



Home Office

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

JUNE 2011

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1: GENERAL INFORMATION

Introduction

This consultation document seeks your comments on the options for transposing Directive 2010/63/EU on the protection of animals used for scientific purposes and on the impact assessment at Part 2.

2. The full text of the Directive is available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF>.

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 12 weeks. The closing date for responses is 5 September 2011.

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/consultations/> 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.
- 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.bis.gov.uk/policies/better-regulation/consultation-guidance>.

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, Adam McArdle. Please DO NOT send your response to this consultation to Adam McArdle. 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:

Adam.McArdle2@homeoffice.gsi.gov.uk

or alternatively write to him at:

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

What happens next?

19. The responses received will be published. Decisions taken in light of the consultation will also be publicised.

2: INTRODUCTION

Background

20. European Directive 2010/63/EU on the protection of animals used for scientific purposes (the Directive) was adopted in September 2010 and came into force on 9 November 2010. Directive 2010/63/EU replaces Directive 86/609/EEC which is transposed into UK legislation by the Animals (Scientific Procedures) Act 1986 (ASPA).

21. In common with other Member States, the UK must transpose the provisions of the new Directive into UK legislation by 10 November 2012. The majority of the provisions of Directive 2010/63/EU must be implemented in UK legislation from 1 January 2013. The mandatory standards of care and accommodation set out in Annex III to the Directive must be implemented by 1 January 2017.

22. Many of the provisions of the Directive are similar to current UK legislation and practice. It places a strong emphasis on minimising the use of animals and the promotion of the 3Rs (the Refinement of scientific procedures; Reduction in numbers of animals used; and their Replacement where possible). It also requires the authorisation of establishments and projects; risk-based inspections; each breeder, supplier and user to establish an animal welfare body to advise on the welfare of animals and the 3Rs; the classification of procedures according to their severity; restrictions on re-use; and the publication of non-technical summaries of licensed projects to aid transparency.

23. Some of its provisions are new or go further than current UK legislation. The Directive extends protection to some invertebrate species (all live cephalopods) and to animals bred for tissues and organs; requires Member States to apply mandatory minimum standards of care and accommodation; requires retrospective review of some categories of project; requires Member States to avoid unnecessary duplication of procedures by accepting regulatory testing data from other Member States; and places restrictions on the use of first generation, captive-bred non-human primates.

24. Other provisions are potentially less stringent than current UK requirements. For example, ASPA provides special protection for non-human primates, cats, dogs and equids, whereas the Directive extends special protection only to non-human primates.

25. Article 2 of the Directive allows Member States to retain current, more stringent national provisions in place on 9 November 2010 provided they are not used to inhibit the free market. The implications of Article 2 and other relevant article are discussed further below.

Transposition objectives

26. The principal objective for transposition is to comply with UK Treaty obligations to transpose the provisions of the Directive into UK legislation fully and appropriately. Important additional objectives are to do so adopting measures which are proportionate; provide for efficient and effective regulation and appropriate standards of animal welfare and protection; promote the use of alternatives to animal use; avoid unnecessary administrative and regulatory burdens; and support the success, sustainability and competitiveness of the UK research and science base.

Impact assessment

27. The consultation stage impact assessment at Part II is the first step in identifying the costs and benefits of the options for transposition of the Directive discussed in this consultation paper. The impact assessment looks at three options for transposition and is based on the best evidence available at the time of its preparation. A further impact assessment will be prepared in the light of this public consultation. Respondents are invited to submit further and better information, including estimated costs and other details, to help refine the impact assessment and ensure that future decisions on options are taken in the light of the fullest and most accurate information available.

Option 1: No change

28. Option 1 is to retain the Animals (Scientific Procedures) Act 1986 (ASPA), current guidance on its implementation and its associated codes of practice. Option 1 provides the baseline for the calculation of any additional costs and savings arising from options 2 and 3, but is not a viable option for the implementation of the Directive as ASPA does not fully transpose its requirements. Failure to transpose the Directive would result in infraction proceedings against the UK and the imposition of daily fines.

Option 2: Transpose the minimum requirements of the Directive

29. Option 2 assumes that the UK will transpose the minimum requirements of the Directive by 'copying out' its provisions into revised UK legislation. 'Copy out' would entail transposing the requirements of the Directive without including more stringent measures unique to the UK. Key potential impacts might arise from a transfer of responsibility for control of individuals using animals from government to establishments and adoption of a minimum frequency programme of audit-style inspections.

Option 3: Retain current higher UK standards and requirements

30. Option 3 envisages that the UK will implement the requirements of the Directive where they are more stringent than those of ASPA and will also retain some more stringent measures in force in the UK on 9 November 2010 where there are clear benefits to science, welfare and/or the conduct of research, such as some current UK care and accommodation requirements; the current UK personal licensing system; and some humane killing methods. Article 2 of the Directive permits Member States to retain such measures.

Summary of findings

31. The impact assessment estimates that retaining some current higher UK standards and requirements (Option 3) will produce lower net costs to the UK than transposition of the minimum requirements of the Directive (Option 2). This is a provisional outcome and we would welcome further and better data through the consultation to develop and strengthen the impact assessment.

Competitiveness

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

Differential impact on establishments and sectors

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

3: SUBJECT MATTER AND SCOPE

Article 1: subject matter and scope

34. The Directive provides for the protection of animals used for scientific or educational purposes until the animals have been killed, rehomed or returned to a suitable habitat or husbandry system. The threshold for protection is set at practices likely to cause pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle according to good veterinary practice.

35. The Directive lays down rules on 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 and killing of animals; the operation of breeders, suppliers and users; and the evaluation and authorisation of projects involving the use of animals in procedures.

36. The Directive applies to live non-human vertebrate animals, including independently feeding larval forms, and foetal forms of mammals as from the last third of their normal development; and live cephalopods. The Directive applies to foetal forms of vertebrates at an earlier stage of development if they are to be allowed to live beyond the last third of development and as a result of the procedures performed are likely to experience pain, suffering, distress or lasting harm after they have reached that stage of development. The Directive also applies where animals are bred specifically so that their organs or tissues may be used for scientific purposes.

37. The Directive does not apply to non-experimental agricultural practices; non-experimental clinical veterinary practices; veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product; practices undertaken for the purposes of recognised animal husbandry; practices undertaken for the primary purpose of identification of an animal.

Article 2: Stricter national measures

38. Article 2 allows Member States to retain stricter national provisions in force on 9 November 2010. Member States are not allowed to use these measures to inhibit the free market by prohibiting or impeding the supply or use of animals from another Member State applying the minimum standards set out in the Directive, or the placing on the market of products developed with the use of such animals. The implications of Article 2 for the transposition of the Directive into UK legislation are discussed, where necessary, under the relevant articles in this consultation document.

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

39. ASPA section 1(2)(a) protects mammals from half way through their gestation period. Under Article 1 of the Directive foetal forms of mammals are protected from the last third of their normal development. There is a large variation in the degree of development of mammals at two thirds through gestation. For example the foetuses of guinea pigs and farm animals are significantly more developed at this stage than those of mice, cats and dogs. However, evidence suggests¹ that whilst a foetus may have the right anatomical pathways to carry the messages of pain, suffering is not experienced without consciousness. This is not reached until some time after an animal has taken its first breath. For all species, the point at which foetuses will spontaneously breathe is beyond the last third of gestation. For these reasons, we believe this provision could be adopted without any adverse welfare effects.

¹ Mellor et al 2007: Birth and hatching: Key events in the onset of 'awareness' in lambs and chicks NZ Veterinary Journal 55 51-60

Legal and animal welfare implications of when consciousness first appears in developing young and of the potential for delayed onset of increased pain sensitivity AAWAS International Conference

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

Exclusion of foetal forms of birds and reptiles from protection

40. ASPA section 1(2)(a) currently protects birds and reptiles from half way through their incubation period. However, under Article 1 birds and reptiles are not protected until they hatch or, in the case of viviparous reptiles, when they are born. This would release from regulation establishments using embryonated eggs in scientific research. The Animal Welfare Act 2006 (AWA) and Animal Health and Welfare (Scotland) Act 2006 (AHW(S)A) do not apply to animals in their foetal or embryonic form². Unless there is scientific evidence that chicks and egg laying reptiles may become conscious and experience pain before hatching we are minded to accept their exclusion from scope.

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

Inclusion of cephalopods

41. ASPA section 1(1) protects only one species of cephalopod, *Octopus vulgaris*. Article 1 extends protection to all live cephalopods. We have limited information about the current use of species of cephalopod other than *Octopus vulgaris* in the UK. We believe relevant work takes place mostly at academic establishments already authorised under ASPA, and that fewer than ten projects are ongoing at any time, working to a voluntary code of practice. These projects will need to be authorised under the new Directive as will any establishments in which they take place. Guidance on methods of killing and accommodation and care requirements for these animals will also need to be developed.

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

Inclusion of animals specifically bred for organs and tissues

42. Although not necessarily counted, in the United Kingdom these animals are already bred and used at designated establishments and subject to the same care and accommodation standards as animals used in procedures. As a consequence, we do not expect their inclusion to have any significant regulatory or animal welfare impact.

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

Absence of special protection for cats, dogs and equidae

43. The Directive provides special protection for non-human primates (see Article 8, below), but not to dogs, cats and equids (although Article 13(2)(b) does require animals of the lowest sentence to be used and Articles 31 and 32 include some additional requirements for record keeping and marking of dogs and cats). These latter species are currently given such protection under ASPA section 5(6).

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

Practices to which the Directive does not apply

44. Under Article 1.4, practices undertaken for the *primary* purpose of identifying an animal are excluded from the scope of the Directive, for example, ear punching mice where the

² AWA section 1(2) and AHW(S)A 16(2)

primary purpose is to identify the mouse, but the tissue piece may also be used for DNA analysis. ASPA 2(5) provides that practices undertaken *solely* for the purpose of identification are not regulated procedures if they cause no more than momentary pain and distress and no lasting harm. We believe the absence of this reference to pain, suffering, distress and lasting harm could allow methods of marking to be used without regulation when they cause more than transient pain, suffering and lasting harm.

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

4. PROVISIONS ON THE USE OF CERTAIN ANIMALS IN PROCEDURES

Article 7: Endangered species

45. The Directive prohibits the use of endangered species³ except where no other species 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, foodstuffs and feed-stuffs and other substances or products; or research aimed at preservation of the species.

46. ASPA 10(3)(c) limits the use of endangered species to research aimed at preservation of the species in question or essential biomedical purposes where the species in question exceptionally proves to be the only one suitable for those purposes.

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

Article 8: Non-human primates

Permissible uses and the definition of 'debilitating condition'

47. The Directive (Recital 17) recognises that the use of non-human primates in scientific procedures is still necessary in biomedical research. It also recognises that due to their genetic proximity to human beings and to their highly developed social skills, their use in scientific procedures raises specific ethical and practical problems in terms of meeting their behavioural, environmental and social needs in a laboratory environment and is of significant concern to the public.

48. Recital 17 further states that the use of non-human primates should be permitted only for 'basic research, the preservation of the respective non-human primate species or when the work, including xenotransplantation, is carried out in relation to potentially life-threatening conditions in humans or in relation to cases having a substantial impact on a person's day-to-day functioning, i.e. debilitating conditions'.

49. These restrictions are reflected in Article 8, which stipulates that non-human primates shall not be used in procedures, with the exception of those procedures meeting the following conditions: (a) the procedure has one of the purposes referred to in (i) points (b)(i)⁴ or (c)⁵ of Article 5 of the Directive and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings; or (ii) points (a)⁶ or (e)⁷ of Article 5. In all cases there must be a scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than non-human primates.

50. For the purposes of the Directive, Article 8 further defines 'a debilitating clinical condition' as 'a reduction of a person's normal physical or psychological ability to function'.

51. There are no equivalent restrictions in ASPA. However, under ASPA 5(6) non-human primates, cats, dogs and equids are currently given special protection and may only be used where no other species are suitable for the purposes of the programme to be specified in the

³ Listed in Annex A to Council Regulation (EC) No 338/97³ regulating trade in species of wild fauna and flora

⁴ (b) translational or applied research with any of the following aims: (i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants

⁵ (c) for any of the aims in point (b) in the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products

⁶ (a) basic research

⁷ (e) research aimed at preservation of the species

project licence or it is not practicable to obtain animals of any other species that are suitable for the purpose.

52. We do not believe the restrictions set out in Article 8 will prevent the continued authorisation of any work previously or currently undertaken under ASPA.

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

53. Further restrictions apply to non-human primates of endangered species listed in Annex A to Council Regulation (EC) No 338/97 which may only be used where the procedures have one of the purposes referred to in (i) points (b)(i) or (c) of Article 5 of the Directive and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings; or (ii) Article 5(e). Again there must be scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than non-human primates and by the use of species not listed in that Annex. ASPA 10(3)(c) limits such use to research aimed at preservation of the species in question or essential biomedical purposes where the species in question exceptionally proves to be the only one suitable for those purposes.

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

Great apes

54. The Directive prohibits the use of great apes, except in research aimed at the preservation of those species or where action is warranted in relation to a life-threatening or debilitating condition endangering human beings where no other species or alternative method would suffice. Any proposal to implement these derogations would require reference to the Commission under the safeguard clause at Article 55 (see below). The UK currently operates a policy ban on the use of great apes. We cannot currently envisage any circumstances in a particular case which would change this approach.

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

Article 9: Animals taken from the wild

55. Article 9 prohibits the use of animals taken from the wild. However, competent authorities may grant exemptions to the prohibition where there is scientific justification – specifically, that the purpose of the procedure cannot be achieved by the use of an animal which has been specifically bred for use in procedures⁸. This is more restrictive than ASPA section 10(3) which allows the use of wild caught animals where no other animal suitable for the purpose of the programme can be obtained from a designated breeder or supplier or another captive bred source⁹.

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

New requirements relating to trapping and capture

⁸ See also Recital 20: ‘...Furthermore, for reasons of animal welfare and conservation, the use of animals taken from the wild in procedures should be limited to cases where the purpose of the procedures cannot be achieved using animals bred specifically for use in procedures.’

⁹ See Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (HC321), paragraph 8.3

56. The Directive sets requirements regarding competence and methods of capture. Notably, the capture of animals in the wild is to be carried out only by competent persons using methods that do not cause the animals avoidable pain, suffering, distress or lasting harm. Capture of a wild animal is not considered to be a regulated procedure under ASPA unless the means of capture is itself the subject of an experiment.

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

Article 10: Animals bred for use in procedures

57. Except where there is a scientific justification, the Directive limits the use of the species listed in Annex I¹⁰ to those which have been bred for use in procedures. Annex I extends the requirement for purpose-breeding to *xenopus (laevis, tropicalis)* and *rana (temporaria, pipiens)* (the most commonly used amphibians), and zebra fish (*Danio rerio*), but, unlike ASPA schedule 2, does not require common quail, ferrets, genetically modified pigs, and genetically modified sheep to be purpose bred.

58. *Xenopus*, *rana* and zebra fish are already largely bred at designated establishments or specialist breeders, and we expect that only minor administrative changes will be required to authorise the relevant breeding facilities. GM pigs and sheep are not currently bred in the UK except under project licence authority. We estimate that deregulating the breeding of common quail and ferrets is likely to have no impact on costs, but may adversely impact scientific outputs and animal welfare standards if the quality of the animals is reduced. We further assume that common quail and ferrets will not be purpose bred in other Member States.

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

59. Under Article 2, Member States are not allowed to use stricter national measures to inhibit the free market by prohibiting or impeding the supply or use of animals from another Member State applying the minimum standards set out in the Directive. Provided they comply with the requirements of the Directive, the ability to supply laboratory animals to the UK will be open to breeders and suppliers across Europe.

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

Non-human primates

60. In order to end the capturing of animals from the wild for breeding purposes, the Directive (Recital 19) envisages that, after an appropriate transition period, only animals that are the offspring of animals bred in captivity, or that are sourced from self-sustaining colonies, should be used in procedures.

61. Annex II specifies the dates¹¹ from which Member States must ensure that only non-human primates which are the offspring of animals bred in captivity (F2+) may be used and Article 10 provides for a feasibility study to be carried out to confirm these dates. Provision is also made in Article 10 for an examination of the feasibility of moving towards sourcing non-

¹⁰ 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 primates, Frog (*Xenopus (laevis, tropicalis)*), Rana (*temporaria, pipiens*), Zebra fish (*Danio rerio*)

¹¹ 1 January 2013 for Marmoset (*Callithrix jacchus*); and for other species, 5 years after the publication of the feasibility study, provided the study does not recommend an extended period.

human primates only from self-sustaining colonies¹². At present, all marmosets and about two thirds of macaques used in the UK are the offspring of captive-bred animals (F2+). The remaining macaques used are F1.

62. Our current policy provides for purpose-bred non-human primates to be obtained from overseas breeding centres known to, and deemed acceptable by, the Home Office when no animals suitable for the purpose are available from designated UK breeders and suppliers. This policy was established in 1995 to support what was effectively a ban on the use of wild-caught primates except where exceptional and specific justification for their use could be provided.

63. Details of overseas breeding centres from which UK users seek to acquire primates are submitted to the Inspectorate for initial appraisal and, if deemed acceptable, for biennial review thereafter. Information about a centre's breeding colonies, including the numbers of F0, F1 and F2 animals used for breeding are included in those details, but relate only to the breeding colony or colonies from which animals may be consigned to the UK for scientific use.

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

Article 11: Stray and feral animals of domestic species

64. The Directive prohibits the use of stray and feral animals of domestic species except in essential studies relating to the health and welfare of the animals, or serious threats to the environment or to human or animal health. There must also be a scientific justification that the purpose of the procedure can be achieved only by the use of a stray or a feral animal. This is a relaxation of the provisions of Directive 86/609/EC under which their use was prohibited. ASPA 10(3)(a) and (b) implements this prohibition through its requirement under Schedule 2 for animals of relevant species to be purpose bred and limitations regarding the use of wild animals.

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

¹² For the purposes of this Article a 'self-sustaining colony' means a colony in which animals are bred only within the colony or sourced from other colonies but not taken from the wild, and where the animals are kept in a way that ensures that they are accustomed to humans.

5. PROCEDURES

Article 3: Definition of 'procedure'

65. The Directive defines a "procedure" as 'any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle according to good veterinary practice. This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition, but excludes the killing of animals solely for the use of their organs or tissues.

66. Under ASPA 2(1), "a regulated procedure" means any experimental or other scientific procedure applied to a protected animal which may have the effect of causing that animal pain, suffering, distress or lasting harm. Regulation starts at the 'skilled insertion of a hypodermic needle'¹³. An experimental or other scientific procedure applied to an animal is also a regulated procedure if (a) it is part of a series or combination of such procedures (whether the same or different) applied to the same animal; and (b) the series or combination may have the effect mentioned in subsection 2(1); and (c) the animal is a protected animal throughout the series or combination or in the course of it attains the stage of its development when it becomes such an animal. In addition, anything done for the purpose of, or liable to result in, the birth or hatching of a protected animal is also a regulated procedure if it may as respects that animal have the effect mentioned in subsection 2(1).

67. Under ASPA 2(7) the killing of a protected animal for a scientific purpose at a designated establishment by a method not listed in Schedule 1 (Appropriate Methods of Humane Killing) is a regulated procedure and requires authorisation under a project licence. This appears not to be the case under the new Directive. The combination of Article 3 and Article 6 (see below) suggests that the use of a method of killing of animals not listed in Annex IV (Methods of Killing Animals) solely for the use of their organs and tissues is not a procedure and will not require project authorisation. However, exemption from using an Annex IV method of killing will be needed. A system will be required to enable exemption to be granted to individuals who are not licence holders and are outside the regulatory system.

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

Article 5: Purposes of procedures

68. Article 5 specifies the purposes for which procedures may be carried out. These are broadly similar to the 'permissible purposes' set out in ASPA section 5(3). We propose to copy out the provisions of Article 5 as they stand.

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

Article 12: Procedures

69. The Directive requires that procedures are always carried out in authorised user establishments, unless an exemption is granted on the basis of scientific justification, and that procedures are only carried out within the framework of a project. These provisions are consistent with ASPA sections 3 and 6.

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

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

¹³ See Guidance on the Operation of the Animals (Scientific Procedures) Act 1986, paragraph 2.16

70. Except where it is inappropriate, Article 14 requires that procedures are carried out under general or local anaesthesia, and that analgesia or another appropriate method is used to ensure that pain, suffering and distress are kept to a minimum. Article 14 further stipulates that procedures that involve serious injuries that may cause severe pain are not to be carried out without anaesthesia. The factors to be taken into account when deciding on the appropriateness of using anaesthesia are whether anaesthesia is judged to be more traumatic to the animal than the procedure itself; and whether anaesthesia is incompatible with the purpose of the procedure. These provisions are consistent with current UK legislation, policy and practice.

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

Neuromuscular blocking agents

71. Article 14 also requires that appropriate anaesthesia or analgesia is used in conjunction with neuromuscular blocking agents. These provisions are less stringent than current UK requirements. The Directive would allow the administration of neuromuscular blocking agents with analgesics instead of general anaesthetics as is current UK policy. As analgesics alone do not remedy any non-pain related distress associated with the use of neuromuscular blocking agents, we believe there is a strong case for retaining current UK provision for systemically administered NMBAs in mammals.

72. However, these arguments may not apply in other animals, such as larval fish and amphibia and embryonic birds, where respiration does not require muscular movement. In such cases, distress caused by a procedure may be insignificant.

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

Article 16: Re-use

73. Article 16 sets out the circumstances in which animals may be re-used. Re-use is generally limited to mild, moderate or non-recovery procedures. However, in exceptional circumstances, and following veterinary examination, re-use may be allowed after use in a severe procedure. These provisions are potentially less stringent than current UK policy and practice. For example the Directive would potentially allow the re-use of animals that have undergone recovery surgery more than once. However, it does relate the authorisation for re-use to the actual severity experienced by the animal which is to be welcomed.

74. Under ASPA 14 there is a requirement for prospective agreement by the Home Office for re-use and this forms part of the harm-benefit assessment. Consent for re-use is generally conditional upon the animal having suffered no significant adverse effects as a consequence of the first use, and its not having been subjected to any intervention which compromises its suitability as a subject for the second or subsequent use. Consent to the re-use of any animal that has experienced significant adverse effects in its previous use is unlikely to be granted.¹⁴

75. The Directive does not explicitly require prior authorisation of re-use. However, it is likely that any re-use will need to be considered as part of the project evaluation required under Article 38 of the Directive. Whilst the decision making framework differs from that currently set out in ASPA, we believe that in practice it will not prove significantly different in terms of outcomes and may be easier to apply.

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

¹⁴ Home Office Guidance paragraph 5.63.

Article 17: End of the procedure

76. The Directive defines the end of a procedure as the point at which no further observations are to be made for that procedure or, for new genetically modified animal lines, when the progeny are no longer observed or expected to experience pain, suffering, distress or lasting harm equivalent to the minimum threshold (set out in Article 3.1). It requires a decision to be taken by a veterinarian or other competent person whether the animal is to be kept alive or killed by a humane method at the end of a procedure and specifies that an animal must be killed when it is likely to continue to experience moderate or severe pain, suffering, distress or lasting harm. Where an animal is to be kept alive, the Directive requires that it is to receive the care and accommodation appropriate to its state of health.

77. Under ASPA 15, animals that have been used in regulated procedures must be humanely killed when, at the end of the series of regulated procedures, they are suffering or are likely to suffer adverse effects as a result of the procedures applied. Where this is not the case and appropriate provision is made on the relevant project licence, under ASPA 10(3D) a veterinary surgeon must determine whether they can be kept alive. Usually this is the Named Veterinary Surgeon or exceptionally, where no veterinary surgeon is available, another suitably qualified person.

78. Under ASPA 10(6D), any animal kept alive after being subjected to a series of regulated procedures at a designated establishment must continue to be kept at the establishment under the supervision of a veterinary surgeon or other suitably qualified person unless consent is obtained from the Home Office for the animal to be moved to another designated establishment and a veterinary surgeon certifies that the animal will not suffer if it ceases to be kept at the designated establishment. Authority must also be obtained from the Home Office for the release of the animal to the wild or for its discharge from the controls of ASPA.

79. We believe the stricter provisions of ASPA could be retained using Article 2.

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

Article 18: Sharing organs and tissues

80. Article 18 requires that Member States facilitate the establishment of programmes for the sharing of organs and tissues of animals killed. The aim is to minimise animal use and costs. Promoting the sharing of organs and tissues is existing UK good practice.

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

6. METHODS OF KILLING

Article 6 and Annex IV: Methods of killing

81. Article 6 requires that animals are killed humanely and Annex IV to the Directive lists the methods to be used for specified animals. Article 6(4) provides a derogation from the use of a mandated method where another method is considered at least as humane on the basis of scientific evidence or where there is a scientific need to use another method. A further derogation in Article 6(5) applies in emergency circumstances.

82. The principles set out in Article 6 are broadly consistent with current UK policy and practice. There are, however, significant differences between the list of permissible methods set out in Annex IV and those currently permissible under Schedule 1 to the 1986 Act. These differences are set out in the table at Appendix I to this consultation paper.

83. We believe some Annex IV methods may impose a higher welfare cost - for example, the use of inert gases for rodents, the use of carbon dioxide for diving birds, and the requirement for prior sedation before cervical dislocation. We believe retention of some methods listed in ASPA Schedule 1 would ensure current UK animal welfare standards are maintained and reduce or eliminate the need for additional training and equipment.

84. In addition, while explicit reference to maceration as a method of confirming death is omitted from the Directive, we believe that instantaneous destruction of the body in a macerator has the effect of exsanguination and destruction of the brain. Therefore, maceration could be considered as a method of achieving the endpoints required under the Directive for confirmation of death.

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

7. CHOICE OF METHODS

Article 4: Principle of replacement, reduction and refinement

85. Article 4 requires Member States to ensure that a scientifically-satisfactory, non-animal method or testing strategy is used wherever possible and that the number of animals used is reduced to a minimum consistent with the objectives of the project. It also requires refinement of procedures, breeding, and accommodation and care to minimise pain, suffering, distress or lasting harm to the animals. These provisions are broadly consistent with the requirements of ASPA and with current UK policy and practice.

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

Article 13: Choice of methods

86. Article 13 prohibits the use of animals in a procedure if a scientifically satisfactory, non-animal method, or testing strategy, is recognised by EU legislation. Where more than one animal method is available, Article 13 mandates use of the method that achieves the best combination in terms of using the minimum number of animals; involving animals with the least capacity to experience pain, suffering, distress or lasting harm; causing the least pain, suffering, distress and lasting harm; and being most likely to provide satisfactory results. These requirements are generally consistent with current requirements under ASPA and we propose to transpose the provisions of Article 13 relating to the choice of methods as the stand.

87. Where a non-animal test has been recognised and accepted under the legislation of the EU, Article 13 appears to prohibit other animal testing strategies which might be required by non-EU regulators. Article 13 does not allow exemption for scientific justification and consequently is more stringent than ASPA. As a result it would appear that the Directive may prohibit some testing done currently in the UK at the request of third country regulators.

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

88. Article 13 also requires that death as an endpoint is avoided and replaced by early and humane end points. Where this is not possible, Article 13 requires that the procedure results in as few deaths as possible and minimises suffering. There is no equivalent provision in ASPA, although, in practice, where death can result from a procedure, we strive to set earlier endpoints so that animals are killed before they reach a point at which death would occur.

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

8. AVOIDANCE OF DUPLICATION OF PROCEDURES AND ALTERNATIVE APPROACHES

Article 46: Avoidance of duplication of procedures

89. The Directive requires that Member States accept data from another Member State that are generated by procedures recognised by EU legislation, unless further procedures need to be carried out regarding that data for the protection of public health, safety or the environment. We believe these provisions are consistent with the existing mutual acceptance of data agreements and current UK practice.

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

Article 47: Alternative approaches

90. Under Article 47, the Commission and the Member States are to contribute to the development and validation of alternative approaches and to take such other steps as they consider appropriate to encourage research in this field. In addition, Member States are to assist the Commission in identifying and nominating suitable laboratories to carry out validation studies. The Commission is to set the priorities for validation studies and allocate the tasks between the laboratories after consulting Member States.

91. At national level, Member States are to ensure the promotion of, and the dissemination of information on, alternative approaches and nominate a single point of contact to provide advice on the regulatory relevance and suitability of alternative approaches proposed for validation. The Commission is to take appropriate action with a view to obtaining the international acceptance of alternative approaches validated in the European Union.

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

Article 48 and Annex VII: Union reference laboratory

92. Article 48 and Annex VII provide that the Union reference laboratory will be responsible for coordinating and promoting the development and use of alternatives to procedures including in the areas of basic and applied research and regulatory testing; coordinating the validation of alternative approaches at the European Union level; acting as a focal point for the exchange of information on the development of alternative approaches; setting up, maintaining and managing public data bases and information systems on alternative approaches and their state of development; promoting dialogue between legislators, regulators, and all relevant stakeholders, in particular, industry, biomedical scientists, consumer organisations and animal welfare groups, with a view to the development, validation, regulatory acceptance, international recognition, and application of alternative approaches. The Union reference laboratory is to participate in validation of alternative approaches.

93. Historically, the UK has encouraged the development and use of alternatives and relevant databases through research funding and education, and through support for the European Centre for the Validation of Alternative Methods (ECVAM) at Ispra, Italy, which we understand will form the basis for the new Union reference laboratory. Continuing this approach, we will give full support the Union reference laboratory and its activities. There are no issues relating to transposition arising from Article 48 and Annex VII.

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

9. SEVERITY OF PROCEDURES

Article 15 and Annex VIII: Classification of severity of procedures

94. The Directive requires that procedures are classified in one of four categories: 'non-recovery', 'mild', 'moderate' or 'severe' using criteria set out in Annex VIII to the Directive. Article 15 also prohibits the authorisation of procedures involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated. This prohibition may be overridden using the safeguard clause at Article 52(3).

95. If humane killing is accepted as a means of limiting severity, and surgical preparation - apart from major surgery - is typically to be classified as moderate severity, the severity classification system set out in Annex VIII to the Directive is similar to current UK arrangements¹⁵. We are not aware of any work currently undertaken in the UK that would require use of the safeguard clause.

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

¹⁵ See Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (HC321), paragraph 5.42.

10. BREEDERS, SUPPLIERS AND USERS

Article 3: Definition of establishment

96. The Directive defines "establishment" 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.

Article 3: Definition of 'breeder', 'supplier' and 'user'

97. Under Articles 3.4, 3.5 and 3.6, 'breeder' means any natural or legal person breeding animals referred to in Annex I with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, or breeding other animals primarily for those purposes, whether for profit or not; 'supplier' means any natural or legal person, other than a breeder, supplying animals with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, whether for profit or not; and 'user' means any natural or legal person using animals in procedures, whether for profit or not.

Article 20: Authorisation of breeders, suppliers and users

98. Article 20 requires that all breeders, suppliers and users are authorised by and registered with the competent authority. Authorisation is dependent on compliance with the requirements of the Directive. The authorisation must specify the person responsible for compliance and the persons referred to in Articles 24(1)¹⁶ and 25¹⁷.

99. Under ASPA 6 and 7, the equivalent authorisation is of the *place* at which the work is carried out which must hold a certificate of designation. We assume that authorisation of breeders, suppliers and users – which, as defined in Articles 3.4, 3.5 and 3.6, we take to be corporate entities rather than places – will require existing certificates of designation to be re-issued on the revised basis. We will take steps to minimise any associated administrative costs.

100. We see the 'person responsible for compliance' as undertaking broadly the same role as the holder of the certificate of designation under ASPA 6(4)(a) and 7(4) and occupying a similarly senior position in the authorised breeder, supplier or user.

101. Article 20(3) specifies that the authorisation of a breeder, supplier or user will need to be renewed for any significant change to their structure or function which could negatively affect animal welfare. Currently ASPA requires certificate holders to notify the Home Office and seek approval for any changes to a designated establishment. The requirements of the new Directive in this regard are less prescriptive and will require careful judgment to apply.

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

Article 21: Suspension and withdrawal of authorisation

102. Article 21 requires the withdrawal or suspension of authorisation where a breeder, supplier or user ceases to comply with the requirements of the Directive. In such cases, Member States are required to ensure the welfare of animals housed at an establishment is not adversely affected. ASPA section 11 provides for licences and certificates to be varied or revoked where there has been a breach of a condition of the licence or certificate. ASPA section 13 provides for licences and certificates to be suspended where it is urgently necessary for the welfare of protected animals.

¹⁶ Persons responsible for the care and welfare of animals and for training and supervision of staff

¹⁷ Designated veterinarian

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

Article 22: Requirements for installations and equipment

103. All breeding, supplying and user establishments will be required to have installations and equipment suited to the species housed and to the effective performance of any procedures carried out there. These provisions are consistent with current UK requirements and practice.

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

Article 28: Breeding strategy for non-human primates

104. The Directive requires breeders of non-human primates to have a strategy for increasing the supply of F2 animals. We believe UK-based establishments already supply only F2 animals.

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

Article 19: Setting free of animals and re-homing

105. The Directive 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 appropriate measures have been taken to safeguard the well-being of the animal. These provisions are consistent with current UK requirements and practice.

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

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

106. Where the setting free or re-homing of animals used or intended for use in procedures is allowed, breeders, suppliers and users will be required to have a scheme that ensures socialisation of the animals to be re-homed. These provisions are generally consistent with the current UK requirements and practice.

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

Article 30: Animal records

107. Article 30 sets out the records to be kept by breeders, suppliers and users on animals. These requirements are similar to the source, use and disposal records UK Certificate Holders are currently required to maintain.

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

108. Article 31(1) sets out the information to be kept on each dog, cat and non-human primate. Article 31(2) requires that each dog, cat and non-human primate must have an individual history file established at birth or as soon as possible afterwards covering any relevant reproductive, veterinary and social information. This file is to accompany the animal while it is kept for the purposes of the Directive. Where an animal is imported from outside the European Union, we anticipate the history file will be established on arrival in the UK. These records are to be kept for three years after the death or re-homing of the animal and made

available to the competent authority on request. These requirements are broadly consistent with current UK requirements and good practice.

Article 32: Marking

109. The Directive requires that each dog, cat and non-human primate is given an individual identification mark, before weaning, in the least painful manner possible. It further requires that unmarked animals taken into establishments must be marked as soon as possible after first receipt and that 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. These requirements are consistent with current UK requirements and good practice.

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

11. CARE AND ACCOMMODATION

Article 33: Care and accommodation

110. Article 33(1) sets out the requirements for the care and accommodation of animals kept in establishments. Member States must ensure that: (a) all animals are provided with accommodation, an environment, 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 kept to a minimum; (c) the environmental conditions in which animals are bred, kept or used are checked daily; (d) arrangements are made to ensure that any defect or avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible; and (e) animals are transported under appropriate conditions. Similar requirements are set out in ASPA 10(6B).

111. Article 33(2) requires Member States to ensure that the care and accommodation standards set out in Annex III to the Directive are applied from the dates specified in that Annex. Member States may allow exemptions from the requirements of paragraph 33(1)(a) and 33(2) for scientific, animal-welfare or animal-health reasons.

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

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

112. Recital 34 to the Directive stipulates that the accommodation and care of animals used in scientific research should be based on the specific needs and characteristics of each species.

113. Recital 35 notes that there are differences in accommodation and care requirements between Member States which distort the internal market. Recital 35 further notes that some of these different requirements no longer reflect the most recent knowledge on the impact of accommodation and care conditions on animal welfare and the scientific results of procedures. Accordingly, Recital 35 concludes that it is necessary to establish harmonised requirements on accommodation and care. Annex III sets out these accommodation and care requirements.

114. Most Annex III standards are to be applied from 1 January 2017. Annex III can be revised to take account of technical and scientific progress (see Article 50).

115. The Annex III requirements are drawn from the guidelines and tables set out in the revised Appendix A¹⁸ to the Council of Europe Convention for the protection of vertebrate animals used for experimental and other scientific purposes (ETS 123). The revision of Appendix A took place over several years and took account of input from Member States, stakeholder organisations and technical experts. Commission Recommendation 2007/526/EC of 18 June 2007 incorporated Appendix A guidelines into Directive 86/609/EEC. The enforceable standards set out in Annex III are based on Commission Recommendation 2007/526/EC.

116. For the most part, Annex III does not include explanatory and guidance material from Appendix A to ETS 123 setting the tables in context. Where it would be useful to do so, we will include this material in revised guidance and codes of practice on accommodation and care to accompany the UK legislation transposing the Directive.

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

¹⁸ Adopted on 15 June 2006

117. A key objective of the revision of Directive 86/609/EEC was to rectify wide variations in the implementation of that Directive by Member States and we strongly support measures to ensure a level playing field across the European Union in relation to accommodation and care standards and the wider provisions of the Directive.

118. We believe incorporation of Annex III standards by Member States will lead to significant improvements in welfare, accommodation and care practices for animals bred, supplied and used in scientific procedures. As Annex III requirements are similar in many areas to existing UK Code of Practice standards we estimate that the changes will have more impact in other Member States than in the UK. There are, however, some areas where present UK Code of Practice standards exceed those set out in Annex III.

119. The UK is obliged to transpose Annex III standards that are higher than current UK requirements. However, where current UK requirements are more stringent than those of Annex III, Article 2 to the Directive would allow them to be retained, should we wish to do so. While we are minded to adopt Annex III unchanged as this reflects the outcome of almost twenty years debate among technical experts and stakeholder groups, and would support the Commission's stated aim of promoting a level playing field, we would not wish to adopt standards which would have a demonstrably negative impact on animal welfare.

120. The table provided at Appendix II to this consultation paper compares the standards set out in Annex III with current UK code of practice requirements and highlights the differences. The impact of these different standards in terms of cost and welfare benefit is considered in the impact assessment at Part II.

Questions: Please see Appendix II for detailed questions on Annex III.

12. COMPETENCE AND AUTHORISATION OF PERSONNEL

Article 23 and Annex V: Competence of personnel

121. Under the Directive, each breeder, supplier and user will be required to have sufficient staff on site and to ensure that they have been adequately educated and trained before carrying out procedures on animals; designing procedures and projects; taking care of animals; or killing animals. Those designing procedures and projects must have received instruction in a scientific discipline relevant to the work being undertaken and have species-specific knowledge. Staff carrying out procedures on animals, designing procedures and projects and taking care of animals must be supervised until they have demonstrated the requisite competence.

122. It is an existing requirement in the UK that designated establishments have sufficient staff on site and that key persons are trained, and adequately supervised until competent.

Impact on the UK personal licensing system

123. Under ASPA 3(a), no-one may apply a regulated procedure to an animal unless 'he holds a personal licence qualifying him to apply a regulated procedure of that description to an animal of that description'. A personal licence is the Secretary of State's endorsement that the holder is a suitable and competent person to carry out, under supervision if necessary, specified procedures on specified classes of animal. It does not authorise the holder to carry out any regulated procedure unless this is part of a programme of work authorised by a project licence. The place of work must be stipulated in both the personal and project licences.

124. An applicant for a personal licence must be at least 18 years of age; have appropriate education and training (including instruction in a relevant scientific discipline) and experience for the purpose of competently handling the protected animals, applying the specified regulated procedures to the specified classes of animal, and taking responsibility for the welfare of the animals; and be competent to apply those techniques in accordance with the conditions included in the licence. A personal licence applicant will usually be expected to provide evidence of appropriate education, training and experience.

125. Under the Directive, Member States can choose to ensure that the requirements of Article 23(1) are met either through a system of authorisation (such as the UK personal licensing system) 'or by other means'. The Directive does not define 'by other means' but we believe that it would provide an opportunity to simplify the current personal licensing system or transfer responsibility for the control of individuals applying procedures to animals from central government to breeders, suppliers and users along with accountability for ensuring the training, supervision and competence of individuals. We further believe it would be essential for such a system to retain a requirement for individuals carrying out procedures on animals to be registered with the competent authority to ensure continuing exemption of actions lawfully done under the transposing legislation from the provisions of the Animal Welfare Act 2006 (AWA)¹⁹.

126. Setting up such a system would entail transitional costs for the Home Office and each user, breeder and supplier. However, as well run ASPA designated establishments will have significant elements of a system of local control already in place, we assume in some cases only part of these would be additional costs. Furthermore, the greater flexibility of such a system would eliminate the administrative burden currently associated with the need to amend personal licences.

Questions: Should the UK: (a) retain its current system of personal licensing using Article 2, as necessary; or (b) adopt a simplified version of that system with greater local accountability? What might be the features of a system involving greater local accountability? What risks might be associated with such a system and how might

¹⁹ See AWA section 58

these be mitigated? What will be the cost to individual breeders, suppliers and users of implementing such a system?

Education and training

127. The Directive requires that Member States publish their minimum requirements for education and training based on the elements listed in Annex V. Member States must also publish their minimum requirements for obtaining, maintaining and demonstrating competence. Current UK education and training requirements are set out in Appendix F to the published Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (HC321).

128. We will publish updated UK requirements in further guidance to accompany the UK legislation transposing the Directive. We are, however, concerned that there is significant scope for Member States to adopt different minimum requirements potentially undermining harmonisation and the free movement of skilled labour – important objectives in the negotiation of the Directive. We are, therefore, pressing for the adoption of common training standards across Europe.

Questions: What specific features would you like to see in a UK or European training system? What elements of current UK training could be omitted whilst still complying with Annex V? How should the quality of individual training and supervision be assured so that new employers are confident about training and competence and to facilitate the transfer of individuals within the UK and across Europe? Would such a system result in any additional costs? If so, please specify. How might the requirement for continuous professional development best be met?

Article 24: Specific requirements for personnel

129. The Directive requires that each breeder, supplier and user has one or more persons on site responsible for overseeing the welfare and care of the animals in the establishment; ensuring that the staff dealing with animals have access to information specific to the species housed in the establishment; and for ensuring that the staff are adequately educated, competent and continuously trained and supervised until they have demonstrated the required competence.

130. The first of these roles is broadly comparable with that of the named animal care and welfare officer (NACWO) under ASPA²⁰ and the second is currently filled by the NACWO or Ethical Review Process. The third is a shift in responsibility from the project licence holder (as required by standard condition 14 of a project licence under ASPA) to the 'person responsible for compliance in the authorised establishment' (i.e., certificate holder equivalent - see Article 20, above) and offers a structure within which local accountability for training and competence must be delivered.

131. We are minded to ensure that the certificate holder equivalent is responsible for overall compliance while allowing the day-to-day work of ensuring competence to be delegated. We also believe that greater local accountability may provide opportunities for training to be more closely tailored to the specific needs of each individual, reflecting a more modern approach to training than 'one size fits all'.

132. Persons responsible for the overall implementation of projects must ensure that any unnecessary pain, suffering, distress or lasting harm that is being inflicted on an animal in the course of a procedure is stopped; oversee that the projects are carried out in accordance with the project authorisation and ensure that in the event of non-compliance, the appropriate measures to rectify it are taken and recorded. These roles are broadly consistent with those of the project licence holder under ASPA.

²⁰ See Home Office Guidance paragraphs 4.55 to 4.58.

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

Article 25: Designated veterinarian

133. The Directive requires that each breeder, supplier and user has a designated veterinarian, or a suitably qualified expert, with expertise in laboratory animal medicine to advise on the well-being and treatment of the animals. These requirements are similar to current UK requirements. We do not envisage any significant change to the role of a designated veterinarian compared to that of a named veterinary surgeon under ASPA²¹.

134. We intend to continue to apply our current policy with respect to “suitably qualified experts”. ASPA²² already makes provision for a person other than a veterinary surgeon to be named on the certificate of designation. The Secretary of State can permit this in exceptional circumstances where no suitable veterinary surgeon is available and the “other suitably qualified person” has considerable, proven expertise relevant to the health and welfare of the particular types of protected animal held and the range of regulated procedures performed at the establishment.

135. The responsibilities of the “other suitably qualified persons” are equivalent to those of Named Veterinary Surgeons with regard to the provision of advice on health and welfare, and ensuring action is taken to protect animals where there is concern for their health or welfare. The Home Office consults the Royal College of Veterinary Surgeons when requests are made for “other suitably qualified persons” to be nominated in place of a veterinary surgeon.

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

²¹ See Home Office Guidance paragraphs 4.59 to 4.63.

²² See Home Office Guidance paragraphs 4.65 to 4.67.

13. PROJECTS

Article 3.2: Definition of 'project'

136. The Directive defines a "project" as 'a programme of work having a defined scientific objective and involving one or more procedures'. This is similar to the equivalent definition under ASPA 5(1).

Article 36: Project authorisation

137. Under the Directive, projects require prior authorisation by the competent authority, and must be carried out in accordance with that authorisation. In addition, no project is to be carried out without having received a favourable project evaluation by the competent authority (see Article 38). ASPA 3 and 5 set similar requirements.

Article 37 and Annex VI: Application for project authorisation

138. An application for project authorisation must be submitted by the user, or the person responsible for the project, and must include: a project proposal; a non-technical project summary; and information on elements listed in Annex VI. We envisage that the level of detail required in applications will reflect the nature of the proposed project but is likely in most cases to be similar to the level of detail currently required under ASPA.

Article 38: Project evaluation

139. Article 38 requires that the project evaluation verifies that the proposed work is justified from a scientific or educational point of view or required by law; the purposes of the project justify the use of animals; and the project is designed so as to enable procedures to be carried out in the most humane and environmentally sensitive manner.

140. The Directive requires an evaluation of the objectives of the project, its predicted scientific benefits or educational value and its compliance with the 3Rs. The project evaluation must also include an assessment of the severity of procedures and a harm-benefit analysis of the project and consider any derogations sought under Articles 6 to 12, 14, 15, 16, and 33. These requirements are very similar to the current process for assessing project applications under ASPA.

141. A decision is also to be made whether and when the project should be assessed retrospectively (see Article 39, below). This is a new requirement.

142. In carrying out the project evaluation the competent authority is to apply appropriate expert knowledge relevant to the areas of science in which animals are to be used; replacement, reduction and refinement (the 3Rs); experimental design, including statistics; veterinary practice in laboratory animal science or wildlife veterinary practice; and animal husbandry and care, in relation to the species that are intended to be used.

143. The project evaluation process must also be transparent. We understand this to mean that the competent authority should publish general information about how project evaluations are conducted rather than specific information about individual evaluations.

144. Finally, subject to safeguarding intellectual property and confidential information, the project evaluation is to be performed impartially and may take into account the opinion of parties independent of the science and the place from which the application is made.

145. We believe the requirements for project authorisation are largely consistent with the project assessment process under ASPA and with current UK policy and practice. The assessment of project applications is currently performed by Home Office inspectors with referral of certain types of applications to the Animal Procedures Committee (APC) or, less frequently, to an external advisor. We believe this is consistent with the procedures required under the Directive.

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

Article 39: Retrospective assessment

146. Article 39 creates a requirement for the retrospective assessment of projects using non-human primates and projects involving procedures classified as "severe" and the option of requiring retrospective assessment of projects involving 'moderate' procedures (to be decided on a case by case basis). Member States may exempt projects involving only procedures classified as "mild" or "non-recovery" from the requirement for a retrospective assessment except where these projects use non-human primates.

147. Retrospective assessment is currently undertaken by the Inspectorate when projects are renewed on expiry²³ as part of the assessment of the application for a new project licence. In addition, retrospective review of projects is currently a requirement of the ethical review process at designated establishments. We estimate that the Directive would require retrospective assessment of fewer projects (about 20%). Where a retrospective assessment is required to satisfy Article 39, we envisage that the project licence holder will be asked to prepare and submit a dossier providing all relevant information on the project to enable the competent authority to complete the retrospective assessment. The dossier might be formally reviewed by the animal welfare body before submission to the competent authority.

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

Article 40: Granting of project authorisation

148. Under the Directive, project authorisations will cover only those procedures considered and agreed in the project evaluation and the severity classifications assigned to those procedures. The project authorisation will also specify the user undertaking the project; the persons responsible for the overall implementation of the project and its compliance with the project authorisation; the establishments in which the project will be undertaken, when applicable; and any specific conditions applied to the project, including whether and when the project is to be assessed retrospectively. Project authorisations may be granted for a period not exceeding five years. These provisions are consistent with current UK arrangements.

Multiple generic projects

149. Recital 43 recognises a need to avoid the imposition of an unnecessary administrative workload and to enhance the competitiveness of Community research and industry. Recital 43 proposes that it should be possible to authorise 'multiple generic projects' when carried out using established methods for testing, diagnostic or production purposes under one group authorisation, without exempting any of these procedures from the project evaluation. Accordingly, Article 40(4) provides that Member States may authorise multiple generic projects if they are to satisfy regulatory requirements or are using animals for production or diagnostic purposes with established methods and are carried out by the same user. We propose to apply the provisions relating to multiple generic projects to toxicological projects, transgenic breeding, antibody production and the production of blood products.

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

²³ About 75% of projects are renewed.

Article 41: Authorisation decisions

150. The Directive specifies that competent authorities must take decisions on project applications and communicate them to applicants within 40 working days from receipt of the complete and correct application. This period includes the project evaluation and may be extended by a further 15 working days for complex or multi-disciplinary projects. The competent authority is to inform applicants of these timescales and where an application is incomplete or incorrect, inform the applicant promptly of the need to supply any additional documentation and of any impact on the timescale for decision. At present, we currently achieve and often exceed our target to process 85% of project applications within 35 days.

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

Article 42: Simplified administrative procedure

151. Under Article 42, Member States may introduce a simplified administrative procedure for projects to satisfy regulatory requirements, or using animals for production or diagnostic purposes with established methods, provided they only involve procedures classified as "non-recovery", "mild" or "moderate" and do not use non-human primates. There is no equivalent provision under ASPA.

152. Applications made under a simplified administrative procedure must specify the user undertaking the project, the person responsible for its overall implementation and compliance and the place at which it will be carried out, but the requirement for a non-technical summary (see Article 43, below) may be waived.

153. The requirement for project evaluation in accordance with Article 38 is not waived and authorisation decisions must be reached within the timescales set out in Article 41(1). Any changes to a project subject to the simplified administrative procedure that might have a negative impact on animal welfare will require a further favourable project evaluation.

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

Article 43: Non-technical project summaries

154. Subject to safeguarding intellectual property and confidential information, Article 43 requires the publication of anonymised, non-technical summaries (abstracts) of authorised projects. These summaries are to be provided by project licence applicants and include information on the objectives of the project, the predicted harms and benefits, and the number and types of animals to be used and should also explain how the 3Rs have been satisfied.

155. Member States may also specify in the non-technical project summary whether the project is to undergo a retrospective assessment. Where this applies, Member States are to ensure that the non-technical project summary is updated with the results of the retrospective assessment.

156. Under Article 37(2), Member States may waive the requirement for non-technical summaries for the categories of project to which simplified administrative procedures may apply (see Article 42). In the UK, we publish abstracts of over 80% of authorised projects under a voluntary, non-statutory scheme. We believe Article 43 would require the publication of significantly fewer non-technical summaries than the UK voluntary scheme.

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

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

157. Under Article 44, amendment or renewal of a project authorisation is required for any change of the project that may have a negative impact on animal welfare. These will require a further favourable project evaluation. Project authorisation may be withdrawn if the project is not carried out in accordance with the project authorisation. In such cases, the welfare of the animals used or intended to be used in the project must not be adversely affected. Member States are to publish conditions for amendment and renewal of project authorisations. This is similar to existing UK legislation and practice.

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

Article 45: Documentation

158. The Directive requires that all relevant documentation, including project authorisations and the project evaluation, is kept for at least three years from the expiry date of the project and shall be made available to the competent authority. The documentation for projects which have to undergo retrospective assessment is to be kept until the retrospective assessment has been completed.

14. ANIMAL WELFARE BODIES

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

159. Article 26 requires each breeder, supplier and user to set up an animal welfare body (AWB) comprising, as a minimum, the person(s) responsible for the welfare and care of the animals and, in the case of a user, a scientific member. The animal welfare body must also receive input from the designated veterinary surgeon, or the expert referred to in Article 25.

160. The AWB is to advise on matters related to the welfare of animals; the application of the 3Rs; establish and review relevant internal operational processes; follow the development and outcome of projects; and advise on re-homing schemes. Records of AWB decisions and advice are to be kept for at least three years and made available to the competent authority upon request.

161. Member States may allow small breeders, suppliers and users to carry out these tasks by other means. We understand this to mean without setting up a formal AWB. The Directive does not define 'small' in this context and we anticipate that decisions on the applicability of this derogation to particular breeders, suppliers and users will need to be made on request and on a case by case basis.

162. Through the standard conditions of certificates of designation²⁴, the UK currently requires designated establishments to have an ethical review process (ERP) with a wider membership than specified for AWBs. The tasks of the ERP²⁵ are broadly similar to those defined for the AWB except that the latter are not required to play a role in project authorisation. ERPs are also currently required to review project applications before they are submitted – a role which sometimes overlaps with the work of the Home Office inspector who assesses the application. This is not a role of the animal welfare body.

163. A fuller comparison of animal welfare bodies and the UK requirement for ethical review processes is provided at Appendix III to this consultation paper.

164. We believe that some users, breeders and suppliers may opt to model their AWBs on their current ERPs, including maintaining a wider membership, and some form of local oversight of applications before they are submitted for evaluation by the competent authority. We would support this approach. ERPs in their present form have made a very significant contribution to animal welfare and the 3Rs since their introduction in the UK in 1999.

165. We are aware of concerns that the adoption of the minimum requirements of the Directive may result in less extensive ethical and other consideration of scientific procedures involving animals within establishments. Bearing in mind our view that the roles of the two bodies are essentially similar, we would welcome views on why this might be the case.

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

²⁴ Annexes B and C, Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (HC321)

²⁵ Annex J, Home Office Guidance (HC321)

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

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

166. The Directive requires each Member State to establish a national committee for the protection of animals used for scientific purposes to advise the competent authority and animal welfare bodies on the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practices. National committees are also to exchange information on the operation of animal welfare bodies and project evaluation and share best practices with the national committees of other Member States.

167. These functions are in some respects similar to those of the Animal Procedures Committee (APC) set up under ASPA sections 19 and 20 to advise the Secretary of State on matters relating to ASPA and its implementation. They are, however, more narrowly focused on animal welfare issues than is the case with the APC, which also considers wider ethical issues. The requirement to 'ensure the sharing of best practice' and the direct relationship with animal welfare bodies suggest a more direct involvement with establishments than is currently exercised by the APC. Similarly, the requirement to exchange information with national committees in other Member States also involves a wider role.

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

16. INSPECTIONS

Article 34: Inspections by the Member State

168. The Directive sets out requirements for regular inspections of all breeders, suppliers and users, to verify compliance with its requirements. The frequency of inspections is to be determined according to a risk assessment for each establishment, taking account of the number and species of animals housed; the breeder, supplier or user's compliance record; the number and types of projects carried out by the user in question; and any information that might indicate non-compliance.

169. Article 34 requires that at least one third of users are to be inspected each year based on the risk assessment. In addition, breeders, suppliers and users of non-human primates must be inspected at least once a year. Article 34 also requires that an appropriate proportion of the inspections are to be carried out without prior warning and that records of inspections are to be kept for at least five years.

170. There are currently 188 designated establishments in England, Scotland and Wales²⁶ to which just under 2000 visits were carried out by Home Office inspectors in 2010. About half of these visits were unannounced. The frequency of visits is partly determined using a risk rating system similar to that envisaged in Article 34. In addition to checking compliance with the requirements of licences and certificates, visits also provide an opportunity for Home Office inspectors to advise on draft licence applications; good practice in animal welfare; and the application of the 3Rs.

171. We estimate implementing the minimum requirements of the Directive would require about 80 inspections per year in the UK with between 3 and 5 years between inspections for some establishments. Because of their reduced frequency, to ensure compliance we assume these inspections would involve a detailed and formal audit of all relevant aspects of compliance at the relevant establishment and that occasional follow up inspections would also be required. We estimate that inspections of this nature involving one of the larger establishments would require between 16 and 20 days of inspector input, including 3 or 4 days on site, and that most would need to be conducted by appointment, rather than unannounced (see the impact assessment at Part II for further detail).

172. We estimate that this minimum approach would be broadly cost neutral compared with current inspection arrangements. However, while such inspections would provide an opportunity to advise on the full range of activities carried out at the establishments, separate arrangements would need to be made if the inspector's advisory role is to continue between inspections, potentially increasing costs.

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

Article 35: Controls of Member State inspections

173. Article 35 enables the Commission to review the infrastructure and operation of national inspections in Member States when there is reason for concern and requires Member States to give all necessary assistance to the Commission in carrying out their review and to take account of the results.

²⁶ There are a further 9 designated establishments in Northern Ireland.

17. REPORTING

Article 54: Reporting

174. Article 54 requires Member States to collect and publish annual statistics 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. The content and format of the statistics has to be finalised by May 2012 after further discussions between the Commission and Member States. It is likely that the minimum EU information requirements will be less extensive than current UK requirements. The UK currently collects and publishes detailed annual statistics of animal use under ASPA, but these do not include information on the actual severity of the procedures carried out.

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

18. SAFEGUARD CLAUSES

Article 55: Safeguard clauses

175. Article 55 sets out procedures under which Member States may provisionally authorise, and the Commission may subsequently confirm or disallow, applications for derogations relating to the restrictions on the use of non-human primates and great apes set out in Article 8 and the authorisation of procedures involving severe pain set out in Article 15. It is our understanding that provisional authorisation by a competent authority does not allow any work to start until the Commission has responded to the application for derogation.

176. Recital 50 makes clear that the application of safeguard clauses is to ensure uniform conditions for implementation across the EU. This is important given the potential for inconsistent interpretation of the severity classification system and terms such as 'debilitating'.

177. We do not currently foresee any circumstances in which we might need to invoke the provisions of Article 55. As explained in respect of Article 8, we do not believe the restrictions on the use of non-human primates will prevent the continued authorisation of any work previously or currently undertaken under ASPA. In addition, we explain that the UK currently operates a policy ban on the use of great apes and we cannot currently envisage any circumstances in a particular case which would change this approach. Similarly, with regard to procedures involving severe pain, we explain at Article 15, above, that we are not aware of any work currently undertaken in the UK that would require use of the safeguard clause.

178. However, we will not know how the derogations will be applied in practice until the Directive is implemented in 2013. It may be necessary for the UK to seek to apply the derogations if the threshold for their application is more stringent than we currently expect. In the circumstances, we are minded to transpose the provisions of Article 55 on a precautionary basis.

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

19. PENALTIES

Article 60: Penalties

179. Article 60 requires Member States to specify the penalties applicable to breaches of the national provisions adopted to implement the Directive and to take all measures necessary to ensure that they are implemented. The penalties must be effective, proportionate and dissuasive.

180. The following sanctions are currently available to the Secretary of State: referral to the prosecuting authorities; revocation, suspension or amendment of licences or certificates; addition of special conditions to licences or certificates; requirements for formal training or re-training; and letters of admonition, with or without requirements for further action to correct perceived deficiencies (such as additional training or altered management practices)²⁷.

181. Although there are some differences in terminology, Part 3 of the UK Regulatory Enforcement and Sanctions Act (RESA) makes provision for a similar range of civil sanctions to be made available to 'a regulator'²⁸. The RESA sanctions are: the power to serve a stop notice prohibiting an activity until specified steps have been taken; the imposition of fixed monetary penalties; and the imposition of discretionary requirements which may include the payment of monetary penalties determined by the regulator; the taking of steps to prevent the continuation or recurrence of an offence; or the taking of steps to restore the position to its pre-offence state. Procedures are laid down in RESA for the application of these sanctions and for appeal against their imposition.

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

²⁷ See Home Office Guidance paragraph 7.10.

²⁸ The definition of 'regulator' includes a person with an enforcement function under enactments listed in Schedule 6 to the Act. ASPA is listed in Schedule 6.

20. OTHER PROVISIONS

Article 50: Adaptation of annexes to technical progress

182. Article 50 provides for Annexes I and III to VII to be amended to reflect technical and scientific progress, taking into account experience gained in the implementation of the Directive. Power to adopt amended provisions is delegated to the Commission as set out in Articles 51, 52 and 53.

Article 56: Committee

183. Article 56 provides for the Commission to be assisted by a Committee made up of representatives of Member States.

Article 59: Competent authorities

184. Under the Directive (Article 3.7), "competent authority" means an authority or authorities or bodies designated by the Member State to carry out the obligations arising from this Directive.

185. Article 59 requires each Member State to designate one or more competent authorities responsible for the implementation of the Directive. These may be bodies other than public authorities for the implementation of specific tasks laid down in this Directive only if there is proof that the body: (a) has the expertise and infrastructure required to carry out the tasks; and (b) is free of any conflict of interests as regards the performance of the tasks. We believe this latter requirement (b) precludes designation of animal welfare bodies as competent authorities responsible for project evaluation.

186. We have no plans to designate any competent authorities other than the Home Office and the Department of Health, Social Security and Public Safety (Northern Ireland) to act as the competent authorities in England, Scotland and Wales, and Northern Ireland, respectively.

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

187. Article 63 amends Article 8 of Regulation (EC) No 1069/2009 which lays down health rules regarding animal by-products and derived products not intended for human consumption. This amendment will be implemented through separate implementing regulations made by Defra.

Article 64: Transitional provisions

188. Article 64 allows 'grandfathering in' of projects authorised before 1 January 2013 and due to expire before 1 January 2018.

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

21. CONFIDENTIALITY (ASPA SECTION 24)

Background to ASPA section 24

189. ASPA 24 prohibits the disclosure by Home Office Ministers and officials of confidential information relating to the use of animals in scientific procedures other than in the discharge of their functions under ASPA. It creates a criminal offence and provides a maximum punishment of two years imprisonment and a fine for unauthorised disclosure of information.

190. Section 24 was included in ASPA to provide assurance to individuals and establishments applying for authorisations, and subsequently carrying out projects, that confidential information and intellectual property provided to the competent authority would be protected.

191. ASPA 24 was reviewed in 2004 as part of a Government-wide exercise to review statutory bars in the run up to the introduction of public access rights under the Freedom of Information Act 2000. The review²⁹ concluded that it should be retained until the effect of the public access rights was known.

192. A further review due in 2006 was delayed pending the outcome of a long-running Freedom of Information case which was finally concluded in the autumn of 2008. In its judgment, the Court of Appeal concluded that ASPA 24 raises a simple question of fact: does the official or other person receiving information know or have reasonable grounds for believing that the relevant information was given in confidence.

193. In the light of this ruling, determining whether ASPA 24 applies in a particular case is relatively straightforward. However, ASPA 24 allows no flexibility, and a strict interpretation could potentially lead to inappropriate outcomes. For example, officials might be considered to be in breach of ASPA 24 if they were to disclose information which although originally received in confidence had since been placed in the public domain by the provider.

194. Unlike Directive 86/609/EEC³⁰, which requires that Member States take all necessary steps to ensure that the confidentiality of commercially sensitive information provided in connection with that Directive is protected, the new Directive focuses on greater transparency in relation to the use of animals in scientific research (see Recital 41). This suggests that retention of ASPA 24 as it stands would not be compatible with the aims of the Directive.

195. Given that some information provided to the competent authority will continue to require protection from disclosure - see Article 38(4) and Article 43(1) – we would welcome views on how ASPA 24 might be amended to eliminate the anomalies described above and provide flexibility in responding to requests for information while protecting proprietary rights and confidential information shared with the competent authority.

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

²⁹ Review of Statutory Provisions on Disclosure: Department for Constitutional Affairs

³⁰ See Article 13(2)

22: ASPA PROVISIONS NOT COVERED BY THE DIRECTIVE

Definition of 'death'

196. ASPA section 1(4) specifies that an animal is to be regarded as continuing to live until the permanent cessation of circulation or the destruction of its brain. We propose to retain this provision which has no equivalent in the Directive.

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

Fees

197. Under ASPA section 8, certificate holders at designated establishments must pay periodic (annual) fees. We propose to retain this requirement.

Licence conditions

198. ASPA section 10(1) provides for the application of conditions to licences and certificates granted under the Act. We propose to retain this power to apply conditions and will publish revised standard licence conditions in future guidance on the operation of the legislation implementing the Directive.

Appeal against licensing decisions

199. ASPA section 12 provides a right of appeal against licensing decisions by the competent authority. We propose to retain this right.

Use of animals in public exhibitions

200. ASPA section 16 prevents animals being used in regulated procedures for the purpose of exhibition to the public or for live television. We propose to retain this prohibition which has no equivalent in the Directive.

Question: Should restriction on public exhibition be retained?

The Inspectorate

201. ASPA Section 18 makes provisions relating to the qualifications, functions and powers of inspectors. We propose to retain these provisions.

Publication of guidance and codes of practice

202. ASPA Section 21 requires the competent authority to publish guidance on how the Secretary of State proposes to exercise her power to grant licences and certificates under the Act and with respect to the conditions she proposes to include in licences and certificates. Section 21 also provides for the publication of codes of practice on the care of protected animals and their use for regulated procedures and for the Secretary of State to approve such codes issued by others. We propose to retain these provisions.

PART II: IMPACT ASSESSMENT

203. Part II (published separately) sets out a consultation stage impact assessment, which is the first step in identifying the costs and benefits of the options for transposition of European Directive 2010/63/EU discussed in this consultation paper. The impact assessment is based on the best evidence available at the time of its preparation.

204. A further impact assessment will be prepared in the light of the public consultation. Respondents are invited to submit estimated costs and other details to help refine the Impact Assessment and ensure that decisions on options are taken in the light of full and accurate information.