Consultation on options for transposition of European Directive 2010/63/EU on the protection of animals used for scientific purposes

Summary report and Government response

May 2012

INTRODUCTION

Background

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).

2. In common with other Member States, the UK has Treaty obligations to transpose the provisions of the new Directive into UK legislation and must complete this process 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 must be implemented by 1 January 2017.

Public consultation on options for transposition

3. The Home Office held a formal public consultation between 13 June and 5 September 2011. The consultation document sought comments on the options for transposing the Directive 2010/63/EU and on the impact assessment published with it. The consultation document contained 76 questions and explained that three options for transposition were being considered.

4. Option 1 (No change) was 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 Directive 2010/63/EU as ASPA does not fully transpose its requirements.

5. Option 2 (Copy out) assumes that the UK will transpose the minimum requirements of Directive 2010/63/EU by ‘copying out’ its provisions into revised UK legislation.

6. Option 3 (Retain some current higher UK standards and requirements) envisages that the UK will retain some measures in force on 9 November 2010 that provide more extensive protection of animals than those required by the Directive. Article 2 of the Directive permits Member States to retain such measures provided they are not used to create barriers to trade.

7. The consultation stage impact assessment published with the consultation document estimated that retaining some current higher UK standards and requirements (Option 3) would entail lower costs to the UK than transposition of the minimum requirements of the new Directive (Option 2). The public consultation invited submission of further and better information to develop and strengthen the impact assessment and in particular to assist in assessing the impact of the new Directive on UK competiveness.

Responses to the consultation

8. Responses were received from 98 organisations and over 13000 individuals.

Table 1: Responses by category

Category	Responses	
	Organisations	Individuals
Animal protection	15	2
Animal welfare & alternatives	15	3
Bioscience sector	61	-
General Public (no specific affiliation)	-	13
Practitioners (laboratory animal care & welfare and training)	7	16
Animal protection / animal welfare generic responses		13,458

9. Responses to each of the questions set out in the consultation document are summarised in the following table.

Article	Issue	Consultation response	Government response	Estimated impact
1. Subject matter and scope Limit on protection of foetal forms of mammals to the last third of the gestation period. Question 1: Is our analysis of the impact of this provision correct? Is there scientific evidence that suggests that the UK should continue to protect mammals from half way through gestation using Article 2 to the Directive?	Under Article 1(3)(a), foetal forms of mammals are protected from the last third of their normal development. ASPA section 1(2)(a) currently protects mammals from half way through their gestation or incubation period.	While animal protection groups favoured retention of current ASPA provisions, no substantive evidence was provided to suggest protection during the last third of development was not sufficient for foetal mammals. Animal welfare and bioscience sector groups supported the change. They found no evidence that foetal forms of mammals prior to the last third of gestation are sentient.	We propose to transpose Article 1(3)(a) as it stands to protect foetal forms of mammals during the last third of normal development. We believe this will give appropriate protection to mammals during the later stages of development. It will also encourage the use of earlier foetal forms and will this contribute to the 3Rs by promoting the use of non-sentient mammalian forms wherever this can achieve the scientific outcome.	There are no additional costs and the savings are small. Based on what is currently licensed, we estimate that there will be no reduction in the number of authorised establishments, a reduction of fewer than 5 project licences, and a reduction of fewer than 15 authorised persons. Moving the point of protection to the last third of normal development will have no adverse impact on animal welfare.
1. Subject matter and scope Exclusion of foetal forms of birds and reptiles from protection. Question 2: Is there scientific evidence to support the continued protection of foetal forms of birds and egg laying reptiles using Article 2 to the Directive?	Under Article 1, birds and reptiles are not protected until they hatch or, in the case of viviparous reptiles, when they are born. ASPA section 1(2)(a) currently protects birds and reptiles from half way through their gestation or incubation period.	Almost all respondents to the public consultation supported continued protection of avian and reptilian foetal forms and several provided evidence supporting protection during the last third of development.	We propose to use Article 2 to protect foetal forms of birds and reptiles during the last third of their normal development (aligning protection with that proposed for mammals). We believe this will give appropriate protection to birds and reptiles during the later stages of development. It will also encourage the use of earlier foetal forms and will thus contribute to the 3Rs by promoting the use of non-sentient forms of birds and reptiles wherever this can achieve the scientific outcome.	Protection of foetal forms of birds and reptiles during the last third of their normal development will significantly reduce the number of procedures on embryonated bird eggs that will be regulated without adversely impacting animal welfare. We estimate that there will be no reduction in the number of authorised establishments, a reduction of fewer than 5 project licences, and a reduction of fewer than 15 authorised persons. The savings to the competent authority are not significant (well under 0.5% of current resource costs). Moving the point of protection to the last third of normal development will have no adverse impact on animal welfare.

Article	Issue	Consultation response	Government response	Estimated impact
1. Subject matter and scope Inclusion of cephalopods. Question 3: Are our assumptions relating to the current use of cephalopods correct? Do you have any further information of the current use of cephalopods?	Article 1(3)(b) extends protection to all live cephalopods. ASPA section 1(1) protects a single species of cephalopod, Octopus vulgaris.	Further information was provided on the use of cephalopods in the UK which was consistent with our assumptions. Work using Octopus species, squid and cuttlefish was cited and it is estimated that up to 10 establishments use these species. Several animal protection/welfare groups suggested that cephalopods should be protected from the time of independent feeding. In practice, this means immediately post-hatching for octopus and squid, and around three days after hatching for cuttlefish.	We propose to transpose Article 1(3)(b) as it stands. We propose to protect all cephalopods from the point when the hatched cephalopod becomes capable of independent feeding.	A previous survey of cephalopod use suggests work takes place almost exclusively at academic institutions that are already designated and that fewer than 10 projects are on-going at any time involving 12-20 persons. The transitional costs will be those of bringing these projects and people into the regulatory system. For project licences we estimate these costs as 40 hours to prepare and 10 hours to assess an application at £60 per hour. Total £30K for 10 project licences (split £24k to establishments and £6k to the Home Office). For personal licences: 2 hours to prepare and 1 hour to assess an application x £60 per hour. Total £3.6k (split £2.4 to establishments and £1.2k to the Home Office). We also estimate about 3 days training per project licence and personal licence applicant (about £750 in total). Grand total £15K We assume care staff in the relevant establishments will already have the necessary species specific knowledge. We also estimate a further 20 hours input from inspectors for initial site visits, travel and training (total £1200) Total costs to establishments about £40 to £45k; total cost to the Home Office £8 to £10k.

Article	Issue	Consultation response	Government response	Estimated impact
1. Subject matter and scope Inclusion of animals specifically bred for organs and tissues. Question 4: Are our assumptions correct that inclusion of these animals within the scope of legislation will not have any significant regulatory or animal welfare impact? Do you have any further relevant information of the current breeding and use of animals bred for organs and tissues?	Under Article 1(2), animals are protected that are bred specifically so that their organs or tissues may be used for scientific purposes. There is no equivalent provision in ASPA.	There was broad agreement with our assumptions regarding the impact of this provision from animal protection and welfare groups and bioscience sector groups. There was also support for these animals to be counted to improve transparency, but some bioscience sector respondents were concerned that the counting of these animals could lead to an increased bureaucratic burden.	The breeding of animals specifically so that their organs and tissues may be used for scientific purposes will be included within the scope of the transposed legislation.	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. No additional personal or project authorisations will be required. Cost neutral.
1. Subject matter and scope Special protection for cats, dogs and horses. Question 5: Is loss of special protection likely to lead to increased use of cats, dogs and horses? Should the UK retain its current special protection for dogs, cats and horses using Article 2 to the Directive?	The Directive provides special protection for non-human primates (see Article 8, below), but not to dogs, cats and horses (although Article 13(2)(b) does require animals of the lowest sentience to be used and Articles 31 and 32 include some additional requirements for record keeping and marking of dogs and cats). Along with primates, dogs, cats and horses are currently given special protection under ASPA section 5(6).	There was widespread support for retention of special protection for dogs, cats and horses. Consultation responses suggested use of these species would be unlikely to increase if special protection is removed.	We propose to use Article 2 to retain special protection for cats, dogs and horses.	We believe retention of special protection for these species will be cost neutral and is essential to maintain public confidence that these animals will continue to be robustly protected.

Article	Issue	Consultation response	Government response	Estimated impact
1. Subject matter and scope Practices to which the Directive does not apply. Question 6: Is our assessment correct that the adoption of Article 1(5)(e) as it stands could allow more painful methods of marking? 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?	Under Article 1(5)(e), practices undertaken for the primary purpose of identifying an animal are excluded from the scope of the Directive. 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.	All animal protection and welfare groups and many bioscience respondents favoured retaining current UK requirements exempting only those methods of marking which cause no more than momentary pain or distress, and no lasting harm. Some users suggested that there are already adequate controls within the Animal Welfare Act and that retaining current UK requirements is not necessary.	We are minded to exempt practices undertaken for the *primary* purpose of identification of an animal subject to retention of the additional requirement that the procedure causes only momentary pain or distress and no lasting harm.	Cost neutral.
2. Stricter national measures	Article 2 allows Member States to retain national provisions in force on 9 November 2010 providing more extensive protection of animals than those set out in Directive 2010/63/EU so long as they are not used to inhibit the free market.	No question. The implications of Article 2 are discussed where necessary under the relevant articles in this consultation report.	See Articles 1, 6, 10, 17, Annex I and Annex III.	

Article	Issue	Consultation response	Government response	Estimated impact
Definition of 'procedure' 67. … under the new Directive ... the use of a method of killing of animals not listed in Annex IV (Methods of Killing Animals) solely for the use of their organs and tissues is not a procedure and will not require project authorisation. However, exemption from using an Annex IV method of killing will be needed. A system will be required to enable exemption to be granted to individuals who are not licence holders and are outside the regulatory system. Question 16: Do you have any proposals as to how this might be achieved?	Definition of 'procedure' The definition of 'procedure' in Article 3 excludes the killing of animals solely for the use of their organs or tissues. Article 6 requires that animals are killed by a method set out in Annex IV unless an exemption has been granted allowing the use of another method. The combination of Article 3 and Article 6 suggests that the killing of animals solely for the use of their organs and tissues by a method not listed in Annex IV is not a procedure and will not require project authorisation, although exemption from use of an Annex IV method of killing will be needed. Under ASPA 2(7) the killing of a protected animal for a scientific purpose at a designated establishment by a method not listed in ASPA Schedule 1 (Appropriate Methods of Humane Killing) is a regulated procedure and requires authorisation under a project licence.	Animal protection and welfare groups, the general public and practitioners predominantly supported retaining current UK provisions, which would require project licence approval for the killing of animals solely for the use of their organs and tissues by a method not listed in Annex IV. Some bioscience sector respondents and practitioners suggested that this could be managed locally through the Animal Welfare Body (see Articles 25 and 26) or by the use of a register held at the establishment.	We are minded to provide for the approval of the use of such methods within the authorisation of breeders, suppliers and users. Alternatively, it may be feasible for this to be handled locally by Animal Welfare Bodies.	As this will occur only rarely, we believe the impact of retaining a system of authorisation will be minimal.

Article	Issue	Consultation response	Government response	Estimated impact
4. Principle of replacement, reduction and refinement Question 25: We propose to transpose the requirements of Article 4 as they stand. Are there any further issues relating to replacement, reduction and refinement we should consider?	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.	The majority of respondents supported transposition of Article 4 unchanged. Importance was placed on the sharing of information in order to ensure wide implementation of 3Rs principles. Animal protection groups remarked that replacement should be given more weight than refinement and reduction.	We propose to transpose the provisions of Article 4 unchanged, along with the provisions of Article 13.	The provisions of Article 4 are consistent with current UK requirements and practice. Cost neutral.
5. Purposes of procedures Question 17: Are there any further issues we should consider in relation to the 'permissible purposes' set out in Article 5?	Article 5 specifies the purposes for which procedures may be carried out. Current UK requirements are set out in ASPA 5(3).	Most bioscience sector groups agreed that Article 5 should be transposed unchanged. Some animal protection and welfare groups opposed the use of animals for the acquisition of vocational skills - Article 5(f). A few bioscience respondents also expressed concern about the possible use of animals for acquisition of manual skills and called for wider debate on this topic. Some users support such use and suggest it will benefit animal welfare. Several users supported the retention of existing policy restrictions on the use of animals for tobacco, offensive weapons and cosmetics testing.	We propose to transpose the provisions of Article 5 unchanged.	The permissible purposes set out in Article 5 are similar to current ASPA requirements. Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
6. Methods of killing Question 24: Do you agree with our analysis of Article 6 and Annex IV? Should the UK retain some methods listed in ASPA Schedule 1 using Article 2? Which methods should be retained?	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. Provisions relating to the killing of protected animals are set out in ASPA 2, 6, 7, 15(1) and 18(3). Appropriate methods of human killing are set out in ASPA Schedule 1.	There was broad agreement across all sectors that some Annex IV methods could impose a higher animal welfare cost. A clear majority favoured retention of current UK methods where appropriate. A number of responses included detailed and referenced justification for the suitability of specific methods.	We propose to transpose the provisions of Article 6 unchanged. At the same time, we propose to retain current UK methods where they are more humane and implement Annex IV by means of a revised Schedule 1. (See Annex IV.)	Implementation of article 6 requirements will be cost neutral. See Annex IV for impact of retaining current UK methods of killing.
7. Endangered species Question 7: Should the UK retain its current restrictions on the use of endangered species using Article 2? What implications would adoption of the provisions of Article 7 of the Directive have for the use of endangered species in the UK?	Article 7 prohibits the use of endangered species[1] 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 specified purposes. 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 exceptionally proves to be the only one suitable for those purposes.	Respondents, across all sectors supported retention of current UK restrictions on the use of endangered species.	We will transpose the provisions of Article 7 in a way that does not weaken the current restrictions on the use of endangered species.	The provisions of Article 7 are broadly consistent with current UK legislation, policy and practice. Cost neutral.

[1] listed in Annex A to Council Regulation (EC) No 338/97[1] regulating trade in species of wild fauna and flora

Article	Issue	Consultation response	Government response	Estimated impact
8. Non-human primates Restrictions on the use of non-human primates Question 8: Do you agree with our analysis of the likely impact of Article 8 on work involving non-human primates? Are there any further issues we should consider when transposing these provisions relating to the use of non-human primates?	Article 8(1) stipulates that non-human primates shall not be used in procedures except where (a) the procedure has one of the purposes referred to in (i) points (b)(i)[2] or (c)[3] 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)[4] or (e)[5] of Article 5. In all cases there must be a scientific justification that the purpose of the procedure cannot be achieved by the use of species other than non-human primates. Under ASPA 5(6), primates (along with dogs, cats and horses) may only be used where no other species is suitable or it is not practicable to obtain other suitable animals.	Most respondents, across all sectors, agreed that currently authorised work will still be permitted within the provisions of Article 8. Many respondents across the animal protection, animal welfare and practitioner sectors argued that the use of non-human primates should be subject to greater controls than provided for in Article 8 alone. However, Article 2 prohibits this. The animal protection and animal welfare sectors also argued for a definition of '*debilitating or potentially life-threatening clinical condition'* in legislation.	We propose to transpose the provisions of Article 8 as they stand. We believe that it would be unwise for the UK to adopt a definition of '*debilitating or potentially life-threatening clinical condition'* unilaterally. However, a Europe-wide definition may provide useful clarity. There has already been discussion of this issue in Brussels and we will press the Commission to bring forward a draft definition for consideration by all Member States.	Cost neutral 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.

[2] (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

[3] (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

[4] (a) basic research

[5] (e) research aimed at preservation of the species

Article	Issue	Consultation response	Government response	Estimated impact
8. Non-human primates Restrictions on the use of endangered species of non-human primates. Question 9: Are there any further issues we should consider when transposing the provisions relating to the use of endangered species of non-human primate?	Under article 8(2), further restrictions apply to the use of 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). 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.	All sectors favoured robust protection for endangered species of non-human primate, with a minority requesting that additional scrutiny be given to any proposals to use such species, for example, by the National Committee (see Article 49).	We propose to transpose the provisions of Article 8 as they stand.	Cost neutral 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.

Article	Issue	Consultation response	Government response	Estimated impact
8. Non-human primates Restrictions on the use of great apes. Question 10: Do you agree that the UK should continue to operate a policy ban on the use of great apes? Are there any further issues we should consider relating to the use of great apes?	Article 8(3) 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 to the Directive. The UK currently operates a policy ban on the use of great apes.	There is widespread support for the retention of the UK policy ban on the use of great apes. A minority opposed retaining the ban. Some animal protection and welfare respondents proposed confirming the ban in the transposing legislation.	We propose to transpose Article 8(3) as it stands to place the prohibition on the use of great apes on to the face of the legislation.	Cost neutral. We assume that there will be no costs or savings if UK legislation is aligned with the revised EU requirement. The only significant change envisaged under Article 8(3) is a potential relaxation allowing the use of great apes under exceptional circumstances. There are, however, no suitable approved facilities for such work in the UK, and no requests to use great apes have been received under ASPA. We cannot currently envisage any circumstances in a particular case in which it would be appropriate to relax that ban and invoke the safeguard clause at Article 55. As explained under Article 55, below, use of the safeguard clause would require secondary legislation and Parliamentary approval providing a high test to satisfy.

Article	Issue	Consultation response	Government response	Estimated impact
9. Animals taken from the wild Prohibition of the use of animals taken from the wild. Question 11: Are there any issues we should consider relating to the prohibition of 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?	Article 9(1) prohibits the use of animals taken from the wild. However, under Article 9(2), 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 procedures. Article 9 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 source.	Animal protection and welfare groups supported stricter measures prohibiting the use of wild animals and several welcomed the stricter measures outlined in Article 9. Some users pointed out that Article 9 may preclude the current use of wild-caught species that are not routinely bred for scientific procedures, such as starlings. Bioscience and welfare sectors raised concerns that the breeding of "wild" animals could increase which could have a negative welfare impact, and increase costs. Several users were concerned that adoption of Article 9 could lead to increased bureaucratic burden when seeking exemptions.	We are minded to implement the provisions of Article 9 by taking a similar approach to that applied currently. This would entail using a project licence condition to prohibit the use of animals taken from the wild except where justified.	These provisions are consistent with current UK legislation, policy and practice. Cost neutral.
9. Animals taken from the wild New requirements relating to trapping and capture. Question 12: What criteria should be applied to ensure the competence of persons capturing animals in the wild?	Article 9(3) 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.	A wide range of criteria and suggested approaches were proposed by respondents to ensure the competence of persons capturing animals from the wild.	We will give further consideration to the suggestions received and will consult further to develop an effective approach to ensuring competence.	We will seek ways to ensure competence without the need for regulation wherever possible, for example, through relevant practitioner organisations. Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
10. Animals bred for use in procedures Question 13: Are our assumptions regarding the impact of Article 10 correct? Is there a case for retaining the current UK requirement that common quail and ferrets should be purpose bred, as permitted by Article 2?	Article 10(1) limits the use of animals belonging to the species listed in Annex I[6] to those which have been bred for use in procedures. ASPA 10(3)(b) places a similar limitation on the use of the species listed in ASPA Schedule 2. Article 10(3) allows competent authorities to grant exemptions from this requirement on the basis of scientific justification.	No specific responses. See Annex I, below.	We propose to transpose Articles 10(1) and 10(3) as they stand.	Cost neutral. See also Annex I, below.
10. Animals bred for use in procedures Opening up the supply of laboratory animals to European sources. Question 13A: What impact will opening up the supply of laboratory animals to European sources have on UK breeders, suppliers and users? Will it have any animal welfare impact?	Provided they comply with the relevant requirements of the Directive, the ability to supply laboratory animals to the UK will be open to breeders and suppliers across the European Union. Under Article 2, Member States may not use stricter national measures to inhibit the free market by prohibiting or impeding the supply of animals from another Member State applying the standards set out in the Directive.	Bioscience sector groups opposed the imposition of additional controls on UK breeders compared with other EU breeders on the grounds that it may result in breeders further consolidating their breeding centres in continental Europe. Such consolidation would lead to longer transport times for animals, impact on welfare and make supply more vulnerable to disruption. There was also concern that poorer welfare standards may apply in overseas establishments.	No legislative action required.	Some establishments suggested that opening up the supply of laboratory animals would have little impact because most animals are sourced locally to reduce cost and this would be likely to continue. As noted by some respondents, sourcing from other Member States would lead to longer transport times for animals, impact on welfare and make supply more vulnerable to disruption.

[6] 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*)

Article	Issue	Consultation response	Government response	Estimated impact
10. Animals bred for use in procedures Non-human primates (capture from the wild) Question 14: What impact will these requirements have on UK breeders, suppliers and users? What impact, if any, is there likely to be on animal welfare?	Annex II specifies the dates[7] 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-human primates only from self-sustaining colonies[8].	Most respondents recognised the animal welfare benefit of ending capture from the wild. A few respondents from the animal welfare, practitioner and bioscience user sectors identified potentially negative welfare impacts, such as the likely production of excess male animals in breeding colonies. Respondents currently using UK-bred primates felt that the requirements would have little or no impact on their use of animals. Others from the animal welfare and bioscience sectors recognised that demand within the UK and Europe for F2+ animals and animals from self-sustaining colonies could outstrip supply and argued that the F2 feasibility study should take account of this. The animal protection sector mostly felt that the UK should comply with Article 10 ahead of the dates set by the F2 feasibility study.	We support the need for a feasibility study to confirm the dates for the mandatory requirement for F2+ primates. We believe the study should be carried out as soon as practicable. 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.	F2+ non-human primates are already the preferred animal in the UK. As the UK already effectively complies with these new provisions, and it is assumed that the lead times to be confirmed by the proposed feasibility study will ensure a sustainable supply of suitable animals at prices similar to those currently paid by UK users, this requirement iis assumed to be cost-neutral.

[7] 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.

[8] 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.

Article	Issue	Consultation response	Government response	Estimated impact
11. Stray and feral animals of domestic species Question 15: Is there a case on animal welfare grounds for retaining the current UK prohibition on the use of stray and feral animals, as permitted by Article 2?	Article 11 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.	Animal protection and welfare groups unanimously supported retention of the UK prohibition as permitted by Article 2. Many user establishments also expressed this view. There was limited support from the bioscience user sector for transposing Article 11 unchanged.	The requirements of Article 11 are broadly consistent with current UK legislation, policy and practice. We, therefore, propose to transpose Article 11 unchanged.	Cost neutral.
12. Procedures Question 18: Are there any further issues we should consider in relation to the provisions on procedures set out in Article 12?	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. ASPA sections 3 and 6 make similar provision.	There was broad agreement from all sectors that there were no further issues regarding Article 12.	We will transpose Article 12 unchanged.	These provisions are consistent with current UK legislation, policy and practice. Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
13. Choice of methods Question 26: The requirements of Article 13 are generally consistent with current UK requirements. We propose to transpose the provisions of Article 13 as they stand. 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?	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. Article 13 does not allow exemption for scientific justification and consequently is more stringent than ASPA. It would also appear to prohibit some testing done currently in the UK at the request of third country regulators.	There was broad agreement that our analysis of the impact of Article 13 is correct. Animal protection and animal welfare sector respondents welcomed the more stringent provisions of Article 13. A significant number of respondents across all sectors felt that the intention of Article 13 in relation to Article 4 and with regard to work other than regulatory tests was ambiguous and called for clarification in UK legislation. The pharmaceutical sector and contract research organisations suggested that regulators should increase efforts to promote international harmonisation of the acceptance of alternative methods.	We will transpose the provisions of Article 13 unchanged, along with the provisions of Article 4. Where necessary, we will provide guidance on Articles 4 and 13.	The pharmaceutical sector and contract research organisations expressed concern that the restrictions of Article 13 will impact on the conduct in the UK of some testing methods sought by third country regulators, with adverse animal welfare and economic consequences. However, no specific examples were cited. The requirements of Article 13 are mandatory.

Article	Issue	Consultation response	Government response	Estimated impact
13. Choice of methods Question 27: We propose to transpose the provisions of Article 13 as they stand. Are there any further issues we should consider relating to the use of death as an endpoint?	Article 13(3) 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. However, 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.	Animal protection groups considered that death as an endpoint should not be allowed or should at least be avoided whenever possible, and therefore had concerns about transposition of Article 13(3) unchanged. The majority of bioscience sector groups supported transposition of Article 13(3) unchanged and many were of the view that the Article was consistent with current practice under ASPA.	We propose to transpose Article 13(3) as it stands. We will provide guidance to clarify how early end points should be implemented to avoid death as an endpoint.	Cost neutral. This requirement is consistent with current UK practice.

Article	Issue	Consultation response	Government response	Estimated impact
14. Anaesthesia Question 19: We propose to transpose the provisions relating to the use of anaesthesia as they stand. Are there any further issues we should consider relating to the use of anaesthesia?	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. ASPA Schedule 2A requires that all experiments are carried out under general or local anaesthesia. Unless anaesthesia is judged to be more traumatic to the animal than the experiment itself or if anaesthesia is incompatible with the object of the experiment. In such cases appropriate legislative and/or administrative measures are to be taken to ensure that no such experiment is carried out unnecessarily	Animal protection and welfare groups broadly agreed with transposition of Article 14 as it stands, but requested guidance. Some believed it could lower UK standards because the need for anaesthesia and analgesia is subject to a test of whether or not it is appropriate. Bioscience sector groups supported copy out of these sections unchanged. However, guidance was requested on Article 14(2)(b).	We will transpose the provisions of Article 14 relating to anaesthesia as they stand. We will provide guidance on Article 14(2)(b).	Cost neutral These provisions are consistent with current UK legislation, policy and practice.

Article	Issue	Consultation response	Government response	Estimated impact
14. Anaesthesia Neuromuscular blocking agents (NMBAs) Question 20: Should current UK provisions relating to the use of neuromuscular blocking agents in mammals be retained? Should we continue to apply the same provisions to other animals?	Article 14(3) requires that appropriate anaesthesia or analgesia is used in conjunction with neuromuscular blocking agents (NMBAs). Article 14(3) also requires that scientific justification is provided for the use of NMBAs in a particular case along with details of the anaesthetic or analgesic regimen. ASPA 17 prohibits the use of NMBAs unless expressly authorised by the personal and project licences under which the procedure is carried out. ASPA 17 further prohibits the use of an NMBA instead of an anaesthetic. Current Home Office guidelines on the use of neuromuscular blocking agents are set out in Appendix K to the published statutory Guidance on the Operation of the Animals (Scientific Procedures) Act 1986.	There was almost unanimous support across all sectors for retention of the current UK provisions relating to the use of neuromuscular blocking agents in mammals, with the majority of respondents citing the need for mandatory anaesthesia. While the majority of responses supported the same provisions being applied to other animals, several substantive responses from the practitioner and bioscience user communities offered qualified support for exempting certain immature forms if distress would not be caused.	We have noted the concerns expressed in the consultation responses. However, we believe sufficient safeguards are provided by the requirement for the use of appropriate anaesthesia or analgesia and scientific justification which will be assessed as part of the relevant project evaluation. We are, therefore, minded to transpose the requirements of Article 14(3) as they stand.	Save for the derogation with respect to the option to use analgesics rather than anaesthetics in conjunction with neuromuscular blocking agents, the revised directive is consistent with current UK policy and practice. That derogation (effectively a minor technical procedural change), if exercised, would be cost-neutral.

Article	Issue	Consultation response	Government response	Estimated impact
15. Classification of severity of procedures Question 31: Are there any areas in which the Annex VIII severity classification is unclear? Are there any additional examples of severity that might be included in guidance on the application of the proposed severity classification system? [See also questions relating to Article 55 below.]	Article 15 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 is similar to the current UK position that 'procedures likely to cause severe pain or distress that cannot be alleviated' will not be licensed. However, under the Directive, this prohibition may be overridden using the safeguard clause at Article 55.	Most respondents in all sectors agreed that there was scope for both clarification and inclusion of additional examples, particularly to define the upper limit of acceptable severity. Some specific examples were given of the types of models and procedures to include. Several animal protection sector respondents want to include a list of procedures that would be prohibited and that cannot be authorised by invoking the safeguard clause (Article 55).	We will transpose Article 15 as it stands. We will produce guidance on the implementation of the severity classification including a definition of terms. We will consult further on developing the examples in Section III of Annex VIII of the Directive for inclusion in guidance. We believe preparation of a list of prohibited procedures would not be desirable as it would move focus to the worst cases which we believe would never be authorised. As explained under Article 55, below, use of the safeguard clause would require secondary legislation and Parliamentary approval. We cannot envisage circumstances in which this would be necessary or justified.	The proposed severity classification system is, for practical purposes, equivalent to current UK arrangements. Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
16. Reuse Question 21: We propose to transpose the provisions of Article 16 relating to re-use as they stand. Are there any further issues relating to re-use we should consider?	Article 16 sets out the circumstances in which animals may be re-used. Re-use is generally only allowed after use in 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. The decision making framework differs from that currently set out in ASPA. However, we believe that in practice it will not prove significantly different in terms of outcomes.	Most in bioscience sector groups and practitioners supported transposition of Article 16 unchanged but some were concerned about the derogation in Article 16(2) allowing re-use after a 'severe' procedure and considered that animals subjected to a severe procedure should not be re-used. Others pointed out rare occasions where re-use of animals that had previously experienced severe procedures could lead to fewer animals undergoing severe procedures overall. Animal protection and welfare groups and their supporters were almost unanimously against transposition unchanged because they viewed it as a weakening of current UK standards. Many expressed the view that re-use should never be allowed.	We will transpose the provisions of Article 16 as it stands but intend to retain our existing requirement for all re-use to be authorised within the project licence. This will ensure that all proposed re-use is considered during project authorisation. We will produce guidance on re-use.	Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
17. End of procedures Question 22: Should we retain current stricter UK requirements relating to the welfare of animals at the end of a regulated procedure? What issues may arise if animals suffering mild effects are released?	The Directive specifies that an animal must be killed at the end of a procedure when it is likely to continue to experience moderate or severe pain, suffering, distress or lasting harm. Under ASPA 15, animals must be humanely killed when, at the end of the series of regulated procedures, they are suffering or are likely to suffer [any] adverse effects as a result of the procedures applied. In addition, 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, and an animal may only be set free or re-homed under certain conditions. Under ASPA 10(6D), any animal kept alive at the end of a procedure 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 Secretary of State 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 Secretary of State for the release of the animal to the wild or for its discharge from the controls of ASPA.	Animal protection and welfare groups unanimously supported retaining stricter UK standards as did the majority of respondents from other sectors.	We propose to retain the current stricter UK provisions that permit an animal to be kept alive at the conclusion of a series of regulated procedures only if it is not suffering or likely to suffer adverse effects.	Cost neutral or minimal. As only a small number of animals will be affected, we do not envisage that retaining current stricter UK provisions will create a significant burden. We believe the potential welfare gain from retaining them outweighs this impact.

Article	Issue	Consultation response	Government response	Estimated impact
18. Sharing of organs and tissues Question 23: How should we facilitate the sharing of organs and tissues? Are there any further issues relating to the sharing of organs and tissues we should consider?	Article 18 requires that Member States facilitate the establishment of programmes for the sharing of organs and tissues of animals. Promoting the sharing of organs and tissues, where it is known to reduce welfare costs without significantly increasing the regulatory burden, is existing UK good practice.	A number of suggestions were received regarding implementation.	We will give further consideration to the suggestions and issues identified in the consultation responses when preparing for implementation.	Cost-neutral.
19. Setting free of animals and re-homing Question 36: We propose to transpose the provisions of Article 19 as they stand. Are there any further issues relating to the setting free and re-homing of animals we should consider?	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. Under ASPA, consent must also be obtained for the release of an animal to the wild or for its discharge from ASPA controls.	The majority of respondents supported transposing Article 19 as it stands, but many suggested adding a requirement for veterinary input prior to the setting free of animals, as currently required. Concern was expressed regarding re-homing of transgenic animals.	We will transpose the provisions of Article 19 as they stand. We will retain the current policy requirement for a veterinary surgeon or other suitably qualified person to provide assurance that animals are fit to be discharged from the controls of the legislation.	These provisions are consistent with current UK requirements and practice. Cost-neutral.

Article	Issue	Consultation response	Government response	Estimated impact
20. Authorisation of breeders, suppliers and users Question 32: Are the changes to the requirements for authorisation of breeders, suppliers and users and the need to notify changes likely to raise any problems? Are there any further issues we should consider in relation to the requirements set out in Article 20?	Article 20(1) 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. Article 20(2) stipulates that the authorisation must specify the person responsible for compliance and the persons referred to in Articles 24(1)[9] and 25[10]. Article 20(4) requires the notification of any changes to the persons referred to in Article 20(2) to the competent authority. 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 as a breeder, supplier or user establishment, or a combination of these.	Several requests were made to maintain named people in the same roles as at present and a similar certificate with a schedule of premises. Some users expressed concern regarding our interpretation of corporate responsibility, which may be an issue for organisations that have multiple certificates.	We will transpose Articles 20(1), 20(2) and 20(4) as they stand. This will entail replacing current certificates of designation authorising places at which regulated procedures, breeding and/or supplying of protected animals may be carried out with licences authorising a legal or natural person (which we interpret as corporate entities) to undertake the activities of using, breeding and/or supplying protected animals.	We estimate that replacing certificates of designation with licences on the revised basis will entail costs for the competent authority and designated establishments. Assuming 2 hours of preparation time by administrative staff at designated establlishments, at a rate of £30 per hour, and 2 hours processing by the competent authority, at an Inspector grade rate of £60 per hour, we estmatethe cost of replacing certific ates for 180 designated establishments to be approxiamtely £30k.

[9] Persons responsible for the care and welfare of animals and for training and supervision of staff
[10] Designated veterinarian

Article	Issue	Consultation response	Government response	Estimated impact
20. Authorisation of breeders, suppliers and users Renewal of authorisation	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.	Animal protection and welfare groups favour retention of the current requirements for prospective approval of changes to the schedule of premises (or equivalent) in certificates of designation. The biosciences sector would prefer a streamlined approach as described in the Directive, which allows some changes locally without prospective approval. An emphasis on welfare rather than on regulation is welcomed by some in bioscience sector groups. But, there is concern in the animal protection sector that a more relaxed system could reduce standards and cause problems with implementation.	We propose to retain existing requirements for the prior approval of specified areas within each establishment and for the specification of the types of animal that may be kept at each establishment. However, we propose to permit change of use of approved areas without prospective approval provided that the variation will not have any adverse consequences for animal welfare. We will provide guidance on the practical operation of these measures.	Cost neutral.
21. Suspension and withdrawal of authorisation Question 33: We propose to transpose the provisions of Article 21 as they stand. Are there any further issues we should consider relating to the suspension and withdrawal of authorisations?	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 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 13 provides for licences and certificates to be suspended where it is urgently necessary for the welfare of protected animals.	The majority of respondents supported transposing Article 21 unchanged. Several respondents suggested that we also retain the time frames and processes as outlined in sections 11 and 13 of ASPA. A request was made for clarification of the level of non-compliance that would result in withdrawal or suspension of an authorisation.	We propose to transpose the provisions of Article 21 as they stand. We will provide guidance on the reporting of non-compliance, the actions that may be taken by the Secretary of State, including suspension and withdrawal of authorisations, and the right to make representations.	These provisions are broadly consistent with current UK requirements and practice. Cost-neutral.

Article	Issue	Consultation response	Government response	Estimated impact
22. Requirement for installations and equipment Question 34: Are there any further issues we should consider in relation to the requirements for installations and equipment set out in Article 22?	Under Article 22, 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 in them.	Very few respondents raised issues in relation to Article 22 and most agreed that it should be transposed unchanged.	We propose to transpose the provisions of Article 22 as they stand.	These provisions are consistent with current UK requirements and practice. Cost-neutral.

Article	Issue	Consultation response	Government response	Estimated impact
23. Competence of personnel Question 41: Should the UK (a) retain its current system of personal licensing using Article 2, as necessary; or (b) adopt a simplified version of that system with greater local accountability? What might be the features of a system involving greater local accountability? What risks might be associated with such a system and how might these be mitigated? What will be the cost to individual breeders, suppliers and users of implementing such a system?	Under Article 23(1), 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. Member States can choose to ensure that the requirements of Article 23(1) relating to the competence of personnel are met either through a system of authorisation (such as the UK personal licensing system) 'or by other means'. Under ASPA, 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.	There was a clear majority across all sectors for the retention of some form of personal licensing system. The animal protection sector mostly sought retention of the current system, while the majority of the biosciences sector favoured a simplified personal licence specifying types of animal, but not individual techniques. There was no appetite for a local registration system.	We propose to retain the current requirement for personal licences. We will explore the opportunities to simplify the detail of personal licence authorities. We will seek to remove current requirements which increase regulation without adding to the effectiveness of the licensing process. We will ensure any changes avoid detrimental impacts on levels of compliance or animal welfare.	Retention of the current personal licensing system is assumed to be cost neutral. However, we expect cost savings to be achievable for both applicants and the competent authority through further refinement of the application process, simplification of personal licences and adoption of an e-licensing system. We will ensure there is no impact on animal welfare.

Article	Issue	Consultation response	Government response	Estimated impact
23. Competence of personnel Question 42: What specific features would you like to see in a UK or European training system? What elements of current UK training could be omitted whilst still complying with Annex V? How should the quality of individual training and supervision be assured so that new employers are confident about training and competence and to facilitate the transfer of individuals within the UK 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 23(2) 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.	The majority of respondents wanted training similar to that required under ASPA, but with modifications as proposed by the Animal Procedures Committee[11].	We will consider further and consult with other Member States to seek a consistent approach which promotes transferability of personnel. The aim will be for a flexible approach which ensures individuals are competent through training and supervision and promotes continued learning. The individual(s) named in Article 24(1)(c) will play a key role. Current modular training will continue to be acceptable until new provisions are implemented.	We will assess the costs when details of the training requirements have been agreed. We will aim to minimise costs.

[11] Module 5 and the training of project licence holders: December 2010.

Article	Issue	Consultation response	Government response	Estimated impact
24. Specific requirements for personnel Question 43: Are there any further issues we need to consider regarding the requirements for personnel?	Article 24 requires that each breeder, supplier and user has one or more persons on site responsible for a) overseeing the welfare and care of the animals in the establishment; b) ensuring that the staff dealing with animals have access to information specific to the species housed in the establishment; and c) ensuring that the staff are adequately educated, competent and continuously trained and supervised until they have demonstrated the required competence. Under ASPA, similar roles are fulfilled by Named Animal Care & Welfare Officers, Ethical Review Processes, Certificate Holders and Project Licence Holders.	Respondents noted that the roles of the persons specified in Article 24 could be fulfilled by the Named Animal Care & Welfare Officer, Ethical Review Process, Certificate Holder and Project Licence Holder, respectively. There was support among respondents from the animal welfare and alternatives, practitioner and bioscience user sectors for the certificate holder to be the person responsible for ensuring that staff are educated, trained and supervised until competent, with delegation of the day to day work involved. There were a significant number of responses suggesting that project licence holders should retain responsibility for persons working on their project. Many respondents highlighted the need to define clearly the roles, functions, responsibilities and accountabilities of the specified persons.	We will transpose Article 24 as it stands. We will provide guidance on key roles and individual responsibilities. We propose to include all of the provisions of Article 24(1) within the defined responsibilities of the person holding the breeder, supplier or user authorisation (the certificate holder equivalent). We will incorporate the requirements of Article 24(2) into the defined responsibilities of the project licence holder.	The requirements of Article 24 are broader than current UK provisions. We assume functions (a) and (b) are already discharged at establishments and represent business as usual costs. We further assume that function (c) is also carried out, but that additional resource may be required to fully meet the requirement in some establishments.

Article	Issue	Consultation response	Government response	Estimated impact
25. Designated veterinarian Question 44: Are there any further issues we need to consider regarding the requirement for a designated veterinarian or other suitably qualified person?	The 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. Similar provision is made in ASPA.	There was widespread concern that the role of the designated veterinarian should not be diminished by comparison with that of the Named Veterinary Surgeon under ASPA. In particular, there was widespread support for the designated veterinarian to be a full member of the Animal Welfare Body, and for personnel within an establishment to be required to seek, and act upon, veterinary advice.	We will transpose Article 25 as it stands. We will provide guidance on the designated veterinarian's responsibilities, training requirements, and issues around potential conflicts of interest.	Cost neutral. 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 ASPA

Article	Issue	Consultation response	Government response	Estimated impact
26. Animal Welfare Body Question 52: Is there a case for animal welfare bodies to have more extensive membership and functions than the minimum requirement set out in Articles 26 and 27? If so, what additional members and functions should be required or recommended in guidance? Might animal welfare bodies play a role in advising on training and competence? How might 'small' establishments be defined and how might they meet the requirements for animal welfare bodies 'by other means'?	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. Through the standard conditions of certificates of designation[12], the UK currently requires designated establishments to have an ethical review process (ERP) with a wider membership than specified for AWBs.	There is widespread support from all sectors for animal welfare bodies to have a broader membership than that set out in the article 26 possibly maintaining a similar membership to the current Ethical Review Process and similar functions.	We propose to transpose Articles 26 as it stands. We will seek to align the new legislation and guidance as closely as the Directive allows to current arrangements for Ethical Review Processes, including membership and functions. We propose to retain the description 'ethical review process'. We will prepare guidance to ensure duplication of work between animal welfare bodies and the competent authority is avoided.	The requirements for local Animal Welfare Bodies are less stringent than those relating to the operation of local ethical review processes in the UK. Fewer persons are involved (in theory in some places a minimum of two might suffice) and there are fewer functions (for example no involvement is required in the pre-authorisation phase of project authorisation). Although there appear to be potential savings to establishments if the minimum EU specification is implemented, in practice we believe that most establishments will model their Animal Welfare Bodies on their current ethical review processes retaining additional features not required by the Directive where this is likely to be beneficial. We consider that any associated additional resource needs should be treated as business as usual.

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

Article	Issue	Consultation response	Government response	Estimated impact
27. Tasks of the Animal Welfare Body Question 52: Is there a case for animal welfare bodies to have more extensive membership and functions than the minimum requirement set out in Articles 26 and 27? If so, what additional members and functions should be required or recommended in guidance? Might animal welfare bodies play a role in advising on training and competence? How might 'small' establishments be defined and how might they meet the requirements for animal welfare bodies 'by other means'?	Article 27 sets out the tasks of the Animal Welfare Body. The tasks of the ERP[13] are broadly similar to those defined for the AWB. ERPs are currently required to review project applications before they are submitted. This is not a role of the animal welfare body.	There is widespread support from all sectors for animal welfare bodies to have a more extensive role than that set out in the article 26 - possibly maintaining similar functions to the current Ethical Review Process.	We will transpose Article 27 as it stands. (See also Article 26, above).	See Article 26.
28. Breeding strategy for non-human primates Question 35: Are our assumptions relating to Article 28 correct? Are there any further issues we should consider in relation to the requirements for a breeding strategy for non-human primates set out in Article 28?	The Directive requires breeders of non-human primates to have a strategy for increasing the supply of F2 animals.	There was general agreement that UK breeding establishments only supply F2 animals. Some bioscience users supported the requirement for a breeding strategy even though UK-based breeding establishments already supply only F2 animals.	We will transpose Article 28 as it stands	Cost neutral. We believe UK-based establishments already supply only F2 animals.

[13] Annex J, Home Office Guidance (HC321)

Article	Issue	Consultation response	Government response	Estimated impact
29. Scheme for re-homing or setting free of animals Question 37: We propose to transpose the provisions of Articles 19 and 29 as they stand. Are there any further issues we should consider relating to these issues?	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.	There was widespread support for Article 29 to be transposed unchanged. A request was made for guidance regarding re-homing schemes and reference was made to the LASA guidelines for the re-homing of laboratory dogs.	We will transpose Article 29 as it stands. We will provide guidance on re-homing.	These provisions are generally consistent with the current UK requirements and practice. However, the requirement for socialisation is new and may require more resource input at establishments and further staff training. Some increase in inspection time may also be required. We believe these costs are unlikely to be significant .
30. Animal records Question 38: We propose to transpose the provisions of Article 30, 31 and 32 as they stand. Are there any further issues we should consider relating to these Articles?	Article 30 sets out the records to be kept by establishments on animals. These are the number and species of animals bred, acquired, supplied, re-homed; humanely killed or that have died; the dates on which animals were acquired, supplied, released or re-homed; and the name and address of the supplying establishment, or recipient, and date of arrival. These records are to be kept for three years and submitted to the competent authority on request.	The majority of respondents agreed that Article 30 should be transposed as it stands. Guidance was requested on the time point from which records should be kept; current good practice in terms of marking; and the meaning of 'identification mark'. It was also noted that animals imported from outside the EU are not required by the Directive to have an accompanying history file and suggested that approval for the use of such animals should be conditional on there being accompanying historical records.	We will transpose Articles 30 as it stands. We will include information on animal records and the marking and identification of animals in guidance.	These requirements are consistent with current UK requirements and good practice. Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
31. Information on dogs, cats and non-human primates Question 38: We propose to transpose the provisions of Article 30, 31 and 32 as they stand. Are there any further issues we should consider relating to these Articles?	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.	The majority of respondents agreed that Articles 31 should be transposed unchanged.	We will transpose Article 31as it stands.	These requirements are consistent with current UK requirements and good practice. Cost neutral.
32. Marking and identification of dogs, cats and non-human primates Question 38: We propose to transpose the provisions of Article 30, 31 and 32 as they stand. Are there any further issues we should consider relating to these Articles?	Article 32 requires that dogs, cats and non-human primates are given an individual identification mark, before weaning, in the least painful manner possible. Unmarked animals taken into establishments must be marked as soon as possible after first receipt. If a dog, cat or non-human primate is moved to another establishment before weaning, and it is not practical to mark it beforehand, a full documentary record must be maintained by the receiving establishment until it is marked. If asked, establishments must explain to the competent authority why an animal is unmarked.	The majority of respondents agreed that Articles 32 should be transposed unchanged.	We will transpose Article 32 as it stands.	These requirements are consistent with current UK requirements and good practice. Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
33. Care and accommodation Question 39: We propose to transpose the provisions of Article 33 as they stand. Are there any further issues we should consider relating to the issues covered by Article 33? Question 40: Are there any specific issues we should consider when preparing guidance and codes of practice on accommodation and care?	Article 33(1) sets out the requirements for the care and accommodation of animals kept in establishments. Similar requirements are set out in ASPA 10(6B). 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.	Several animal protection and animal welfare sector respondents expressed concerns about Article 33(3), which allows exemptions from the requirements in 33(1)(a) or 33(2) to provide animals with care and accommodation appropriate to their health and well being. Several respondents also suggested that examples should be provided of the exemptions envisaged under Article 33(3). Practitioners and bioscience sector groups mostly supported transposition of Article 33 unchanged, but a significant number of respondents across all sectors argued for the retention of all of the provisions in ASPA Section 10(6B). The need to clarify the term “under appropriate conditions” in Article 33(1)(e) was also highlighted.	We propose to transpose the provisions of Article 33 as they stand by combining all of the current requirements of ASPA Section 10(6B) and the additional requirement of Article 33(1)(e).	Cost neutral. NB The impact of implementing mandatory care and accommodation standards is discussed separately at Annex III below.

Article	Issue	Consultation response	Government response	Estimated impact
34. Inspections by Member States Question 54: What system of inspection would best meet UK needs? What impact would adoption of a detailed and more formal, but less frequent audit-style approach to inspection have on (a) establishments; (b) public confidence? What aspects of the current UK inspection system should be retained? How might it be improved?	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, Article 34 further 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. The UK currently operates a system of risk-based inspection visits in which the local inspector maintains a cooperative working relationship with licensees and named persons and provides advice to maintain standards, promote the 3Rs and ensure non-compliance is avoided.	There is almost universal support from all sectors for retention of the current UK system of inspection.	We will transpose Article 34 as it stands. We are committed to maintaining a strong and properly resourced inspectorate and a full, risk-based programme of inspections. The relationship between inspectors, licence holders and animal care staff is crucial to the effective implementation of the regulatory framework and we will not jeopardise that relationship.	Cost neutral.
35. Controls of Member State inspections	Article 35 enables the Commission to review the infrastructure and operation of national inspections by Member States when there is a reason for concern and requires Member States to give all necessary assistance to the Commission and to take account of the results.	No question.	No issues	This is a responsibility placed on the Commission. It is unlikely to require additional national resource. Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
36. Project authorisation Question 45: We propose to transpose the provisions of Article 36, 37 and 38 as they stand. Are there any further issues we should consider relating to project authorisation and evaluation?	Under Article 36, 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. ASPA 3 and 5 set out similar requirements.	No significant issues were raised in respect of Article 36.	We propose to transpose the provisions of Article 36 as they stand.	These requirements are consistent with current UK requirements and good practice. Cost neutral.
37. Application for project authorisation Question 45: We propose to transpose the provisions of Article 36, 37 and 38 as they stand. Are there any further issues we should consider relating to project authorisation and evaluation?	Under Article 37, 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 (see separate entry, below).	No significant issues were raised in respect of Article 37.	We propose to transpose the provisions of Article 37 as they stand.	These requirements are consistent with current UK requirements and good practice. We envisage that the level of detail required in applications will be proportionate and reflect the nature of the proposed project. It is likely in most cases to be similar to the level of detail currently required under ASPA. Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
38. Project evaluation Question 45: We propose to transpose the provisions of Article 36, 37 and 38 as they stand. 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 38(1) 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. Article 38(2) stipulates that the project evaluation must include an assessment of the severity of procedures and a harm-benefit analysis of the project and consider any derogations sought under Articles 6 to12, 14, 15, 16, and 33. Article 38(3) requires that 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. Under ASPA 18, Home Office inspectors advise the Secretary of State on applications for personal and project licences, on requests for their variation or revocation and on their periodic review.	Various suggestions were made regarding referral of applications to the national committee and external experts. Many were similar to the criteria currently used for referral of applications to the Animal Procedures Committee. No other issues were identified.	We propose to transpose the provisions of Article 38(1), 38(2) and 38(3) as they stand. We propose that project evaluations should continue to be performed by Home Office inspectors as is currently the case under ASPA 18(2)(a). We will give further consideration to the criteria for referral of applications for further advice.	These requirements are consistent with current UK requirements and good practice. We assume they will not require any significant changes to the current UK system in which the Secretary of State has access to relevant expertise through the Animals Scientific Procedures Inspectorate, the Animal Procedures Committee, and independent experts. Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
38. Project evaluation Question 45: We propose to transpose the provisions of Article 36, 37 and 38 as they stand. What type of information should be placed in the public domain about the project evaluation process to ensure transparency of the process?	Article 38(4) stipulates that the project evaluation process shall be transparent.	On transparency, animal protection and welfare groups suggested individual project evaluations should be published along with non-technical summaries (see Article 43). Bioscience sector groups suggested publication of more general information about how project evaluations are carried out.	We will ensure an appropriate level of transparency in the project evaluation process and publish our proposals to achieve this in due course.	Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
39. Retrospective assessment Question 46: Should we extend the requirement for retrospective assessment to some or all projects involving procedures classified as "mild" or "non-recovery"? What should be the process for retrospective review and should this involve the animal welfare body?	Article 39 creates a requirement for the retrospective assessment of projects using non-human primates, and projects involving procedures classified as "severe", and allows the option of requiring retrospective assessment of projects involving 'moderate' procedures to be decided on a case by case basis. Under Article 39(3), 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. There is currently no legislative requirement in the UK for projects to be retrospectively assessed. However, a form of retrospective assessment is currently undertaken by the Home Office inspectorate when projects are renewed on expiry as part 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.	Most respondents supported retrospective assessment for all projects regardless of severity, although the response from bioscience sector groups was more mixed compared to other sectors. There was a great deal of support for the Animal Welfare Body to play a role in retrospective assessment, but there was some concern that this would have implications for the impartiality of the reviewers, and some raised the importance of external reviewers.	We are minded to transpose the Article 39 as it stands, but to adopt a policy to extend mandatory retrospective assessment to all licences using cats, dogs and horses, as well as non-human primates, i.e. all specially protected species. We are also minded not apply a blanket exemption to all 'mild' or 'non-recovery' projects (as permitted under Directive). Instead, we propose to consider the need for retrospective assessment of all non-mandatory categories of project on a case by case basis as part of the project authorisation process. We believe it would be desirable for Animal Welfare Bodies to review projects when fulfilling their role under Article 27(1)(d). The input required should be proportionate to the project under review.	We estimate that 100 projects would require retrospective assessment each year (from Year 4 onwards) if the derogation in Article 39(3) is applied. We envisage that parent establishments would prepare and submit dossiers providing all relevant data to enable the competent authority to complete the assessment. Thie associated cost has been estimated by establishments at £1100 per project (Total for 100 projects: £110k). We further estimate each assessment would require 5 hours input by the competent authority (£30k for 100 projects, costed at £60 per hour[14]). Total annual cost £140k (£1400 per project).

[14] Calculated at Home Office Inspector (Civil Service Grade 6) rates. We assume work at establishments will be carried out by staff of similar seniority.

Article	Issue	Consultation response	Government response	Estimated impact
40. Granting of project authorisation	Under Article 40, 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.	No issues.	We will transpose Article 40 as it stands.	These requirements are consistent with current UK requirements and good practice. Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
40. Granting of project authorisation Question 47: Are there any other categories of project that should be covered by the provisions for multiple generic projects?	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. This provision is closely modelled on the current UK approach to authorisation of projects for regulatory toxicology testing.	Animal protection and welfare groups strongly opposed the concept of generic projects for any purpose. Several respondents from all sectors were against generic projects in work involving non-human primates. For establishments in favour of generic projects, reassurance was sought that the definition of toxicology project would include drug metabolism and pharmacokinetics (DMPK) studies and pharmaceutical safety studies. Other categories of project that individual respondents considered should be covered were regulatory batch release testing of biological materials, assessment of feedstuffs for animals, and non-surgical xenograft/allograft of neoplastic cells.	We propose to transpose Article 40(4) as it stands. Failure to transpose it would significantly increase the inspectorate resource required to authorise relevant work and would have a major adverse impact on the ability of UK contract research establishments to operate efficiently. We will provide a working definition of ‘multiple generic project’ in future guidance.	Implementation of Article 40(4) may provide opportunities for savings for both applicants and the competent authority. For the purposes of this impact assessment we assume it will be cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
41. Authorisation decisions Question 48: How should 'complex and multidisciplinary projects' be defined for the purposes of Article 41?	Article 41 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.	No specific comments received.	We will transpose Article 41 as it stands. We will give further consideration to how best to define 'complex and multi-disciplinary project' and provide advice in guidance. We have concerns that the 15 day extension allowed for the evaluation of such projects may be insufficient for the most complex applications.	We assume compliance with Article 41 can be achieved without additional resource. The current UK processing target is to deal with 85% of applications within 35 working days. This target is currently being met and exceeded, with a mean processing time of less than 20 days. Cost neutral.
42. Simplified administrative procedure Question 49: Should the UK adopt a simplified administrative procedure for relevant categories of project? What form should the simplified administrative procedure take?	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.	The majority of respondents across all sectors did not support the adoption of a simplified administrative procedure. A significant number of practitioners recognised no need for such an approach given the turnaround times currently achieved for project applications.	We are minded not to transpose Article 42. We already process project applications efficiently and do not see any advantage in adoption of this measure.	Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
43. Non-technical summaries Question 50: Should we waive the requirement for non-technical summaries for some projects involving only mild or moderate procedures? Or, should we continue to aim to publish non-technical summaries for all authorised projects? What details should be included in non-technical summaries?	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. 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. 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 (those classified as non-recovery, mild or moderate; not involving non-human primates; and falling into specified categories of work). In the UK, we currently publish about 400 abstracts per year (for over 80% of authorised projects) under a voluntary, non-statutory scheme.	Most respondents supported publication of non-technical summaries for all projects, including those classified as non-recovery, mild or moderate. Suggestions for content varied widely.	We will transpose Article 43 as it stands. We have no plans to make use of the derogation in article 37(2). We believe there will be significant benefits to transparency and public understanding to be gained from publishing non-technical summaries for all projects to ensure a balanced picture is provided about the full range of authorised work undertaken using animals.	Were non-technical summaries to be required for all projects - on a mandatory or voluntary basis – we estimate that 500 non-technical summaries will be published each year at a cost of £60k (split equally between establishments and the Home Office). This would comprise 1 hour preparation costs and 1 hour to process by the Competent Authority at £60 per hour. We assume the costs of updating non-technical summaries to include the outcome of retrospective assessments, where required, is subsumed in the costs set out at Article 39, above .

Article	Issue	Consultation response	Government response	Estimated impact
44. Amendment, renewal and withdrawal of a project authorisation Question 51: Are there any risks involved in limiting the requirement to amend or renew project authorisations to changes that may have a negative impact on animal welfare? If so, how might the risks be mitigated?	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.	Respondents across all sectors identified significant risks if changes are made to projects without reference to the competent authority from potential differences in interpretation of what might be a negative impact; changes affecting the harm/benefit assessment that may not be evaluated; non-compliance as a result of a lack of clarity about what is authorised; and loss of public confidence in the regulatory system. Retaining the current system in which all amendments require authorisation, as a means to eliminate the risks, was supported by the majority of the animal protection and general public respondents and approximately half of practitioners. The majority within the bioscience user and animal welfare and alternatives sectors supported submitting proposed amendments to the Animal Welfare Body, either for approval of those with no adverse welfare consequences or to confirm that submission to the Home Office is required.	We propose to transpose Article 44 as it stands and will publish detailed guidance on the amendment, renewal and withdrawal of a project authorisation when we have given further detailed consideration to the legal and practical requirements of project authorisation. We note the concerns expressed that public confidence may be harmed if changes are made to projects without reference to the competent authority.	Some savings may be achievable but are not readily quantifiable. These may be offset by a higher risk of non-compliance for the reasons identified in consultation responses. For the purposes of this impact assessment we assume that implementation of Article 44 will be cost neutral.
45. Documentation	Article 45 requires that all relevant documentation, including project authorisations and the opinion on the project evaluation, are kept for at least three years from the expiry date of the project or, where relevant, until any retrospective assessment has been completed.	No question.	We propose to transpose the provisions of Article 45 as they stand.	These requirements are consistent with current UK requirements and good practice. Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
46. Avoidance of duplication of procedures Question 28: We propose to transpose the provisions of Article 46 as they stand. Are there any further issues we should consider relating to avoidance of duplication of procedures?	Article 46 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.	There was significant support amongst animal welfare and protection groups for Article 46 to be transposed unchanged. There was also broad support for Article 46 from bioscience sector groups. Some respondents suggested the creation of a UK/EU database of experiments. Some practitioners expressed concern that part of good scientific practice is to repeat an experiment in their own laboratory to ensure repeatability before starting related work.	We propose to transpose the provisions of Article 46 as they stand.	This provision is assumed to be consistent with the existing Mutual Acceptance of Data agreements and current UK practice, and to be cost-neutral. Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
47. Alternative approaches Question 29: Are there any further issues we should consider in relation to the provisions for alternative approaches set out in Article 47?	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. 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.	Bioscience sector groups supported the approach laid out in Article 47. Animal protection and welfare groups suggested strategies to encourage alternative approaches. For example, using thematic reviews to identify targets for replacement. There was wide support for the NC3Rs to be a national focal point for promotion and dissemination of information, although animal protection and welfare groups requested more emphasis on replacement than reduction and refinement. An expansion of the role of the Animal Procedures Committee (National Committee) was also suggested as was the creation of a new database of alternatives which would be managed by the National Committee; inclusion of 3Rs principles in the National Curriculum; and the creation of 'Replacement Science'. Some respondents expressed concern as to how the provisions of Article 47 will be enacted.	We propose to transpose the provisions of Article 47(1), (2), (4) and (5) as they stand. Article 47(3) and (6) are matters for the Commission. We will give further consideration to the suggestions provided by respondents.	Cost neutral. Current UK arrangements provide most of what is required. It is not clear at this stage who will bear the cost of validation studies allocated to nominated laboratories.

Article	Issue	Consultation response	Government response	Estimated impact
48. Union Reference Laboratory Question 30: Are there any further issues we should consider in relation to the Union reference laboratory?	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	Few further issues were raised. Animal protection and welfare groups considered that more work is needed on replacement than reduction and refinement. They suggested that human and animal tissue banks could be incorporated into the Union Reference Laboratory which could promote the replacement of animal use. It was also suggested that an annual report on the work of the Union Reference Laboratory would be useful. Several respondents questioned the suitability of the European Centre for the Validation of Alternative Methods (ECVAM) for this role and suggested that it would require increased resources.	No legislative action required.	The Article and Annex impose obligations on the Commission and are cost neutral for the purposes of this impact assessment

Article	Issue	Consultation response	Government response	Estimated impact
49. National Committee for the protection of animals used for scientific purposes Question 53: Should the Animal Procedures Committee form the basis for the new National Committee? Are there any models other than the Animal Procedures Committee on which the new National Committee might be based? What membership and what range of expertise will the new National Committee require to enable it to meet the requirements set out in Article 49? How might this expertise be accessed?	Article 49 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.	Some respondents thought that the current Animal Procedures Committee should be expanded with a wider membership and remit. Others thought it should be disbanded and a new committee formed. There was also support for the NC3Rs to act as the national committee.	We will transpose Article 49 as it stands. We will give further consideration to the membership and range of expertise required by the National Committee taking account of the published Code of practice for Scientific Advisory Committees and advice commissioned from the Animal Procedures Committee. We will also take account of the recommendations of the Academy of Medical Sciences on the authorisation of projects involving animals containing human material (ACHM) when agreeing the functions of the Committee.	We assume that the requirements of Article 49 can be satisfied without adding to the resources currently provided to the Animal Procedures Committee. Cost neutral.
50. Adaptation of Annexes to technical progress Question 58: Are there any issues we should consider in relation to Article 50?	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.	There was a limited response to this question. Respondents requested development of a process by which the UK will contribute to this, and expressed the view that the UK should take a lead and not wait for the review of the Directive in 2017 (see Article 58), and that all stakeholders should be involved.	We will keep the Annexes under review and bring the need for changes promptly to the attention of the Commission and other Member States.	This is an obligation placed on the Commission. Cost neutral.
51. Exercise of delegation	See Article 50.	No question.	No legislative action required.	This Article deals with the Commission's obligations, It is not relevant to this Impact Assessment.
52. Revocation of delegation	See Article 50.	No question.	No legislative action required.	This Article deals with the Commission's obligations, It is not relevant to this Impact Assessment.

Article	Issue	Consultation response	Government response	Estimated impact
53. Objections to delegated acts	See Article 50.	No question.	No legislative action required.	This Article deals with the Commission's obligations, It is not relevant to this Impact Assessment.
54. Reporting Question 55: Should the UK continue to publish a full range of statistics as in the current annual statistics report? Is there scope for streamlining UK statistics? Are there additional statistics it would be useful to publish?	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 August 2012 after further discussions between the Commission and Member States. Member States are required to submit statistical information to he Commission by 10 November 2015 and every year thereafter. The UK already publishes detailed annual statistics of procedures using living animals.	Animal protection and welfare groups and bioscience sector groups were divided on this issue with the former preferring publication of a full range of statistics and the latter preferring a streamlined publication harmonised with other EU Member States. Suggestions were received for streamlining and clarifying reporting.	We will transpose the requirements of Article 54 as they stand. Discussions are on-going with the Commission and other Member States about the statistical information to be collected and submitted to the Commission. We will consider and consult on any consequential impact on the UK statistical collection when these discussions are completed.	Although the nature of the information to be reported has yet to be determined, it is likely that the minimum EU information requirements will be less extensive than current UK requirements. This may provide some minor annual savings for project licence holders beginning in Year 2 (2014, the first year for which statistics will be collected for submission under these revised arrangements). There will, however, be transitional costs of implementing the new reporting requirements in Year 1 arising from the need to make changes to recording arrangements and the introduction of arrangements to record and report the actual severity of procedures applied to animals. We estimate these at £50k per designated establishment. (Total £9 million.) Should it be required, retention of current UK requirements may entail an additional cost to establishments if they differ significantly from the minimum EU requirements. It is not possible to estimate these costs at this stage.

Article	Issue	Consultation response	Government response	Estimated impact
55. Safeguard clauses Question 56: Is our analysis of the likely need to invoke the provisions of Article 55 correct? Are there any areas of work currently authorised that you believe may require reference to the Commission under Article 55?	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.	Most responses focused on whether Article 55 should be transposed without reference to the Home Office analysis. Animal protection and welfare groups opposed transposition. The bioscience user community broadly supported the Home Office rationale for transposition. No currently authorised work that might require reference to the Commission was cited. Two groups called for a policy 'ban' on using Art. 55 if transposed. Several respondents called for the UK to exercise its right not to allow the use of primates in long-lasting severe procedures.	No legislative action required. There is no requirement to transpose Article 55 as such. If in future it was considered appropriate to invoke any of its provisions it would be necessary to bring forward further secondary legislation and seek the approval of Parliament.	Should Article 55 need to be invoked, some administrative costs would be incurred by the Competent Authority and project applicants would incur a delay in proceeding with the relevant programmes of work. We assess the likelihood of Article 55 being invoked as very low. Cost neutral.
56. Committee Question 58: Are there any issues we should consider in relation to Article 56?	Article 56 provides for the Commission to be assisted by a Committee made up of representatives of Member States.	The sole respondent to this question argued that this committee must balanced in its composition between science and welfare representatives.	No legislative action required. Article 56 creates obligations for the Commission rather than Member States.	This is an obligation placed on the Commission. There may be a cost to the competent authority arising from meetings of the committee. These are assumed to be 'business as usual' costs. Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
57. Commission report	Article 57 requires the Commission to submit a report on implementation of the Directive to the European Parliament and the Council by 10 November 2019 and every five years thereafter. The Commission must also submit a statistical report by the same date and every three years thereafter.	No question.	No legislative action required.	This is an obligation placed on the Commission. Cost neutral.
58. Review	Article 58 requires the Commission to review the Directive by 10 November 2017.	No question.	No legislative action required.	This is an obligation placed on the Commission. There are no costs or savings to Member States.
58. Review	Thematic reviews Article 58 provides that the Commission shall, where appropriate and in consultation with Member states and stakeholders conduct periodic thematic reviews of the 3Rs.	A number of suggestions were made for the thematic review process Animal welfare and bioscience users supported the need for the NC3Rs be involved. The animal protection sector suggested that the National Committee should be involved. Other issues identified included that topics could include health surveillance, environmental enrichment, imaging and telemetry and that there should be a published report on the findings.	No legislative action required. We will give careful consideration to the suggestions provided by respondents and consult further with stakeholders to develop a programme of reviews. We will also work closely with the Commission and other Member States.	There are no costs or savings to Member States other than minor administrative costs relating to thematic reviews.

Article	Issue	Consultation response	Government response	Estimated impact
59. Competent authorities Question 58: Are there any issues we should consider in relation to Article 59?	Article 59 requires each Member State to designate one or more competent authorities responsible for the implementation of the Directive. Under 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. 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.	There was support from both animal welfare groups and bioscience respondents for the Home Office to continue as the competent authority. Some animal protection and animal welfare groups proposed the creation of a new public body dedicated to advancing animal welfare. One group suggested that the competent authority should be DEFRA. Bioscience sector groups suggested that the Animal Welfare Body should be designated the competent authority for the purposes of retrospective review and this was supported by others.	The Home Office and Department of Health, Social Security and Public Safety (Northern Ireland) will continue to take responsibility for implementation of relevant legislation in England, Scotland and Wales, and Northern Ireland, respectively. We believe the requirement that the competent authority must be free of any conflict of interests precludes designation of animal welfare bodies as competent authorities responsible for project evaluation.	Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
60. Penalties Question 57: Should the UK incorporate the penalties from Part 3 of the Regulatory Enforcement and Sanctions Act 2008 (RESA) into transposing legislation? Should they include provision for monetary penalties?	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. ASPA currently specifies a number of criminal sanctions for breaches of its provisions. These can be found in sections 22, 23, 24 and 25 and relate to breaches of ASPA sections 3, 7, 14, 15, 16, 17, 18, 23, 24 and 25.	Most animal protection and welfare groups support the incorporation of the penalties set out in Part 3 of RESA, including monetary penalties. An additional suggestion was the use of penalty points and licence endorsement, and reduced penalties for self-reporting. The research/user sector wanted to see a level playing field across the EU with respect to penalties. There was a general expectation that the magnitude of the penalty should be transparent, consistent and proportionate to the severity of the infringement.	We will explore the feasibility of adopting the civil penalties set out in RESA separately from transposition. We will also explore the feasibility of the use of penalty points and licence endorsement. We will monitor the approach to penalties likely to be adopted by other Member States to ensure UK measures are proportionate	Cost neutral.
61. Transposition	Article 61 requires Member States to transpose the Directive by 10 November 2012 and implement its provisions from 1 January 2013.	No question.	We will transpose the Directive by 10 November 2012 and implement its provisions from 1 January 2013.	This places a cost on Member States arising from transposition and implementation of legislation. We assume this is to be considered a business as usual cost.
62. Repeal	Directive 86/609/EEC is repealed with effect from 1 January 2013 (except for Article 13 which is repealed from 10 May 2013).	No question.	No legislative action required.	Cost neutral.
63. Amendment of Regulation (EC) No 1069/2009 Question 58: Are there any issues we should consider in relation to Article 63?	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.	No issues identified	No issues relevant to transposition. This amendment has been implemented through separate implementing regulations made by Defra.	Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
64. Transitional provisions Question 58: Are there any issues we should consider in relation to Article 64?	Article 64 allows 'grandfathering in' of projects authorised before 1 January 2013 and due to expire before 1 January 2018.	No issues directly relating to transposition were identified but concerns were expressed that the three tier licensing system, under which 'grandfathered in' project licences will have been granted should be retained for those projects, and that retrospective review should apply to them.	We will provide guidance on the transitional provisions.	We assume that the costs of 'grandfathering in' will be absorbed by the competent authority and should be treated as 'business as usual' costs.
65. Entry into force	-	No question.	No legislative action required.	N/A
66. Addressees	-	No question.	No legislative action required.	N/A
Annex I. List of animals referred to in Article 10 which have been bred for use in procedures Omission of common quail and ferrets from the list of animals required to be purpose-bred. Question 13: Is there a case for retaining the current UK requirement that common quail and ferrets should be purpose bred, as permitted by Article 2?	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). Unlike ASPA Schedule 2, Annex I does not require common quail, ferrets, genetically modified pigs, and genetically modified sheep to be purpose bred.	Almost all respondents across all sectors supported the continuation of the UK requirement for purpose breeding of ferrets and recognised the potential welfare costs and reduced science quality if this was not the case.	We propose to use Article 2 to retain the current UK requirement for the purpose breeding of ferrets We do not propose to retain the current requirement relating to common quail as the species is not used in sufficient numbers to justify purpose breeding.	Purpose breeding of ferrets is already a UK requirement and is assumed to impose no additional costs. We estimate the scientific benefit to be gained from continuing to require purpose breeding of ferrets will outweigh the small additional cost of regulation. 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.

Article	Issue	Consultation response	Government response	Estimated impact
Annex II. List of non-human primates and dates referred to in the second sub-paragraph of Article 10(1)	Annex II provides the timetable for requiring that non-human primates used for experimental and other scientific purposes are the offspring of non-human primates that have been bred in captivity (termed F2+) or are sourced from self-sustaining colonies. NB: These requirements do not come into effect until feasibility studies have been undertaken by the Commission, and Member States may permit exceptions based upon scientific justification.	No question. See Article 10.	All marmosets currently used in the UK are already F2+: as are all UK purpose-bred macaques and almost all macaques imported for scientific use.	F2+ non-human primates are already the preferred animal in the UK, and it is assumed that the Commission report and timelines will ensure continuity of supply with no significant increase in price. This component is therefore assumed to be cost-neutral.

Article	Issue	Consultation response	Government response	Estimated impact
Annex III. Requirements for establishments and for the care and accommodation of animals	Section A of Annex III to the Directive sets out general requirements for the physical facilities and environmental control in user, breeding and supplying establishments and for the care of animals. Section B sets out species-specific requirements for enclosure sizes and other factors.		The UK is obliged to transpose Annex III standards where they are stricter than current UK requirements.	The major additional costs arising from implementation of Annex III stricter standards relate to the housing of rats, mice, guinea pigs and rabbits, for the short period from post-weaning until they are used in procedures. Relevant space requirements are increased by approximately one third. This is likely to have a significant impact, on breeders in particular and to a lesser extent on users. It is likely that either additional capacity will need to be built to house the same number of animals, or that production will decrease as fewer animals can be kept in the current space. We estimate[15] that the required additional UK capital investment would be between £10 million and £16 million in the period Year 0 to Year 4 (2012-2016), with the commercial sector passing on the costs to users with a potential increase in the cost per animal of up to 30%.

[15] Based on evidence provided by a single stakeholder with relevant and detailed operational knowledge.

Article	Issue	Consultation response	Government response	Estimated impact
Annex III **Table 1.2: Rats** Cage heights for rats over 250 grams that are post-weaned stock held at breeders or held and used at user establishments. Question 64: Is there a welfare need/benefit for retaining 20cm cage height for rats that are >250g and that are post-weaned stock or being used?	Annex III, Table 1.2, specifies 18 cm as the minimum cage height for rats of all weights. The current UK user and breeder codes of practice specify 18 cm for breeding female rats and their litters, and weaned rats up to 250 grams. UK user and breeder codes of practice specify 20 cm for rats over 250 grams when held as post-weaned stock at breeders and when held and used at user establishments.	All animal welfare and protection groups that specifically answered this question were strongly in favour of retaining 20cm height for rats over 250grams rather than the Annex III requirement of 18cm. Evidence presented by animal protection groups suggested that even 20cm is still too low for large adult rats to stand fully upright. Many individual practitioners and bioscience sector groups who answered this question were also in favour of retaining 20cm height. It was argued that higher cage heights allow rats to rear on their hind limbs, which is a natural behaviour that cannot be expressed in cages of lower height. Breeders and bioscience sector groups favoured transposing Annex III unchanged to harmonise standards across Europe. Concerns were expressed that UK-specific cages required to meet a specification for higher rat cage heights would entail a price premium and that room holding capacities would decrease leading to loss of competitiveness. No specific evidence or costs were offered.	We propose to retain the current UK specification for all rats. We will encourage provision of cages allowing more effective rearing behaviour through a revised code of practice.	As the majority of rats for use in procedures will leave the breeder at less than 250grams, we believe the impact on breeders will largely be cost neutral. On those relatively few occasions when post-weaned stock rats remain with the breeder into adulthood i.e. well beyond 250grams, such stock will require 20cm cages and thus incur some additional cost. The impact of needing to use 20cm high cages will be higher costs of cages (we estimate ~30% price premium) and ~10% fewer animals housed in any given space. As users (and many breeders) already have 20cm high cages, this will be cost neutral until they need to replace their current cages (we estimate in 5 to 10 years). Many users are also already using higher cages – 23 to 25cm high.

Article	Issue	Consultation response	Government response	Estimated impact
Annex III **Table 1.3: Gerbils** Cage heights for gerbils in breeding and post-weaned stock at breeders and suppliers.	Annex III, Table 1.3, specifies a minimum cage height of 18cm for gerbils, stock, procedures and breeding. The current UK breeder code of practice specifies 20 cm for all gerbils. We are not aware of any commercial breeding of gerbils in the UK. The UK user code of practice specifies 18cm for gerbils (and rats) up to 250 grams which is far in excess of the adult weight achieved by this species.	There was very little specific comment in the consultation regarding gerbils. It was acknowledged that similar to rats and hamsters, gerbils should have sufficient cage height to rear, but no evidence was presented to suggest that 18 cm would not be sufficient to allow this.	We propose to retain the current UK minimum cage height for gerbils. We will emphasise the need for provision of deep litter through a revised code of practice.	Cost neutral. Given the minority use of gerbils and the fact that most would be housed in rat cages, we assess the impact of retaining the current UK minimum cage height would be very limited.
Annex III **Table 1.4: Hamsters** Cage heights for hamsters Question 65: Is there a welfare need/benefit for retaining 15cm cage height?	Annex III, Table 1.4 specifies 14 cm as the minimum cage height for hamsters of all weights. The current UK user and breeder codes of practice specify 15 cm.	There was little specific comment in the consultation regarding this species however there was strong support from animal welfare and protection groups to retain a cage height of 15cm. Many of these groups suggested that our current heights are too low and that 16-17cm would be more appropriate. The Breeders and bioscience sector groups however are in favour of transposing Annex III unchanged, but did not specifically mention hamsters.	We propose to retain the current UK minimum cage for hamsters. We will encourage provision of cages high enough to allow rearing behaviour through a revised code of practice.	Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
Annex III. **Tables 2.1 to 2.4: Rabbits** Minimum enclosure size for rabbits. Question 66: Is there a welfare need/benefit for retaining current UK Code of Practice minimum floor areas for some weights of rabbits over 10 weeks of age? Is there a welfare need/benefit for retaining current UK Code of Practice minimum enclosure sizes for does without litters?	The UK user code of practice specifies minimum floor areas (cm^2) per rabbit over 10 weeks of age for different specified weight ranges. Some of these recommendations are larger than those required under Annex III. For example, for a weight range of 4-5kg, the UK Code of Practice requires 5400 cm^2 for a singly housed rabbit (or 3300 x 2 cm^2 for 2 rabbits) compared to only 4200 cm^2 for 1 or 2 rabbits under Annex III. The UK breeders' code of practice specifies enclosure sizes for does plus litters. Whilst the combined floor area of the cage/enclosure plus nest box specified in Annex III is similar to or larger than the UK Breeder code of practice, the nest box may only be available shortly before littering and removed after weaning. Consequently does may be kept in cages/enclosures smaller than UK requirements for significant periods of time.	Most animal protection groups supported retaining current UK Code of Practice standards. The response from other sectors was mixed. Several respondents noted that the slightly smaller allowances for socially housed animals were intended to encourage social housing, so retaining higher requirements might mean fewer animals would be housed socially and hence have a negative impact on welfare. Some expressed concern that smaller cages for some sizes of rabbits do not allow freedom to express normal behaviours. Large rabbits may not be able to stretch out, and will only have very limited space to hop.	We propose to retain current UK requirements where they are stricter.	Cost neutral.

Article	Issue	Consultation response	Government response	Estimated impact
Annex III. **Tables 4.1 and 4.2: Dogs** The minimum enclosure size for dogs up to 20 kilograms (kg) in weight. Question 67: Is there a welfare need/benefit for retaining the larger minimum enclosure size? Is there a welfare need/benefit for retaining the larger minimum enclosure size?	Annex III, Tables 4.1 to 4.2 specify 4 m^2 as the minimum enclosure size for one or two dogs up to 20 kg. The UK user code of practice specifies a minimum enclosure size of 4.5 m^2 for two dogs up to 20 kg, but, allows the use of a shelf to be included in the minimum floor area providing there is adequate height for the animal above the shelf. UK users can, therefore, comply with Annex III and the UK code of practice by providing a 4.0 m^2 pen with a shelf of 0.5m^2 or greater. The UK breeders' code of practice specifies 2.25 m^2 per animal and that no dog must be kept in a pen of less than 4.5 m^2. For breeders, there is no provision allowing a shelf to be included in the floor area.	All animal welfare and protection groups were strongly in favour of retaining the current size of 4.5m^2 for dog pens for welfare and public confidence reasons, but groups from other sectors were in favour of transposing Annex III unchanged which would mean reducing the minimum allowed dog pen size to 4.0 m^2. As noted above, in practice, UK users may already use a 4.0 m^2 pen if a shelf of 0.5 m^2, or greater, is also provided.	We propose to retain the current UK standard of 4.5 m^2 for users and breeders. We will continue to allow users the option to comply by providing a 4 m^2 pen with a shelf of 0.5m^2 or greater. We will review standard operating procedures with designated establishments to ensure appropriate provision of social and environmental enrichment, including exercise.	Since current UK breeders already provide 4.5m^2 pens, we expect this to be cost neutral. However new breeding facilities will need to be constructed to this higher standard at an estimated additional cost of between 10% and 15% capital investment and running cost compared with competitors in other Member States

Article	Issue	Consultation response	Government response	Estimated impact
Annex III. **Tables 6.1 to 6.4: Non-Human Primates** Minimum enclosure size for breeding pairs of marmosets. Question 68: Is there a welfare need/benefit from retaining the slightly larger minimum floor area for breeding pairs of marmosets?	Annex III, Tables 6.1 to 6.4 specify 0.5 m^2 x 1.5 m as the minimum enclosure size for 1 or 2 animals plus offspring up to 5 months old. A further minimum volume of 0.2m^3 must be provided for each additional animal over 5 months. The UK breeders' code of practice specifies 0.55 m^2 x 1.5 m for a breeding pair plus one generation of offspring and 1.0 m^2 x 1.5 m for a family group (8 animals maximum). The UK Code of Practice specifies larger minimum pen dimensions for a breeding pair plus up to three additional animals over 5 months of age. For larger family groups, the Annex III minima are greater. For all family groups Annex III allows greater flexibility between pen height and floor area than the Code of Practice.	We asked if there was a welfare need or benefit to retain the slightly larger minimum floor area (0.55m^2 versus 0.50m^2) for breeding pairs of marmosets. There was an overwhelming response to this question from all answering it specifically that the UK minimum floor area should be retained. One animal protection group pointed out that space alone is insufficient for consideration and that there needs to be sufficient complexity and enrichment within that space to allow monkeys to climb, perch and explore. References were provided. Breeders supported transposing Annex III unchanged to harmonise accommodation standards across Europe.	We propose to retain minimum cage volumes based on the current UK standard for breeding pairs and family groups (Annex III minima will supersede the code of practice for large family groups)	We estimate the impact to be insignificant given relative minority use and universal support for retaining current UK minimum floor area in the public consultation.

Article	Issue	Consultation response	Government response	Estimated impact
Annex III. **Table 7.1: Cattle** Trough space for ad lib feeding of individual polled cattle. Question 69: Is there a welfare need/benefit to retention of current minimum trough space allocations for ad libitum feeding of individual polled cattle?	Annex III, Table 7.1 differentiates between ad lib feeding and restricted feeding and permits lower trough space for ad lib feeding. Requirements for restricted feeding are generally higher than current UK standards. The UK user code of practice recommends two to three times these standards, but does not differentiate between ad lib and restricted feeding.	Virtually all respondents who offered comment agreed that UK standards should be retained where they are higher than those specified in Annex III to the Directive on the basis of a) quoted published evidence; b) informed veterinary experience. Three respondents made the comment that Annex III should be transposed unchanged because a) the size requirements seemed arbitrary; b) there was no practical welfare need/benefit to retaining current minimum trough space allocations for ad lib feeding of individual polled cattle; c) of the need to harmonise accommodation standards across Europe.	We propose to retain current UK requirements.	Cost neutral
Annex III. **Table 7.2: Sheep and goats** Space allocations for housing and trough space for sheep and goats. Question 70: Is there a welfare need/benefit to retaining current space allocations for most weights of sheep and goats?	Annex III, Table 7.2 (below) specifies minimum enclosure size, floor area per animal and trough space for ad lib and restricted feeding. In most cases, the current UK code of practice allowances are higher than Annex III.	Virtually all respondents who offered comment recommended the retention of current UK Code of Practice standards where these exceed those in Annex III. The Breeders and one practitioner organisation favoured adopting Annex III standards.	We will retain current UK housing and trough space requirements. We will omit the requirement for minimum partition heights for sheep.	Cost neutral

Article	Issue	Consultation response	Government response	Estimated impact
Annex III. **Table 7.3: Pigs and minipigs** Space allocations for group housed pigs and minipigs. Inclusion of trough space and water flow rates. Question 71: Is there a welfare need/benefit to retaining the current minimum floor area per animals and are there likely to be welfare issues if minimum water flow rates and trough space allowances are not specified?	Annex III, Table 7.3 (below) specifies minimum floor area for pigs and minipigs of various weights. The current UK code of practice minimum floor area allowances when pigs are housed in social groups are higher than Annex III. The UK code of practice also specifies a minimum trough space allowance. In addition, Appendix A (ETS123) specifies water flow rates for pigs. These have not been included in Annex III. However, the rate of water flow was considered to be important for pig welfare by the Appendix A Pig Expert Group.	In the public consultation, in addition to seeking views on the need to retain current minimum floor area per animals, we also asked whether there are likely to be welfare issues if minimum water flow rates and trough space allowances are not specified. Most respondents who offered comment recommended the retention of current UK Code of Practice standards. Breeders were the only exception.	We will retain current UK minimum floor areas per animal and include the minimum lying space from Annex III. We will retain current UK trough space allowances where they exceed those in Annex III. Water flow rates cannot be included in mandatory requirements as they are not included Annex III or current UK requirements.	Cost neutral
Annex III. **Table 7.4: Equines** Space allocations for equines. Question 72: Is there a welfare need/benefit to retention of the current space allocations for equines?	Annex III, Table 7.4 (below) specifies minimum floor areas for equines held singly or in groups. The current UK code of practice minimum floor area allowances are higher than Annex III.	Virtually all respondents who offered comment recommended the retention of current UK Code of Practice standards. The one practitioner organisation stated that UK space allocations are excessive, add a burden and have no welfare benefit.	We propose to retain current UK requirements.	Cost neutral

Article	Issue	Consultation response	Government response	Estimated impact
Annex IV. Methods of killing animals Question 24: Should the UK retain some methods listed in ASPA Schedule 1 using Article 2? Which methods should be retained?	Annex IV specifies the methods to be used when killing animals and the species to which they are to be applied. Appropriate methods of human killing are set out in ASPA Schedule 1.	There was broad agreement across all sectors that some Annex IV methods could impose a higher animal welfare cost . A clear majority favoured retention of current UK methods where appropriate. A number of responses included detailed and referenced justification for the suitability of specific methods.	We propose to retain current UK methods of killing where they are more humane and implement Annex IV by means of a revised Schedule 1.	We do not expect retention of current UK methods to impact on costs. Retaining some methods listed in ASPA Schedule 1 will ensure current UK animal welfare standards are maintained and reduce or eliminate the need for additional training and equipment. Should the Commission require justification for the retention of methods the transitional cost of producing dossiers identifying and analysing available supporting evidence would be approximately £80-100K[16]. We judge this to be low/medium likelihood. There is a likely cost to the competent authority of about £30K to produce a code of practice on how the methods should be applied and on the provision that should be made for types of animal not identified in Annex IV.

[16] Based on experience of previous, similar exercises.

Article	Issue	Consultation response	Government response	Estimated impact
Annex IV. Methods of killing animals **Birds, rodents and rabbits: Cervical Dislocation** Question 62: Should sedation be used where it is in the welfare interests of the animal?		All respondents supported the use of sedation or anaesthesia prior to cervical dislocation, but the majority indicated that this should be optional and not required. Those who wanted it to be optional explained that, correctly performed, cervical dislocation alone may be less stressful than the addition of sedative to the protocol. All who commented supported the retention of Schedule 1 weight limits, where they were lower than those specified in Annex IV.	We will take account of these responses when revising ASPA Schedule 1 (see Annex IV, above).	See above.
Annex IV. Methods of killing animals **Rodents: Inert Gases** Question 63: Concerns have been expressed that there is currently insufficient evidence that this method is humane: should it require specific justification?		No responses supported the use of inert gases for killing rodents. Limited comment was received on its use for birds, most not supporting the use. It was acknowledged that the method is currently used as a stunning method in the slaughter of pigs, but concerns were raised over the specialised equipment needed and how humane the method is.	We intend to omit the use of inert gases as a method of killing for birds and rodents from the revised Schedule 1	See above.

Article	Issue	Consultation response	Government response	Estimated impact
Annex V. List of elements referred to in Article 23(3) relating to minimum requirements for education and training	The elements are: 1. National legislation in force relevant to the acquisition, husbandry, care and use of animals for scientific purposes; 2. Ethics in relation to human-animal relationship, intrinsic value of life and arguments for and against the use of animals for scientific purposes; 3. Basic and appropriate species-specific biology in relation to anatomy, physiological features, breeding, genetics and genetic alteration; 4. Animal behaviour, husbandry and enrichment; 5. Species-specific methods of handling and procedures, where appropriate; 6. Animal health management and hygiene; 7. Recognition of species-specific distress, pain and suffering of most common laboratory species; 8. Anaesthesia, pain relieving methods and killing; 9. Use of humane end-points; 10. Requirement of replacement, reduction and refinement; 11. Design of procedures and projects, where appropriate.	No question.	We will transpose the requirements of Annex V as they stand. See also Article 23.	Cost neutral. Consistent with current UK requirements and practice.

Article	Issue	Consultation response	Government response	Estimated impact
Annex VI. List of elements referred to in /Article 37(1)(c) – information required in project applications.	These elements are: 1. Relevance and justification of the following: (a) use of animals including their origin, estimated numbers, species and life stages; (b) procedures: 2. Application of methods to replace, reduce and refine the use of animals in procedures; 3. The planned use of anaesthesia, analgesia and other pain relieving methods; 4. Reduction, avoidance and alleviation of any form of animal suffering, from birth to death where appropriate; 5. Use of humane end-points; 6. Experimental or observational strategy and statistical design to minimise animal numbers, pain, suffering, distress and environmental impact where appropriate; 7. Reuse of animals and the accumulative effect thereof on the animals; 8. The proposed severity classification of procedures; 9. Avoidance of unjustified duplication of procedures where appropriate; 10. Housing, husbandry and care conditions for the animals; 11. Methods of killing; 12. Competence of persons involved in the project.	No question.	We will transpose the requirements of Annex VI as they stand. See also Article 37.	Cost neutral. Consistent with current UK requirements and practice.
Annex VII. Duties and tasks of the union reference laboratory	No question.	No question.	See Article 48.	-
Annex VIII. Severity classification of procedures	No question.	No question.	See Article 15.	-

Article	Issue	Consultation response	Government response	Estimated impact
Confidentiality (ASPA section 24) Question 59: How might ASPA 24 be amended to provide greater flexibility regarding disclosure of information while protecting proprietary rights and intellectual property?	ASPA 24 prohibits the disclosure of confidential information relating to the use of animals in scientific procedures by Home Office Ministers and officials and members of the Animal Procedures Committee 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 unlawful disclosure. Unlike Directive 86/609/EEC[17], 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).	Most respondents across all sectors did not favour retention of section 24 in its current form, citing its incompatibility with the Directive's commitment to transparency and the barrier it can be to the sharing of best practice and information on the 3Rs. Most also recognised that personal details, intellectual property and commercial information will continue to require protection.	We have noted the consultation responses and will consider the options for revising section 24. We will publish our conclusions separately, in due course.	We will estimate the impact when we have identified and considered the options for revising section 24.
Definition of 'death' Question 60: Should ASPA section 1(4) be retained? What would be the effect if it were not retained?	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.	There was a large majority across all sectors in favour of retaining ASPA section 1(4).	We will retain the definition of 'death' in ASPA Section 1(4).	Cost neutral.

[17] See Article 13(2)

Article	Issue	Consultation response	Government response	Estimated impact
Use of animals in public exhibitions Question 61: Should restriction on public exhibition be retained?	ASPA section 16 prevents animals being used in regulated procedures for the purpose of exhibition to the public or for live television.	There was an overwhelming majority for retaining the current ban. A few respondents called for a definition of "exhibition" and a few questioned whether keeping it would be in the spirit of harmonisation across the EU.	We will retain the current prohibition on the use of animals in regulated procedures for the purpose of exhibition to the public or for live television.	Cost neutral. Public confidence may be adversely impacted if this prohibition is not retained.
Competitiveness Question 74: We would particularly welcome data enabling the impact of the proposal on UK competitiveness to be assessed more fully. This has been identified by the Regulatory Policy Committee as a weak area in the impact assessment.		Animal protection/welfare groups suggest that higher animal welfare puts the UK at an advantage because best practice and other factors may attract workers. Some bioscience workers were concerned that the cost of maintaining animals will increase following transposition. Funders already questioned the cost of animals and compared UK costs unfavourably with major competitors. Several establishments made general comments about transposition negatively impacting on UK competitiveness. Several comments were also made regarding the importance of keeping a level playing field across the EU.	We have noted the consultation responses and will take them into account in preparing a final impact assessment.	We estimate that the measures we are minded to retain will have no significant impact on costs or competitiveness and are necessary to maintain animal welfare standards and/or public confidence.

Article	Issue	Consultation response	Government response	Estimated impact
Different impacts on establishments and sectors Question 75: There are a number of areas in which the requirements of the Directive may have different impacts depending on the sector implementing them (for example, industry or higher education institutions). Some of these different impacts have been identified in the impact assessment at Part II. We would, however, welcome further and better information on such effects both in general and as they relate to specific provisions in the Directive.	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).	The animal protection and welfare groups did not provide specific answers to this question. Practitioners suggested that there may be impact on wildlife and trapping work but they were uncertain as to exactly what the impact would be until they know how the Directive is going to be transposed. Several practitioners expressed concern that higher education institutions may not be able to absorb increased internal regulatory functions. They also were concerned that UK welfare standards could be lower under the new legislation. Many bioscience establishments expect to require additional staff to carry out new or expanded functions required by the Directive. There may also be a cost for new software requirements. The total cost to breeders over 4 years of implementation is estimated to be £16 million. Others stressed the importance of being able to obtain animals from any authorised breeder in the EU without restriction.	We have noted the consultation responses and will take them into account in preparing a final impact assessment.	Where possible we will identify different impacts on sectors in the final impact assessment.