties.

Q43: Do you have any comments on the provisions for audit of the operation of national inspections?

Section 4: Requirements for projects

Article 35: Authorisation of projects

146. The proposal requires that projects must be authorised in advance by the relevant competent authority and that the granting of authorisation is dependent upon a favourable ethical evaluation.

147. An alternative approach, currently available under Directive 86/609, would be to allow certain projects to be notified to the competent authority. This approach would require the ethical evaluation specified in Article 37 to be carried out at the place at which the project would be undertaken. Notification of projects would have a number of implications in the UK where current practice under ASPA is for all project authorisations to be granted by the competent authority (Home Office).

148. One of these affects the role of inspectors. A feature of the regulatory regime under ASPA is the discussion that often takes place at an early stage between applicants (or prospective applicants) and the Animals (Scientific Procedures) Inspectorate. This serves to ensure that project proposals meet most of the key requirements of ASPA before they are finalised and submitted for assessment and that there is clarity at the time of granting about what is and is not authorised in a project licence.

149. The opportunity for such discussions with inspectors could not be guaranteed where projects are assessed at the parent establishment and it is likely that inspectors would instead focus principally on monitoring compliance with the requirements of the directive. Establishments would also need to allocate resources to carry out the evaluation currently done by the UK regulators.

150. Also, where locally approved projects were found to be non-compliant, Article 22 of the directive would require authorisation to be withdrawn or suspended and work to be immediately stopped, resulting in animal wastage, unnecessary suffering and delay while problems are rectified.

Q44: What are your views on the proposal for authorisation of projects and on possible provision for notification of projects?

Article 36: Application for project authorisation

151. Under Article 36, applications must include the project proposal, a non-technical project summary and information (listed in Annex VII) on:

    a) the relevance and justification of (a) the use of animals including their origin, estimated numbers, species and life stages; (b) the procedures;
    b) demonstrating that existing methods to replace, reduce and refine the use of animals in procedures have been applied;
    c) demonstrating the competence of persons involved in the project; the planned use of anaesthesia, analgesia and other pain relieving methods;
    d) the reduction, avoidance and alleviation of any form of animal suffering from birth to death;
    e) housing, husbandry and care conditions of the animals;
    f) use of early and humane end-points;
    g) the experimental or observational strategy and statistical design to minimise animal numbers, suffering and environmental impact;
    h) the life time experience and re-use of animals; and
    i) the avoidance of unnecessary duplication of procedures.

152. For mild projects not involving the use of non-human primates, Member States may permit applicants to submit a reduced project proposal.

153. We are broadly content that the general classes of information required are similar to current UK requirements and with the ability to ensure information requirements are proportionate to the scale, complexity and sensitivity of the programme of work. However, we are concerned that how these arrangements will work in practice will be largely determined by the severity classification system which is currently to be developed after the revised Directive has been agreed (see Article 15).

Q45: Do you have any comments on the proposed content of applications for project authorisation?

Article 37: Ethical evaluation

154. Article 37 stipulates that the ethical evaluation will be carried out by the relevant competent authority; must verify that the project is scientifically justified or required by law; that the purpose of the project justifies the use of animals; and that the project is designed to enable procedures to be carried out in the most humane and environmentally sensitive manner. The ethical evaluation must also include:

    a) an evaluation of the objectives of the project, the predicted scientific benefits or educational value;
    b) an assessment of compliance with the requirements of replacement, reduction and refinement;
    c) an assessment of the classification of the severity of procedures;
    d) a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress, and to the environment, where appropriate, is justified by the expected advancement of science that ultimately benefits human beings, animals or the environment and the likely direct benefits of the project to human beings, animals or the environment; and
    e) an assessment of any scientific justification for exemptions from the requirements of Articles 6, 7, 8, 9, 10, 12, 14 and 16.

155. In carrying out the ethical evaluation, the competent authority must take account of advice from experts in

    a) the areas of scientific use for which animals will be used;
    b) experimental design, including statistics where appropriate;

c) veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;
d) animal husbandry and care, in relation to the species that are intended to be used;
e) the practical application of replacement, reduction and refinement;
f) applied ethics; and,
g) where appropriate, environmental science.

156. Finally, the proposal requires that ethical evaluation is carried out in a transparent manner and integrates the opinion of independent parties (lay or external members).

157. We agree that Article 37 identifies appropriate information requirements for ethical evaluation and project authorisation. Information requirements in the UK will need some adjustments, but with no significant increase in the regulatory burden. We also note that the Animals Scientific Procedures Inspectorate has access to all of the required expertise for ethical evaluation, should the functions of the UK competent authority continue to be carried out by a central government department. We will need to consider carefully how the requirement to take account of "the opinion of independent parties" will be implemented.

Q46: Do you have any comments on the proposals for ethical evaluation of projects?

Article 38: Retrospective assessment

158. Article 38 requires that the ethical evaluation should also determine whether to subject the project to retrospective assessment and the deadline for its completion. Retrospective assessments are to evaluate whether the objectives of the project were achieved; the harm inflicted on the animals; and the elements that may contribute to the further implementation of replacement, reduction and refinement. All projects using non-human primates are to undergo a retrospective assessment, but projects involving only procedures classified as "up to mild" will be exempt.

159. This is a new requirement, but already common practice in the UK when project licences are amended or renewed, but it is not done routinely when programmes of work finally end. The resource costs should not be high, and the information gathered should help to validate or improve the operation of the regulatory system. However, as drafted, it is not clear if it is the establishment's Permanent Ethical Review Body or the competent authority that identifies the need for retrospective assessment, nor is it clear if it is the users or the competent authority who prepare them. We will support amendments to clarify this in the text.

Q47: Do you have any comments on the provisions for retrospective assessment of projects? Or our belief that further clarification is required?

Article 39: Records of ethical evaluation

160. The proposal requires that establishments should retain records of ethical evaluations for at least three years from the expiry date of the project authorisation and submit those records to the competent authority on request. This implies that establishments are provided with copies of ethical evaluations carried out by the competent authority.

Q48: Do you have any comments on the provisions relating to records of ethical evaluation?

Article 40: Non-technical project summaries

161. Subject to safeguards for proprietary rights and confidential information, Article 40 stipulates that the non-technical summary required to accompany a project application shall include information on the objectives of the project, including the likelihood of achieving them, the potential harm, and details of the number and types of animals to be used; and evidence of compliance with the Three Rs.

162. Based on the ethical evaluation, the user establishment must specify in the project summary whether a project is to undergo a retrospective assessment and by what deadline. The user establishment must also update the non-technical project summary with the results of the retrospective assessment. Project summaries of authorised projects and any updates to them are to be published by Member States.

163. We support the publication of project details. The UK currently operates a voluntary scheme and publishes abstracts of over 80% of licensed projects. We are concerned that the Article 36(2) derogation permitting user establishments to submit a reduced project application in respect of some "mild" studies would apply to almost half of current UK projects and would in practice significantly reduce the amount of information published. Separately, we will consider carefully whether the safeguards for proprietary rights and confidential information are sufficiently robust.

Q49: Do you have any comments on the requirement for project summaries and its impact on current UK practice?

Article 41: Granting of project authorisation

164. Article 41 stipulates that the project authorisation will be limited to the procedures which have been subject to ethical evaluation and to the severity classifications assigned to those procedures and may be granted for a period not exceeding four years. The project authorisation must also identify the persons in the establishment responsible for the overall implementation of the project; the user establishments in which the project will be undertaken; in the case of field studies, the user establishment which is responsible for the project; and at least one person demonstrating species specific knowledge.

165. Member States may allow the authorisation of multiple projects (which we understand to be equivalent to the thematic licences granted under ASPA permitting the testing of specified classes of materials) when those projects are required by law. User establishments will be required to keep records of project authorisations for at least three years from their expiry date and to submit those records to the relevant competent authority upon request.

166. Other than authorities being limited to a maximum of four years, this provision is broadly similar to the current UK framework. The Commission has offered no rationale for the four-year maximum duration, and a reduction from 5 years to 4 years will entail a significant increase in user costs and impact on competent authority resources. We will seek to amend the maximum duration to 5 years. Other minor adjustments required to current information requirements should not involve any significant increase in the regulatory burden.

Q50: Do you have any comments on the provisions for granting of project authorisations? Or our preference for retaining a five-year maximum duration for project authorisations?

Article 42: Amendment, renewal and withdrawal of a project authorisation

167. Article 42 provides that the competent authority may amend or renew a project authorisation at the request of the user establishment, subject to a further favourable ethical evaluation. Where there is non-compliance with its terms, the competent authority may also withdraw a project authorisation. Where a project authorisation is withdrawn, the welfare of the animals used or intended to be used in the project must not be adversely affected. Member States will be required to publish detailed conditions for the amendment and renewal of project authorisations. These requirements are broadly acceptable.

Q51: Do you have any comments on the provisions for the amendment, renewal and withdrawal of project authorisations?

Article 43: Authorisation decisions

168. After ethical evaluation, which we understand to be a separate process, competent authorities will be required to decide and communicate the outcome of applications to the user establishment at the latest within 30 calendar days from the submission of the application, or 60 calendar days where the project is non-routine, multi-disciplinary and innovative. For projects classified "up to mild" and not using non-human primates, authorisation will be granted automatically if these timescales are not met.

169. Currently in the UK, we reach decisions on 85% of project applications within 35 working days days, with an average processing time of 18 working days. However there are, and always will be, complex and exceptional cases which take longer.

170. We agree that applications should be dealt with promptly and that applicants should know when to expect a decision, but we have concerns about the impact of this proposal on public confidence that applications are subject to thorough consideration, and are compliant with national legislation. Also, allowing authorisation by default risks undermining the credibility of the regulatory system and increases the risk of unjustified, unnecessary and poorly refined animal use. We would particularly welcome views on this aspect of the proposal.

Q52: Do you have any comments on the proposed provisions relating to authorisation decisions?

Chapter V: Avoidance of duplication and alternative approaches

Article 44: Unnecessary duplication of procedures

171. To avoid unnecessary duplication of procedures, Member States will be required to accept data required by law and generated by procedures recognised by Community legislation from other Member States, unless further procedures need to be carried out for the protection of public health, safety or the environment. Members States will also be required to ensure the sharing of data generated outside the area of testing required by law, subject to safeguarding confidential information.

172. For regulatory testing, with certain exceptions, Article 44 would require the mutual acceptance of data generated by commonly agreed means and to the required standard; and, again subject to certain exceptions, the mandatory publication of other animal research data.

173. We note that the Commission's Impact Assessment provides no evidence that duplication of procedures is a significant problem in practice and where it is known to take place, for example, to enable the release of batches of some vaccines, this would still be permissible.

174. We also recognise that there are concerns that mandatory disclosure of client data would drive contract research out of the EU. In the UK most regulatory testing is undertaken in contract research organisations, the data belongs to the client not the laboratory, and many of the clients are not based in the EU.

175. For non-regulatory testing there are concerns that the publication of non-peer reviewed research findings would make it difficult to distinguish between reliable and unreliable findings.

Q53: Do you have any comments on the provisions relating to the sharing of data and any practical suggestions how data sharing might be implemented in practice?

Article 45: Alternative approaches

176. Article 45 requires the Commission and Member States to contribute to the development and validation of alternative approaches implementing the Three Rs and providing the same level of information as that obtained in procedures using animals and to take such other steps as they consider appropriate to encourage research in this field.

177. We agree that there needs to be a commitment to make progress with the Three Rs and support this proposal in principle. We will, however, seek clarification as to what is meant by 'contribute' and whether the Commission will seek powers to direct or control activities at national level or require a specific financial contribution. Also, we note that although elements of the Member States' contribution in this area are set out in Article 46, the proposal does not explain what the Commission's duties or contribution will be.

Q54: Do you have any comments on the provisions to encourage the development of alternative approaches?

Article 46: National reference laboratories

178. The Commission considers there to be an increasing need for new methods to be developed and proposed for validation by the European Centre for the Validation of Alternative Methods (ECVAM). To "provide the necessary mechanisms at Member State level", the proposal requires Member States to designate a national reference laboratory for the validation of alternative methods replacing, reducing and refining the use of animals within one year of

the Directive's entry into force. To be designated, such laboratories must be accredited in accordance with Directive 2004/10/EC (relating to the application of the principles of good laboratory practice and the verification of tests on chemical substances). The Commission will publish the list of national reference laboratories.

179. National reference laboratories will be required to have suitably qualified staff with adequate training in alternative methods and the validation process and techniques applied in their area of competence; possess the equipment and products needed to carry out the tasks assigned to them; have an appropriate administrative infrastructure; and ensure that confidentiality is respected.

180. Their functions will be to cooperate with the Commission in their area of competence; participate in pre-validation and validation of alternative methods under the co-ordination of the Commission; communicate information on the availability and application of alternative methods received from the Commission to the relevant authorities of the Member State; provide scientific and technical assistance to the relevant authorities of the Member States for the acceptance and implementation of alternative methods; and provide training on the use of alternative methods to persons referred to in Article 20(1).

181. After consulting the national reference laboratories, the Commission will set the priorities for validation studies and allocate tasks between those laboratories for carrying out those studies. National reference laboratories will be required to declare any conflict of interest on any task being undertaken.

182. All UK stakeholders who have expressed an opinion agree that more needs to be done to develop and validate alternative methods. However, while we agree that Member States must play their part in this work, no reference laboratory currently exists in the UK and on the face of it this requirement will involve a significant financial cost, even though the Commission's impact assessment identifies the annual cost to each Member State as only £100,000.

183. We believe the obligation should be on Member States to assist the Commission in placing validation studies in existing laboratories not to provide dedicated facilities. This would be more cost effective and more likely to achieve the required policy objective. We will pursue this line in the negotiation of the directive.

184. In addition, it is not clear what input the Commission itself will provide; who will do the essential preparatory work, manage the funding, co-ordinate studies in progress, and assess and implement the findings. It may be that one or more 'virtual' centres will be needed to fulfil this role at a national or European level. Likewise, it is not explained what is to be the future role of ECVAM and its scientific advisory committee (ESAC). We believe the proposal should be revised to address these concerns.

Q55: What are your views on the proposed requirements for the designation and functions of national reference laboratories?

Article 47: National animal welfare and ethics committee

185. The proposal requires Member States to establish a national animal welfare and ethics committee to advise the competent authorities and permanent ethical review bodies on issues relating to the acquisition, breeding, accommodation, care and use of animals in procedures and to ensure sharing of best practices. The national animal welfare and ethics committees will be required to exchange information on the operation of permanent ethical review bodies and ethical evaluation and share best practices within the Community.

186. We support this proposal in principle, but we will need to consider carefully how such a national body will be constituted and how it impacts on other existing bodies. The envisaged role is somewhat different to that currently carried out in the UK by the Animal Procedures Committee, which is independent and advises Home Office Ministers on matters relating to the operation of ASPA. It is also a different role to that currently undertaken by the National Centre for the Three Rs.

Q56: What are your views on the proposed requirement for a national animal welfare and ethics committee and how it might be staffed and resourced?

Chapter VI: Final provisions

Article 48: Adaptation of annexes to technical progress

187. Article 48 provides for the Commission to adapt Annexes II to VII to take account of technical and scientific progress following the comitology procedure. We agree that it is essential that the technical annexes are regularly updated to make best provision for animal welfare and science.

Q57: Do you have any comments on the proposed arrangements for updating the technical annexes?

Article 49: Reporting

188. The proposal requires that Member States provide the Commission with information on the implementation of this Directive and in particular Articles 10(1), 25, 27, 33, 37, 38, 40 and 44 within six years from transposition and every five years thereafter.

189. In addition, Member States must collect and publish annually statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures. Member States must submit statistical information to the Commission by three years from the transposition date and every year thereafter in a common format to be established by the Commission within 18 months from entry into force of the Directive.

190. We support these requirements in principle, but are concerned that the statistical requirements will not be established until after adoption of the directive. We believe every effort should be made to avoid prolonged negotiation to establish a common format.

Q58: Do you have any comments on the proposed reporting requirements?

Article 50: Safeguard clause

191. Member States may provisionally authorise the use of great apes in procedures having one of the purposes referred to in Article 5(2)(a), (3) or (5) where it has justifiable grounds for believing that action is essential for the preservation of the species or in relation to an unexpected outbreak of a life-threatening or debilitating clinical condition in human beings provided that the purpose of the procedure cannot be achieved by the use of other species or by the use of alternative methods. The reference to Article 5(2)(a) excludes the reference to animals or plants.

192. Where this provision is invoked, the Member State must immediately inform the Commission and the other Member States, giving reasons for its decision and submitting evidence of the situation. The Commission must then reach a decision on the proposal using the comitology procedure within 60 days of receipt of the information from the Member State. The Commission's decision must either authorise the provisional measure for a time period defined in the decision; or require the Member State to revoke the provisional authorisation.

193. As reported under Article 8, above, great apes have never been used as laboratory animals under ASPA and in 1997 we gave a commitment that we will not allow their use in the future. This remains our position.

Q59: Do you have any views on the safeguard clause? And its likely impact on current practice in the UK?

Article 51: Committee

194. Article 51 provides for the Commission to be assisted by a committee, but its terms of reference, composition and resources are not defined. The committee will shape further development of the EU legislative framework. We note that the current Directive makes provision for a similar committee, which the Commission has never convened, and did not use as a resource to develop the current proposal. We would prefer greater clarity on the remit of the committee and will seek to have its terms of reference and general composition set out in the Directive.

Q60: Do you have any views on the proposal for the Commission to be assisted by a committee and of the need for the directive to contain more information on its terms of reference and composition?

Article 52: Commission report

195. Article 52 requires the Commission to provide the European Parliament and Council with a statistical report and a report on the implementation of the Directive seven years after transposition and every five years thereafter. (See also Article 49). The Commission reports will be compiled from, and informed by, information collated and submitted by Member States. We support this proposal, but are concerned that the timing and frequency of implementation reports is likely to be insufficient to take account of technical progress and other implementation issues. In particular, we believe the technical annexes will need more frequent attention.

Q61: Do you have any views on the requirements for an implementation report?

Article 53: Review

196. Article 53 requires the Commission to review the Directive ten years after entry into force. We support this proposal and would also like to see regular, thematic reviews of the operation of individual elements of the directive, which could, in turn, inform the ten-year review and provide insights into whether the policy objectives are being delivered.

Q62: Do you have any views on the proposal for review of the directive?

Article 54: Competent authorities

197. Article 54 requires Member States to designate one or more competent authorities responsible for the implementation of the Directive. The Commission will publish the list of competent authorities, which need not be public bodies.

198. We would particularly welcome views on this aspect of the proposal. This article provides an opportunity to review a number of options – a single UK national competent authority (as now), regionally-based competent authorities, competent authorities based on non-governmental organisations or designated establishments, or some form of self-regulation – for example, in which ethical evaluation is carried out by user establishments. A key priority must be to ensure public confidence in the arrangements that are agreed whilst achieving an efficient and effective regulatory system.

Q63: What are your views on the provisions for competent authorities and the best option for the UK?

Article 55: penalties

199. Article 55 requires Member States to lay down rules on the penalties applicable to infringements of the national provisions adopted to implement the Directive and to ensure that they are implemented. The penalties must be effective, proportionate and dissuasive. Member States must notify the Commission of the relevant provisions when the Directive is transposed and of any subsequent amendment affecting them.

200. The principles to be applied are consistent with current UK good regulatory practice. However, we have concerns that, elsewhere, Article 22 of the proposal, requiring that Member States “shall suspend or withdraw” authorisations for non-compliance with the requirements of the Directive (effectively invalidating all authorities and requiring that animals are killed), seems both to limit the powers of Member States to make provision for dealing with non-compliance; and to require the imposition of a single and disproportionate penalty for non-compliance regardless of the circumstances of the case.

201. We consider Article 55 is sufficient on its own to ensure penalties fit the circumstances of any non-compliance.

Q64: Do you have any views on the provisions for penalties?

Article 56: Transposition

202. Article 56 provides that Member States will have 18 months to adopt legislative measures to comply with the Directive.

Article 57: Repeal

203. Article 57 provides for repeal of Directive 86/609/EEC.

Article 58: Transitional provisions

204. Article 58 requires Member States to adopt and publish the laws, regulations and administrative provisions necessary to comply with the Directive within 18 months of the Directive entering into force and communicate to the Commission the text of those provisions and a correlation table between those provisions and the Directive. Member States must apply those provisions from 1 January of the year following the date of transposition. The provisions must contain a reference to the Directive or be accompanied by such a reference on the occasion of their official publication.

Article 59: Entry into force

205. The Directive will enter into force on the twentieth day following its publication in the Official Journal of the European Union.

Article 60: Addressees

206. The Directive is addressed to Member States.

Q65: Do you have any views on Articles 56, 57, 58, 59 or 60?

Annex I: Invertebrate species referred to in Article 2(2)

207. Lists the invertebrate species referred to in Article 2(2) - cyclostomes, cephalopods and decapod crustaceans. Although headed 'species', Annex I lists broad classes of invertebrate animals (cyclostomes e.g. lamprey; cephalopods e.g. octopus and squid; and decapod crustaceans e.g. crabs, lobsters and shrimp) referred to in Article 2(2).

208. We are concerned that there is insufficient evidence of potential capacity to suffer to offer protection to these general classes of animal; and that the pass or fail performance criteria for the inclusion of these classes of animal, and which would in due course be applied if protection was ever extended to other classes of animal, are not explained. There is little evidence for inclusion of immature forms of these groups. We, therefore, intend to oppose the inclusion of these animals (see Article 2, above).

Q66: Do you have any views on Annex I?

Annex II: List of animals referred to in Article 10

209. Lists the types of protected animals that should be purpose bred and which should be obtained from approved breeders. Namely:

- Frog (Xenopus (laevis, tropicalis), Rana (temporaria, pipiens)),
- Mouse (Mus musculus),
- Rat (Rattus norvegicus),
- Guinea Pig (Cavia porcellus),
- Syrian (Golden) Hamster (Mesocricetus auratus), Chinese Hamster (Cricetulus griseus),
- Mongolian gerbil (Meriones unguiculatus),
- Rabbit (Oryctolagus cuniculus),
- Dog (Canis familiaris),
- Cat (Felis catus),
- All species of non-human primate.

210. Annex II can be updated by comitology.

211. As noted under Article 10, above, ASPA already makes similar provision for mice, rats, hamsters, gerbils, guinea pigs, rabbits, cats, dogs and non-human primates. However, some species currently on the equivalent UK list – common quail and genetically modified sheep and pigs – are omitted. This is unlikely to have a significant impact. Annex II adds frog species, which can be accommodated with limited resource cost, but there may some instances where purpose-bred animals are not available.

Q67: Do you have any views on Annex II?

Annex III: List of non-human primates referred to in Article 10(1)

212. Annex III lists the species of non-human primate and the dates by which Member States must ensure that only animals which are the offspring of those bred in captivity may be used. (see also Article 10, above).

Q68: Do you have any views on Annex III?

Annex IV: Care and accommodation standards referred to in Article 32

213. Annex IV sets out detailed accommodation and care standards, both general and species-specific.

Q69: Do you have any comments on the accommodation and care standards set out in Annex IV?

Annex V: Humane methods of killing animals

214. Annex V specifies humane killing methods appropriate to specific species and classes of animal, which may be updated by comitology. This list would replace the current UK list of preferred humane killing methods which is broader in scope (see also Article 6, above).

Q70: Do you have any comments on the humane killing methods set out in Annex V?

Annex VI: List of elements referred to in Article 20(4)

215. Annex VI lists the elements to be covered by minimum education and training requirements for persons. These can be updated by comitology. The detailed content is delegated to individual Member States. See also Article 20, above.

Q71: Do you have any comments on Annex VI?

Annex VII: List of elements referred to in point 3 of Article 36

216. Annex VII lists the elements required in an application for project authorisation. These can be updated by comitology. In general terms, the types of information listed map well onto current UK requirements.

Q72: Do you have any comments on Annex VII?

Section C: Consultation stage impact assessment on the European Commission's proposal for a new directive on the protection of animals used for scientific purposes

217. The following pages contain a partial impact assessment. This sets out our initial assessment of the costs and benefits of the proposals discussed in this consultation paper.

218. We must emphasise that the impact assessment is, at this stage, only partial and that further work is needed to ensure that the full impact of the proposed Directive has been identified. This is particularly true in the case of option 3 (negotiate changes to the proposal) where the current wide cost estimate will be refined as the text is amended through the co-decision process.

219. Respondents are invited to submit costs and other data to assist in refining the impact assessment and to ensure that future decisions are taken in the light of information which is as full and accurate as possible. We would also welcome advice on any knock on effects of the proposals that we may have overlooked.

Summary: Intervention & Options

Department /Agency: Home Office	Title: Impact Assessment of the European Commission's Proposal to Amend Directive 86/609/EEC.	
Stage: Consultation	Version: 0.3	Date: 27 March 2009
Related Publications: European Commission Proposal to Amend Directive 86/609/EEC: http://eur-lex.europa.eu/LexUriServ.do?uri=CELEX:52001PC0703:EN:NOT		

Available to view or download at:

http://www.homeoffice.gov.uk/about-us/haveyoursay/current-consultations

Contact for enquiries: Jon Richmond Telephone: 01382 223189

What is the problem under consideration? Why is government intervention necessary?

Directive 86/609/EEC, which regulates the use of animals for experimental and other scientific purposes, is now out of date and not uniformly implemented in all Member States. This has left those with higher standards (such as the UK) at a competitive disadvantage. Lack of harmonisation has also restricted the free movement of labour, and there exist inefficiencies created by duplication and wastage. Government intervention is necessary to ensure the continued success, sustainability and competitiveness of the UK science-base.

What are the policy objectives and the intended effects?

The UK policy objectives are to ensure that: Member States (such as the UK) that already operate to high standards are not competitively disadvantaged; to promote harmonisation and a more level economic playing field; make proper provision for the protection of animals used for experimental and other scientific purposes; and promote the development, validation, acceptance and use of methods and strategies that replace, reduce and refine the use of animals for scientific purposes.

What policy options have been considered? Please justify any preferred option.

1. Retain the current UK and EU legislation.
2. Accept the European Commission's proposal to amend Directive 86/608/EEC, which regulates the use of animals for scientific purposes, as it stands.
3. Negotiate changes to the proposal to minimise additional UK compliance costs whilst delivering our high-level objectives.

Option 3 is currently preferred, and the consultation will both evaluate the level of support for this option, and provide insights into how it can be achieved.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

The policy will be reviewed and evaluated five years after a revised Directive is implemented in the UK.

Ministerial Sign-off For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

Phil Woolas Date: 6th April 2009

Summary: Analysis & Evidence

Policy Option: 2	Description: Implementation of the Commission Proposal.

COSTS

ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups'
One-off (Transition)	Yrs	Public sector: £3.8 million
£ 1.7 million	7	Commercial sector: £98.7 million
Average Annual Cost (excluding one-off)		Third sector: £6.1 million Academia/ Funders sector: £35.3 million
£ 18.8 million	7	Total Cost (PV) £ 129.8 million

Other key non-monetised costs by 'main affected groups' Loss of competitiveness against other economic regions, loss of scientific capability and capacity, inabillity to conduct key lines of research.

BENEFITS

ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups'
One-off	Yrs	Public sector: -
£ -	7	Commercial sector: £14.4 million
Average Annual Benefit (excluding one-off)		Third sector: - Academia/ Funders sector: £0.5 million
£ 2.2 million	7	Total Benefit (PV) £ 13.4 million

Other key non-monetised benefits by 'main affected groups' Increased transparency and public and political confidence. Enhanced UK competitiveness. More rapid availability of advanced test methods. Freer movement of skilled labour in Europe leading to lower wage pressures.

Key Assumptions/Sensitivities/Risks The UK (and Europe) could become less competitive compared to non-EU regions, resulting in investment and talent being relocated outside the EU; the resulting directive may not reflect the principles of Better Regulation; and the potential benefits to the UK may only be achieved at a disproportionate cost.

Price Base Year 2009	Time Period Years 7	Net Benefit Range (NPV) £ -116.4 million	NET BENEFIT (NPV Best estimate) £ -116.4 million

What i s the geographic coverage of the policy/option?				UK
On what date will the policy be implemented?				Estimated 2013
Which organisation(s) will enforce the policy?				Central Government
What is the total annual cost of enforcement for these organisations?				£ 1 million
Does enforcement comply with Hampton principles?				Yes
Will implementation go beyond minimum EU requirements?				No
What is the value of the proposed offsetting measure per year?				£ 0
What is the value of changes in greenhouse gas emissions?				£ 0
Will the proposal have a significant impact on competition?				Yes
Annual cost (£-£) per organisation (excluding one-off)	Micro N/K	Small N/K	Medium N/K	Large N/K
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices)	(Increase - Decrease)
Increase of £ 1.2m (annual)	Decrease of £ 90k (annual) Net Impact £ 1.1m (annual)

Key: Annual costs and benefits: (Net) Present

Summary: Analysis & Evidence

Policy Option: 3	Description: Negotiate changes to the proposal to minimise additional UK compliance costs whilst delivering other benefits and the Commission's high-level objectives.

COSTS

ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups'
One-off (Transition)	Yrs	Public sector: £0 - £3.8 million
£ 0 - 1.7 million	7	Commercial sector: £0 - £98.7 million
Average Annual Cost (excluding one-off)	Yrs	Third sector: £0 - £6.1 million
		Academia/ Funders sector: £0 - £35.3 million
£ 0 - 18.8 million	7	Total Cost (PV) £ 0 - 129.8 million

Other key non-monetised costs by 'main affected groups'
Loss of competitiveness against other economic regions, loss of scientific capability and capacity, inabillity to conduct key lines of research if this objective is not fully achieved.

BENEFITS

ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups'
One-off	Yrs	Public sector: -
£ -	7	Commercial sector: £14.4 million
Average Annual Benefit (excluding one-off)		Third sector: -
		Academia/ Funders sector: £0.5 million
£ 0 - 2.2 million	7	Total Benefit (PV) £ 0 - 13.4 million

Other key non-monetised benefits by 'main affected groups'
Increased transparency and public and political confidence. Enhanced UK competitiveness. More rapid availability of advanced test methods. Freer movement of skilled labour in Europe leading to lower wage pressures.

Key Assumptions/Sensitivities/Risks If the objective is not fully achieved the UK (and Europe) could become less competitive compared to non-EU regions, resulting in investment and talent being relocated outside the EU; the resulting directive may not reflect the principles of Better Regulation; and the potential benefits to the UK may only be achieved at a disproportionate cost.

Price Base Year 2009	Time Period Years 7	Net Benefit Range (NPV) £ 0 – (-)116.4 million	NET BENEFIT (NPV Best estimate) £ 0 – (-)116.4 million

What is the geographic coverage of the policy/option?			UK	
On what date will the policy be implemented?			Estimated 2013	
Which organisation(s) will enforce the policy?			Central Government	
What is the total annual cost of enforcement for these organisations?			£ 1 million	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£ 0	
What is the value of changes in greenhouse gas emissions?			£ 0	
Will the proposal have a significant impact on competition?			Yes	
Annual cost (£-£) per organisation (excluding one-off)	Micro N/K	Small N/K	Medium N/K	Large N/K
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (annual) (Increase - Decrease)
Increase of £0-1.2m (annual) Decrease of £ 0-90k (annual) Net Impact £ 0 - 1.1m (annual)

Key: Annual costs and benefits: (Net) Present

Evidence Base (for summary sheets)

Background

1. Approximately 11 million animals are used each year for scientific purposes in the European Union. 3.2 million of these animals are used annually in the United Kingdom (UK) and are covered by a European Directive. Of these 3.2 million animals 97% are rodents, fish and birds – with cats, dogs, horses and nonhuman primates combined accounting for less than 0.5% of the animals used. Approximately one third of the total UK reported animal use relates to the production and use of genetically altered animals, and the current European Directive makes no provision for these animals.

2. The European Directive 86/609/EEC, which was adopted in 1986 and never amended to reflect technical progress, makes legal provision at EU level for the protection of animals used for experimental and other scientific purposes. It has been transposed into UK legislation by the Animals (Scientific Procedures) Act 1986.[7] The European Commission is now considering amending the Directive.[8]

3. The Government is holding a formal consultation to inform the UK negotiating position regarding a revised directive regulating animal research. This is necessary to ensure the continued success, sustainability and competitiveness of the UK science-base, as the Proposal is developed through the European Union (EU) Co-decision Procedure.

4. The proposed directive will replace Directive 86/609/EEC, which the Commission considers is now out of date and not uniformly implemented in all Member States. A revised directive has the potential to acknowledge the significant advances in scientific methods and in our understanding of animal welfare made over the last twenty years, redress the absence of a need for statutory ethical evaluation and authorisation of animal use, promote the development and use of better test methods, and raise EU standards to those seen in those Member States (such as the UK) whose policies and practices have already remedied these deficiencies.

Problem for Consideration and Rationale for Intervention

5. Countries, such as the UK, which have already adjusted their regulatory systems to remedy the technical and other issues the Commission now seeks to address, can be considered to be at a competitive disadvantage compared to those with lower standards in terms of authorisation procedures, compliance costs, infrastructure costs, and general operating costs. This is true for those involved with the production of animals for scientific use, and those who use the animals for scientific purposes.

6. This lack of harmonisation also restricts the free movement of skilled labour, sets the scene for unnecessary duplication of studies causing inefficiencies and animal wastage, and provides insufficient incentive to develop or implement more refined or replacement methods. The UK Government sees the development of a new directive as the means by which standards can be raised and these defects remedied.

7. UK Government intervention is needed to avoid these difficulties and promote the continuing success, sustainability and competitiveness of the UK science-base sector. Without intervention the EC Directive could be developed without UK input and could leave the UK (and other European countries) at a disadvantage compared to non-EC countries.

Policy Objectives and intended benefits

8. The Commission's objective is to update the regulatory framework for the animal-science sector to bring about a strong convergence of standards that ensures a level playing field for industry and researchers and a significant improvement in animal welfare and protection over the life-time experience of experimental animals.

7 http://www.archive.official-documents.co.uk/document/hoc/321/321-xa.htm
8 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52008PC0543:EN:NOT

9. The high level policy objectives, shared by the Commission and the UK, are to bring about the following:

- harmonised EU regulatory requirements which promote a level economic playing field and the free movement of skilled labour to ensure that those who currently operate to high standards are not at a disadvantage;
- to promote transparency and public understanding of, and confidence in, the necessity for responsible regulation of animal research;
- to promote the development, validation, uptake and use of alternative test methods;
- to ensure high standards of animal welfare to comply with European Community animal welfare commitments; and
- to promote high quality science.

Sectors and groups affected

10. In the UK, under the provisions of the 1986 Act, there are currently 14,000 individuals, undertaking 4,000 licensed programmes of work at 200 establishments. There is evidence that the relevant sectors of the UK science-base dependent on the use of animals for experimental and other scientific purposes have an estimated 100,000 employees in skilled and/or highly paid jobs, and a total annual research and development spend in excess of £5 billion.

11. The revised directive will impact on the sectors of the UK research base which produce, keep and use animals for experimental and other scientific purposes: and those who fund these activities. These organisations are in the commercial, public, and third sectors. The precise (but small) number of SMEs affected is not currently known, but the resulting regulatory costs (and/or benefits) will be in proportion to their scale of protected animal production and use.

12. This consultation impact assessment focuses on direct costs, savings and benefits, some of which can be monetised and some of which cannot. Consideration must also be given to indirect impacts, potential unintended consequences and other contingencies (such as, the potential loss of research and development, investment and personnel, if work is relocated outside the EU as a result of new EU regulatory requirements). Additional summary material relating to Specific Impact Tests is appended at Annex C.

UK Impact assessment – consideration of options

13. Three options have been considered:

- Option 1: Retain the current EU and UK legislation;
- Option 2: Accept the European Commission's proposal to amend Directive 86/608/EEC, which regulates the use of animals used for scientific purposes, as it stands;
- Option 3: Negotiate changes to the proposal to minimise additional UK compliance costs whilst delivering our high-level objectives.

Option 1: Retain the current EU and UK legislation.

14. This is not a viable option. A new Directive will still be developed through the EU co-decision procedure, and we will be required to transpose and implement it in the UK or otherwise face infraction proceedings.

Q. Do you agree that the retention of Directive 86/609/EEC and current UK legislation (Option 1) is not a viable option? If you disagree, please explain your reasons.

Option 2: Implement the Commission proposal as it stands.

15. For the purposes of this Consultation Impact Assessment the detailed provisions of the European Commission Proposal are considered under eight functional headings (a summary of how the Commission Proposal article numbers fall under these functional groups is given at Annex A).

- Scope and Definitions
- Authorisation, Enforcement and Information Requirements

- Animal Welfare and Alternatives
- Non-human Primates
- Procedures
- Personnel and Training
- Places
- Compliance

16. These are outlined below in paragraphs 25 to 37, with more information on how they relate to current UK policy and practice provided in the related consultation document. Monetised costs, non-monetised costs, savings/benefits and risks are summarised in Annex B.

Option 3: Negotiate changes to the proposal to minimise additional UK compliance costs whilst delivering the Commission's high-level objectives.

17. Negotiated changes to the Commission Proposal could ensure that the best provision for the UK is made in terms of animal welfare and science to ensure the continuing success, sustainability and competitiveness of the UK science-base. In practice, however, it is to be expected that only a subset of any UK counter-proposals would be accepted. The formal consulation will provide additional information that will inform any subsequent decisions about which additional options and compromises would be most acceptable.

Costs and benefits

Option 1

18. This option, which assumes that regulation at both the EC and UK level does not change, forms the baseline from which all other costs and benefits are assessed.

Option 2

19. The main additional costs relate to manpower (e.g. numbers of staff and man-hours), investment in infrastructure (e.g. upgrading of existing facilities, and the provision of additional infrastructure to maintain capacity), other operating costs (e.g. support services, and cost of animals), and loss of research capability and capacity (e.g. decommissioning and relocation of some currently permissible lines of research).

20. The main benefits relate to increased transparency, additional support for the development of alternative test methods, the freer movement of skilled labour within Europe leading to lower wage pressures, and more harmonised European practices. Some monetised benefits relate to increased business opportunities for those who supply goods and services to the UK science-base.

21. The main risks of this approach are that:

- the principles of Better Regulation are not given due consideration at EU level, and any potential non-monetised benefits to the UK are only obtained at a disproportionate cost;
- Europe (and the UK) become less competitive compared to non-EU regions where compliance costs are significantly lower and other categories of animal use are permissible, resulting in investment and talent being relocated outside the EU;
- a new Directive will not be adequately enforced and the benefits of harmonisation not realised.

22. The assumptions and figures used for this consultation impact assessment relate to differences between current UK provision and practice and the Commission Proposal. They are based upon operational insights from the current licensing and inspection programmes (particularly with respect to the likely effects on the numbers of authorisations); an evaluation of some current compliance costs by Price Waterhouse Cooper which was accepted by the Davidson Review (particularly with respect to some unit costs); and material provided by stakeholders including scientists, professional bodies, animal welfare and animal protection groups, funding bodies, and other Government Departments (relating largely to unit costs and volumetrics).

23. Although the best available information has been used, it is expected that the formal consultation will produce more robust data to develop additional options and inform subsequent impact assessments.

24. It is assumed for the purposes of this exercise that the Proposal, if adopted, would be implemented in the UK in accordance with the principles of Better Regulation. Where there are new European provisions but where the relevant practices, outputs and costs are considered to represent existing good business practice (for example the majority of animals produced and used for organs and tissues are already bred, kept and used at establishments authorised within the current UK framework and working to Home Office Codes of Practice) relevant elements of these provisions are considered to be 'business as usual' and cost neutral.

Scope and Definitions

25. The Commission wishes to make better provision for animal welfare by extending legal protection to animals bred for organs and tissues, specified classes of invertebrate animals, and specified immature forms.

26. The proposed protection of immature forms is less stringent than current UK provision: however this change (eliminating the need for fewer than 10 current UK project authorisations) will produce negligible reductions in the UK regulatory burden.

27. The protection of animals bred for organs and tissues (coupled with separate provisions relating to their humane killing) would, it is currently estimated, extend regulation to in excess of an additional 1 million animals a year, largely bred, kept and used at places regulated under the current UK regulatory system, or whose welfare is currently protected under existing UK animal welfare legislation. This is likely, if implemented in the most efficient way possible, to require about 250 additional project authorisations and a small number of additional establishment and personal authorisations.

28. The addition of classes of invertebrates (including specified immature forms) will extend protection to tens of millions of animals which, for the purposes of UK legislation, are not currently considered to be capable of experiencing pain, suffering or distress. It is estimated on the basis of the information available that about 150 additional project authorisations and 250 personal investigator authorisations will be required, with up to 20 additional establishment authorisations.

Authorisation, Enforcement and Information Requirements

29. With respect to the current UK framework the most relevant new provisions set out in the Proposal relate to:

- additional authorisations for persons, projects and establishments;
- four year (maximum) project licence authorisation (increasing associated current UK costs by 25%);
- restrictions on the current permissible uses of protected animals (requiring research programmes, currently estimated to be less than 1% of currently licensed work, are decommissioned and/or relocated outside the EU, with consequential reductions in the UK research capability);
- additional information requirements; and
- mandatory suspension or withdrawal of establishments' authorisations for any non-compliance (resulting in the suspension or revocation of all related personal and project authorisations, and consequential disruption to research and testing, and animal wastage).

Animal Welfare and Alternatives

30. The relevant new provisions contained in the Proposal relate mainly to:

- additional classes of animal to be purpose bred;
  - a number of additional establishment authorisations will be required (current estimate of the order of 30), and additional investment may be needed to meet the required minimum standards of care and accommodation, with costs passed on to the UK science-base.
- a “closed list” of approved humane killing methods;
  - requiring additional training, authorisations and equipment, and in some cases a need to undertake further work to establish the potential impact on data-streams;
  - UK stakeholders have expressed concern that this list does not make best provision for animal welfare, and will increase UK animal welfare costs;
- mandatory minimum standards of animal accommodation and care;
  - although many of the provisions reflect current UK good practice, some facilities will require additional investment (over and above that normally required as ‘business as usual costs’ as facilities are re-equipped or refurbished) to meet the mandatory minimum standards;
  - without additional investment in supplementary infrastructure this will reduce production and holding capacity – decreasing the supply and increasing the costs of purpose-bred animals (for some classes of animal the commercial breeders estimate costs could increase, and production decrease, by 20%), and reducing research capacity;
  - the preliminary analysis suggests that in the UK there is a danger (as the provisions are set out in engineering standards with no flexibility to adapt these to best meet local needs) of animal welfare in some cases being compromised rather than enhanced;
- the establishment of a national reference laboratory to assist the Commission with the validation of alternative methods;
  - although a detailed technical specification is set out in the Proposal, the policy objective is that Member States assist the Commission to fund and place validation studies in high quality laboratories;
  - on that basis we accept the Commission’s estimate that the costs to each Member State will be of the order of 100,000 Euros a year - assuming the EU provides the additional resource necessary to plan, coordinate and act on the findings.

Non-human Primates

31. The relevant elements of the Proposal make provision for:

- the use of great apes only under exceptional circumstances;
  - this is weaker than the current UK effective prohibition and, as suitable UK facilities do not exist, this is assumed to be cost neutral to the UK;
- new limitations on the use of non-human primates;
  - ending legitimate lines of research which will be decommissioned and/or relocated, taking associated investment and expertise outside the UK and EU;
- moving within a fixed time to the use of only purpose-bred animals that are themselves the off-spring of animals of animals bred in captivity (F2+);
  - no European strategy or funding is provided for achieving this;
  - the increased production costs of such animals will be passed on to the UK science-base;
  - demand may continue to exceed supply, and important research will be delayed or relocated outside the UK;
  - although from first principles it is to be expected that F2+ animals would be better experimental subjects, there are known welfare problems with some current production facilities.

Procedures

32. The main relevant new provisions in the Proposal relate to:

- a Severity Classification System to be developed after the new directive is finalised;
  - this will determine the impact of many other elements of the proposal (including the re-use of animals, the reporting and administrative requirements, and permissible class of animal use);
  - in addition to the impact on other provisions, their development and implementation at national level will require the provision of detailed guidance understood and implemented by 15,000 people.
- a framework for the permissible re-use of animals;
  - this is more restrictive than the current UK framework;
  - it would require, for example assuming the surgical preparation would typically be considered to be of moderate severity, the use of additional animals (including dogs and non-human primates), the performance of additional surgical procedures, reduction in the UK research capacity and increased costs.
- an inviolable termination condition;
  - a requirement for the humane killing of subsets of animals likely to suffer for longer periods will prevent the use of a number of animal models of diseases for which new or better treatments are required;
  - such advances may be delayed, but it is likely research, and the related investment and expertise, would be relocated outside the UK and EU.

Personnel and Training

33. The Proposal identifies additional classes of persons to be trained, some details of the training to be offered, and a requirement for each Member State to develop a suitable national training system.

34. In addition to the costs of developing and overseeing such a system, it is likely (assuming that existing practitioners are automatically transferred in) that, after the induction of those being brought into the regulatory system for the first time by the expanded scope of the legislative provisions, an additional 100 persons will require such training each year.

35. UK stakeholders have expressed concern that the intended benefits of this element of the proposal (assurance that those trained anywhere in the EU are competent, and the resulting freer movement of skilled labour) will not be seen unless there is a common EU training framework and qualification system.

Places

36. The Proposal makes provision for the establishment of institutional level Permanent Ethical Review Bodies with administrative responsibilities over and above those currently required in the UK. The benefits should include sound institutional support for the systems required to make best local provision for animal welfare and good science.

Compliance

37. The relevant elements of the Proposal include:

- a risk-based inspection programme,
  - requiring the retraining of current inspectors, but with the potential for a reduced inspection schedule;
- a National Animal Welfare and Ethics Committee;
- current UK good regulatory practice makes provision for financial penalties rather than prosecution as one means of dealing with non-compliance. Any benefit (income to the regulator) is off-set by consequential costs (to the regulated).

Q. Do you have any comments on the functional headings and grouping of articles used for this impact assessment?

Option 3:

38. This option will involve working to negotiate changes to the Proposal to minimise additional UK compliance costs whilst delivering the Commission's high-level objectives and required outputs.

39. We believe the current UK system already largely delivers the required policy objectives and outputs, through the appropriate practices, relating to high animal welfare standards, and sound governance of the production, care and use of animals for experimental and other scientific purposes.

40. We have already developed and apply key operational components of the Proposal. For example:

- the UK regulatory framework takes full account of the 3Rs;
- protection extends to selected immature and inverebrate forms, and genetically altered animals;
- all projects are subjected to ethical evaluation and authorisation by the national competent authority, with summary information on the majority of licensed work being published, overseen by a risk-based inspection programme;
- all establishments operate local ethical review processes to support high standards of welfare and science;
- a severity classification exists, and the re-use of animals is regulated in line with the principles of the 3Rs;
- the standards of care and accommodation required and practiced in the UK take account of the Council of Europe provisions from which those in the Proposal are derived;
- mandatory training programmes are in place for key personnel.

41. We believe we have achieved this in a way which not only makes better provision for the optimisation of animal welfare at local level, but at more reasonable compliance costs.

42. We are concerned that the Proposal as it stands has the potential to compromise animal welfare (for example providing insufficient flexibility to make best provision for local needs), prevents research required to address unmet healthcare needs, and significantly increase UK and EU compliance costs damaging competitiveness compared to other economic regions.

43. We believe this option makes proper provision to manage the perceived risks, maintain high standards and competitiveness, and achieve the additional benefits (such as taking account of scientific progress, resolution of areas of uncertainty, and the freer movement of skilled labour) that would be provided by a level EU economic and regulatory playing field.

44. It is however unrealistic to expect to completely achieve this as the Proposal progresses through the EU legislative process. With that in mind, the formal UK consultation will provide the insights required to prioritise the issues, devise a preferred negotiating strategy, and better inform future consideration of options, benefits and costs.

Options Overview

45. The purposes of the impact assessment and consultation include to validate and gather evidence, to judge support for a preferred approach; and identify the elements on which the UK will adopt the strongest negotiating position.

- Option 3, seeking to align key elements of the new EU provisions to current UK practice, is preferred: it makes the best provision for the UK in terms of animal welfare, science and the continuing success, sustainability and competitiveness of the UK science-base – whilst maintaining current high national standards and delivering the Commission's high level policy objectives.
- Option 2, implementing the proposal as it stands, can be seen as the second choice, and our current analysis of the costs, saving, benefits and consequences are detailed in Annex B of this document. Although many of the Proposal component parts are similar to the the current UK system in nature, they differ significantly in detail and technical

content. In addition, many aspects of the Proposal lack clarity. The resource costs in implemention would be high, and any resulting scientific or welfare gains low (or in some cases damaging). We believe direct implementation of the current Proposal would damage the success, sustainability and competitivenss of the UK science-base.

- Option 1, retaining the current UK framework and not implementing any new EU requirements, has been rejected. The new directive will be developed and agreed through the co-decision procdure, and a new directive will emerge with or without our playing an active role. Disengaging from the process will achieve nothing, indeed it would disadvantage UK interests. Failing to transpose the changes into UK law would leave the UK open to infraction proceedings and could damage trade and relations within the European Community. For these reasons this approach is not recommended.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	Results in Evidence Base?	Results annexed?
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	No	No
Disability Equality	No	No
Gender Equality	No	No
Human Rights	No	No
Rural Proofing	No	No

Annexes

Annex A: Proposal Provisions and Functional Headings

The full text of the European Commission Proposal to Amend Directive 86/609/EEC can be seen at: <http://eur-lex.europa.eu/LexUriServ.do?uri=CELEX:52001PC0703:EN:NOT>

Scope and Definitions

Article 1: Subject Matter
Article 2: Scope
Article 3: Definitions
Article 5: Purposes of procedures

Authorisation, Enforcement and Information Requirements

Article 20: Authorisation of persons
Article 21: Authorisation of establishments
Article 23: Requirements for installations and equipment
Article 24: Requirements for personnel in establishments
Article 29: Records on animals
Article 30: Information on dogs, cats and non-human primates
Article 35: Authorisations of procedures
Article 36: Application for the project authorisation
Article 37: Ethical evaluation
Article 38: Retrospective assessment
Article 39: Records of ethical evaluation
Article 40: Non-technical project summaries
Article 41: Granting of project authorisation
Article 42: Amendment, repeal and withdrawal of a project authorisation
Article 43: Authorisation decisions
Article 49: Reporting
Article 54: Competent Authorities
Article 55: Penalties

Animal Welfare and Alternatives

Article 4: Replacement, reduction and refinement
Article 6: Humane methods of killing
Article 7: Endangered species other than non-human primates
Article 8: Non-human primates
Article 9: Animals taken from the wild
Article 10: Animals bred for use in procedures
Article 11: Stray and feral animals of domestic species
Article 32: Care and accommodation
Article 45: Alternative approaches
Article 46: National reference laboratories for alternative methods
Article 50: Safeguard clause

Non-human Primates

Article 8: Non-human primates
Article 10: Animals bred for use in procedures
Article 27: Breeding strategy for non-human primates
Article 30: Information on dogs, cats and non-human primates
Article 50: Safeguard Clause

Procedures

Article 12: Procedures
Article 13: Methods used in procedures
Article 14: Anaesthesia

Article 15: Classification of severity of procedures
Article 16: Re-use
Article 17: End of the procedure
Article 18: Sharing of organs and tissues
Article 19: Setting free or animals and re-homing

Personnel and Training

Article 20: Authorisation of persons
Article 24: Requirements for personnel in establishments

Places

Article 25: Permanent ethical review body
Article 26: Tasks of permanent ethical review body
Article 28: Re-homing scheme
Article 31: Marking
Article 39: Records of ethical evaluation

Compliance

Article 22: Suspension and withdrawal of authorisation
Article 33: National Inspections
Article 34: Control of national inspections
Article 47: National animal welfare and ethics committee
Article 55: Penalties

Annex B

Option 2: Monetised and Non-Monetised Costs and Benefits or Implementing the Proposal as it Stands.

1. The main evidence is drawn from:

   - published information relating to animal use in the UK;
   - operational information from the Home Office inspection programme and other activities;
   - a Price Waterhouse Cooper review of compliance costs (which suggested, for example, that in the commercial sector the annualised costs for each authorised individual could reach £3,000);
   - information from other published sources; and
   - information provided by stakeholders.

Q. Can you suggest any additional sources of evidence to supplement those used in developing this impact assessment?

2. In many cases relevant cost issues will relate not only to compliance costs, but also to the impact on stakeholder confidence and the continued success, sustainability and competitiveness of the UK and EU science-base. Some stakeholders have expressed concerns that elements of the proposal (including provisions relating to permissible classes of work, the use of non-human primates, the re-use of animals, inflexible standards of care and accommodation, the mandatory withdrawal of authorities for non-compliance, and data-sharing) will make the UK and EU much less competitive than other economic regions.

3. Whilst no attempt is made to estimate the costs of potential disinvestment and loss of skilled labour for any of the functional headings, it is estimated that for each 1% disinvestment UK annual spending on research and development would fall by £50 million, and 1,000 highly skilled or highly paid jobs would be lost.

4. No monetary value has yet been assigned to the benefits associated with increased transparency, improved animal welfare, or increased development and use of alternative methods.

Q. Can you suggest how we might estimate the monetary value of increased transparency, improved animal welfare, or increased development and use of alternative methods? Can you suggest any sources of evidence to enable such an estimate to be made?

5. Where there is ‘read-across’ between different elements of the proposal, every effort has been made to avoid ‘double-counting’ of the potential costs and benefits.

Scope and definitions

6. A key policy objective is to extend appropriate protection to all live animals capable of experiencing pain, suffering, and distress produced and used for experimental and other scientific purposes.

7. With respect to immature forms, additional classes of invertebrate animals, and animals bred and used for organs and tissues, it is assumed a proportionate approach can be taken to authorisation (involving essentially straightforward project authorisations) and training (requiring little additional training for those already believed to be technically competent).

8. It is estimated on the basis of available operational information and stakeholder feedback that there will be transitional costs (staff training; additional authorisations - 30 additional establishments, 400 additional projects, and 250 additional persons – and upgrading of facilities); and ongoing costs (overheads related to the additional authorisations).

9. Using unit costs based upon what is known of current operating costs, the expected additional monetised costs are currently estimated as:

Sector Affected	Transitional Costs	Additional Annual Costs	Savings and Benefits
Government	£140,000	£45,000	
3rd Sector Funders	£100,000	£25,000	
Academia/funders	£250,000	£60,000	
Commercial Sector	£120,000	£30,000	

10. It is not possible to monetise the potential benefits to science, welfare, transparency and harmonisation as these are difficult to cost, and it is not clear there are currently avoidable welfare problems, or poor quality science, that will be remedied by the new provisions.

11. There may be potential read-across and costs to other business sectors (e.g. farming, fisheries and aquaculture) if is it generally accepted that invertebrate and immature forms are capable of experiencing pain, suffering and distress.

Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the extended scope of the proposed new directive?

Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the extended scope? Can you suggest any sources of evidence to enable such an estimate to be made?

Authorisation, enforcement and information requirements

12. It is currently estimated that:

- the costs for additional authorisations will be at similar unit costs to those imposed in well managed places under the current UK system;
- in 60% of cases some form of retrospective evaluation of projects is already undertaken for other reasons;
- less than 1% of animal use currently authorised in the UK would become impermissible and there would be costs, rather than savings, associated with their decommissioning and (in some instances) relocation of investment and manpower outside the EU;
- the level and nature of non-compliance would be similar to that currently seen in the UK, and that the mandatory penalty of suspension or withdrawal of authorities for non-compliance would invalidate all related authorities;
- there would be no significant savings with respect to non-technical summaries – although only 60% of the material currently produced and published in the UK would require to be published under the Proposal, similar documentation is likely to be required by local ethical review bodies.

Sector Affected	Transitional Costs	Additional Annual Costs	Savings and Benefits
Government		£120,000	
3rd Sector Funders	£110,000		
Academia/funders	£220,000	£1,700,000	£70,000
Commercial Sector	£650,000	£2,500,000	£50,000

13. The savings relate to there being 25% fewer project licence amendments if project authorisation is for a maximum of four years.

14. It is not possible to monetise the potential benefits to science, welfare, transparency and harmonisation as these are difficult to cost, and it is not clear there are currently avoidable welfare problems, or poor quality science, that will be remedied by the new provisions.

Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the authorisation, enforcement and information requirements under the proposed new directive?

Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of those authorisation, enforcement and information requirements? Can you suggest any sources of evidence to enable such an estimate to be made?

Animal welfare and alternatives

15. The figures shown in the table below have been prepared on the basis that:

- the Commission's estimate of the costs of a national reference laboratory for the 3Rs are accurate;
- a light touch can be taken with respect to the regulation of humane killing;
- a proportion of the costs of meeting the minimum standards of care and accommodation can be discounted as 'business as usual costs';
- the breeders' estimates of impact on capacity and costings are generally accurate;
- that additional costs of purpose bred animals produce additional income for breeders, and represent additional costs to users;
- new infrastructure and capacity is provided to ensure that sufficient purpose-bred animals are produced to meet demand.

Sector Affected	Transitional Costs	Additional Annual Costs	Savings and Benefits
Government	£100,000	£150,000	
3rd Sector Funders	£300,000	£120,000	
Academia/funders	£1,500,000	£1,700,000	
Commercial Sector	£3,500,000	£2,000,000	£800,000

16. The saving/benefit of £800,000 relates to the additional potential profitability of those who purpose-breed animals.

Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to animal welfare and alternatives?

Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to animal welfare and alternatives? Can you suggest any sources of evidence to enable such an estimate to be made?

Non-human primates

17. The most relevant elements are the move to using only F2+ animals, and the impermissibility of some current programmes of work (e.g. work not relevant to life-threatening or debilitating diseases, and other work using disease models resulting in animal suffering and distress).

18. The assumption is made that sufficient F2+ animals will be available, at a 30% cost premium over F1 animals – and that UK academic users are already using F2+ animals.

19. It is also assumed there will be costs rather than savings arising from impermissible classes of use, as research programmes are decommissioned and relocated outside the EU.

20. No estimate is included of the additional impact if there is additional disinvestment, and no cost is assigned to writing-off previous investment in unneeded specialist facilities.

Sector Affected	Transitional Costs	Additional Annual Costs	Savings and Benefits
Government		£30,000	
3rd Sector Funders			
Academia/funders	£2,500,000		
Commercial Sector	£1,200,000	£5,000,000	

21. From first principles it seems unlikely that the UK could establish the infrastructure to become self-sufficient sufficient within 10 years, and that the level of investment required would be of the order of £100,000,000 – assuming that sufficient founder breeding-stock was available.

Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to non-human primates?

Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to non-human primates? Can you suggest any sources of evidence to enable such an estimate to be made?

Procedures

22. The assumptions made include that the severity classification system will be generally similar to that currently operated by the UK; that surgical preparation would be usually be classified as moderate severity and that surgically prepared animals could not therefore be re-used, and that the required use of general anaesthetics and analgesics is similar to current UK practice.

Sector Affected	Transitional Costs	Additional Annual Costs	Savings and Benefits
Government	£60,000		
3rd Sector Funders		£600,000	
Academia/funders	£300,000	£400,000	
Commercial Sector	£600,000	£2,500,000	£1,200,000

23. The figures include some provision to increase capacity to produce and use additional animals (as permissible re-use would decrease, the number of animals required would increase), and the savings shown reflect the profitability of those who would produce the required additional animals. Users have provided, for example, indicative costs of £1,300 for each additional rat, and up to £9,000 for each additional dog with implantable devices to provide data, and this data has been taken into account in producing the costings shown above.

24. This is one element of the proposal where the new EU provisions would make the EU less competitive than other economic regions.

Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to procedures?

Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to procedures? Can you suggest any sources of evidence to enable such an estimate to be made?

Personnel and training

25. The main costs relate to the induction training of additional persons, and expected subsequent increases in running costs for inducting additional users and for continued professional development. It is assumed unit costs will be as at present, and that those currently deemed to be competent will be automatically transferred into the new system.

Sector Affected	Transitional Costs	Additional Annual Costs	Savings and Benefits
Government	£40,000		
3rd Sector Funders		£30,000	
Academia/funders	£40,000	£40,000	
Commercial Sector	£40,000	£40,000	

Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to personnel and training?

Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to personnel and training? Can you suggest any sources of evidence to enable such an estimate to be made?

Places

26. The main costs relate to the establishment and operation of ethical review bodies – discounted against the running costs of existing well-run local ethical review bodies.

27. It is likely that these new bodies will not function efficiently until there is sufficient experience to allow subsequent benchmarking, from which good practice guidelines can be developed.

Sector Affected	Transitional Costs	Additional Annual Costs	Savings and Benefits
Government	£50,000		
3rd Sector Funders			
Academia/funders	£40,000	£200,000	
Commercial Sector	£40,000	£150,000	

Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to places?

Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to places? Can you suggest any sources of evidence to enable such an estimate to be made?

Compliance

28. The main costs will be incurred by the regulator – retraining staff and establishing and maintaining a National Animal Welfare and Ethics Committee. No allowance is made for the costs of transposing and implementing new legislation in the UK, or the preparation and promulgation of guidance documents and codes of practice.

Sector Affected	Transitional Costs	Additional Annual Costs	Savings and Benefits
Government	£120,000	£100,000	
3rd Sector Funders			
Academia/funders			
Commercial Sector			

Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to compliance?

Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to compliance? Can you suggest any sources of evidence to enable such an estimate to be made?

Further Assumptions

29. Apart from where the European Commission has provided clarification on the intended policy objectives, and taking account of obviously wrongly worded articles (for example the mistaken exclusion of non-invasive procedures from regulation) the assumption has been made that the proposal would be implemented as published. It is assumed that UK transposition and implementation would reflect the current UK Better Regulation agenda.

30. Timing of costs and benefits:

Scope and Definition

- Transitional costs to Government- all assumed to occur pre introduction.
- Transitional costs to 3rd Sector Funders- ⅓ of the costs pre introduction, ⅓ in years 1 to 4 and ⅓ in years 5-7.
-

- Transitional costs to Academia/Funders- ⅓ of the costs pre introduction, ⅓ in years 1 to 4 and ⅓ in years 5-7.
- Transitional costs to Commercial sector- ⅓ of the costs pre introduction, ⅓ in years 1 to 4 and ⅓ in years 5-7.

Authorisation, Enforcement and Information Requirements

- Transitional costs 3rd Sector Funders- ⅔ pre introduction, ⅓ years 1-2.
- Transitional costs Academia/ funders – ⅔ pre introduction, ⅓ years 1-2.
- Transitional costs Commercial sector – ⅔ pre introduction, ⅓ years 1-2.

Animal Welfare and Alternatives

- Transitional costs government- pre introduction
- Transitional costs 3rd Sector funders- ⅔ pre introduction, ⅓ years 1-2.
- Transitional costs Academia/ funders- ⅓ pre introduction, ⅓ year 1-2 and ⅓ year 3-4.
- Transitional costs Commercial Sector- ⅓ pre introduction, ⅓ year 1, ⅓ year 2.

Non-human primates

- Transitional costs Academia/ funders- ⅔ pre introduction, ⅓ years 1-2.
- Transitional costs Commercial sector- ⅔ pre introduction, ⅓ years 1-2.

Procedures

- All transitional costs pre introduction.

Personnel and Training

- Transitional costs Government- pre introduction.
- Transitional costs Academia/funders- ½ pre introduction, ½ year 1.
- Transitional costs Commercial sector- ½ pre introduction, ½ year 1.

Places

- All transitional costs pre introduction.

Compliance

- Transitional costs to Government- ⅔ pre introduction, ⅓ year 1.

All annual benefits and costs are assumed to be constant and occur every year from year 1, though there may be minor fluctuations over a four-year cycle.

Q. Do you have any comments on the assumptions we have made about the timing of transitional costs and benefits?

Annex C

Specific Impact Tests

Competition Assessment

The competition filter	
Question	Answer yes or no
Q1:In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential firms that existing firms do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential firms that existing firms do not have to meet?	No
Q8: Is the market characterised by rapid technological change?	Yes
Q9: Would the regulation restrict the ability of firms to choose the price, quality, range or location of their products?	No

On the basis of the above “competition filter”, completed 6 March 2009, a full Competition Assessment is considered unnecessary.

Small Firms Impact Test

Checklist

A.

Does the regulation apply to small businesses or affect the business environment in which they operate?

Yes

Will costs fall disproportionately on small businesses?

No

What are the characteristics of small businesses likely to be affected? – For example, number of businesses, size, ownership type (sole proprietor, partnership, limited company, etc), geographic distribution?

Sole proprietorship and venture capital start-up companies in England, Wales and Scotland.

B.

Consider whether alternative approaches (including, but not limited to, exemptions, simplified inspections, less frequent reporting) might be appropriate for firms with fewer than 20 employees.[9]

This will be done as the EU proposal is developed – but the current EU proposal provides no alternative mechanism.

9 For all regulations that affect business, policy makers are now required to consider whether alternative approaches (e.g. flexibilities or exemptions) are appropriate for firms with up to 20 employees. This requirement was announced in the Government’s 2008 Enterprise Strategy -. For more information, see http://www.berr.gov.uk/bbf/enterprise-smes/enterprise-framework/index.html

Consider whether a complete or partial exemption would be appropriate for micro and small businesses (those with fewer than 50 employees).

This will be done as the EU proposal is developed – but the current EU proposal provides no alternative mechanism.

C.

Contact a reasonable number (e.g. 10) of representative businesses.

All affected small business are represented within a range of established liaison groups. Small business will also respond to the planned consultation.

Obtain feedback about the likely effects of the proposal:

- How serious is the problem the proposal seeks to address in relation to smaller firms?

  No different to the remainder of those who would be regulated.

- What changes will smaller firms have to make to the way their business operates?

  Primarily changes to administrative practices.

- Is there likely to be a greater impact on the operations and performance of smaller business than others[10]?

  No.

- What are the likely approximate costs and benefits of the proposal for small business?

  No well run small business should incur additional annual operating costs in excess of £1K.

- Will exempting (either fully or partially) smaller firms from the policy materially affect the potential benefits from the policy?

  Not an option: compliance with EU requirements will be objective.

- Are there alternative approaches for smaller firms, which would not materially affect the potential benefits from the policy?

  No.

D.

Determine if there is likely to be a greater impact on the operations and performance of small business than others:

No.

Whether alternative approaches (including, but not limited to, exemptions, simplified inspections, less frequent reporting) are appropriate for firms with fewer than 20 employees.

A risk-based approach will be taken: the regulatory and compliance burdens will be in proportion to their size and scale of animal use.

Whether exemptions are appropriate for small firms (those with up to 50 employees).

Current EU Proposal makes no such provision.

10 It is normal for the impact of measures to bear more heavily on small businesses because they do not enjoy the economies of scale of larger firms

E.

Contact a wider sample of representative businesses. Obtain feedback about likely effects of the proposals, including estimates of costs and benefits that can withstand external scrutiny. Consider again if the proposal will have a greater effect on small business. Consider alternative approaches for smaller firms.

These will be done as and when required as the Proposal progresses through the EU parliamentary process.

Q. Do you have any comments on the small impact test?

Other specific impact tests have been considered (Legal Aid, Sustainable Development, Carbon Assessment, Other Environment, Health Impact, Race Equality, Disability Equality, Gender Equality, Human Rights, and Rural Proofing) but none are considered relevant for this consultation impact assessment.