EXPLANATORY MEMORANDUM TO

THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986 AMENDMENT REGULATIONS 2012

2012 No.

1. This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments and the Secondary Legislation Scrutiny Committee.

2. Purpose of the instrument

2.1 These regulations amend the Animals (Scientific Procedures) Act 1986 to transpose European Directive 2010/63/EU on the protection of animals used for scientific purposes.

3. Matters of special interest to the Joint Committee on Statutory Instruments and the Secondary Legislation Scrutiny Committee

3.1 None.

4. Legislative Context

4.1 European Directive 2010/63/EU on the protection of animals used for scientific purposes (the new Directive) was adopted in September 2010 and came into force on 9 November 2010.

4.2 Directive 2010/63/EU replaces Directive 86/609/EEC, which is transposed into current United Kingdom legislation by the Animals (Scientific Procedures) Act 1986 (ASPA).

4.3 Member States have until 10 November 2012 to transpose the provisions of the new Directive into national legislation. National legislation must be implemented from 1 January 2013.

4.4 The European Commission published its proposal for a new Directive to replace directive 86/609/EC in November 2008.

4.5 The House of Commons European Scrutiny Committee B debated the Commission's proposal on 3 February 2009.

4.6 Sub-Committee D (Environment and Agriculture) of the House of Lords EU Scrutiny Committee conducted an inquiry into the proposal taking evidence between May and October 2009 and published its final report on 10 November 2009. The Government's response was sent to the Committee on 7 January 2010 and the Committee's report was debated on 10 February 2010.

4.7 A transposition note explaining how each of the provisions of the Directive has been transposed is attached.

5. Territorial Extent and Application

5.1 This instrument applies to the United Kingdom.

6. European Convention on Human Rights

6.1 Lord Taylor of Holbeach has made the following statement regarding Human Rights: In my view the provisions of the Animals (Scientific Procedures Act 1986 Amendment Regulations are compatible with the Convention rights.

7. Policy background

7.1 These regulations are required to amend and revise current United Kingdom legislation – the Animals (Scientific Procedures) Act 1986 – to transpose the requirements of Directive 2010/63/EU.

7.2 Directive 2010/63/EU establishes revised measures for the protection of animals used for scientific purposes to replace those set out in Directive 86/609/EEC. It has three main objectives: a) to rectify wide variations in the implementation of Directive 86/609 by Member States; b) to strengthen the protection of animals used in scientific procedures; and c) to promote the 3Rs – strategies that Replace, Reduce and Refine the use of animals in scientific procedures.

7.3 Many of the provisions of the new Directive are similar to current United Kingdom legislation and practice. It places a strong emphasis on minimising the use of animals and the promotion of the 3Rs. It also requires the authorisation of establishments using, breeding and/or supplying protected animals and the authorisation of projects in which they are used.

7.4 The Directive also creates a requirement for all Member States to implement risk-based inspections; each breeder, supplier and user to establish an animal welfare body to advise on the welfare of animals and the 3Rs; the classification of procedures according to their severity; restrictions on the re-use of animals; the publication of non-technical summaries of licensed projects to aid transparency; and seeks to eliminate the use of wild-caught non-human primates for breeding and use in procedures. The UK already has arrangements similar to each of these in place.

7.5 Some of the provisions of the Directive are new or go further than current United Kingdom legislation. The new Directive extends protection to some invertebrate species (all cephalopods) and to animals bred primarily for tissues and organs; requires Member States to apply mandatory minimum standards of care and accommodation; requires retrospective review of some

categories of project; and requires Member States to avoid unnecessary duplication of procedures by accepting data from other Member States;

7.6 Other provisions are potentially less stringent than current United Kingdom requirements. For example, the Animals (Scientific Procedures) Act 1986 provides special protection for non-human primates, cats, dogs and horses, whereas the Directive extends special protection only to non-human primates. Also, unlike the Animals (Scientific Procedures) Act 1986, the Directive does not provide protection for immature forms of birds and reptiles.

7.7 Article 2 to the new Directive allows Member States to retain national provisions in force on 9 November 2010 giving more extensive protection of animals than those set out in the new Directive providing they do not interfere with the supply or use of animals bred or kept in another Member State in accordance with the Directive so as to interfere with the free market.

8. Consultation outcome

8.1 A public consultation on the Commission's proposal was held between 8 May and 3 July 2009. The consultation document set out an initial analysis of the proposal and included a consultation stage impact assessment. Responses were received from 87 organisations and over 1000 individuals. There was general support for the Commission's high level objectives.

8.2 Following adoption of Directive 2010/63/EU a second public consultation on the options for transposition was launched on 13 June 2011 and closed on 5 September 2011. Responses were received from over 13000 individuals and 98 organisations.

8.3 The majority of respondents supported the retention of current United Kingdom animal welfare requirements where these were stricter than those set out in the Directive. There was also support for streamlining regulation where this would not harm animal welfare or weaken the controls on the use of animals in regulated scientific procedures.

8.4 The Government's response to the second public consultation was published on 17 May 2012. This explained that the Directive would be transposed retaining current stricter United Kingdom standards where appropriate, for example, special protection for cats, dogs and horses, protection for immature forms of birds and reptiles and larger enclosure and cage sizes for some species of protected animal. This was justified on animal welfare grounds and to maintain public confidence that animals used in experiments and testing will continue to be adequately protected.

8.5 Draft Animals (Scientific Procedures) Act 1986 Amendment Regulations were published in July 2012. Comments on these were received from bioscience sector, animal welfare and animal protection groups and some individual practitioners. These comments have been taken into account in the final drafting of this instrument.

9. Guidance

9.1 Guidance on the implementation of the amended legislation is being prepared and will be published for consultation before the amended legislation comes into force on 1 January 2013. Under section 21, of the amended legislation, this guidance will be subject to the negative resolution procedure. The current statutory guidance will be repealed by negative resolution procedure.

10. Impact

10.1 A final stage impact assessment has been prepared and cleared with the Regulatory Policy Committee who assessed it as fit for purpose and awarded it a 'green' rating.

10.2 The final stage impact assessment showed that the option to transpose the Directive retaining stricter UK animal welfare standards where they apply has lower implementation costs than the option to copy out the minimum requirements of the Directive. Retention of stricter standards is lower cost because it requires fewer changes to current arrangements.

10.3 The impact on business is £2.51 million per year (net cost on 2009 prices); £19.6 million net present value over 10 years. The impact on the public sector is cost neutral.

10.4 The impact assessment is attached to this memorandum and will be published with this Explanatory Memorandum on www.legislation.gov.uk.

11. Regulating small business

11.1 The legislation applies to small business. Directive 2010/63/EU does not allow small business to be exempted from its requirements, but it does allow a proportionate 'risk-based' approach to be taken to inspection and other aspects of regulation. This is reflected in the regulations. We will use this flexibility to keep the impact on small business to a minimum.

12. Monitoring & review

12.1 The operation of the amended legislation will be monitored using advice from inspectors, operational information; regular liaison with those affected; periodic reviews by the national committee for the protection of animals used in scientific procedures (set up under Article 49 of the New Directive); and by periodic reviews by the European Union.

13. Contact

13.1 Martin Walsh, Animals in Science Regulation Unit, Home Office: Telephone: 020 7035 0746. Email: Martin.Walsh@homeoffice.gsi.gov.uk, can answer any queries regarding the instrument.

TRANSPOSITION NOTE FOR DIRECTIVE 2010/63/EU ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES

Background

Directive 2010/63/EU on the protection of animals used for scientific purposes replaces Directive 86/609/EEC which is transposed into current United Kingdom legislation by the Animals (Scientific Procedures) Act 1986 (ASPA).

Objectives of Directive 2010/63

Directive 2010/63/EU establishes revised measures for the protection of animals used for scientific purposes to replace those set out in Directive 86/609/EEC. It has three main objectives: a) to rectify wide variations in the implementation of Directive 86/609 by Member States; b) to strengthen the protection of animals used in scientific procedures; and c) to promote the 3Rs – strategies that Replace, Reduce and Refine the use of animals in scientific procedures.

Comparison with current UK legislation and practice

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

Some of its provisions are new or go further than current UK legislation. The new Directive extends protection to some invertebrate species (all cephalopods) and to animals bred primarily for tissues and organs; requires Member States to apply mandatory minimum standards of care and accommodation (Annex III); requires retrospective review of some categories of project; requires Member States to avoid unnecessary duplication of procedures by accepting regulatory testing data from other Member States; and seeks to eliminate the use of wild-caught non-human primates for breeding and use in procedures.

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

Article 2: retention of national provisions

Article 2 to the new Directive allows Member States to retain national provisions in force on 9 November 2010 giving more extensive protection of

animals than those set out in the new Directive providing they are not used to inhibit the free market.

The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012

The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 amend the Animals (Scientific Procedures) Act 1986 to transpose Directive 2010/63/EU.

Citation, commencement and transitional provision

Regulation 1 provides that the regulations will come into force on 1 January 2013 except where other dates are specified for specific provisions.

Amendment of the Animals (Scientific Procedures) Act 1986

Regulation 2 explains that the Animals (Scientific Procedures) Act 1986 (ASPA) will be amended as in the following regulations.

Protected animals

Regulation 3 changes the point of protection of immature forms from half way though gestation to the last third of normal development – in line with Article 1(3)(a) - and extends protection to all cephalopods - as required by Article 1(3)(b). Protection of immature forms of birds and reptiles is retained, also from the last third of development.

Regulated procedures

Regulation 4 amends the definition of a 'regulated procedure' in ASPA section 2(1), to transpose Article 3(1). Regulation 4(6) inserts a new subsection to include in that definition the modification of an animal's genes and the breeding of animals with harmful genetic defects under given circumstances.

Regulation 4(8) amends ASPA Section 2(7) to define as regulated procedures certain methods of humane killing carried out at places other than a place specified in a Section 2C licence (see below). This, in conjunction with Regulation 15, transposes Article 6. Regulation 4(8) also inserts a revised ASPA Section 2(8) defining practices which are not regulated procedures under the amended Act. This transposes Article 1(5).

Principles of replacement, reduction and refinement

Regulation 5 transposes Article 4(1), 4(2) and 4(3) by inserting a new Section 2A requiring the Secretary of State to exercise his or her functions with a view to ensuring compliance with the principles of replacement, reduction and refinement. Regulation 5 also inserts definitions of these terms.

Licensing of undertakings

Regulation 6 inserts a new section 2B - prohibiting the use, breeding and/or supplying of protected animals without authorisation – and a new section 2C – setting out the requirements which must be met for the licensing of such activities.

These include the nomination of (a) a person to be responsible for overseeing the welfare and care of the animals kept at the place specified in the licence; (b) a veterinary surgeon with expertise in laboratory animal medicine, or other suitably qualified person, to provide advice on the welfare and treatment of those animals; (c) a person to be responsible for ensuring that the persons dealing with those animals have access to any information they need about the species concerned; (d) a person to be responsible for ensuring that the persons dealing with those animals are adequately educated and trained and are supervised until they have demonstrated the requisite competence; and (e) a person to be responsible for ensuring that the conditions of the licence are complied with.

These provisions transpose Articles 20(1), 20(2), 20(4), 24 and 25.

As from 1 January 2013 ‘Section 2C licences’ will replace ‘Certificates of Designation’ under which scientific procedure establishments, breeding establishments and supplying establishments are currently authorised.

Personal licences

Regulation 7 amends section 3 to remove the current requirement for the place where regulated procedures are performed to be specified in the personal licence. This will enable personal licence holders to carry out regulated procedures at any place specified in the project licence that authorises the procedures and will obviate the need to amend the personal licence before working at additional places.

Regulation 8 amends section 4 so that the holder of a personal licence will be authorised to apply “regulated procedures of specified descriptions”, (i.e. categories of techniques), rather than “specified regulated procedures” (individual techniques) as at present. This will enable the current personal licence to be simplified without impacting on animal welfare.

Applicants seeking a personal licence for a particular category of techniques will have to provide evidence of education and training appropriate for that category before being granted a licence. The assurance of training, supervision and determination of competence in individual techniques will be the responsibility of the establishment under the auspices of the ‘training and competence officer’ named in its Section 2C licence (see Licensing of undertakings, above).

Project licences

Regulation 9 replaces ASPA Section 5.

New Section 5 retains the existing definition of a ‘project licence’. Section 5(4) provides that a project licence may specify a programme of work which consists of multiple generic projects in the circumstances set out in Article 40(4).

New Section 5A sets out the requirements for an application for a project licence, including the content of the non-technical summary which must form part of the application. Section 5A also sets out what the Secretary of State must do if he or she receives an incomplete or incorrect application, the requirements for acknowledging applications and the timescales within which a decision on an application must be communicated to the applicant. These provisions transpose Articles 37 (Section 5A (1) - (3)), and 41 (Section 5A (4) – (9)).

New Section 5B sets out how an application for a project licence is to be evaluated including the expertise to be applied in carrying out an evaluation, the issues to be considered and confirmed, the criteria to be applied when classifying the severity of any regulated procedures and the need to determine whether and, if so, when a project should be subject to retrospective assessment. These provisions transpose Article 36(2) (Section 5B(1)), Article 38 (Section 5B(2) – (4) and (8) & (9)), Article 15(1) (Section 5B(6)) and Article 39(2) (Section 5B(7)).

New section 5C specifies to whom a licence may be granted and also specifies the purposes for which a project may be carried out. Section 5C(5) prohibits the use of great apes in regulated procedures. These provisions transpose Article 40.2(a) (Section 5C(1)), Article 23(2) (Section 5C(2)), Article 5 (Section 5C(3)), Articles 7 & 8 (Section 5C(4)), and Article 8(3) (Section 5C(5)).

New Section 5D sets requirements relating to the content of project licences, including that they must specify the name of the person to whom the licence is granted and the holder of the Section 2C licence in respect of a place specified in the licence. It must also state whether and, if so, when the project is to be subject to retrospective assessment. Section 5D also requires the Secretary of State to publish the non-technical summary that accompanied the application, including a statement regarding whether and when the project will be retrospectively assessed. These provisions transpose Article 40(2) (Section 5D(2), (3) & (5)), Articles 15 and 16 (Section 5D(4)) and Article 43 (Section 5D(6) & (7)).

New Section 5E sets requirements regarding the duration of a project licence up to a maximum of five years, what will happen on the death of a project licence holder, a requirement that the Secretary of State should establish and publish conditions he or she will take into account in determining whether to vary or renew a project licence and that any variation or renewal should be subject to a further favourable evaluation in line, as necessary, with Section 5B. These provisions transpose Article 40.3 (Section 5E(1)) and Article 44

(Section 5E(5) & (6)); and retain existing measures enabling limited continuity of a project licence on the death of the holder (Section 5E(2) – (4)).

New Section 5F sets out detailed the requirements relating to the carrying out of retrospective assessments of projects. These provisions transpose Article 39.

New Section 5G specifies the documents to be kept by the Secretary of State relating to project applications and licences. These provisions transpose Article 45.

Conditions in licences

Regulation 10 replaces ASPA Section 10 relating to the conditions to be included in licences granted under this Act. The detailed requirements for conditions are set out in new Schedule 2C (see below).

Section 10(4) retains the existing measure that permits the delegation by personal licensees of certain non-technical tasks to unlicensed assistants and may be slightly modified following further consideration.

Failure to comply with licence condition, etc

Regulation 11 inserts a new Section 11 specifying the actions open to the Secretary of State where the holder of a licence has failed to comply with its conditions or a provision of this Act. These include issue of a compliance notice and variation, suspension or revocation of a licence. These provisions collectively transpose Articles 21(1), 23(2), 44(4) and 60.

Right to make representations

Regulation 12 amends ASPA Section 12 dealing with the right of a licence holder to make representations against a decision the Secretary of State is minded to take to vary or revoke a licence.

Duty to ensure welfare of animals is not adversely affected by revocation or suspension (of licences)

Regulation 13 inserts a new Section 13A stipulating that where the Secretary of State revokes or suspends a licence, he or she must take steps to ensure the welfare of protected animals is safeguarded. These provisions transpose Articles 21(1) and 44(4).

Re-use of protected animals

Regulation 14 replaces ASPA Section 14 stipulating that a protected animal that has already been subjected to one or more series of regulated procedures must not be re-used in a further series of regulated procedures without the consent of the Secretary of State.

New Section14 also sets out the conditions that are to be met in relation to re-use. In particular, new Section 14(6) stipulates that in the case of animal that has been subjected to a regulated procedure the actual severity of which has been classified as “severe”, the consent of the Secretary of State must relate to the specific animal concerned and the Secretary of State may give consent only if (a) the Secretary of State has consulted a veterinary surgeon who has examined the animal about whether consent should be given; and (b) the Secretary of State is satisfied that there are exceptional circumstances that justify the animal being used for the further regulated procedure.

These provisions transpose Article 16.

Manner in which protected animals are to be killed

Regulation 15 inserts new Section 15A which sets out detailed requirements relating to the killing of animals. These provisions transpose Article 6.

Neuromuscular blocking agents

Regulation 17 replaces ASPA Section 17. New Section 17 prohibits the use of a neuromuscular blocking agent in the course of a regulated procedure unless (a) the person is expressly authorised to do so by the personal licence and the project licence under which the procedure is carried out; and (b)the agent is used in combination with such level of anaesthesia or analgesia as is determined in accordance with the project licence. It also stipulates that the Secretary of State must not grant a project licence that authorises the use of a neuromuscular blocking agent unless he or she is satisfied, on the basis of a scientific justification, that the purposes of the programme of work specified in the licence cannot be achieved without the use of such an agent.

These provisions transpose Article 14(3) and place on the face of the Act the requirement for a scientific justification for the use a neuromuscular blocking agent. While the current prohibition on using a neuromuscular blocking agent in place of an anaesthetic has not been retained on the face of the Act the requirement for specific authorisation of the use of a neuromuscular blocking agent in both personal and project licences will ensure that animal welfare safeguards are maintained.

Setting free and re-homing protected animals

Regulation 18 inserts a new Section 17A prohibiting the setting free or re-homing of protected animals without the consent of the Secretary of State and setting out the conditions which must be met before such consent is given. These provisions transpose Article 19.

Inspections

Regulation 19 amends ASPA Section 18 relating to the duties and functions of inspectors. In relation to visits of inspection the regulation introduces a requirement on the Secretary of State to determine an appropriate risk-based

inspection programme to be followed by the Inspectorate. These provisions transpose Article 34.

Committee for the protection of animals used for scientific purposes

Regulation 20 replaces ASPA Sections 19 and 20 dealing with the Animal Procedures Committee which is to be replaced with a new committee to be known as the Committee for the Protection of Animals Used for Scientific Purposes. New Section 19 sets out the arrangements for the appointment of a chair and members of the committee. The number of members is not specified and is to be determined by the Secretary of State. New Section 20 sets out the functions of the committee. These provisions transpose Article 49.

Sharing of organs and tissues

Regulation 21 inserts new Section 20A providing that the Secretary of State should take such steps as he or she considers appropriate to facilitate the establishment of programmes for the sharing of the organs and tissues of animals killed for use for scientific purposes. These provisions transpose Article 18.

Alternative strategies

Regulation 22 inserts new Section 20B which requires the Secretary of State to support the development of alternative strategies (i.e. scientific methods and testing strategies which do not use protected animals, or which, compared to existing scientific methods and testing strategies, use fewer protected animals or reduce the pain, suffering or lasting harm caused to protected animals). These provisions transpose Article 47.

Statistics and reporting

Regulation 23 inserts new Section 21A dealing with the publication of annual statistics of animals used for scientific purposes and their reporting to the European Commission. Section 21A requires that the statistical information reported to the Commission must include information on the actual severity of the regulated procedures, and on the origin and the species of any primates used in regulated procedures.

Section 21A also requires the Secretary of State to report each year on methods of killing specified in Section 2C licences other than those specified in Annex IV to the Directive. (Annex IV methods are set out in Schedule 1 to this Act.)

Section 21A also requires the Secretary of State to send information on the implementation of the Directive to the European Commission by 10 November 2018 and every five years thereafter.

These provisions transpose Article 54.

Penalties for contraventions

Regulation 24 provides penalties for contravention of specified sections of the amended Act. These provisions transpose Article 60 which requires Member States to lay down penalties for infringements of their national legislation. These penalties must be effective, proportionate and dissuasive.

Powers of entry

Regulation 25 amends ASPA Section 25 relating to powers of entry to premises in which a breach of the Act is suspected.

Minor and consequential amendments

Regulation 26 makes minor and consequential amendments to the Act.

Regulation 26(18) amends ASPA Schedule 2 (listing animals which must be purpose bred for use in regulated procedures) to transpose Annex I of the Directive by including frogs (Rana and Xenopus species) and zebra fish. Ferrets are to be retained in Schedule 2 as explained in the Government response to the consultation.

Other minor and consequential amendments etc

Regulation 27 amends section 5(4) of the Dangerous Wild Animals Act 1976 (dangerous wild animals not to be kept without a licence: exemptions for animals kept for scientific procedures etc).

Regulation 28 amends section 148 of the Serious Organised Crime and Police Act 2005 (harming an animal research organisation or intimidating a connected person: definition of “animal research organisation”).

Regulation 29 amends section 58 of the Animal Welfare Act 2006 (application of the Act: exceptions for places and animals used for scientific procedures etc).

Regulation 30 amends rule 3 of the Animals (Scientific Procedures) (Procedure for Representations) Rules 1986 (interpretation etc).

Regulation 31 revokes the Animals (Scientific Procedures) Act (Amendment) regulations 1993.

Regulation 32 revokes the Animals (Scientific Procedures) Act (Amendment) Order 1993 (protection of Octopus vulgaris).

Regulation 33 amends article 2(2) of the Animals (Scientific Procedures) Act 1986 (Fees) (No 1) Order 1996 (deficits to be taken into account when fixing fees: relevant functions).

Regulation 34 revokes paragraphs 3 to 6 of the Schedule to the Animals (Scientific Procedures) Act 1986 (Amendment) Regulations 1998 (amendments to the Animals (Scientific Procedures) Act 1986).

Regulation 35 amends article 7(1)(d) of the Dangerous Wild Animals (Northern Ireland) Order 2004 (dangerous wild animals not to be kept without a licence: exemptions for animals kept for scientific procedures etc).

Regulation 36 revokes Paragraph 6 of Schedule 9 to the Veterinary Medicines Regulations 2006 (administration of substance or article not to count as a regulated procedure under the Animals (Scientific Procedures) Act 1986 in certain cases) and the heading immediately preceding it.

Regulation 37 amends article 70(3)(c) of the Avian Influenza and Influenza of Avian Origin in Mammals (Scotland) Order 2006 (measures on suspicion or confirmation of avian influenza: designation of premises to which things may be moved).

Regulation 38 amends article 71(3)(c) of the Avian Influenza and Influenza of Avian Origin in Mammals (England) (No. 2) Order 2006 (measures on suspicion or confirmation of avian influenza: designation of premises to which things may be moved).

Regulation 39 amends article 71(3)(c) of the Avian Influenza and Influenza of Avian Origin in Mammals (Wales) (No. 2) Order 2006 (measures on suspicion or confirmation of avian influenza: designation of premises to which things may be moved).

Regulation 40 amends regulation 71(3)(c) of the Avian Influenza and Influenza of Avian Origin in Mammals (Northern Ireland) Regulations 2007 (measures on suspicion or confirmation of avian influenza: designation of premises to which things may be moved).

Regulation 41 amends Section 52 of the Welfare of Animals Act (Northern Ireland) 2011 (application of the Act: exceptions for places and animals used for scientific procedures etc).

Transitional provision

Regulation 42 inserts Schedule 3 making transitional provisions.

Schedule 1: Additional conditions for the granting of certain project licences

Regulation 9(2) provides for the insertion of a new Schedule 2B making additional conditions for the granting of certain project licences. These relate to conditions which must be satisfied before authorisation can be given for the use of endangered and non-endangered primates, the use of endangered animals that are not primates and the use of cats, dogs and equidae.

In the latter case, Condition 9 is that the purpose of the programme of work to be specified in the licence can be achieved (a) only by the use of cats, dogs or equidae; or (b) only by the use of cats, dogs, equidae and other animals which it is not practicable to obtain. This retains special protection for cats, dogs and horses as currently provided by Section 5(6) of ASPA.

The other provisions transpose Article 7(1), 8(1) and 8(2).

Schedule 2: Conditions in licences

Regulation 10(2) inserts new Schedule 2C. Part 1 of new Schedule 2C sets out the requirements for the conditions to be applied to Section 2C licences: Part 2 sets out the requirements for the conditions to be applied to personal licences; Part 3 sets out the requirements for the conditions to be applied to project licences.

Part 1: Conditions in section 2C licences

Condition 6 requires that a section 2C licence must include a condition requiring the holder to establish and maintain an Animal Welfare and Ethical Review Body. This transposes Article 26 and 27.

Condition 7 requires that a Section 2C licence authorising the breeding of non-human primates must include a condition requiring the holder to have in place a strategy for increasing the proportion of primates bred from primates bred in captivity. This transposes Article 28.

Condition 11 requires that a Section 2C licence must include a condition relating to the general care and accommodation of protected animals kept at the place specified in the licence and that such condition should ensure that any applicable standard in Annex 3 of the Directive and any additional or higher standard set out in any code of practice issued or approved under ASPA section 21 in force on 9 November 2010 is met. These requirements transpose Article 33 and Annex III and maintain stricter current UK standards where applicable.

Part 2: Conditions in personal licences

Condition 13 requires that a personal licence should include a condition requiring the holder to act at all times in a manner consistent with the principles of replacement, reduction and refinement (the 3Rs).

Conditions 14 and 15 require that a personal licence should include various conditions relating to the application of regulated procedures.

Part 3: Conditions in project licences

Condition 17 requires that a project licence should include a condition requiring the holder to ensure that the specified programme of work does not involve the application of any regulated procedure to which there is a

scientifically satisfactory alternative method or testing strategy not entailing the use of a protected animal. This transposes Articles 4 and 13.

Condition 20 requires that a project licence should include a condition for the purpose of ensuring that a regulated procedure is not applied to an animal that may cause the animal severe pain, suffering or distress that is likely to be long-lasted and cannot be ameliorated. This transposes Article 15(2).

Condition 25(1) requires that a project licence should include a condition prohibiting the use of stray animals of domestic species. This transposes Article 11. No provision is made for an exemption from this condition.

Condition 25(1) also requires that a project licence should include a condition prohibiting the use of feral animals of domestic species. Condition 25(2) provides for an exemption to this condition.

Schedule 3: Transitional provision

Regulation 42 inserts Schedule 3 making transitional provisions relating to existing licences and certificates granted under the Animals (Scientific Procedures) Act 1986. Schedule 3 also makes new conditions for personal, project and Section 2C licences

Transposition table

The following table (Annex A) provides further information about the implementation of the provisions of Directive 2010/63/EU and the amendment of the Animals (Scientific Procedures) Act 1986 (referred to as ASPA in the table).

Home Office
October 2012

ANNEX A

Transposition of Directive 2010/63/EU on the protection of animals used for scientific purposes through the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012

Transposition Table

Article	Subject matter	Implementation
1(1)	Explains the subject matter and scope of the Directive.	Regulation 4(3) inserts new ASPA section 2(1A)
1(2) 1st paragraph	Article 1(2) provides that the Directive shall apply where animals are used or intended to be used in procedures, or bred specifically so that their organs or tissues may be used for scientific purposes.	Regulation 6 inserts new ASPA section 2B(1) and (2)
1(2) 2nd paragraph	The Directive applies until protected animals have been killed, re-homed or returned to a suitable habitat or husbandry system.	Nothing required
1(2) 3rd paragraph	The elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia, analgesia or other methods does not exclude the use of an animal in procedures from the scope of the Directive.	Transposed by current ASPA section 2(4).

Article	Subject matter	Implementation
1(3)(a)	Under Article 1(3)(a), foetal forms of mammals are protected from the last third of their normal development. Birds and reptiles are not protected until they hatch or, in the case of viviparous reptiles, when they are born.	Regulation 3(b) amends section 1(2)(a) to change the point of protection from halfway through the gestation period to the last third of normal development Protection of immature forms of birds and reptiles is retained in amended section 1(2)(a) (as allowed by Article 2 to the Directive).
1(3)(b)	Article 1(3)(b) extends protection to all live cephalopods.	Regulation 3(a) amends ASPA section 1(1) and regulation 3(c) inserts new section 1(2A). ASPA section 1(3)(a) is amended consequentially by regulation 3(d).
1(4)	Article 1(4) provides that the directive shall apply to animals at an earlier stage of development than set out in Article 1(3)(a) if the animal is to be allowed to live beyond that stage and is likely to experience pain, suffering, distress or lasting harm as a result of the procedures performed after it has reached that stage.	Regulation 4(5) inserts new ASPA section 2(2A).
1(5)(a) to (e)	Article 1(5) lists practices to which the Directive does not apply.	Regulation 4(8) inserts revised sections 2(8)(a) to 2(8)(e) and 2(8A).

Article	Subject matter	Implementation
1(5)(f)	Article 1(5)(f) provides that the Directive shall not apply to practices not likely to cause pain, suffering, distress or lasting harm equivalent to that caused by the introduction of a needle in accordance with good veterinary practice.	Regulation 4(2) amends ASPA section 2(1) for Article 1(5)(f).
1(6)	Article 1(6) provides that the Directive shall apply without prejudice to Council Directive 76/768/EEC relating to cosmetic products.	Not necessary to transpose.
2	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 providing they are not used to inhibit the free market.	Not necessary to transpose.

Article	Subject matter	Implementation
3(1) 1st paragraph	Defines 'procedure'.	Regulation 4(2) amends the definition of 'regulated procedure' in section 2(1). Regulation 4(3) inserts new ASPA section 2(1A). Regulations 4(4)(a), (b) and (c) amend ASPA section 2(2). Regulation 4(5) inserts new ASPA section 2(2A). Regulation 4(8) inserts new ASPA section 2(8A).
3(1) 2nd paragraph	Provides that the definition of 'procedure' includes the breeding, creation and maintenance of genetically modified animals.	Regulation 4(6) inserts new ASPA sections 2(3A) and 2(3B).
3(1) 2nd paragraph	Provides that the definition of 'procedure' excludes the killing of animals for the use of their organs or tissues.	Regulation 4(8) amends ASPA 2(7). Some methods of killing retained as regulated procedures for welfare reasons using Article 2.
3(2)	Definition of 'project'.	ASPA section 5(1) retained unchanged defines project (licence).
3(3)	Definition of 'establishment'.	Not included

Article	Subject matter	Implementation
3(4)	Definition of ‘breeder’.	Regulation 6 inserts new ASPA section 2B(2)(b).
3(5)	Definition of ‘supplier’.	Regulation 6 inserts new ASPA section 2B(2)(c).
3(6)	Definition of ‘user’.	Regulation 6 inserts new ASPA section 2B(2)(a).
3(7)	Definition of ‘competent authority’.	Not required.
4(1)	Article 4(1) requires Member States to ensure that a scientifically-satisfactory, non-animal method or testing strategy is used wherever possible.	Regulation 5 inserts new ASPA section 2A for Article 4(1). Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 1,13 and 17.
4(2)	Article 4(2) requires that the number of animals used is reduced to a minimum consistent with the objectives of the project.	Regulation 5 inserts new ASPA section 2A for Article 4(2). Regulation 10(2) inserts new ASPA Schedule 2C paragraph 18.
4(3)	Article 4(3) requires refinement of procedures, breeding, and accommodation and care to minimise pain, suffering, distress or lasting harm to the animals.	Regulation 5 inserts new ASPA section 2A for Article 4(3). Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 14(b).

Article	Subject matter	Implementation
4(4)	Requires that in the choice of methods, Article 4 is implemented in accordance with Article 13.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 17.
5(a) to (g)	Article 5 specifies the purposes for which procedures may be carried out.	Regulation 9(1) inserts new ASPA section 5C(3).
6(1)	Article 6(1) requires that animals are killed humanely	Regulation 15 inserts new ASPA section 15A.
6(2)	Article 6(2) requires that animals are killed in breeder, supplier and user establishments by a competent person.	Regulation 15 inserts new ASPA section 15A(1). Regulation 10(2) inserts new ASPA Schedule 2C, paragraphs 1 and 2.
6(3)	Article 6(3) requires that methods of killing set out in Annex IV to the Directive are to be used for specified animals.	Regulation 15 inserts new ASPA sections 15A(2), 15A(4) and 15A(5). Regulation 16 amends Schedule 1 to ASPA.
6(4)	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.	Regulation 15 inserts new ASPA sections 15A(2), 15A(3), 15A(6) and 15A(7).

Article	Subject matter	Implementation
6(5)	A further derogation in Article 6(5) applies in emergency circumstances.	Regulation 15 inserts new ASPA section 15A(9).
7(1)	Article 7(1) 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.	Regulation 9(1) inserts new ASPA section 5C(4). Regulation 9(2) inserts Schedule 2B, paragraph 3.
7(2)	Article 7(2) provides that Article 7(1) does not apply to species of non-human primate	Nothing required
8(1)	Article 8(1) stipulates that non-human primates shall not be used in procedures except for specified purposes 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.	Regulation 9(1) inserts new ASPA section 5C(4) and retains special protection for cats, dogs and equidae. Regulation 9(2) inserts Schedule 2B, paragraph 2 for Article 8(1) and paragraph 4 for cats, dogs and equidae.

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

Article	Subject matter	Implementation
8(2)	Under article 8(2), further restrictions apply to the use of non-human primates of endangered species.	Regulation 9(1) inserts new ASPA section 5C(4). Regulation 9(2) inserts Schedule 2B, paragraph 1.
8(3)	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.	Regulation 9 inserts new ASPA section 5C(5).
9(1)	Article 9(1) prohibits the use of animals taken from the wild.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 25(1)(c).
9(2)	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.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 25(3).

Article	Subject matter	Implementation
9(3)	Article 9(3) sets requirements regarding competence and methods of capture. 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.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraphs 25(4) and 25(5).
10(1)	Article 10(1) limits the use of animals belonging to the species listed in Annex I to the Directive to those which have been bred for use in procedures.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 25(1)(e).
10(1)	Article 10(1) also provides that, from the dates set out in Annex II, non-human primates listed in Annex II may be used for experimental and other scientific purposes only where they are the offspring of non-human primates that have been bred in captivity or are sourced from self-sustaining colonies.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraphs 25(1)(d) and 25(6). Article 10(1) paragraph 2 in respect of cynomolgus and rhesus monkeys will be transposed at a future date but in advance of the date set in Annex 2 of the Directive.

Article	Subject matter	Implementation
10(1)	Article 10(1) further provides that the Commission is to conduct a feasibility study of these requirements, in consultation with Member States and stakeholders, and, where appropriate, make proposals for amendments to Annex II.	Not necessary to transpose.
10(2)	Article 10(2) requires the Commission to analyse the feasibility of sourcing non-human primates only from self sustaining colonies.	Not necessary to transpose.
10(3)	Article 10(3) allows competent authorities to grant exemptions from the requirements of Article 10(1) on the basis of scientific justification.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 25(3).
11(1)	Article 11 prohibits the use of stray and feral animals of domestic species.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraphs 25(1)(a) and (b).

Article	Subject matter	Implementation
11(2)	Article 11(2) allows competent authorities to grant exemptions from the requirements of Article 11(1) where there is an essential need for studies relating to the health and welfare of the animals, or serious threats to the environment or to human or animal health and there is scientific justification that the purpose of the procedure can be achieved by the use of a stray or a feral animal.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 25(2). The exemption applies only to feral animals of domestic species, not stray animals.
12(1)	Article 12(1) requires that procedures are always carried out in authorised user establishments, unless an exemption is granted on the basis of scientific justification.	Transposed by current ASPA sections 3(c), and by regulation 9(1), which inserts new ASPA sections 5(2) and 5(3).
12(2)	Article 12(2) requires that procedures are only carried out within the framework of a project.	Transposed by current ASPA sections 3(b) and 5(1).
13(1)	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.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 17.

Article	Subject matter	Implementation
13(2)	Where more than one animal method is available, Article 13(2) mandates the 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.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 18.
13(3)	Article 13(3) 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.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraphs 14(e) and 22. Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 18(2).

Article	Subject matter	Implementation
14(1)	Except where it is inappropriate, Article 14(1) 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(1) further stipulates that procedures that involve serious injuries that may cause severe pain are not to be carried out without anaesthesia.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 15.
14(2)	Article 14(2) specifies the factors to be taken into account when deciding on the appropriateness of using anaesthesia.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 15.
14(3)	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.	Regulation 17 inserts revised ASPA section 17.

Article	Subject matter	Implementation
14(4)	Article 14(4) specifies the requirements for treatment of an animal which may suffer pain once anaesthesia has worn off.	Regulation 10(2) inserts new Schedule 2C, paragraph 15(3).
14(5)	Article 14(5) provides that appropriate action shall be taken to minimise the suffering of an animal as soon as the purpose of the procedures has been achieved.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 22(b).
15(1)	Article 15(1) 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.	Regulation 9(1) inserts new ASPA sections 5B(3)(c), 5B(6) and 5D(4).
15(2)	Subject to the safeguard clause in Article 55(3), Article 15(2) prohibits the authorisation of procedures involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraphs 14(a) 14(d) and 20.

Article	Subject matter	Implementation
16(1)	Article 16(1) 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.	Regulation 14 replaces ASPA section 14 with a new ASPA section 14.
16(2)	Article 16(2) provides that in exceptional circumstances, and following veterinary examination, re-use may be allowed after use in a severe procedure.	Regulation 14 inserts new ASPA section 14(6).
17(1)	Article 17(1) defines the point at which a procedure shall be deemed to have ended.	Defined in effect by existing ASPA sections 1(1) and 15, and new ASPA section 17A inserted by Regulation 18.
17(2)	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.	Transposed by existing ASPA section 15 Regulation 10(2) inserts new ASPA Schedule 2C, paragraphs 14(f) and 24.
17(3)	Article 17(3) requires that where an animal is to be kept alive it is to receive the care and accommodation appropriate to its state of health.	Regulation 10(2) inserts ASPA Schedule 2C, paragraph 11.

Article	Subject matter	Implementation
18	Article 18 requires that Member States facilitate the establishment of programmes for the sharing of organs and tissues of animals.	Regulation 21 inserts new ASPA section 20A.
19	Article 19 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.	Regulation 18 inserts new ASPA section 17A.
20(1) 1st paragraph	Article 20(1) requires that all breeders, suppliers and users are authorised by and registered with the competent authority.	Regulation 6 inserts new ASPA section 2B. Regulation 6 inserts new ASPA section 2C(1).
20(1) 1st paragraph	Such authorisation may be granted for a limited period.	Discretion in Article 20(1), paragraph 1 to grant for a limited period will not be transposed. Regulation 6 inserts new ASPA section 2C(9) which provides for a licence to remain in force until revoked.
20(1) 2nd paragraph	Authorisation is dependent on compliance with the requirements of the Directive.	Regulation 6 inserts new ASPA section 2C(2) and 2C(3).

Article	Subject matter	Implementation
20(2)	Article 20(2) stipulates that the authorisation must specify the person responsible for compliance and the persons referred to in Articles 24(1) and 25.	Regulation 6 inserts new ASPA section 2C(4) and 2C(5)(e).
20(3)	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.	Regulation 6 inserts new ASPA section 2C(10). Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 3(b).
20(4)	Article 20(4) requires the notification of any changes to the persons referred to in Article 20(2) to the competent authority.	Regulation 6 inserts new ASPA section 2C(10). Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 3(a).
21(1)	Article 21(1) requires the withdrawal or suspension of authorisation where a breeder, supplier or user ceases to comply with the requirements of the Directive.	Regulation 11 replaces ASPA section 11 with a new ASPA section 11.

Article	Subject matter	Implementation
21(2)	Where authorisation is withdrawn or suspended, Article 21(2) requires Member States to ensure the welfare of animals housed at an establishment is not adversely affected.	Regulation 13 inserts new ASPA section 13A.
22(1)	Under Article 22(1) Member States must ensure all breeding, supplying and user establishments have installations and equipment suited to the species housed and to the effective performance of any procedures carried out in them.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 4(1).
22(2)	Article 22(2) requires that the design, construction and functioning of installations and equipment shall ensure that the procedures are carried out as effectively as possible, provide reliable results and minimise pain, suffering, distress or lasting harm.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 4(2).
22(3)	Article 22(3) provides that for the purposes of Article 22(1) and (2) the requirements set out in Annex III to the Directive are complied with.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 4(3) & (4).

Article	Subject matter	Implementation
23(1)	Under Article 23(1), each breeder, supplier and user will be required to have sufficient staff on site.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 5.
23(2)(1st sub-paragraph)	Under the first sub-paragraph of Article 23(2), staff shall be adequately educated and trained before a) carrying out procedures on animals; b) designing procedures and projects; c) taking care of animals; or d) killing animals.	Regulation 7(2) amends ASPA section 3. Regulation 8(5) amends ASPA section 4(4A). ASPA sections 3(a) and 4(4A)(a) transpose Article 23(2)(a). New ASPA section 5C(2), inserted by Regulation 9(1), transposes Article 23(2)(b) New ASPA Schedule 2C, paragraph 5, inserted by Regulation 10(2), transposes Article 23(2)(c). New ASPA Schedule 2C, paragraph 2, inserted by Regulation 10(2), transposes Article 23(2)(d).
23(2)(2nd sub-paragraph)	Under the second sub-paragraph of Article 23(2), those designing procedures and projects must have received instruction in a scientific discipline relevant to the work being undertaken and have species specific knowledge.	Regulation 9(1) inserts new ASPA section 5C(2).

Article	Subject matter	Implementation
23(2)(3rd sub-paragraph)	Under the third sub-paragraph of Article 23(2), staff carrying out procedures on animals (a), taking care of animals (c) or killing animals (d) must be supervised until they have demonstrated the requisite competence.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 19 for (a). Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 5 for (c). Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 2 for (d).
23(2)(4th sub-paragraph)	Under the fourth sub-paragraph of Article 23(2), Member States may choose to ensure that the requirements of Article 23(2) relating to the competence of personnel are met either through a system of authorisation 'or by other means'.	Regulation 6 inserts new ASPA sections 2B and 2C. Regulation 10(2) inserts new Schedule 2C, paragraphs 2 and 5. Existing ASPA section 3(a) and (b) establishes authorisation through licences. Regulation 9 inserts new ASPA section 5C(2). Regulation 8(5) amends existing ASPA section 4(4A). Regulation 11 replaces ASPA section 11 with a new ASPA section 11.

Article	Subject matter	Implementation
23(3)	Article 23(3) 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.	Nothing needed on the face of the Act.
23(4)	Article 23(4) provides that the Union may adopt non-binding guidelines on the requirements of Article 23(2).	Not necessary to transpose.
24(1)	Article 24(1) 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.	Regulation 6 inserts new ASPA section 2C(4), 2C(5)(a), 2C(5)(c),2C(5)(d) and 2C(6).

Article	Subject matter	Implementation
24(2)	Article 24(2) requires Member States to ensure that the persons specified in Article 40(2)(b) shall ensure that unnecessary pain, etc, inflicted on an animal in the course of a procedure is stopped; and that projects are carried out in accordance with the project authorisation.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraphs 14(c), 21 for the first part of Article 24(2). Existing ASPA section 22(2) and new ASPA Schedule 2C, paragraph 28, inserted by Regulation 10(2) transpose the second part of Article 24(2).
25	Article 25 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.	Regulation 6 inserts new ASPA section 2C(4) and 2C(5)(b).
26(1)	Article 26(1) requires each breeder, supplier and user to set up an animal welfare body (AWB).	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 6(1).
26(2)	Article 26(2) requires that the Animal Welfare Body shall comprise, 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.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 6(2).

Article	Subject matter	Implementation
26(3)	Article 26(3) provides that Member states may allow small breeders, suppliers and users to fulfil the tasks of an Animal Welfare Body laid down in article 27(1) by other means.	The discretion in this Article has not been transposed.
27(1)	Article 27(1) sets out the tasks of the Animal Welfare Body.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 6(1)(b).
27(2)	Article 27(2) requires Member states to ensure that records of any advice given by Animal Welfare Bodies and of any decision taken as a result are kept for at least three years.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 6(4) and 6(5).
28	Article 28 requires breeders of non-human primates to have a strategy for increasing the supply of animals that are the offspring of animals bred in captivity.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 7.
29	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.	Regulation 18 inserts new ASPA section 17A, subsection (3)(c).

Article	Subject matter	Implementation
30(1)	Article 30(1) sets out the records to be kept by establishments on animals.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 8(a).
30(2)	Article 30(2) provides that these records are to be kept for three years and submitted to the competent authority on request.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 8(b).
31(1)	Article 31(1) sets out the information to be kept on each dog, cat and non-human primate.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 9.
31(2)	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.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 9.
31(3)	Article 31(3) provides that these records are to be kept for three years after the death or re-homing of the animal and submitted to the competent authority on request.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 9.

Article	Subject matter	Implementation
32(1)	Article 32(1) requires that dogs, cats and non-human primates are given an individual identification mark, before weaning, in the least painful manner possible.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 10.
32(2)	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.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 10.
32(3)	Unmarked animals taken into establishments must be marked as soon as possible after first receipt.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 10.
32(4)	If asked, establishments must explain to the competent authority why an animal is unmarked.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 10.
33(1)	Article 33(1) sets out the requirements for the care and accommodation of animals kept in establishments.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 11(1).

Article	Subject matter	Implementation
33(2)	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.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 11(2) and 11(3).
33(3)	Under Article 33(3), Member States may allow exemptions from the requirements of paragraph 33(1)(a) and 33(2) for scientific, animal-welfare or animal-health reasons.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 11(4) and 11(5).
34(1)	Article 34(1) requires Member States to ensure that competent authorities carry out regular inspections of all breeders, suppliers and users, to verify compliance with its requirements.	Regulations 19(2)(b) and 19(3) replace ASPA sections 18(2)(b) to (e) with new ASPA sections 18(2)(b) and 18(2A) to 18(2E). Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 12(a), 16(a) and 27(a).
34(2)	The frequency of inspections is to be determined according to a risk assessment for each establishment, taking account of factors specified in Article 34(2).	Regulations 19(3) inserts new ASPA section 18(2C).

Article	Subject matter	Implementation
34(3)	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.	Regulation 19(3) inserts new ASPA section 18(2D).
34(4)	An appropriate proportion of the inspections are to be carried out without prior warning.	Regulation 19(3) inserts new ASPA section 18(2B).
34(5)	Records of inspections are to be kept for at least five years.	Regulation 19(3) inserts new ASPA section 18(2E).
35(1)	Article 35(1) requires the Commission to review the infrastructure and operation of national inspections by Member States when there is a reason for concern.	Not necessary to transpose.
35(2)	Article 35(2) requires Member States to give all necessary assistance to the Commission in carrying out controls.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 12(b), 16(b) and 27(b).
35(3)	Article 35(3) requires Member States to take account of the results of the control.	Nothing required on the face of the Act.

Article	Subject matter	Implementation
36(1)	Under Article 36(1), projects require prior authorisation by the competent authority, and must be carried out in accordance with that authorisation.	ASPA section 3(b) transposes Article 36(1).
36(2)	In addition, no project is to be carried out without having received a favourable project evaluation by the competent authority.	Regulation 9(1) inserts new ASPA section 5B(1).
37(1)	Under Article 37(1), 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.	Regulation 9(1) inserts new ASPA section 5A(1).
37(2)	Member States may waive the requirement for a non-technical summary for projects referred to in Article 42(1).	Discretion in Article 337(2) to waive the requirement will not be transposed.

Article	Subject matter	Implementation
38(1)	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.	Regulation 9(1) inserts new ASPA sections 5B(2) and 5B(8).
38(2)	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.	Regulation 9(1) inserts new ASPA section 5B(3).
38(3)	Article 38(3) requires that in carrying out the project evaluation the competent authority is to consider expertise 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.	Regulation 9(1) inserts new ASPA section 5B(4).

Article	Subject matter	Implementation
38(4)	Article 38(4) stipulates that the project evaluation process shall be transparent.	Regulation 9(1) inserts new ASPA section 5B(9).
39(1)	Article 39(1) creates a requirement for the retrospective assessment of projects and sets out the factors which must be evaluated.	Regulation 9(1) inserts new ASPA section 5F(1) and 5F(2).
39(2)	Article 39(2) stipulates that all projects using non-human primates, and projects involving procedures classified as "severe", shall undergo retrospective assessment.	Regulation 9 inserts new ASPA sections 5B(3)(h) and 5B(7).
39(3)	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.	The discretion in Article 39(3) has not been transposed.

Article	Subject matter	Implementation
40(1)	Under Article 40(1), project authorisations will cover only those procedures considered and agreed in the project evaluation and the severity classifications assigned to those procedures.	Regulation 9(1) inserts new ASPA section 5B(1). Regulation 9(1) inserts new ASPA 5B(3)(c).
40(2)	Article 40(2) requires that the project authorisation will also specify the a) user undertaking the project; b) the persons responsible for the overall implementation of the project and its compliance with the project authorisation; c) the establishments in which the project will be undertaken, when applicable; and d) any specific conditions applied to the project, including whether and when the project is to be assessed retrospectively.	Regulation 9(1) inserts new ASPA sections 5D(3) for Article 40(2)(a). Regulation 9(1) inserts new ASPA sections 5C(1),5D(2(a) and 5D(2)(b) for Article 40(2)(b). Current ASPA section 5(1) and new ASPA sections 5(2) and 5(3) inserted by Regulation 9(1) transpose Article 40(2)(c). Regulation 9(1) inserts new ASPA sections 5D(5) for Article 40(2)(d).
40(3)	Article 40(3) provides that project authorisations may be granted for a period not exceeding five years.	Regulation 9(1) inserts new ASPA section 5E(1).

Article	Subject matter	Implementation
40(4)	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.	Regulation 9(1) inserts new ASPA section 5(4).
41(1)	Article 41(1) 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	Regulation 9(1) inserts new ASPA section 5A(7).
41(2)	The period in article 41(1) may be extended by a further 15 working days for complex or multi-disciplinary projects.	Regulation 9(1) inserts new ASPA sections 5A(8) and 5A(9).
41(3)	The competent authority is to inform applicants of these timescales.	Regulation 9(1) inserts new ASPA section 5A(6).

Article	Subject matter	Implementation
41(4)	Where an application is incomplete or incorrect, the competent authority is to inform the applicant promptly of the need to supply any additional documentation and of any impact on the timescale for decision.	Regulation 9(1) inserts new ASPA section 5A(4).
42(1)	Under Article 42(1), 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.	The discretion in Article 42(1) has not been transposed.
42(2)	Article 42(2) sets out the conditions to be met by Member States when introducing a simplified administrative procedure.	Not transposed.
42(3)	Article 42(3) requires that if changes to a project covered by Article 42 may have a negative impact on animal welfare they shall be subject to a further project evaluation.	Not transposed.

Article	Subject matter	Implementation
42(4)	Article 40(4) provides that Article 40(3) and 40(4), 41(3) and 44(3), 44(4) and 44(5) shall apply mutatis mutandis to projects authorised under Article 42.	Not transposed.
43(1)	Article 43(1) provides that, subject to safeguarding intellectual property and confidential information, non-technical project summaries shall 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.	Regulation 9(1) inserts new ASPA sections 5A(2) and 5A(3)
43(2)	Under Article 43(2), 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.	Regulation 9(1) inserts new ASPA section 5D(7)(a).

Article	Subject matter	Implementation
43(3)	Article 43(3) requires that Member States publish the non-technical summaries of authorised projects and any updates thereto.	Regulation 9(1) inserts new ASPA sections 5D(6), 5D(7) and 5F(3).
44(1)	Under Article 44(1), amendment or renewal of a project authorisation is required for any change of the project that may have a negative impact on animal welfare.	Regulation 9(1) inserts new ASPA section 5E(5).
44(2)	Article 44(2) provides that any amendment of renewal of a project will require a further favourable project evaluation.	Regulation 9(1) inserts new ASPA section 5E(5).
44(3)	Article 44(3) provides that project authorisation may be withdrawn if the project is not carried out in accordance with the project authorisation.	Regulation 11 replaces ASPA section 11 with a new ASPA section 11.
44(4)	Article 44(4) provides that in such cases, the welfare of the animals used or intended to be used in the project must not be adversely affected.	Regulation 13 inserts new ASPA section 13A.

Article	Subject matter	Implementation
44(5)	Article 44(5) requires Member States to publish conditions for amendment and renewal of project authorisations.	Regulation 9(1) inserts new ASPA section 5E(6).
45(1)	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.	Regulation 9(1) inserts new ASPA section 5G(1) and 5G(2).
45(2)	Where relevant, documentation shall be retained until any retrospective assessment has been completed.	Regulation 9(1) inserts new ASPA section 5G(3).
46	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.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 26.

Article	Subject matter	Implementation
47(1)	Under Article 47(1), 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.	Regulation 22 inserts new ASPA sections 20B(1) and 20B(2)(c).
47(2)	Under Article 47(2), Member States are to assist the Commission in identifying and nominating suitable laboratories to carry out validation studies.	Regulation 22 inserts new ASPA section 20B(2)(a).
47(3)	Article 44(3) provides that the Commission is to set the priorities for validation studies and allocate the tasks between the laboratories after consulting Member States.	Not necessary to transpose.
47(4)	Under Article 44(4), Member States are to ensure the promotion of, and the dissemination of information on, alternative approaches.	Regulation 22 inserts new ASPA section 20B(2)(d).

Article	Subject matter	Implementation
47(5)	Article 44(5) requires Member States to nominate a single point of contact to provide advice on the regulatory relevance and suitability of alternative approaches proposed for validation.	Regulation 22 inserts new ASPA section 20B(2)(b).
47(6)	Article 44(6) requires the Commission to take appropriate action with a view to obtaining international acceptance of alternative approaches validated in the Union.	Not necessary to transpose.
48(1)	Article 48(1) provides that the duties and tasks of the Union reference Laboratory shall be as set out int Annex VII to the Directive.	Not necessary to transpose.
48(2)	Article 48(2) provides that the Union reference Laboratory may collect charges for the services it provides that do not contribute directly to the 3Rs.	Not necessary to transpose.
48(3)	Article 48(3) provides tha detailed rules may be adopted for the implementation of Article 48(2).	Not necessary to transpose.

Article	Subject matter	Implementation
49(1)	Article 49(1) 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.	Regulation 20 replaces ASPA sections 19 and 20 with revised sections 19 and 20.
49(2)	Article 49(2) provides that 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.	Regulation 20 replaces ASPA sections 19 and 20 with revised sections 19 and 20.
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.	Not necessary to transpose.

Article	Subject matter	Implementation
51	See Article 50.	Not necessary to transpose.
52	See Article 50.	Not necessary to transpose.
53	See Article 50.	Not necessary to transpose.
54(1)	Article 54(1) provides that Member States shall by 10 November 2018, and every 5 years thereafter, send the information on the implementation of this Directive and in particular Articles 10(1), 26, 28, 34, 38, 39, 43 and 46 to the Commission.	Regulation 23 inserts new ASPA section 21A(5).
54(2)	Article 54(2) provides that Member States shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures. Member States shall submit that statistical information to the Commission by 10 November 2015 and every year thereafter.	Regulation 23 inserts new ASPA sections 21A(1), (2) and (3). Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 23.

Article	Subject matter	Implementation
54(3)	Article 54(3) provides that Member States shall submit to the Commission, on annual basis, detailed information on exemptions granted under Article 6(4)(a).	Regulation 23 inserts new ASPA section 21A(4).
54(4)	Article 54(4) provides that the Commission shall by 10 May 2012 establish a common format for submitting the information referred to in paragraphs 1, 2, and 3 of this Article in accordance with the regulatory procedure referred to in Article 56(3).	Not necessary to transpose.
55(1)	Article 55(1) allows a Member State to adopt a provisional measure authorising the use of non-human primates for the purposes set out in Article 8(1)(a)(i) other than with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life threatening clinical conditions.	Not necessary to transpose.
55(2)	Article 55(2) makes similar provision for the adoption of a provisional measure authorising the use of great apes.	Not necessary to transpose.

Article	Subject matter	Implementation
55(3)	Article 55(3) makes provision for the adoption of a provisional measure authorising procedures involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated as referred to in Article 15(2).	Not necessary to transpose.
55(4)(1st sub paragraph)	Under article 54(4) a Member State adopting a provisional measure must inform the Commission and other Member States giving reasons and submitting supporting evidence.	Not necessary to transpose.
55(4)(2nd sub paragraph)	The Commission is put matters referred under the first sub paragraph of Article 55(4) to the committee referred to in Article 56(1) within 30days of receipt and in accordance with the regulatory procedure referred to in Article 56(3) either authorise the provisional measure or require the Member State to revoke it.	Not necessary to transpose.
56(1)	Article 56(1) provides that the Commission shall be assisted by a committee	Not necessary to transpose.

Article	Subject matter	Implementation
56(2)	Provides that Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.	Not necessary to transpose.
56(3)	Provides that Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.	Not necessary to transpose.
57(1)	Article 57(1) 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.	Not necessary to transpose.
57(2)	The Commission must also submit a statistical report by the same date and every three years thereafter.	Not necessary to transpose.
58	Article 58 requires the Commission to review the Directive by 10 November 2017.	Not necessary to transpose.

Article	Subject matter	Implementation
58	Article 58 provides that the Commission shall, where appropriate and in consultation with Member states and stakeholders conduct periodic thematic reviews of the 3Rs.	Not necessary to transpose.
59(1)	Article 59 requires each Member State to designate one or more competent authorities responsible for the implementation of the Directive.	Not necessary to transpose.
59(2)	Member states are to communicate details of a national authority serving as a contact point for the purposes of the Directive by 10 February 2011.	Not necessary to transpose.
60	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.	Regulation 11 replaces ASPA section 11 with a new ASPA section 11. Regulation 24 inserts new ASPA sections 22(A1), 22(3)(za), 22(3A) and 22(4A).

Article	Subject matter	Implementation
61(1)	Article 61 requires Member States to transpose the Directive by 10 November 2012 and implement its provisions from 1 January 2013.	Not necessary to transpose.
61(2)	Member States are to communicate to the Commission the text of the main provisions of their national transposing the Directive.	Not necessary to transpose.
62	Directive 86/609/EEC is repealed with effect from 1 January 2013 (except for Article 13 which is repealed from 10 May 2013).	Not necessary to transpose.
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.	Not necessary to transpose
64(1)	Article 64(1) provides that Member states shall not apply provisions adopted in accordance with Articles 36 to 45 to projects approved before 1 January 2013 and the duration of which does not extend beyond 1 January 2018.	Regulation 42 and Schedule 3 make transitional provision.

Article	Subject matter	Implementation
64(2)	Article 64(2) provides that projects approved before 1 January 2013 and the duration of which extends beyond 1 January 2018 shall obtain authorisation before 1 January 2018.	Regulation 42 and Regulation Schedule 3 make transitional provision.
65	Article 65 provides for the Directive to enter in force on the 20th day following its publication in the Official Journal of the European Union.	Not necessary to transpose.
66	The Directive is addressed to Member States.	Not necessary to transpose.
Annex I	Annex I lists animals which may only be used in procedures if they have been purpose-bred.	Regulation 26(18) amends ASPA Schedule 2.

Article	Subject matter	Implementation
Annex II	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: The requirements pertaining to cynomolgus and rhesus monkeys and to other species of non-human primate, other than marmosets, do not come into effect until feasibility studies have been undertaken by the Commission, and Member States may permit exceptions based upon scientific justification.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 25(1)(d) in respect of marmosets. There is no need to transpose the requirements of Annex II in respect of other species of non-human primate at present.
Annex III	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.	Regulation 10(2) inserts new ASPA Schedule 2C, paragraphs 11(2) and 11(3).

Article	Subject matter	Implementation
Annex IV	Annex IV specifies the methods to be used when killing animals and the species to which they are to be applied.	Regulation 16(3) amends ASPA Schedule 1 inserting new paragraph 3. Regulation 16(4) amends ASPA Schedule 1 Table A.
Annex V	Annex V provides a list of elements referred to in Article 23(3) relating to minimum requirements for education and training	No need to transpose. Education and training requirements referring to Annex V will be published separately in due course in accordance with Article 23(3).
Annex VI	Annex VII provides a list of elements referred to in Article 37(1)(c) – information required in project applications.	Regulation 9(1) inserts new ASPA section 5A(c).
Annex VII	Annex VII sets out the duties and tasks of the union reference laboratory.	No need to transpose.
Annex VIII	Annex VIII sets out the assignment criteria for the severity classification of procedures.	Regulation 9(1) inserts new ASPA section 5B(6). Regulation 10(2) inserts new ASPA Schedule 2C, paragraph 23.