

# **Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 – changes to existing licences and certificates**

## **About this guide**

This guide outlines and explains how the changes to the Animals (Scientific Procedures) Act 1986 (ASPA) brought in by the new European Directive on the protection of animals used for scientific purposes (2010/63/EU) will affect existing licences and certificates of designation.

These changes will apply from 1 January 2013.

The guide highlights the key changes that you will need to act on immediately. It also describes other changes that do not require you to do anything as they will happen automatically.

It will be necessary to obtain re-authorisation of certain activities or for the use of certain types of animal because the Directive and new ASPA introduce additional criteria that must be satisfied. We have done our best to make the re-authorisation process as simple as possible and in many cases will not require further input from you. In most cases we will be able to provide that re-authorisation simply by letter.

If you are an existing certificate or licence holder you will not need to take part in any further training. However, you must familiarise yourself with the new regulations and the new conditions on your licence(s).

This guide is set out in four sections:

- Certificate holders – see section 1
- Personal licence holders – see section 2
- Project licence holders – see section 3
- What to do next – see section 4

We recommend that you read all four sections to understand how new ASPA affects all types of certificate and licence.

The numbers in square brackets refer to paragraphs in the Annex to this guide where you will find more detailed information about the transitional arrangements. We will be issuing comprehensive guidance to new ASPA early in 2013.

## **1: Certificate holders**

### **Important: please note**

#### ***Changes to Certificates of Designation***

- Certificates of designation will automatically become section 2C licences on 1 January 2013. We intend to call these ‘establishment licences’. They will allow you to continue the same activity as you do now – that is breeding, supplying and/or applying scientific procedures. **[1]**
- Certificate holders will automatically become the holders of the establishment licences. **[2]**

- Current Named Veterinary Surgeons ( NVSs) and Named Animal Care & Welfare Officers (NACWOs) will automatically continue their roles under the new establishment licence and their titles will not change. **[3]**
- The new establishment licences will include details of three additional named people – a ‘training officer’, an ‘information officer’ and a ‘person responsible for compliance with the licence’. Initially, the establishment licence holder will hold these three roles. **[4 and 5]** You will be able to nominate other members of staff for these roles after 1 January 2013.

### **Key changes needing your immediate action**

#### ***Using cephalopods***

- All cephalopods (octopus, squid, cuttlefish and nautilus) will now be protected species. This means you must ensure that anyone carrying out work in your establishment involving regulated procedures in cephalopods has the appropriate project and personal licences in place.
- This work can only take place in approved areas. You will need to have your certificate of designation amended if the areas in which cephalopods are being used are not already approved for holding and using aquatic species. **[9 and 10]**
- If cephalopods are being used at premises that are not part of a designated establishment, a new establishment licence will be required for this purpose. **[8]**

#### ***Breeding and supplying frogs and zebra fish***

- From 1 January 2013, certain species of frog (*Xenopus laevis*; *Xenopus tropicalis*; *Rana temporaria*; and *Rana pipiens*) and zebra fish may only be bred at, or supplied from, an establishment with an establishment licence.
- If your establishment is already designated as a breeder or supplier and you are breeding or holding these species in an area already approved for aquatic species, we will be able to issue the necessary authorisation by letter without further input from you. **[13]**
- If, however, your establishment is not currently designated as a breeder or supplier, or you are breeding these species in an area not already approved for aquatic species you will need to have your certificate of designation amended accordingly. **[12]**
- If these animals are being bred at premises that are not part of a designated establishment, a new establishment licence will be required to breed and/or supply animals for this purpose. **[11]**

#### ***Breeding and supplying Schedule 2 animals specifically for tissues or organs***

- From 1 January 2013, animals listed in new ASPA Schedule 2 being bred or supplied specifically for the scientific use of their tissues or organs may only be bred at, or supplied from, an establishment with an establishment licence.
- If your establishment is already designated as a breeder or supplier and you are breeding these species in an area already approved for holding them, you need take no action. **[16]**
- If your establishment is not already designated as a breeder or supplier, or the animals are being bred or held for supply in areas of your establishment that are not approved, you will need to have your certificate of designation amended accordingly. **[15]**

### ***Breeding of other species primarily for scientific use***

- If, after 1 January 2013, you are breeding animals *other than those listed in new ASPA Schedule 2 primarily* for use in regulated procedures, or specifically for the scientific use of their tissues or organs, you must be licensed as a breeder.
- If your establishment is already designated as a breeder and you are breeding these other species in an area already approved for those species we will be able to issue the necessary authorisation by letter without further input from you. **[19]**
- If, however, your establishment is not currently designated as a breeder, and/or you are breeding those 'other' species in an area not already approved for their holding, you will need to have your certificate of designation accordingly. **[18]**
- If these animals are being bred at premises that are not part of a designated establishment, a new establishment licence will be required to breed and/or supply animals for this purpose. **[17]**

### ***Exemptions to care and accommodation standards***

- Rarely, certificates of designation may give a specific exemption from the need to provide an appropriate environment and minimum care and accommodation standards for animals. If your certificate does this, you will need to ask us to re-authorise the exemption(s). We will do so if they are necessary for scientific, animal welfare or animal health reasons. **[20]**

### ***Non-Schedule 1 methods of killing***

- If your certificate of designation currently authorises the use of any non-Schedule 1 methods of killing, this authorisation will end on 31 December 2012. You will need to ask us to re-authorise these methods. We will do so if we are satisfied, on the basis of scientific evidence, that the method you are using is at least as humane as one of the methods of killing listed in ASPA Schedule 1 for that species. **[21]**

### **You also need to know that ...**

- From 1 January 2013, the standard conditions on your establishment licence will automatically be replaced with the conditions set out on our website at [http://www.homeoffice.gov.uk/publications/science-research-statistics/animals/transposition\\_of\\_eudirective/establishment\\_licences](http://www.homeoffice.gov.uk/publications/science-research-statistics/animals/transposition_of_eudirective/establishment_licences) . Any additional conditions that conflict with the new ASPA or with the new standard conditions will no longer apply. Also, any additional condition that authorises an exemption from one of the standard conditions will cease to have effect.
- The existing local Ethical Review Process (ERP) will automatically become the Animal Welfare and Ethical Review Body (AWERB). The same people will be involved. **[6]**

## **2: Personal licence holders**

### **Key changes needing your immediate action**

#### ***Use of cephalopods***

- All cephalopods will now be protected. This means that you may only apply regulated procedures to a cephalopod if you have the appropriate authority in your personal licence. You will need to have your licence amended unless it already includes cephalopods.

#### **You also need to know that ...**

- From 1 January 2013, the standard conditions on your personal licence will automatically be replaced with the conditions set out on our website at [http://www.homeoffice.gov.uk/publications/science-research-statistics/animals/transposition\\_of\\_eudirective/personal\\_licences](http://www.homeoffice.gov.uk/publications/science-research-statistics/animals/transposition_of_eudirective/personal_licences). Any additional conditions that conflict with the new ASPA or with the new standard conditions will no longer apply.

## **3: Project licence holders**

### **Key changes needing your immediate action**

#### ***Use of cephalopods***

- You will now need a project licence for any work involving the use of cephalopods in regulated procedures. You will need to apply for a new project licence or to amend an existing licence to authorise this work. [22]

#### ***Use of frogs and zebra fish***

- Unless an exemption is authorised by the Secretary of State, you can no longer use certain species of frog (*Xenopus laevis*; *Xenopus tropicalis*; *Rana temporaria*; and *Rana pipiens*) and zebra fish in regulated procedures if they have not been purpose-bred. [23]

#### ***Breeding as a 'permissible purpose'***

- 'Breeding of animals' will no longer be a permissible purpose under new ASPA. If your project licence specifies this as the **sole** purpose, in most cases we will be able to confirm by letter the purpose(s) for which animals are being bred. [25]

### ***Re-authorising the use of certain animals, procedures and activities***

- You will need to be re-authorised for the following:
  - The use in regulated procedures of:
    - any feral domestic animal; [27]\*
    - any wild-caught animal; [28]
    - marmosets that are the offspring of animals not bred in captivity or that have not been obtained from a self-sustaining breeding colony; [29]
    - Schedule 2 animals that have not been bred for use in procedures; [30]\*
    - endangered primates; [31]
    - non-endangered primates; [32]
    - endangered species other than primates; [33]
  - The administration of neuromuscular blocking agents. [34]
  - The setting free or re-homing of an animal at the end of procedures. [37] and [38]\*
- For the activities marked \* you will need to submit a request for re-authorisation to the Home Office. For the other activities, in most cases we expect to be able to issue the re-authorisation by letter without further input from you.

### ***Re-use of animals***

- If your project licence authorises the re-use of animals that have been used previously in 'mild' or 'moderate severity' procedures you must ensure that you meet certain new conditions. These relate to the actual severity of the previous procedures, restoring the animal's health and well-being, and the likely severity of the procedures in which you intend to re-use the animal. [35]
- You will have to ask us on a case-by-case basis to authorise the re-use of animals that have been used previously in a 'substantial' procedure. [36]

### ***Methods of humane killing not listed in Schedule 1***

- Any existing authorities in your project licence which allow you to use non-Schedule 1 methods of killing will only remain valid as long as you can justify scientifically that the aims of your work would not be met by using a method of killing listed in Schedule 1. Providing you can meet this requirement you need take no further action. [36]

### **You also need to know that ...**

- From 1 January, the standard conditions on your project licence will automatically be replaced with the conditions set out on our website at [http://www.homeoffice.gov.uk/publications/science-research-statistics/animals/transposition\\_of\\_eudirective/sc\\_project\\_licences](http://www.homeoffice.gov.uk/publications/science-research-statistics/animals/transposition_of_eudirective/sc_project_licences). Any additional conditions that conflict with the new ASPA or with the new standard conditions will no longer apply. Also, any additional condition that authorises an exemption from one of the standard conditions will cease to have effect.
- There are no changes to existing protocol severity limits. However, 'unclassified' and 'substantial' procedures will be re-named automatically as 'non-recovery' and 'severe' respectively. No amendment to project licences will be required.

#### 4. What to do next

- If your work falls into any of the categories requiring a new licence or an amendment to an existing certificate or licence [8-12, 14, 15, 17, 18 & 22] or certain of the categories requiring re-authorisation [20, 21, 27, 30 & 38] **you need to take action now to meet the requirements.**
- **If you need to submit applications for new or amended licences to the Home Office you should do so as soon as possible and by 30 November at the latest.**
- **Similarly, if you need to request re-authorisation you should do so using the attached pro-forma as soon as possible and by 30 November at the latest.**
- Please refer to the Annex for full details of the action you need to take in each case.

##### ***Applying for new licence***

If you need a new establishment, personal or project licence please contact the Duty Officer Tel. 020 7035 0477 or email [aspa.london@homeoffice.gsi.gov.uk](mailto:aspa.london@homeoffice.gsi.gov.uk).

##### ***Amending a certificate of designation***

If you need to amend your certificate of designation it will be granted with effect from 1 January 2013 in the form of an establishment licence. Please contact the Duty Officer Tel. 020 7035 0477 or email [aspa.london@homeoffice.gsi.gov.uk](mailto:aspa.london@homeoffice.gsi.gov.uk).

##### ***Amending a personal or project licence***

If you need to amend your personal licence or your project licence please send your application for amendment to your local Home Office licensing centre in the usual manner, marking the application '*Urgent – New ASPA Transitional*'.

##### ***Requesting re-authorisation***

If any element of your work requires re-authorisation we anticipate being able to provide the necessary authorisation by letter. Where you are required to apply for re-authorisation please use the simple pro-forma attached for that purpose.

## ANNEX: Details of the new authorisations or exemptions required

New authorisations or exemptions required – user, breeding and supplying establishments			
Activity	Context	Action required	Timing
1 Conversion of certificates of designation to section 2C licences	A certificate of designation in force on 31 December 2012 will be treated as a section 2C licence. In accordance with new section 2B of the amended Act, that licence will authorise the holder to carry on an undertaking involving the same activities as those associated with the type of establishment specified on the existing certificate of designation. <b><i>Schedule 3, paragraphs 3(1) and 11(1)</i></b>	<ul style="list-style-type: none"> <li>• Certificate holders to note. No further action required.</li> </ul>	November 2012
2 Certificate holders to become the holders of the 2C licences	The holder of the certificate of designation in force on 31 December 2012 will be deemed to be the holder of the section 2C licence from 1 January 2013. <b><i>Schedule 3, paragraphs 3(2) and 11(2) &amp; (3)</i></b>	<ul style="list-style-type: none"> <li>• Certificate holders to note. No further action required.</li> </ul>	November 2012
3 Current NACWOs and NVSs to become the person(s) responsible for welfare & care of animals and the designated veterinarian(s) in the establishment.	The named animal care and welfare officer(s) and the named veterinary surgeon(s) will be deemed to be respectively the person responsible for overseeing the welfare and care of the animals kept at the place specified in the section 2C licence, and the veterinary surgeon with expertise in laboratory animal medicine, or other suitably qualified person, to provide advice on the welfare and treatment of those animals. <b><i>Schedule 3, paragraphs 3(3) &amp; (4) and 11(4) &amp; (5)</i></b>	<ul style="list-style-type: none"> <li>• Certificate holders to note. No further action required.</li> </ul>	November 2012

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>4 Additional named persons – the Named Information Officer and the Named Training and Competency Officer.</p>	<p>The holder of the certificate of designation will be deemed to be responsible (as the named information officer) for ensuring that those dealing with animals have access to any information they need about the species concerned [section 2B(5)(c)].</p> <p>The holder of the certificate of designation will also be deemed to be responsible (as the named training and competency officer) for ensuring that those dealing with animals are adequately educated and trained and are supervised until they have demonstrated the requisite competence [section 2B(5)(d)].</p> <p><b><i>Schedule 3, paragraphs 3(5) and 11(6)</i></b></p>	<ul style="list-style-type: none"> <li>• Certificate holders to note. No further action required by certificate holders prior to 1/1/13.</li> <li>• In the absence of any conflicts of interest, the same person may hold two or more of the ‘named’ roles at an establishment. However, the transitional arrangements are intended to be just that and it is expected that during the course of 2013 holders of section 2C licences will nominate other suitably qualified individuals to undertake these roles and submit their licences for amendment accordingly.</li> </ul>	<p>November 2012</p>
<p>5 Named Person Responsible for Ensuring Compliance</p>	<p>The holder of the certificate of designation will be deemed to be the person responsible for ensuring that the conditions of the licence are complied with (the Named Person Responsible for Compliance) [section 2B(5)(e)].</p> <p><b><i>Schedule 3, paragraphs 3(5) and 11(6)</i></b></p>	<ul style="list-style-type: none"> <li>• Certificate holders to note. No further action required.</li> </ul>	<p>November 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>6 Animal Welfare &amp; Ethical Review Bodies – personnel.</p>	<p>The amended Act requires the holder of the section 2C licence to establish and maintain an Animal Welfare and Ethical Review Body (AWERB). This replaces the current requirement for a local ethical review process (ERP). Pending publication of revised Guidance on the Operation of the Act, the existing ERP, which has been approved by the Secretary of State will be deemed to satisfy the legal requirements for an Animal Welfare and Ethical Review Body</p> <p>The amended Act requires that both a NACWO and an NVS are members of the AWERB and that at a scientific procedures establishment a “person with such scientific credentials as are specified in the licence” (i.e. a project licence holder or other scientist acceptable to the Secretary of State) is also a member. The remaining membership will be as specified in Appendix J of the Guidance</p> <p><b><i>Schedule 3, paragraphs 6(1)&amp;(2) and 15(1)&amp;(2)</i></b></p>	<ul style="list-style-type: none"> <li>• Certificate holders to note. No further action required prior to publication of the revised Guidance in 2013.</li> </ul>	<p>November 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>7 Animal Welfare &amp; Ethical Review Bodies – tasks.</p>	<p>The tasks of the Animal Welfare and Ethical Review Body are set out are those set out in paragraphs (a) to (e) of Article 27.1 of the Directive together with any other tasks included in paragraph 7 of Appendix J of the Home Office Guidance.</p> <p>These tasks will be rationalised and set out in full in the revised Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 when published in 2013.</p> <p><b><i>Schedule 3, paragraphs 6(1)&amp;(3) and 15(1)&amp;(3)</i></b></p>	<ul style="list-style-type: none"> <li>• Certificate holders to note and ensure all required tasks are undertaken from 01/01/13. No other action required by certificate holders prior to publication of the revised Guidance in 2013.</li> </ul>	<p>November 2012</p>
<p>8 Regulated procedures in cephalopods undertaken at an establishment not currently designated.</p>	<p>The amended Act will extend the inclusion of invertebrates within the definition of a “protected animal” from Octopus vulgaris to any living cephalopod. From 1 January 2013, work involving the application of regulated procedures to all cephalopods may be carried out only at, or in conjunction with, a section 2C licensed establishment. Where regulated procedures are carried out solely at a place other than an establishment (e.g. a field study) a section 2C licence will still be required.</p>	<ul style="list-style-type: none"> <li>• New users to prepare &amp; submit section 2C licence applications. Applications will need to identify holder, all named persons and provide details of AWERB.</li> <li>• Facilities and infrastructure to be assessed for suitability prior to grant of licence. New section 2C licence application will have to be processed in advance; licence to take effect from 1 January 2013.</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>9 Regulated procedures in cephalopods undertaken at an establishment currently designated only as a breeder and/or supplier AND/OR areas within establishment not approved for aquatic species.</p>	<p>The amended Act will extend the inclusion of invertebrates within the definition of a “protected animal” from Octopus vulgaris to any living cephalopod. From 1 January 2013, work involving the application of regulated procedures to all cephalopods may be carried out only at, or in conjunction with, a section 2C licensed establishment. Where regulated procedures are carried out solely at a place other than an establishment (e.g. a field study) a section 2C licence will still be required.</p>	<ul style="list-style-type: none"> <li>• Certificate holders to submit application for amendment to certificate of designation to include designation as a scientific procedures establishment and/or to approve use of relevant areas for holding and use of aquatic species (if not already approved).</li> <li>• Facilities and infrastructure may need to be assessed for suitability for aquatic species. Amendment to be processed in advance – variation to take effect from 1/1/2013.</li> </ul>	<p>November 2012</p> <p>November/ December 2012</p>
<p>10 Regulated procedures in cephalopods undertaken at an establishment currently designated as a scientific procedure establishment AND relevant areas within establishment approved for aquatic species.</p>	<p>The amended Act will extend the inclusion of invertebrates within the definition of a “protected animal” from Octopus vulgaris to any living cephalopod. From 1 January 2013, work involving the application of regulated procedures to these additional animals may be carried out only at, or in conjunction with, a section 2C licensed establishment. Where regulated procedures are carried out solely at a place other than an establishment (e.g. a field study) a section 2C licence will still be required.</p>	<ul style="list-style-type: none"> <li>• Certificate holders to note. No variation required to certificate of designation prior to 1 January 2013.</li> </ul>	<p>November 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>11 Breeding or supply of new Schedule 2 species (for use in regulated procedures or for the scientific use of their tissues or organs).</p> <p>(A) - Establishment not currently designated.</p> <p>See also 12 and 13.</p>	<p>Schedule 2 to the Act will be amended to include additional species of animal. From 1 January 2013 anyone breeding or supplying certain species of frog (<i>Xenopus laevis</i>, <i>Xenopus tropicalis</i>, <i>Rana temporaria</i> or <i>Rana pipiens</i>) or zebra fish with a view to their use in regulated procedures or for the scientific use of their tissues or organs will have to be authorised to do so by a section 2C licence.</p> <p>No authorisation is currently required to breed or supply these species. Where those species are being bred at, or supplied from, a designated establishment new authorisation will be required from 1 January 2013 to enable the breeding or supplying of those species to continue. Authorisation can be given only when the Secretary of State is satisfied that the care and accommodation available at the establishment is suitable for the type of animal in question.</p> <p><b><i>Schedule 3, paragraph 12</i></b></p>	<ul style="list-style-type: none"> <li>• New breeders &amp; suppliers to prepare &amp; submit section 2C licence applications. Applications will need to identify holder, all named persons and provide details of AWERB.</li> <li>• Facilities and infrastructure to be assessed for suitability prior to grant of licence. New section 2C licence application will have to be processed in advance; licence to take effect from 1 January 2013.</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>12 Breeding or supply of new Schedule 2 species (for use in regulated procedures or for the scientific use of their tissues or organs).</p> <p>(B) Establishment designated but not as a breeder / supplier <b>AND/OR</b> relevant areas not already approved for holding aquatic species.</p> <p>See also 11 and 13.</p>	<p>Schedule 2 to the Act will be amended to include additional species of animal. From 1 January 2013 anyone breeding or supplying certain species of frog (<i>Xenopus laevis</i>, <i>Xenopus tropicalis</i>, <i>Rana temporaria</i> or <i>Rana pipiens</i>) or zebra fish with a view to their use in regulated procedures or for the scientific use of their tissues or organs will have to be authorised to do so by a section 2C licence.</p> <p>No authorisation is currently required to breed or supply these species. Where those species are being bred at, or supplied from, a designated establishment new authorisation will be required from 1 January 2013 to enable the breeding or supplying of those species to continue. Authorisation can be given only when the Secretary of State is satisfied that the care and accommodation available at the establishment is suitable for the type of animal in question.</p> <p><b>Schedule 3, paragraph 12</b></p>	<ul style="list-style-type: none"> <li>• Certificate holders to submit application for amendment to certificate of designation to include designation as a breeding and/or supplying establishment (if not already designated as such) and/or to approve use of relevant areas for breeding and supply of aquatic species (if not already approved).</li> <li>• Facilities and infrastructure may need to be assessed for suitability for aquatic species. Amendment to be processed in advance – variation to take effect from 1 January 2013.</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>13 Breeding or supply of new Schedule 2 species (for use in regulated procedures or for the scientific use of their tissues or organs).</p> <p>(C) Establishment already designated as a breeder/ supplier <b>and</b> relevant areas already approved for holding aquatic species.</p> <p>See also 11 and 12.</p>	<p>Schedule 2 to the Act will be amended to include additional species of animal. From 1 January 2013 anyone breeding or supplying certain species of frog (<i>Xenopus laevis</i>, <i>Xenopus tropicalis</i>, <i>Rana temporaria</i> or <i>Rana pipiens</i>) or zebra fish with a view to their use in regulated procedures or for the scientific use of their tissues or organs will have to be authorised to do so by a section 2C licence.</p> <p>No authorisation is currently required to breed or supply these species. Where those species are being bred at, or supplied from, a designated establishment new authorisation will be required from 1 January 2013 to enable the breeding or supplying of those species to continue. Authorisation can be given only when the Secretary of State is satisfied that the care and accommodation available at the establishment is suitable for the type of animal in question.</p> <p><b>Schedule 3, paragraph 12</b></p>	<ul style="list-style-type: none"> <li>ASRU expect to be able to provide re-authorisation by letter without further input from certificate holders.</li> <li>Certificate holders to note and to await letter of re-authorisation.</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>14 Breeding of existing Schedule 2 species at an establishment not currently designated for use of their tissues or organs for scientific purposes</p>	<p>Section 2B of the amended Act includes as a regulated activity breeding or supply of animals listed in Schedule 2 to the Act with a view to the use of their tissues or organs for scientific purposes. No authorisation is currently required to breed or supply animals for this purpose. From 1 January 2013 anyone breeding or supplying Schedule 2 animals for that purpose will have to be authorised to do so by a section 2C licence.</p> <p>Where, for that purpose, Schedule 2 species are being bred at, or supplied from, premises that are not part of an establishment designated by a certificate issued under section 7 of the Act, it will be necessary to apply for a new section 2C licence to take effect from 1 January 2013.</p>	<ul style="list-style-type: none"> <li>• New breeders &amp; suppliers to prepare &amp; submit section 2C licence applications. Applications will need to identify holder, all named persons and provide details of AWERB.</li> <li>• Facilities and infrastructure to be assessed for suitability prior to grant of licence. New section 2C licence application will have to be processed in advance; licence to take effect from 1 January 2013.</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>15 Breeding of existing Schedule 2 species for use of their tissues or organs for scientific purposes . Establishment currently designated as a scientific procedure establishment but not as a breeder and/or supplier AND/OR areas within establishment not approved for relevant use</p>	<p>Section 2B of the amended Act includes as a regulated activity breeding or supply of animals listed in Schedule 2 to the Act with a view to the use of their tissues or organs for scientific purposes. No authorisation is currently required to breed or supply animals for this purpose. From 1 January 2013 anyone breeding or supplying Schedule 2 animals for that purpose will have to be authorised to do so by a section 2C licence.</p> <p>Where Schedule 2 species are already being bred at, or supplied from, a designated establishment for scientific use of their tissues or organs, the certificate of designation will need to be submitted for amendment prior to 1 January 2013 if the establishment is not designated appropriately as a breeding or supplying establishment and/or if the areas within the establishment where the animals are bred or held for supply are not already approved for that use</p>	<ul style="list-style-type: none"> <li>• Certificate holders to submit application for amendment to certificate of designation to include designation as a breeding and/or supplying establishment (if not already designated as such) and/or to approve use of relevant areas for breeding and supply of relevant species.</li> <li>• Facilities and infrastructure may need to be assessed for suitability. Amendment to be processed in advance – variation to take effect from 1 January 2013.</li> </ul>	<p>November 2012</p> <p>November/ December 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>16 Breeding of existing Schedule 2 species with a view to the use of their tissues or organs for scientific purposes. Establishment currently designated as a breeder and/or supplier AND areas within establishment already approved for relevant use.</p>	<p>Section 2B of the amended Act includes as a regulated activity breeding or supply of animals listed in Schedule 2 to the Act with a view to the use of their tissues or organs for scientific purposes. No authorisation is currently required to breed or supply animals for this purpose. From 1 January 2013 anyone breeding or supplying Schedule 2 animals for that purpose will have to be authorised to do so by a section 2C licence.</p> <p>Where Schedule 2 species are being bred at, or supplied from, a designated establishment for scientific use of their tissues or organs, the certificate of designation will need to be submitted for amendment prior to 1 January 2013 if the establishment is not designated appropriately as a breeding or supplying establishment and/or if the areas within the establishment where the animals are bred or held for supply are not already approved for that use</p>	<ul style="list-style-type: none"> <li>• Certificate holders to note. No action required</li> </ul>	<p>November 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>17 Breeding of non-Schedule 2 species (<b>primarily</b> for scientific use).</p> <p>(A) Establishment not currently designated.</p> <p>See also 18 &amp; 19</p>	<p>Section 2B of the amended Act includes as a regulated activity the breeding of animals other than those listed in Schedule 2 to the Act when it is carried on primarily for purposes of providing animals for use in regulated procedures of for the scientific use of their tissues or organs. From 1 January 2013 anyone engaged in this activity will have to be authorised to do so by a section 2C licence.</p> <p>Where these animals are being bred at premises that are not part of a designated establishment, it will be necessary to apply for a new section 2C licence to take effect from 1 January 2013.</p>	<ul style="list-style-type: none"> <li>• New breeders to prepare &amp; submit section 2C licence applications. Applications will need to identify holder, all named persons and provide details of AWERB.</li> <li>• Facilities and infrastructure to be assessed for suitability prior to grant of licence. New section 2C licence application will have to be processed in advance; licence to take effect from 1 January 2013.</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>18 Breeding of non-Schedule 2 species (<b>primarily</b> for scientific use).</p> <p>(B) Establishment designated but not as a breeder <b>AND/OR</b> relevant areas not already approved for holding those 'other' species.</p> <p>See also 17 and 19.</p>	<p>Section 2B of the amended Act includes as a regulated activity the breeding of animals other than those listed in Schedule 2 to the Act when it is carried on primarily for purposes of providing animals for use in regulated procedures of for the scientific use of their tissues or organs. From 1 January 2013 anyone engaged in this activity will have to be authorised to do so by a section 2C licence.</p> <p>No authorisation is currently required to breed these animals. Where they are already being bred at a designated establishment new authorisation will be required from 1 January 2013 to enable their breeding to continue. Authorisation can be given only when the Secretary of State is satisfied that the care and accommodation available at the establishment is suitable for the type of animal in question.</p>	<ul style="list-style-type: none"> <li>• Certificate holders to submit application for amendment to certificate of designation to include designation as a breeding establishment (if not already designated as such) and/or to approve use of relevant areas for breeding of non-Schedule 2 species.</li> <li>• Facilities and infrastructure may need to be assessed for suitability for aquatic species. Amendment to be processed in advance – variation to take effect from 1 January 2013.</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>19 Breeding of non-Schedule 2 species (<b>primarily</b> for scientific use).</p> <p>(C) Establishment designated as a breeder <b>and</b> relevant areas already approved for holding those 'other' species.</p> <p>See also 17 and 18.</p>	<p>Section 2B of the amended Act includes as a regulated activity the breeding of animals other than those listed in Schedule 2 to the Act when it is carried on primarily for purposes of providing animals for use in regulated procedures of for the scientific use of their tissues or organs. From 1 January 2013 anyone engaged in this activity will have to be authorised to do so by a section 2C licence.</p> <p>No authorisation is currently required to breed these animals. Where they are already being bred at a designated establishment new authorisation will be required from 1 January 2013 to enable their breeding to continue. Authorisation can be given only when the Secretary of State is satisfied that the care and accommodation available at the establishment is suitable for the type of animal in question.</p>	<ul style="list-style-type: none"> <li>• ASRU expect to be able to provide re-authorisation by letter without further input from certificate holders.</li> <li>• Certificate holders to note and to await letter of re-authorisation.</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>20 Exemption from new section 2C licence conditions 4(3) &amp; 4(7) (provision of appropriate environment, and care &amp; accommodation standards)</p>	<p>Exemption from the requirements to provide animals with an environment, housing, freedom of movement, food and water appropriate for the health and well-being, and specified minimum standards of care and accommodation may be given in an additional condition or elsewhere in the schedule of the certificate of designation.</p> <p>Under the amended Act such exemption may be given only when the Secretary of State is satisfied that the exemptions are necessary for scientific, animal welfare or animal health reasons. Any existing exemptions from the provision of appropriate environment, and care &amp; accommodation standards will be annulled by paragraphs 5 and 14 of Schedule 3 to the Amendment Regulations. Any such exemptions will have to be re-authorised in accordance with the new requirement.</p>	<ul style="list-style-type: none"> <li>• Certificate holders to submit application for re-authorisation of the exemption. Requests will need to be assessed against the criteria specified in new Schedule 2C paragraph 11(5).</li> <li>• Re-authorisation may be given by letter and will be required before 1 January 2013</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – user, breeding and supplying establishments**

Activity	Context	Action required	Timing
<p>21 Authorisation of non-Schedule 1 methods of killing in a 2C licence</p>	<p>Authorisation for the use of methods of humane killing other than those listed in Schedule 1 for animals that are not undergoing or that have not undergone regulated procedures is currently given via an additional condition of the certificate of designation.</p> <p>New section 15A(6) of the amended Act permits a section 2C licence to specify such a method of killing as being appropriate to a description of animal only if the Secretary of State is satisfied, on the basis of scientific evidence, that the method is at least as humane as one of the methods of killing appropriate to that description of animal under Schedule 1.</p> <p>Fresh authorisation for all such methods of killing in accordance with the new requirements will be required from 1 January 2013</p>	<ul style="list-style-type: none"> <li>• Certificate holders to submit application for re-authorisation for use of any non-Schedule 1 methods currently listed in the certificate of designation.</li> <li>• Requests for authorisation will need to be assessed against the criteria specified in new section 15A(6). Re-authorisation may be given by letter and will be required before 1 January 2013</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – project licences**

Activity	Context	Action required	
<p>22 Use of cephalopods (in addition to Octopus vulgaris)</p>	<p>Section 1 of the Act is being amended to extend the inclusion of invertebrates within the definition of a “protected animal” from Octopus vulgaris to any living cephalopod. From 1 January 2013 anyone undertaking a programme of work involving the application of regulated procedures to a cephalopod will require project licence authority to do so.</p> <p>New project licences will be required (or variations to existing licences where current non-regulated use of cephalopods relates to a programme of work specified in an existing project licence).</p>	<ul style="list-style-type: none"> <li>• Prospective project licence holders to prepare &amp; submit applications for new or amended project licences.</li> <li>• Applications for new and amended project licences will have to be processed in advance to enable new or amended licences to take effect from 1 January 2013.</li> </ul> <p>NB Action also required for related 2C licences and personal licences</p>	<p>November 2012</p> <p>December 2012</p>
<p>23 Use of new Schedule 2 species (frogs and zebra fish)</p>	<p>Schedule 2 to the Act is being amended to include certain species of frog (<i>Xenopus laevis</i>, <i>Xenopus tropicalis</i>, <i>Rana temporaria</i> or <i>Rana pipiens</i>) and zebra fish. From 1 January 2013 unless an exemption is authorised by the Secretary of State these animals may not be used in regulated procedures unless they have been bred for that purpose.</p>	<ul style="list-style-type: none"> <li>• Project licence holders to note. Request for authorisation of exemption dealt with in [30] below.</li> </ul>	<p>November 2012</p>

**New authorisations or exemptions required – project licences**

Activity	Context	Action required	
<p>24 Qualifications of project licence holder</p>	<p>Project licence holder must meet the requirements of section 5C(2)(a) to (c) (instruction in a relevant scientific discipline, specific knowledge and education &amp; training for designing programmes of work) Schedule 3, paragraph 26(2))</p> <p>Successful completion of Modules 1, 2 and 5 (or exemption from them) considered to meet the requirements of section 5C(2)(a) to (c).</p> <p><b>Schedule 3, paragraph 26(2)</b></p>	<ul style="list-style-type: none"> <li>ASRU will confirm that the current requirement to have completed Modules 1, 2 and 5 (or exemption from them) has been satisfied. If so, then no further action is required by project licence holders.</li> </ul>	<p>November 2012</p>
<p>25 The programme of work specified in the licence may only be carried out for one (or more) of the purposes specified in section 5C(3)(a) to (g)</p>	<p>Current permissible purpose 5(3)(g) (breeding of animals for experimental or other scientific use) is no longer specified as a permissible purpose. Holders of project licences that currently specify only breeding as a purpose will need to submit their project licences for amendment to specify the purpose(s) for which animals are being bred. Note that this will apply only to the breeding of genetically modified and harmful mutant animals for which project licence authority is required.</p> <p><b>Schedule 3, paragraph 26(3)</b></p>	<ul style="list-style-type: none"> <li>ASRU will review project licences with “breeding of animals” as the currently specified sole permissible purpose to identify the appropriate purpose(s) for which animals are being bred.</li> <li>Where the purpose(s) of the procedures for which animals are being bred is unclear ASRU will seek further information from project licence holders. Otherwise no action is required by project licence holders.</li> <li>ASRU will confirm the relevant new permissible purpose(s) by letter.</li> </ul>	<p>November 2012</p> <p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – project licences**

Activity	Context	Action required	
<p>26 Protocol severity limits of “unclassified” and “substantial” to be re-named “non-recovery” and “severe”</p>	<p>New section 5B(3) of the Act requires the Secretary of State, when carrying out the evaluation of a programme of work, to classify the likely severity of each of the series of regulated procedures that would be applied as part of that programme. Section 5B(6) requires that that classification be carried out using the criteria in Annex 8 of the Directive, which gives the severity categories as “non-recovery”, “mild”, “moderate” and “severe”.</p> <p>The effect of the transitional provisions will be to treat current severity limits of “unclassified” and “substantial” respectively as “non-recovery” and “severe”. (The severity limits of “mild” and “moderate” accord with those in the Directive and so remain unchanged).</p> <p><b><i>Schedule 3, paragraph 23</i></b></p>	<ul style="list-style-type: none"> <li>• Project licence holders to note. No further action required.</li> </ul>	<p>November 2012</p>

**New authorisations or exemptions required – project licences**

Activity	Context	Action required	
<p>27 Authorisation for the use in regulated procedures of a feral animal of a domestic species</p>	<p>Under the amended Act, the Secretary of State may authorise the use in regulated procedures of a feral animal of a domestic species only if she is satisfied that there is specific scientific justification as required by new Schedule 2C paragraph 25(2).</p> <p>That justification is more specific than that currently required by the Act and it is necessary to re-authorise the use in accordance with the new requirements.</p> <p><b><i>Schedule 3, paragraph 25</i></b></p>	<ul style="list-style-type: none"> <li>• Project licence holders to note they will no longer have authority for the use of feral animals after 31/12/12.</li> <li>• If such authority is required holders of project licences currently authorising the use of feral domestic animals must seek renewed authorisation.</li> <li>• Requests for authorisation will be assessed against the criteria specified in new Schedule 2C, paragraph 25(2). Re-authorisation may be given by letter and will be required before 1 January 2013</li> </ul>	<p>November 2012</p> <p>November 2012</p> <p>December 2012</p>
<p>28 Authorisation for the use in regulated procedures of an animal taken from the wild.</p>	<p>Under the amended Act, the Secretary of State may authorise the use in regulated procedures of an animal taken from the wild only if she is satisfied that there is specific scientific justification as required by new Schedule 2C paragraph 25(3).</p> <p>That justification is more specific than that currently required by the Act and it is necessary to re-authorise the use in accordance with the new requirements.</p> <p><b><i>Schedule 3, paragraph 25</i></b></p>	<ul style="list-style-type: none"> <li>• ASRU expect to be able to provide re-authorisation by letter without further input from project licence holders.</li> <li>• Project licence holders to note and to await letter of re-authorisation.</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – project licences**

Activity	Context	Action required	
<p>29 Authorisation for the use in regulated procedures of marmosets that are the offspring of animals not bred in captivity or that have not been obtained from a self-sustaining breeding colony.</p>	<p>Under the amended Act, the Secretary of State may authorise the use in regulated procedures of marmosets that are the offspring of animals not bred in captivity or that have not been obtained from a self-sustaining breeding colony only if she is satisfied that there is specific scientific justification as required by new Schedule 2C paragraph 25(3).</p> <p>That justification is more specific than that currently required by the Act and it is necessary to re-authorise the use in accordance with the new requirements.</p> <p><b>Schedule 3, paragraph 25</b></p>	<ul style="list-style-type: none"> <li>Project licence holders to note that any work involving the use of marmosets that are the offspring of animals not bred in captivity or that have not been obtained from a self-sustaining breeding colony will require specific authorisation from 1/1/2013.</li> </ul>	<p>November 2012</p>
<p>30 Authorisation for the use in regulated procedures of Schedule 2 animals that have not been bred for use in procedures.</p>	<p>Under the amended Act, the Secretary of State may authorise the use in regulated procedures of animals of a description specified in Schedule 2 which have not been bred for use in procedures only if she is satisfied that there is specific scientific justification as required by new Schedule 2C paragraph 25(3).</p> <p>That justification is more specific than that currently required by the Act and it is necessary to re-authorise the use in accordance with the new requirements.</p> <p><b>Schedule 3, paragraph 25</b></p>	<ul style="list-style-type: none"> <li>Project licence holders to note that this restriction applies only to animals that have not been bred for use in procedures - <b>it does not apply to animals purpose-bred outside of the UK</b>, e.g. genetically altered mice obtained from Japan.</li> <li>Holders of project licences authorising the use of Schedule 2 animals that have not been purpose-bred will need to seek re-authorisation for use of those animals in regulated procedures after 31/12/12</li> <li>Requests for re-authorisation will be assessed against the criteria specified in new Schedule 2C, paragraph 25(3). Re-authorisation may be given by letter and will be required before 1 January 2013.</li> </ul>	<p>November 2012</p> <p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – project licences**

Activity	Context	Action required	
<p>31 Work in endangered primates</p>	<p>A programme of work involving the application of regulated procedures to endangered primates may be authorised only if the Secretary of State has verified that:</p> <p>1. The programme of work is to be carried out for one of the following purposes:</p> <p>(a) for the purpose mentioned in paragraph (b)(i) or (c) of section 5C(3) and, in addition, for the purpose of the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in man;</p> <p>(b) for purpose mentioned in paragraph (e) of section 5C(3);</p> <p>AND</p> <p>2. There is scientific justification to the effect that the purpose of the programme of work to be specified in the licence cannot be achieved by the use of animals which are not primates; and not of a species listed in Annex A to Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein.</p> <p><b><i>Schedule 3, paragraphs 26(4)(a) and 27(1)</i></b></p>	<ul style="list-style-type: none"> <li>Project licence holders to note that any work involving the use of endangered primates will require specific authorisation from 1/1/2013.</li> </ul>	<p>November 2012</p>

**New authorisations or exemptions required – project licences**

Activity	Context	Action required	
<p>32 Work in non-endangered primates</p>	<p>A programme of work involving the application of regulated procedures to non-endangered primates may be authorised only if the Secretary of State has verified that:</p> <p>1. The programme of work is to be carried out for one of the following purposes:                      (a) for the purpose mentioned in paragraph (b)(i) or (c) of section 5C(3) and, in addition, for the purpose of the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in man;                      (b) for purpose mentioned in paragraphs (a) or (e) of section 5C(3);</p> <p>AND</p> <p>2. There is scientific justification to the effect that the purpose of the programme of work to be specified in the licence cannot be achieved by the use of animals which are not primates.</p> <p><b><i>Schedule 3, paragraphs 26(4)(b) and 27(2)</i></b></p>	<ul style="list-style-type: none"> <li>• ASRU expect to be able to provide re-authorisation by letter and in most cases without further input from project licence holders.</li> <li>• Where further information is required about the purpose of the programme of work ASRU will contact the relevant project licence holders individually. Otherwise no action is required by project licence holders.</li> <li>• Project licence holders to note and to await letter of re-authorisation or request for additional information as above.</li> </ul>	<p>November 2012</p> <p>November 2012</p> <p>November/ December 2012</p>

**New authorisations or exemptions required – project licences**

Activity	Context	Action required	
<p>33 Work in endangered animals other than primates</p>	<p>A programme of work involving the application of regulated procedures to endangered animals other than primates may be authorised only if the Secretary of State has verified that:</p> <p>1. The programme of work is to be carried out for a purpose mentioned in paragraph (b)(i), (c) or (e) of section 5C(3);</p> <p>AND</p> <p>2. There is scientific justification to the effect that the purpose of the programme of work to be specified in the licence cannot be achieved by the use of animals which are not of a species listed in Annex A to Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein.</p> <p><b><i>Schedule 3, paragraphs 26(4)(c) and 27(3)</i></b></p>	<ul style="list-style-type: none"> <li>• ASRU expect to be able to provide re-authorisation by letter without further input from project licence holders.</li> <li>• Project licence holders to note and to await letter of re-authorisation.</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – project licences**

Activity	Context	Action required	
<p>34 Use of neuromuscular blocking agents</p>	<p>The use of neuromuscular blocking agents will continue to be strictly controlled under the amended Act. The administration of any such substance must be specified explicitly in both project and personal licences. A neuromuscular blocking agent may not be administered instead of an anaesthetic; and other than in exceptional and specifically justified cases involving the use of larval or non-mammalian embryonic forms, agents may not be used without an adequate level of anaesthesia and analgesia to ensure the animal remains unconscious and unable to feel pain.</p> <p>New section 17(2) of the amended Act introduces a further specific limitation that the Secretary of State must not grant a project licence that authorises the use of a neuromuscular blocking agent unless 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. Paragraph 26(7) of Schedule 3 removes any authorisation for the use of neuromuscular blocking agents after 31 December 2012. Fresh authorisation can be given only in accordance with the new requirement.</p> <p><b><i>Schedule 3, paragraphs 26(7) and 27(4)</i></b></p>	<ul style="list-style-type: none"> <li>• ASRU expect to be able to provide re-authorisation by letter without further input from project licence holders.</li> <li>• Project licence holders to note and to await letter of re-authorisation.</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – project licences**

Activity	Context	Action required	
<p>35 Re-use of protected animals which <b>have not</b> undergone any previous procedures classified as “substantial”.</p>	<p>Amended section 14 of the Act continues to require the Secretary of State’s consent for the re-use of any protected animal. It also sets three conditions that must be met relating to the actual severity of the previous procedures, restoration of the animal’s health and wellbeing, and the likely severity of the procedures in which the animal is to be re-used. Provided those conditions continue to be met, existing consent for re-use given by the Secretary of State in the project licence will remain valid after 31 December 2012.</p> <p><b><i>Schedule 3, paragraph 29</i></b></p>	<ul style="list-style-type: none"> <li>• Project licence holder to note the requirements of amended section 14 of the Act. No further action is required.</li> </ul>	<p>November 2012</p>
<p>36 Re-use of protected animals which <b>have</b> undergone a previous regulated procedure classified as “substantial”.</p>	<p>The amended Act places strict controls on the re-use of any animal that has been subjected to a regulated procedure or a series of regulated procedures classified as “severe”. In exceptional circumstances that justify such an animal being used for further regulated procedures, the Secretary of State’s consent may be given only on a case by case basis, and only after she has consulted a veterinary surgeon, who has examined the animal, about whether consent should be given in accordance with amended section 14(6) of the Act.</p> <p><b><i>Schedule 3, paragraph 29</i></b></p>	<ul style="list-style-type: none"> <li>• Project licence holders to note that any existing authorisation for re-use after a previous substantial severity procedure will cease and that case by case authorisation will be required from 1/1/13.</li> </ul>	<p>November 2012</p>

**New authorisations or exemptions required – project licences**

Activity	Context	Action required	
<p>37 Setting free (at the end of procedures) a protected animal that has been taken from the wild and has undergone procedures <b><u>without ever being held at a designated establishment</u></b></p>	<p>Under new section 17A the Secretary of State’s consent is required before an animal may be set free or re-homed at the end of a series of regulated procedures. The Secretary of State may give that consent only if satisfied that specific criteria (set out in sections 17A(3) and (4)) are met. Currently there is no requirement for the criteria in section 17A((3)(c) and (4) to be met before authorising the release of an animal from the controls of the Act at the end of procedures.</p> <p>Existing authorisation in the project licence for the setting free or re-homing of protected animals at the end of a series of regulated procedures will cease to have effect from 1 January 2013.</p> <p>However, in the case of animals taken from wild and then released back into the wild following regulated procedures of short duration without ever being held at a designated establishment it is likely that those additional criteria will already have been met.</p> <p><b><i>Schedule 3, paragraph 31</i></b></p>	<ul style="list-style-type: none"> <li>• ASRU expect to be able to provide re-authorisation by letter without further input from project licence holders.</li> <li>• Project licence holders to note and to await letter of re-authorisation.</li> </ul>	<p>November 2012</p> <p>December 2012</p>

**New authorisations or exemptions required – project licences**

Activity	Context	Action required	
<p>38 Setting free (at the end of procedures) or re-homing a protected animal that has undergone procedures <b><u>and at any stage has been held in a designated establishment</u></b></p>	<p>Under new section 17A the Secretary of State’s consent is required before an animal may be set free or re-homed at the end of a series of regulated procedures. The Secretary of State may give that consent only if satisfied that specific criteria (set out in sections 17A(3) and (4)) are met. Currently there is no requirement for the criteria in section 17A(3)(c) and (4) to be met before authorising the release of an animal from the controls of the Act at the end of procedures.</p> <p>Existing authorisation in the project licence for the setting free or re-homing of protected animals at the end of a series of regulated procedures will cease to have effect from 1 January 2013.</p> <p><b><i>Schedule 3, paragraph 31</i></b></p>	<ul style="list-style-type: none"> <li>• Project licence holders to note.</li> <li>• Holders of project licences currently authorising the setting free or re-homing of animals will need to seek renewed authorisation.</li> <li>• Requests for authorisation will be assessed in accordance with new section 17A(3) and (4) of the amended Act for which additional supporting information may be required. Re-authorisation may be given by letter.</li> </ul>	<p>November 2012</p> <p>November 2012</p> <p>November / December 2012</p>
<p>39 Killing animals by methods other than those appropriate for the animal in Schedule 1.</p>	<p>Non-Schedule 1 methods of killing will be permissible under new section 15A, subsection (3)(b), only if there is a scientific justification that the purposes of the programme of work specified in the licence cannot be achieved if a method of killing appropriate to that description of animal under Schedule 1 is used.</p> <p><b><i>Schedule 3, paragraph 26(6)</i></b></p>	<p>Project licence holders to note that existing authorities to use non-Schedule 1 methods after 31 December 2012 remain valid only if the project licence holder is satisfied that “there is a scientific justification that the purposes of the programme of work specified in the licence cannot be achieved if a method of killing appropriate to that description of animal under Schedule 1 is used”. No further action is required.</p>	<p>November 2012</p>

## Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012

### Application for re-authorisation of specified activities

*This application should be completed by holders of certificates of designation and project licences where existing authorisation ceases to have effect as a result of the Transitional Provision of the Amendment Regulations and the holder is required to seek re-authorisation. Completed applications should be sent to Home Office, ASRU, Mail Point 20b 4<sup>th</sup> Floor Seacole Building SW, 2 Marsham Street, London SW1P 4DF.*

PCD / PPL ref	
Name of Holder	
Address	
Contact Telephone Number	
Email address	

**I seek re-authorisation of the following activities, which are currently authorised in my certificate of designation / project licence (mark all that apply and provide the information required in the free text box below ).**

Activity requiring re-authorisation (certificate of designation)	Information required	(X)
20 Exemption from new section 2C licence conditions 4(3) & 4(7) (provision of appropriate environment, and care & accommodation standards)	Explain why continued exemption is necessary for scientific, animal welfare or animal health reasons.	
21 Authorisation of non-Schedule 1 methods of killing in a 2C licence	For each method of humane killing specified in the certificate of designation provide the scientific evidence to support your opinion that the method is at least as humane as one of the methods of killing appropriate to that description of animal under Schedule 1.	

Activity requiring re-authorisation (project licence)	Justification required	(X)
27 Authorisation for the use in regulated procedures of a feral animal of a domestic species	Explain, as a scientific justification, why the purposes of the programme of work can be achieved only by the application of regulated procedures to feral animals of the species in question and why the work is essential (a) to protect the health or welfare of the animals of the species in question ; or (b) to avoid a serious threat to human or animal health or the environment.	

