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DRAFT STATUTORY INSTRUMENTS

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**2012 No.**

**The Animals (Scientific Procedures)  
Act 1986 Amendment Regulations 2012**

**Citation and commencement**

1.—(1) These Regulations may be cited as the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012.

(2) These Regulations come into force on 1 January 2013, subject to sub-paragraphs (3) and (4).

(3) The following provisions come into force for the purposes specified on the day after the day on which these Regulations are made—

- (a) regulation 14, for the purposes of the Secretary of State granting consents under section 14(6) of the Animals (Scientific Procedures) Act 1986;
- (b) regulation 18, for the purposes of the Secretary of State granting consents under section 17A of that Act;
- (c) paragraphs 5, 7, 12, 14, 16, 25, and 27 of Schedule 3 (and regulation 42 so far as relating to those paragraphs), for the purposes of the Secretary of State granting authorisations under those paragraphs.

(4) Paragraphs (a) and (d) of regulation 26(9) come into force on 1 January 2015.

**Amendment of the Animals (Scientific Procedures) Act 1986**

2. The Animals (Scientific Procedures) Act 1986(1) is amended as follows.

**Protected animals**

3. In section 1(2) (definition of “protected animal”)—

- (a) in subsection (1) at the end insert “and any living cephalopod”;
- (b) in subsection (2)(a) for “half” substitute “two-thirds of”;
- (c) after subsection (2) insert—

“(2A) Any living cephalopod in its embryonic form is not a protected animal.”;

- (d) in subsection (3)(a) for “invertebrates of any description” substitute “any description of invertebrates other than cephalopods”.

**Regulated procedures**

4.—(1) Section 2(3) (definition of “regulated procedure”) is amended as follows.

(2) In subsection (1) for the words from “experimental” to the end substitute “procedure applied to a protected animal for a qualifying purpose which may have the effect of causing the animal a

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(1) 1986 c. 14.

(2) Section 4 was amended by S.I. 1993/2103.

(3) Section 2(6) was substituted by S.I. 2006/2407.

level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.”

(3) After subsection (1) insert—

“(1A) A procedure is applied to an animal for “a qualifying purpose” if—

- (a) it is applied for an experimental or other scientific purpose (whether or not the outcome of the procedure is known); or
- (b) it is applied for an educational purpose.”

(4) In subsection (2)—

- (a) for the words from the beginning to “animal” (in the first place it occurs) substitute “A procedure applied to an animal for a qualifying purpose”;
- (b) in paragraph (a) omit “such”;
- (c) after paragraph (a) insert—

“(ab) each of the other procedures in the series or combination is applied for a qualifying purpose; and”.

(5) After subsection (2) insert—

“(2A) A procedure applied to an animal for a qualifying purpose is also a regulated procedure if—

- (a) at the time the procedure is applied the animal has not attained the stage of its development when it is a protected animal;
- (b) the animal is to be allowed to live until after it attains that stage of its development; and
- (c) the procedure is likely to have the effect mentioned in subsection (1) after the animal attains that stage (whether or not it is also likely to have that effect before the animal attains that stage).”

(6) After subsection (3) insert—

“(3A) The modification of an animal’s genes is a regulated procedure if—

- (a) the animal is a protected animal and the modification may have the effect mentioned in subsection (1); or
- (b) the animal is to be allowed to live until after it attains the stage of its development when it is a protected animal and the modification may have the effect mentioned in subsection (1) after it has attained that stage (whether or not it is also likely to have that effect before the animal attains that stage).

(3B) The breeding of an animal is a regulated procedure if—

- (a) the animal is bred from an animal whose genes have mutated or been modified or from a descendant of an animal whose genes have mutated or been modified;
- (b) the animal is to be allowed to live until after it has attained the stage of its development when it is a protected animal; and
- (c) after the animal has attained that stage the animal may experience pain, suffering, distress or lasting harm of a level mentioned in subsection (1) by reason of the mutation or modification referred to in paragraph (a).

(3C) For the purposes of subsections (3A) and (3B), references to the modification of an animal’s genes include the modification before the animal comes into being of any genetic material by virtue of which it comes into being”.

(7) Omit subsections (5) and (6).

(8) For subsections (7) and (8) substitute—

“(7) Killing a protected animal is a regulated procedure only if—

- (a) it is killed for experimental or other scientific use;
- (b) the place where it is killed is—
  - (i) a place that is specified in a licence granted under section 2C, or
  - (ii) a place that is specified in a project licence by virtue of section 5(3), and
- (c) the method employed to kill the animal is not—
  - (i) a method that is appropriate to that description of animal under Schedule 1, or
  - (ii) in a case within paragraph (b)(i), a method that is specified as being appropriate to that description of animal in the licence granted under section 2C.

(8) Notwithstanding anything in this section, the following are not regulated procedures—

- (a) non-experimental agricultural practices;
- (b) non-experimental clinical veterinary practices;
- (c) practices undertaken for the purposes of recognised animal husbandry;
- (d) the administration of any substance or article to an animal for research purposes in accordance with an animal test certificate granted under the Veterinary Medicines Regulations 2011(4);
- (e) the ringing, tagging or marking of an animal, or the application of any other humane procedure for the primary purpose of enabling an animal to be identified, provided that it causes only momentary pain or distress (or none at all) and no lasting harm.

(8A) References in this section to “a procedure” include both invasive and non-invasive procedures.”

## **Principles of replacement, reduction and refinement**

5. After section 2 insert—

### **“2A Principles of replacement, reduction and refinement**

(1) The Secretary of State must exercise his or her functions under this Act with a view to ensuring compliance with the principles of replacement, reduction and refinement.

(2) For the purposes of this Act—

- (a) the principle of replacement is the principle that, wherever possible, a scientifically satisfactory method or testing strategy not entailing the use of protected animals must be used instead of a regulated procedure;
- (b) the principle of reduction is the principle that whenever a programme of work involving the use of protected animals is carried out the number of protected animals used must be reduced to a minimum without compromising the objectives of the programme;
- (c) the principle of refinement is the principle that the breeding, accommodation and care of protected animals and the methods used in regulated procedures applied

to such animals must be refined so as to eliminate or reduce to the minimum any possible pain, suffering, distress or lasting harm to those animals.”

### **Licensing of undertakings**

6. After section 2A insert—

*“Licensing of undertakings*

#### **2B Prohibition of unlicensed undertakings**

(1) A person must not, whether for profit or otherwise, carry on at any place an undertaking which involves one or more of the activities mentioned in subsection (2) unless the person is authorised to do so by a licence under section 2C.

(2) The activities are—

- (a) the applying of regulated procedures to protected animals;
- (b) the breeding of relevant protected animals with a view to—
  - (i) their use in regulated procedures, or
  - (ii) the use of their tissues or organs for scientific purposes,
 or the breeding of protected animals (other than relevant protected animals) primarily for purposes within sub-paragraph (i) or (ii);
- (c) the keeping of relevant protected animals which have been bred elsewhere and are to be supplied with a view to —
  - (i) their use elsewhere in regulated procedures, or
  - (ii) the use elsewhere of their tissues or organs for scientific purposes.

(3) In this section “relevant protected animal” means a protected animal of a description specified in Schedule 2 to this Act.

#### **2C Licensing of undertakings**

(1) A licence under this section is a licence granted by the Secretary of State which authorises the holder to carry on at a specified place an undertaking which involves the activities mentioned in subsection (2) of section 2B or such of those activities as are specified in the licence.

(2) The Secretary of State may grant a licence under this section only if satisfied that the person who is to be the holder and the place that is to be specified are in compliance with the requirements of the Animals Directive.

(3) An application for a licence under this section shall be made to the Secretary of State in such form and shall be supported by such information as the Secretary of State may reasonably require.

(4) A licence under this section shall not be granted unless the application nominates for inclusion in the licence pursuant to subsection (5) persons appearing to the Secretary of State to be suitable for that purpose.

(5) A licence under this section shall specify—

- (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.
- (6) If the Secretary of State thinks fit, the same person may be specified under two or more of the paragraphs of subsection (5).
- (7) If it appears to any person specified in a licence pursuant to paragraph (a) or (b) of subsection (5) that the health or welfare of any animal kept at the place specified in the licence gives rise to concern, that person shall—
- (a) notify the person holding a personal licence who is in charge of the animal; or
  - (b) if there is no such person or it is not practicable to notify that person, take steps to ensure that the animal is cared for and, if it is necessary for it to be killed, that it is killed in accordance with section 15A (manner in which protected animals are to be killed).
- (8) In any case to which subsection (7) applies the person specified in the licence pursuant to paragraph (a) of subsection (5) may also notify the person (if different) specified pursuant to paragraph (b) of that subsection; and the person specified pursuant to either paragraph of that subsection may also notify one of the inspectors appointed under this Act.
- (9) A licence under this section shall continue in force until revoked.
- (10) Where—
- (a) there has been or is to be a significant change to the structure or function of the place specified in a licence under this section, and
  - (b) the change may have a negative effect on animal welfare,
- the Secretary of State shall vary the licence as appropriate (or if necessary revoke it).”

### **Personal licences**

7.—(1) Section 3 (prohibition of unlicensed procedures) is amended as follows.

- (2) In the words before paragraph (a) after “shall” insert “personally”.
- (3) In paragraph (c) omit “the personal licence and”.

8.—(1) Section 4(5) (personal licences) is amended as follows.

- (2) In subsection (1)—
  - (a) for “to apply specified regulated procedures” substitute “personally to apply regulated procedures of specified descriptions”;
  - (b) omit “at a specified place or specified places”.
- (3) In subsection (3)—
  - (a) for paragraph (a) substitute—
    - “(a) is for the time being specified in a relevant section 2C licence by virtue of section 2C(5)(d);”;

- (b) in paragraph (b) for the words from “biological” to “the” (in the second place it occurs) substitute “education,”;
- (c) omit the words after paragraph (b).
- (4) After subsection (3) insert—
  - “(3A) For the purposes of subsection (3)(a), a section 2C licence is “relevant” if it authorises the holder to carry on an undertaking which involves the applying of regulated procedures to protected animals.”
- (5) In subsection (4A)(a)—
  - (a) omit “(including instruction in a relevant scientific discipline)”;
  - (b) for “to be specified in the licence” substitute “that the licence would qualify the person to apply”.

## **Project licences**

- 9.—(1) For section 5 substitute—

### **“5 Project licences: general**

(1) A project licence is a licence granted by the Secretary of State which specifies a programme of work and authorises the application, as part of that programme, of specified regulated procedures to animals of specified descriptions at a specified place or specified places.

(2) A place may not be specified in a project licence unless it is a place at which a person is authorised by a section 2C licence to carry on an undertaking involving the applying of regulated procedures to protected animals.

(3) But subsection (2) does not apply in any case in which it appears to the Secretary of State, on the basis of a scientific justification, that the programme or procedures authorised by the project licence require a different place to be specified.

(4) In the circumstances set out in Article 40.4 of the Animals Directive, a project licence may specify a programme of work which consists of multiple generic projects.

### **5A Application for a project licence**

- (1) An application for a project licence must—
  - (a) specify the programme of work the applicant wishes to be specified in the project licence;
  - (b) specify the regulated procedures, the descriptions of animal and the place or places the applicant wishes to be specified in the project licence;
  - (c) include information on the matters set out in Annex 6 of the Animals Directive;
  - (d) include such other information as the Secretary of State may reasonably require; and
  - (e) be accompanied by a project summary.
- (2) A project summary is a statement, in non-technical language, which (subject to subsection (3)(a))—
  - (a) describes the proposed programme of work and states the objectives of the programme, the predicted harm and benefits of the programme and the number and types of animal to be used in the programme;
  - (b) demonstrates that the proposed programme of work would be carried out in compliance with the principles of replacement, reduction and refinement.

- (3) A project summary must not contain—
- (a) any information of a confidential nature or any information the publication of which may lead to the infringement of any person’s intellectual property rights;
  - (b) names or addresses or any other information from which the identity of the applicant or any other person can be ascertained.
- (4) If the Secretary of State receives an incomplete or incorrect application for a project licence the Secretary of State must, as soon as practicable, inform the applicant of the following matters—
- (a) the fact that the application is incomplete or incorrect;
  - (b) the additional information that needs to be provided by the applicant to complete or correct the application; and
  - (c) the fact that the period mentioned in subsection (7) will not begin until the Secretary of State has received the additional information.
- (5) Subsections (6) to (9) apply if the Secretary of State receives a complete and correct application for a project licence or receives information from an applicant that completes or corrects an application for a project licence.
- (6) The Secretary of State must as soon as practicable—
- (a) acknowledge receipt of the application or (as the case may be) receipt of the information; and
  - (b) inform the applicant of the effect of subsections (7) to (9).
- (7) Within the period of 40 working days beginning with the day on which the Secretary of State receives the application or (as the case may be) the information, the Secretary of State must—
- (a) grant a project licence to the applicant (in the terms specified in the application under subsection (1)(a) and (b) or in those terms with such modifications as the Secretary of State thinks appropriate); or
  - (b) serve on the applicant a notice under section 12(1) indicating the Secretary of State’s intention to refuse the project licence.
- (8) On one occasion within the period mentioned in subsection (7), the Secretary of State may by notice to the applicant extend the period by up to 15 working days.
- (9) The Secretary of State may exercise the power in subsection (8) only if, and to the extent that, the Secretary of State considers its exercise is justified by the complexity or multi-disciplinary nature of the proposed programme of work.

### **5B Determining an application: evaluation of the programme of work**

- (1) A project licence must not be granted unless the Secretary of State has carried out in accordance with this section a favourable evaluation of the programme of work to be specified in the licence.
- (2) For this purpose, the evaluation of a programme of work is favourable only if it verifies—
- (a) that carrying out the programme of work is justified from a scientific or educational point of view or is required by law;
  - (b) that the purposes of the programme of work justify the use of protected animals; and
  - (c) that the programme of work is designed so as to enable the regulated procedures applied as part of it to be applied in the most humane and environmentally sensitive manner possible.

- (3) In carrying out the evaluation of a programme of work the Secretary of State must—
- (a) evaluate the objectives of the programme of work and its predicted scientific benefits or educational value;
  - (b) assess the compliance of the programme of work with the principles of replacement, reduction and refinement;
  - (c) classify as “non-recovery”, “mild”, “moderate” or “severe” the likely severity of each regulated procedure that would be applied as part of the programme of work;
  - (d) carry out a harm-benefit analysis of the programme of work to assess whether the harm that would be caused to protected animals in terms of suffering, pain and distress is justified by the expected outcome, taking into account ethical considerations and the expected benefit to human beings, animals or the environment;
  - (e) assess any scientific justification which is relevant (by virtue of sections 5(3), 15A(7) or 17(2), paragraphs 1(4), 2(4) or 3(3) of Schedule 2B or paragraph 25(2), (3) or (5) of Schedule 2C) to the question of whether or on what terms a project licence may be granted in respect of the programme of work;
  - (f) assess whether there is any justification for an exemption under paragraph 26(2) of Schedule 2C;
  - (g) assess whether carrying out the programme of work would give rise to any scientific reason for an exemption under paragraph 11(5) of Schedule 2C;
  - (h) determine, on the assumption that a project licence is granted in respect of the programme of work, whether and (if so) when the programme should be retrospectively assessed under section 5F.
- (4) In carrying out the evaluation of a programme of work the Secretary of State must consider—
- (a) expertise in the area of science for which it is intended that protected animals will be used (including expertise in the application of the principles of replacement, reduction and refinement when working in that area of science);
  - (b) expertise in experimental design (including expertise in statistics where appropriate);
  - (c) expertise in veterinary practice in laboratory animal science or, where appropriate, expertise in wildlife veterinary practice;
  - (d) expertise in animal husbandry and care in relation to the species of protected animals that are intended to be used.
- (5) For the purposes of subsection (3)(c) a series of regulated procedures applied to an animal for a particular purpose is to be treated as constituting a single regulated procedure.
- (6) When classifying the likely severity of a regulated procedure under subsection (3)(c) the Secretary of State must use the criteria in Annex 8 of the Animals Directive.
- (7) The Secretary of State must determine that a programme of work should be retrospectively assessed under section 5F if the programme would involve—
- (a) the application of regulated procedures to primates; or
  - (b) the application of regulated procedures the likely severity of which has been classified under section (3)(c) as “severe”.
- (8) The evaluation of a programme of work must be carried out with a degree of detail appropriate for the type of programme and must be carried out in an impartial manner.
- (9) The Secretary of State must publish information as to the process by which he proposes to evaluate programmes of work under this section.



### **5C Determining an application: further provision**

(1) A project licence must not be granted except to a person who undertakes responsibility for the overall implementation of the programme of work to be specified in the licence.

(2) A project licence must not be granted to a person unless the Secretary of State has verified that—

- (a) the person has received instruction in a scientific discipline relevant to the programme of work to be specified in the licence;
- (b) the person has specific knowledge relating to the species of animal that is to be subjected to regulated procedures as part of that programme of work; and
- (c) the person has appropriate education and training for the purpose of designing programmes of work involving the application of regulated procedures.

(3) A project licence must not be granted unless the Secretary of State has verified that the programme of work to be specified in the licence is to be carried out for one of the following purposes—

- (a) basic research;
- (b) translational or applied research with one of the following aims—
  - (i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, animals or plants;
  - (ii) the assessment, detection, regulation or modification of physiological conditions in man, animals or plants; or
  - (iii) the improvement of the welfare of animals or of the production conditions for animals reared for agricultural purposes;
- (c) the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs or any other substances or products, with one of the aims mentioned in paragraph (b);
- (d) the protection of the natural environment in the interests of the health or welfare of man or animals;
- (e) research aimed at preserving the species of animal subjected to regulated procedures as part of the programme of work;
- (f) higher education or training for the acquisition, maintenance or improvement of vocational skills;
- (g) forensic inquiries.

(4) Schedule 2B (which requires the Secretary of State to verify that additional conditions are met before granting a project licence that would authorise the use of endangered animals, primates, cats, dogs or equidae) has effect.

(5) The Secretary of State must not grant a project licence that would authorise the application of regulated procedures to great apes.

### **5D Granting a project licence**

(1) This section applies where a project licence is granted in relation to a programme of work.

(2) The project licence must—

- (a) specify the name of the person to whom the licence is granted; and

- (b) contain a statement that the person is responsible for the overall implementation of the programme of work and for ensuring that the programme is carried out in compliance with the conditions of the licence.
- (3) The project licence must specify the name of any person who at the time the project licence is granted holds a section 2C licence granted in respect of a place specified in the project licence.
- (4) The project licence must state how the Secretary of State classified the likely severity of each of the regulated procedures specified in the licence (see section 5B(3)(c)).
- (5) The project licence must state what determination the Secretary of State made as to whether and, if so, when the programme of work should be retrospectively assessed under section 5F (see section 5B(3)(h)).
- (6) The Secretary of State must publish a copy of the project summary that accompanied the application for the project licence.
- (7) But before doing so the Secretary of State must alter the copy so that—
  - (a) it states what determination the Secretary of State made as to whether and when the programme of work should be retrospectively assessed under section 5F; and
  - (b) it includes such additional information as the Secretary of State thinks appropriate in order to assist a person who reads the summary.

#### **5E Duration of a project licence and further evaluation etc**

- (1) Unless revoked and subject to the following provisions of this section, a project licence shall continue in force for such period as is specified in the licence and may be renewed for further periods but (without prejudice to the grant of a new licence in respect of the programme in question) no such licence shall be in force for more than five years in all.
- (2) A project licence shall terminate on the death of the holder unless a qualifying person notifies the Secretary of State of the death within seven days of becoming aware of it.
- (3) Where the Secretary of State receives a notification under subsection (2) the project licence shall, unless the Secretary of State otherwise directs, continue in force until the end of the period of 28 days beginning with the date of the notification.
- (4) For the purposes of subsection (2), a person is a “qualifying person” in relation to a project licence if—
  - (a) the person is the holder of a section 2C licence granted in respect of a place specified in the project licence; or
  - (b) in a case where the project licence does not specify a place in respect of which there is a section 2C licence, the person is the holder of a personal licence who was engaged on the programme in question.
- (5) A project licence may not be varied or renewed unless the Secretary of State has carried out a further favourable evaluation of the relevant programme of work; and for this purpose section 5B applies with any necessary modifications.
- (6) The Secretary of State must establish and publish conditions which he or she will take into account in determining whether to vary or renew a project licence.

#### **5F Retrospective assessment of programme of work**

- (1) This section applies where—
  - (a) a project licence is granted in respect of a programme of work; and

- (b) the Secretary of State made a determination under section 5B(3)(h) that the programme of work should be retrospectively assessed under this section.
- (2) At the time determined by the Secretary of State under section 5B(3)(h), the Secretary of State must assess the following matters—
  - (a) whether the programme of work has been carried out;
  - (b) whether the objectives of the programme of work have been achieved;
  - (c) the amount of harm caused to animals by the carrying out of the programme of work (including the number of animals subjected to regulated procedures as part of the programme of work, the species of animals subjected to those procedures and the severity of those procedures); and
  - (d) whether any lessons can be learnt from the programme of work which may contribute to the further implementation of the principles of replacement, reduction and refinement.
- (3) Following the assessment the Secretary of State must—
  - (a) alter the copy of the relevant project summary published under section 5D(6) so that it includes a report on the assessment; and
  - (b) publish the copy as altered.
- (4) The Secretary of State may by notice require the holder or former holder of the licence to provide the Secretary of State with specified information, or information of a specified kind, for the purpose of enabling the Secretary of State to assess the matters mentioned in subsection (2).
- (5) Information required to be provided by a notice under subsection (4) must be provided within such period as may be specified.

### **5G Documents to be kept by Secretary of State**

- (1) Where a person applies for a project licence the Secretary of State must keep the documents specified in subsection (2) at least until the end of the period of three years beginning immediately after—
  - (a) the expiry of the project licence (if the application for the licence is successful); or
  - (b) (if not) the period mentioned in section 5A(7), taking into account any extension of that period under section 5A(8).
- (2) The documents referred to above are—
  - (a) the application for the licence and the documents submitted in support of it;
  - (b) documents setting out the results of the evaluation carried out under section 5B and of any evaluation carried out under section 5E(5);
  - (c) the project licence itself, or the notice (served under section 12(1)(a)) of intention to refuse the application for the licence;
  - (d) documents containing information provided for the purposes of any assessment under section 5F;
  - (e) documents setting out the results of any such assessment (if completed before the end of the three-year period mentioned in subsection (1)); and
  - (f) any other documents prepared or received by the Secretary of State in relation to the licence which the Secretary of State considers should be kept.
- (3) If section 5F applies in relation to a project licence and the assessment under that section is not completed until after the end of the three-year period mentioned in subsection (1), the

Secretary of State must keep the documents specified in subsection (2)(a), (b), (c), (d) and (f) until the assessment is completed.”

(2) After Schedule 2A insert the Schedule set out in Schedule 1 to these Regulations.

### Conditions in licences

**10.**—(1) For section 10(6) substitute—

#### “10 Conditions

(1) Schedule 2C makes provision as to the conditions that must be included in a licence granted under this Act.

(2) A licence granted under this Act may include such other conditions as the Secretary of State thinks fit.

(3) Breach of a condition in a licence does not invalidate the licence; but as to the consequences of a breach, see section 11 (failure to comply with licence conditions etc).

(4) If a personal licence includes a condition permitting the holder to use assistants to perform, under the holder’s direction, tasks not requiring technical knowledge, nothing done by an assistant in accordance with the condition contravenes section 3.”

(2) After Schedule 2B (inserted by regulation 9(2)) insert the Schedule set out in Schedule 2 to these Regulations.

### Failure to comply with licence conditions etc

**11.** For section 11 (variation and revocation) substitute—

#### “11 Failure to comply with licence conditions etc

(1) Subsections (2) to (5) apply where it appears to the Secretary of State that the holder of a licence under this Act is failing or has failed to comply with—

- (a) a condition of the licence, or
- (b) a provision of this Act.

(2) The Secretary of State may issue the holder of the licence with a notice (“a compliance notice”) which—

- (a) specifies the condition or provision that the Secretary of State considers the holder is failing or has failed to comply with;
- (b) specifies the action the Secretary of State considers should be taken by the holder to ensure that the failure is not continued or repeated;
- (c) specifies any action the Secretary of State considers should be taken by the holder to eliminate or reduce any consequences of the failure;
- (d) requires the holder to take that action within such time as is specified in the notice; and
- (e) explains the effect of subsection (3).

(3) If a compliance notice has been issued and it appears to the Secretary of State that the holder of the licence has failed to comply with it, the Secretary of State may revoke the licence (unless the compliance notice has been withdrawn, or the notice has been varied and the holder is in compliance with the notice as varied).

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(6) Section 10 was amended by [S.I. 1998/1974](#) and [S.I. 1993/2102](#).

- (4) If it appears to the Secretary of State that—
- (a) remedial action needs to be taken to safeguard the welfare of protected animals for the time being kept by or on behalf of the holder of the licence, and
  - (b) the holder of the licence is not willing or able to take that action,
- the Secretary of State may take that action (whether or not a compliance notice has already been issued).
- (5) If the Secretary of State does not act under subsection (2) or (4) the Secretary of State may suspend, revoke or vary the licence.
- (6) A licence under this Act may also be suspended, revoked or varied by the Secretary of State in any case in which it appears to the Secretary of State that it is appropriate to do so or at the request of the holder.
- (7) A reference in this section to suspending a licence is a reference to suspending the operation of the licence either for a specified period or until further notice.”

### **Right to make representations**

- 12.—(1) Section 12 (right to make representations) is amended as follows.
- (2) For subsection (1) substitute—
- “(1) Where the Secretary of State proposes—
    - (a) to refuse a licence under this Act;
    - (b) to revoke or vary a licence under this Act otherwise than at the request of the holder; or
    - (c) to suspend a licence, otherwise than at the request of the holder, under section 11, he shall serve on the applicant or the holder a notice of his intention to do so.”
- (3) In subsection (4) omit “or certificate”.
- (4) In subsection (6) for “vary or revoke the licence or certificate” substitute “revoke, suspend or vary the licence”.
- (5) After that subsection insert—
- “(6A) Where subsection (1)(c) applies and the suspension is for a specified period of twelve months or less, this section has effect as if—
    - (a) in subsection (3), for the words “may make written representations and, if desired, oral representations to a person appointed for that purpose by the Secretary of State” there were substituted “may make written representations to the Secretary of State”; and
    - (b) subsections (5) and (6) were omitted.”

### **Duty to ensure welfare of animals not adversely affected by revocation or suspension**

13. After section 13 insert—

#### **“13A Duty to ensure welfare of animals not adversely affected by revocation or suspension**

Where the Secretary of State revokes or suspends a licence under this Act, the Secretary of State must take steps to ensure that the revocation or suspension does not have an adverse effect on the welfare of the protected animals for the time being kept by or on behalf of the holder of the licence.”

## Re-use of protected animals

### 14. For section 14(7) substitute—

#### “14 Re-use of protected animals

(1) A protected animal that has been subjected to one or more regulated procedures must not be used for a further regulated procedure unless the Secretary of State has consented to such further use and the following conditions are met.

(2) The first condition is that—

- (a) the actual severity of the regulated procedure, or each of the regulated procedures, previously applied to the animal has been classified in accordance with conditions included in a project licence by virtue of paragraph 23 of Schedule 2C, and
- (b) in a case where more than one regulated procedure has previously been applied to the animal, the actual severity of no more than one of those procedures has been classified as “severe”.

(3) The second condition is that a veterinary surgeon with knowledge of the lifetime experience of the animal has advised that the animal’s general state of health and well-being has been fully restored following the application of the previous procedure or procedures.

(4) The third condition is that—

- (a) the further procedure is to be applied as part of a programme of work specified in a project licence; and
- (b) the likely severity of the further procedure was classified by the Secretary of State under section 5B(3)(c) as “non-recovery”, “mild” or “moderate”.

(5) For the purposes of subsection (1), the consent of the Secretary of State may relate to the specific animal concerned or may relate to animals used in specified procedures or specified circumstances.

(6) But in the case of an 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.

(7) For the purposes of this section, a series of regulated procedures applied to an animal for a particular purpose is to be treated as constituting a single regulated procedure.”

## Manner in which protected animals are to be killed

### 15. After section 15 insert—

#### “15A Manner in which protected animals are to be killed

(1) Subject to subsections (8) and (9), a person must not intentionally kill a relevant protected animal unless—

- (a) the person kills the animal in a place that is specified in a section 2C licence;
- (b) the person kills the animal using an appropriate method; and

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(7) Section 14 was substituted by [S.I. 1998/1974](#).

- (c) the person is registered in a register kept by the holder of the section 2C licence (in compliance with a condition included in the licence by virtue of paragraph 2 of Schedule 2C) as being competent to kill animals of that description using that method.
- (2) An animal is killed using an appropriate method if—
  - (a) the method used is one that is appropriate to that description of animal under Schedule 1; or
  - (b) the method used is one that is specified as being appropriate to that description of animal in the section 2C licence granted in respect of the place where the animal is killed.
- (3) An animal is also killed using an appropriate method if—
  - (a) the animal is being or has been subjected to a regulated procedure as part of a programme of work specified in a project licence; and
  - (b) the animal is killed using a method that is specified as being appropriate to that description of animal in the project licence.
- (4) An animal is also killed using an appropriate method if—
  - (a) the animal is being or has been used in an agricultural research project the aim of which requires animals to be kept in similar conditions to those in which commercial farm animals are kept;
  - (b) the animal is killed in a way that complies with Article 4 of Council Regulation (EC) No 1099/2009 on the protection of animals at the time of killing; and
  - (c) the process of killing is completed by one of the methods listed in sub-paragraphs (a) to (e) of paragraph 1 of Schedule 1.
- (5) An animal is also killed using an appropriate method if—
  - (a) the method is applied to the animal while it is unconscious;
  - (b) the animal does not subsequently regain consciousness; and
  - (c) the process of killing is completed by one of the methods listed in sub-paragraphs (a) to (e) of paragraph 1 of Schedule 1.
- (6) A section 2C licence may specify 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 that are appropriate to that description of animal under Schedule 1.
- (7) A project licence may specify a method of killing as being appropriate to a description of animal only if the Secretary of State is satisfied, on the basis of a scientific justification, that the purposes of the programme of work specified in the licence cannot be achieved if a method of killing that is appropriate to that description of animal under Schedule 1 is required to be used.
- (8) A person may kill an animal in a place not specified in a section 2C licence if—
  - (a) the place is specified in a project licence in reliance on section 5(3);
  - (b) the animal is being or has been subjected to a regulated procedure at that place as part of a programme of work specified in that licence; and
  - (c) that licence specifies a section 2C licence for the purposes of this subsection.

Where this exception applies, the reference in subsection (1)(c) or (2)(b) to the section 2C licence mentioned there shall be read as a reference to the section 2C licence specified as mentioned in paragraph (c) above.

(9) A person may kill an animal otherwise than in accordance with subsection (1) if it is necessary for the animal to be killed as a matter of urgency for animal welfare, public health, public security or environmental reasons.

(10) Where a person applies a regulated procedure to a protected animal and the procedure causes the animal to die, the person is not to be treated for the purposes of this section as having intentionally killed the animal (even if the death of the animal was the likely outcome of the procedure).

(11) In this section “relevant protected animal” means a protected animal which—

- (a) is being or has been used in a regulated procedure;
- (b) is being or has been kept for use in a regulated procedure;
- (c) has been bred for use in a regulated procedure; or
- (d) is being or has been kept for the purpose of being supplied for use in a regulated procedure.

(12) A protected animal that is killed in a place specified in a section 2C licence for the use of its tissues or organs for scientific purposes shall also be treated as a relevant protected animal for the purposes of this section.”

**16.—**(1) Schedule 1(8) (appropriate methods of humane killing) is amended as follows.

(2) Omit paragraph 2 and the words “Subject to paragraph 2 below,” in paragraph 1.

(3) Immediately before Table A insert—

“**3.—**(1) A requirement in Table A for prior use of a sedative or anaesthetic—

- (a) is subject to sub-paragraph (2); and
- (b) is not to be read as prohibiting the prior use of sedative or anaesthetic in any cases where it is not required by that Table.

(2) Nothing in this Schedule requires or permits the prior use of sedative or anaesthetic where the distress likely to be caused by administering it is greater than the distress likely to be caused by using the appropriate method of killing without sedative or anaesthetic.

(4) In Table A—

- (a) in the second entry, for the words in the right hand column substitute “Birds and Rodents up to 1.5 kg (but not neonatal rodents)”;
- (b) in the left hand column of the third entry, after “neck” insert “(with the prior use of a sedative or anaesthetic in the case of rodents and rabbits over 150 g and birds over 250 g)”;
- (c) in the right hand column of the third entry, for “Birds up to 3 kg” substitute “Birds up to 1 kg”;
- (d) in the left hand column of the fifth entry, after “bullet,” in paragraph (i) insert “using appropriate rifles, guns and ammunition” and in paragraph (ii) omit “, percussion”.

### **Neuromuscular blocking agents**

**17.** For section 17 substitute—

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(8) Schedule 1 was amended by [S.I. 1996/3278](#), [S.I. 1997/226](#).



### **“17 Neuromuscular blocking agents**

(1) A person must not use 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.

(2) The Secretary of State must not grant a project licence that authorises the use of a neuromuscular blocking agent unless the Secretary of State 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.”

### **Setting free and re-homing protected animals**

18. After section 17 insert—

#### **“17A Setting free and re-homing protected animals**

(1) A person who holds a licence under this Act must not set free a relevant protected animal, or permit any person acting on their behalf to do so, unless—

- (a) the Secretary of State has consented to the setting free of the animal; or
- (b) the animal is set free during the course of a series of regulated procedures.

(2) A person who holds a licence under this Act must not re-home a relevant protected animal, or permit any person acting on their behalf to do so, unless the Secretary of State has consented to the re-homing of the animal.

(3) The Secretary of State must not consent to the setting free or re-homing of a relevant protected animal unless satisfied—

- (a) that the animal’s state of health allows it to be set free or re-homed;
- (b) that the setting free or re-homing of the animal poses no danger to public health, animal health or the environment;
- (c) that there is an adequate scheme in place for ensuring the socialisation of the animal upon being set free or re-homed; and
- (d) that other appropriate measures have been taken to safeguard the animal’s well-being upon being set free or re-homed.

(4) The Secretary of State must not consent to the setting free of a relevant protected animal which has been taken from the wild unless the Secretary of State is also satisfied that the animal has undergone a programme of rehabilitation or that it would be inappropriate for the animal to be required to undergo such a programme.

(5) For the purposes of this section—

- (a) “relevant protected animal” has the same meaning as in section 15A(11);
- (b) a reference to a person who holds a licence under this Act includes a reference to a person who held a licence under this Act which is no longer in force;
- (c) an animal is not to be treated as being “re-homed” if it is moved to live in a place which is for the time being specified in a section 2C licence.”

## Inspections

19.—(1) Section 18 (inspectors) is amended as follows.

(2) In subsection (2)—

(a) in paragraph (a) for “personal and project licences” substitute “licences under this Act”;

(b) for paragraphs (b) to (e) substitute—

“(b) to comply with any direction given by the Secretary of State under subsection (2A).”

(3) After subsection (2) insert—

“(2A) The Secretary of State may give a direction to an inspector which—

(a) specifies the holder of a licence under this Act;

(b) requires the inspector to visit the place specified in the licence, or in the case of a personal licence such places as the inspector considers appropriate, for the purpose of determining whether the holder is complying with the provisions of this Act and the conditions of the licence;

(c) requires the inspector to provide a report to the Secretary of State on the holder’s compliance with those provisions and conditions; and

(d) in a case where the inspector considers that the holder has failed or is failing to comply with any of those provisions or conditions, requires the inspector to include within the report advice as to the action to be taken by the Secretary of State.

(2B) A direction under subsection (2A) may require visits carried out in pursuance of the direction to be carried out without notice to the holder of the licence concerned.

(2C) In determining the frequency with which a direction under subsection (2A) should be given in respect of the holder of a licence, the Secretary of State must take into account—

(a) the record of the holder in complying with the provisions of this Act and the conditions of the licence;

(b) any information suggesting that the holder has failed or is failing to comply with any of those provisions or conditions; and

(c) in the case of a holder of a section 2C licence—

(i) the number and the species of protected animals kept at the place specified in the licence; and

(ii) the number and the type of regulated procedures, if any, carried out at that place.

(2D) The Secretary of State must seek to ensure that during the course of any year—

(a) a direction is given under subsection (2A) in respect of one third of the persons who hold section 2C licences that authorise the carrying on of an undertaking involving the applying of regulated procedures to protected animals;

(b) a direction is given under subsection (2A) in respect of each person who holds a section 2C licence and keeps non-human primates at the place specified in the licence.

(2E) Any report provided to the Secretary of State by virtue of subsection (2A)(c) must be kept by the Secretary of State for a period of at least five years.”

## **The Committee for the Protection of Animals Used for Scientific Purposes**

20. For sections 19 and 20 (the Animal Procedures Committee) substitute—

### **“19 The Committee for the Protection of Animals Used for Scientific Purposes**

(1) There is to be a committee to be known as the Committee for the Protection of Animals Used for Scientific Purposes.

(2) The Committee is to consist of a chair and other members appointed by the Secretary of State.

(3) Members of the Committee are to be appointed for such periods as the Secretary of State may determine.

(4) A person may resign as a member of the Committee or as its chair by notice in writing to the Secretary of State.

(5) The Secretary of State may terminate the appointment of a member if satisfied that—

- (a) for a period of six months beginning not more than nine months previously the member has, without the consent of the other members, failed to attend the meetings of the Committee;
- (b) the member is an undischarged bankrupt or has made an arrangement with his or her creditors;
- (c) the member is for any reason incapable of acting as a member; or
- (d) the member has been convicted of such a criminal offence, or the member’s conduct has been such, that it is not in the Secretary of State’s opinion fitting that the member should remain a member.

(6) The Secretary of State may make payments to the chair by way of remuneration and may make payments to the chair and the other members in respect of expenses incurred by them in the performance of their duties.

(7) The Secretary of State may also defray any other expenses of the Committee.

### **20 Functions of the Committee**

(1) The Committee must provide advice to the Secretary of State and the Animal Welfare and Ethical Review Bodies on such matters relating to the acquisition, breeding, accommodation, care and use of protected animals as the Committee may determine or as may be referred to the Committee by the Secretary of State.

(2) In its consideration of any matter the Committee shall have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

(3) The Committee must take such steps as it considers appropriate to ensure the sharing of best practice in relation to the acquisition, breeding, accommodation, care and use of protected animals.

(4) The Committee must take such steps as it considers appropriate to share the following information with the foreign committees—

- (a) information on the manner in which the Secretary of State evaluates applications for project licences;
- (b) information on the operation of the Animal Welfare and Ethical Review Bodies.

(5) The Secretary of State may provide the Committee with such information as the Committee requests for the purpose of enabling the Committee to exercise its duties under this section.

(6) In this section—

“the Animal Welfare and Ethical Review Bodies” means the bodies established and maintained in pursuance of conditions included in section 2C licences by virtue of paragraph 6 of Schedule 2C;

“the foreign committees” means the committees established in Member States other than the United Kingdom in compliance with Article 49 of the Animals Directive.”

### **Sharing of organs and tissues**

21. Before section 21 insert—

#### **“20A Sharing of organs and tissues**

The Secretary of State must take such steps as he or she considers appropriate to facilitate the establishment of programmes for the sharing of the organs and tissues of killed animals with persons who wish to use the organs and tissues for scientific purposes.”

### **Alternative strategies**

22. After section 20A insert—

#### **“20B Alternative strategies**

(1) The Secretary of State must support the development and validation of alternative strategies.

(2) In particular, the Secretary of State must—

- (a) assist the European Commission in identifying and nominating suitable laboratories to carry out validation studies on alternative strategies;
- (b) nominate a person the Commission may contact for advice on the regulatory relevance and suitability of alternative strategies proposed by the Commission for validation;
- (c) take such other steps as the Secretary of State considers appropriate to encourage research into alternative strategies;
- (d) ensure the promotion of, and dissemination of information about, alternative strategies.

(3) The Secretary of State may make grants to any person concerned with the development, promotion or validation of alternative strategies.

(4) “Alternative strategies” means 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, distress or lasting harm caused to protected animals.”

### **Statistics and reporting**

23. After section 21 insert—

### **“21A Statistics and reporting**

(1) In each year, beginning with the year 2015, the Secretary of State must by 10 November—

- (a) collect and publish statistical information on the use of protected animals in regulated procedures during the previous year;
- (b) lay that information before Parliament; and
- (c) send that information to the European Commission.

(2) The statistical information must include information—

- (a) on the actual severity of the regulated procedures, and
- (b) on the origin and the species of any primates used in regulated procedures.

(3) The Secretary of State must each year send to the European Commission information on the methods of killing that have been specified in section 2C licences for the purposes of section 15A(2)(b).

(4) The Secretary of State must by 10 November 2018, and by 10 November in every fifth year thereafter, send to the European Commission information on the implementation of the Animals Directive (and, in particular, Articles 10(1), 26, 28, 34, 38, 39, 43 and 46 of the Directive).”

### **Penalties for contraventions**

**24.**—(1) Section 22(9) (penalties for contraventions) is amended as follows.

(2) Before subsection (1) insert—

“(A1) Any person who carries on an undertaking involving the applying of regulated procedures to protected animals in contravention of section 2B shall be guilty of an offence and liable—

- (a) on conviction on indictment, to imprisonment for a term not exceeding two years or to a fine or to both;
- (b) on summary conviction in England and Wales, to imprisonment for a term not exceeding six months or to a fine not exceeding the statutory maximum or to both;
- (c) on summary conviction in Scotland or Northern Ireland, to imprisonment for a term not exceeding three months or to a fine not exceeding the statutory maximum or to both.”.

(3) In subsection (3)—

(a) before paragraph (a) insert—

“(za) contravenes section 2B otherwise than by carrying on an undertaking involving the applying of regulated procedures to protected animals;

(zb) fails to comply with a notice under section 5F(4);”;

(b) in paragraph (a), omit “7(1) or (2),”.

(4) After subsection (3) insert—

“(3A) Any person who contravenes section 15A or 17A above shall be guilty of an offence and liable on summary conviction—

- (a) in England and Wales, to imprisonment for a term not exceeding 51 weeks or to a fine not exceeding the fifth level on the standard scale or to both;

- (b) in Scotland or Northern Ireland, to imprisonment for a term not exceeding three months or to a fine not exceeding the fifth level on the standard scale or to both.”
- (5) After subsection (4) insert—
  - “(4A) A person who kills an animal in contravention of section 15A above shall not be guilty of an offence by virtue of subsection (3A) above if the person shows that he did not know and had no reason to believe that the animal was a relevant protected animal (within the meaning of section 15A).”
- (6) In relation to an offence committed before the commencement of paragraph 3 of Schedule 27 to the Criminal Justice Act 2003(10)—
  - (a) the reference to six months in subsection (A1)(b) of section 22 of the Animals (Scientific Procedures) Act 1986 (inserted by paragraph (2) above) is to be read as a reference to three months;
  - (b) the reference to 51 weeks in subsection (3A)(a) of that section (inserted by paragraph (4) above) is to be read as a reference to three months.

### **Powers of entry**

- 25.**—(1) Section 25 (powers of entry) is amended as follows.
- (2) In subsection (2), for “this section” substitute “subsection (1)”.
  - (3) After that subsection insert—
    - “(2A) If a justice of the peace or in Scotland a sheriff is satisfied by information on oath that—
      - (a) the Secretary of State has power to take action under section 11(4) or is under a duty to take steps under section 13A, and
      - (b) entry to a particular place is needed for that purpose,
 the justice or sheriff may issue a warrant authorising specified officers of the Secretary of State to enter that place for that purpose, if need be using such force as is reasonably necessary to secure entry.
    - (2B) A warrant under subsection (2A) must require the specified officers to be accompanied by a constable and by an inspector appointed under this Act.”
  - (4) In subsection (3), at the end of paragraph (a) omit “or” and insert—
    - “(aa) intentionally obstructs a person specified in a warrant issued under subsection (2A) in the exercise of a power under section 11(4) or a duty under section 13A; or”.

### **Minor and consequential amendments to the Animals (Scientific Procedures) Act 1986**

- 26.**—(1) Omit sections 6 and 7 (scientific procedure establishments and breeding and supplying establishments) and the italic cross-heading before section 6.
- (2) Before section 8 insert the following italic cross-heading—
 

“*Licences: general provisions*”.
  - (3) In section 8 (fees) for “certificate issued under section 6 or 7 above” substitute “section 2C licence”.
  - (4) Omit the italic cross-heading before section 9.
  - (5) In section 9 (consultation)—
    - (a) in subsection (1)—

- (i) for “licence or issuing a certificate” substitute “section 2C licence or a project licence”;
- (ii) for “the Animal Procedures Committee” substitute “the Committee for the Protection of Animals Used for Scientific Purposes”;
- (b) after subsection (1) insert—
  - “(1A) Before granting a personal licence under this Act the Secretary of State may consult one of those inspectors, an independent assessor or that Committee.”
- (6) In section 13 (suspension in cases of urgency) omit the words “or certificate” in each place they occur.
- (7) In section 15(1) (killing animals at conclusion of regulated procedures)—
  - (a) in paragraph (b) after “effects” insert “as a result of being subjected to the series”;
  - (b) for the words from “cause the animal” to the end substitute “ensure that the animal is immediately killed in accordance with section 15A”.
- (8) In section 18 (inspectors), in subsection (3), for the words after “require it to be immediately killed” substitute “in accordance with section 15A”.
- (9) In section 21 (guidance, codes of practice and statistics)—
  - (a) in the heading for “, codes of practice and statistics” substitute “and codes of practice”;
  - (b) in subsection (1), omit “and certificates” (in both places);
  - (c) in subsection (3), for “Animal Procedures Committee” substitute “Committee for the Protection of Animals Used for Scientific Purposes”;
  - (d) omit subsection (7).
- (10) In section 22 (penalties for contraventions)—
  - (a) in subsection (4), for “17(a)” substitute “17”;
  - (b) in subsection (5), for “designated establishment” substitute “place specified in a section 2C licence”;
  - (c) in subsection (5A), for “designated establishment” substitute “place specified in a section 2C licence”.
- (11) In section 23 (false statements), in subsection (1) omit “or certificate”.
- (12) In section 25 (powers of entry) in subsection (2) for “designated establishment” substitute “place specified in a section 2C licence.”
- (13) In section 26(11) (prosecutions) in subsection (1)(b) for “designated establishment” substitute “place specified in a section 2C licence”.
- (14) In section 27(12) (repeal, consequential amendments and transitional provisions), in subsection (3), for “designated breeding establishment” substitute “place specified in a section 2C licence by virtue of section 2B(2)(b)”.
- (15) In section 29(13) (application to Northern Ireland)—
  - (a) in subsection (3), for “19(6)” substitute “19(4)”;
  - (b) in subsection (4)—
    - (i) in the opening words, omit the words from “section 20(5)” to “and in”;

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(11) Section 26 was amended by the Animal Welfare Act 2006, section 64, Schedule 3, paragraph 12(2).

(12) Section 5(4) of the Dangerous Wild animals Act 1976 was amended the Animals (Scientific Procedures) Act 1986.

(13) Section 29 was amended by 2006 c. 45 and 2011 c. 16.

- (ii) in sub-paragraph (a), for “the Assembly” substitute “the Northern Ireland Assembly”;
- (c) after subsection (4), insert—
  - “(4A) In section 21A(1) above for the reference to Parliament there shall be substituted a reference to the Northern Ireland Assembly.”
- (d) for subsection (6) substitute—
  - “(6) In section 25 above for the references to information on oath there shall be substituted references to a complaint on oath.”
- (16) In section 30 (short title, interpretation and commencement)—
  - (a) in subsection (2)—
    - (i) omit the definition of “designated”;
    - (ii) at the appropriate places insert the following definitions—
      - ““the Animals Directive” means Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes;”
      - ““section 2C licence” means a licence granted under section 2C.”
  - (b) after subsection (2) insert—
    - “(2A) Any reference in this Act to an Annex of the Animals Directive is a reference to the Annex as amended from time to time.”
- (17) In Schedule 1(14), in the shoulder reference, for “Sections 2, 6, 7, 10, 15(1) and 18(3)” substitute “Sections 2 and 15A”.
- (18) In Schedule 2(15)—
  - (a) for the title substitute “ANIMALS THAT ARE “RELEVANT PROTECTED ANIMALS” FOR THE PURPOSES OF SECTION 2B”;
  - (b) in the shoulder reference, for “Sections 7 and 10” substitute “Section 2B”;
  - (c) for “Mouse” substitute “Any mouse of the species *Mus musculus*”;
  - (d) for “Rat” substitute “Any rat of the species *Rattus norvegicus*”;
  - (e) for “Hamster” substitute “Any hamster of the species *Mesocricetus auratus* or *Cricetulus griseus*”;
  - (f) for “Rabbit” substitute “Any rabbit of the species *Oryctolagus cuniculus*”;
  - (g) for “Gerbil” substitute “Any gerbil of the species *Meriones unguiculatus*”;
  - (h) at the end of the list of animals insert—
    - “Any frog of the species *Xenopus laevis*, *Xenopus tropicalis*, *Rana temporaria* or *Rana pipiens*  
Zebra fish”.
- (19) Omit Schedule 2A(16).

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(14) Schedule 1 was amended by [S.I. 1996/3278](#) and [S.I. 1997/226](#).

(15) Schedule 2 was amended by [S.I. 1993/2103](#) and [S.I. 1998/1674](#).

(16) Schedule 2A was inserted by [S.I. 1998/1974](#).



### Other minor and consequential amendments etc

**27.** In section 5(4)(17) of the Dangerous Wild Animals Act 1976(18) (dangerous wild animals not to be kept without a licence: exemptions for animals kept for scientific procedures etc), for “a designated establishment” substitute “the place specified in a section 2C licence”.

**28.**—(1) Section 148 of the Serious Organised Crime and Police Act 2005(19) (harming a animal research organisation or intimidating a connected person: definition of “animal research organisation”) is amended as follows.

(2) In subsection (1), after “subsection” insert “(1A),”.

(3) After subsection (1) insert—

“(1A) A person or organisation falls within this subsection if the person or organisation holds a licence granted under section 2C of the 1986 Act (licensing of undertakings involving the use of animals for scientific procedures).”

(4) In subsection (2), for the words from “including” to the end of the subsection substitute “including a place specified in a licence granted under that section or under section 5 of the 1986 Act (licensing of projects involving the use of animals for scientific procedures).”

(5) In subsection (3)—

(a) before paragraph (a) insert—

“(za) the holder of a licence granted under section 2C of the 1986 Act,  
(zb) a person specified under section 2C(5) of that Act,”;

(b) at the end of paragraph (a), insert “or”;

(c) omit paragraphs (c) and (d).

**29.**—(1) Section 58 of the Animal Welfare Act 2006(20) (application of the Act: exceptions for places and animals used for scientific procedures etc) is amended as follows.

(2) In subsection (2), for the words from “which is” to the end substitute “which is specified in a licence granted under section 2C of the Animals (Scientific Procedures) Act 1986 (licensing of undertakings involving the use of animals for scientific procedures).”

(3) In subsection (3), for paragraphs (a) to (d) substitute—

“(a) is being kept at a place specified in a licence granted under section 2C of the Animals (Scientific Procedures) Act 1986, and

(b) is being so kept for the purposes of, or in connection with, an activity mentioned in section 2B(2) of that Act that is pursued at that place in the course of carrying on the undertaking authorised by the licence.”

(4) Omit subsection (4).

**30.** In rule 3 of the Animals (Scientific Procedures) (Procedure for Representations) Rules 1986(21) (interpretation, etc), in the definition of “applicant”, for the words from “or certificate under the Act” to the end substitute “under the Act, or the holder of such a licence, who wishes to make written or oral representations under section 12(3) or (4) of the Act in respect of—

(a) a proposal to refuse, revoke, vary or suspend the licence; or

(b) the inclusion of any condition in the licence.

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(17) Section 5(4) was amended by section 27(2) of 1986 c. 14.

(18) 1976 c.38.

(19) 2005 c. 15.

(20) 2006 c. 45.

(21) S.I. 1986/1911.

**31.** The Animals (Scientific Procedures) Act (Amendment) Regulations 1993(**22**) are revoked.

**32.** Article 3 of the Animals (Scientific Procedures) Act (Amendment) Order 1993(**23**) (*Octopus vulgaris* invertebrates capable of independent feeding to be protected animals under the Act) is revoked.

**33.**—(1) In article 2(2) of the Animals (Scientific Procedures) Act 1986 (Fees) (No 1) Order 1996(**24**) (deficits to be taken into account when fixing fees: relevant functions), for “the Animals Procedure Committee” substitute “the Committee for the Protection of Animals Used for Scientific Purposes”.

(2) Paragraph (1) does not apply in relation to any deficit incurred by the Animals Procedure Committee before its abolition by regulation 20 of these Regulations.

**34.** In the Schedule to the Animals (Scientific Procedures) Act 1986 (Amendment) Regulations 1998(**25**) (amendments to the Animals (Scientific Procedures) Act 1986), paragraphs 3 to 6 are revoked.

**35.** In article 7(1)(d) of the Dangerous Wild Animals (Northern Ireland) Order 2004(**26**) (dangerous wild animals not to be kept without a licence: exemptions for animals kept for scientific procedures etc), for “a designated establishment” substitute “the place specified in a section 2C licence”.

**36.** Paragraph 6 of Part 1 of Schedule 9 to the Veterinary Medicines Regulations 2006(**27**) (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 are revoked.

**37.** In article 70(3)(c) of the Avian Influenza and Influenza of Avian Origin in Mammals (Scotland) Order 2006(**28**) (measures on suspicion or confirmation of avian influenza: designation of premises to which things may be moved), for “licensed under sections 4 or 5” substitute “specified in a licence granted under section 2C”.

**38.** In article 71(3)(c) of the Avian Influenza and Influenza of Avian Origin in Mammals (England) (No. 2) Order 2006(**29**) (measures on suspicion or confirmation of avian influenza: designation of premises to which things may be moved), for “licensed under sections 4 or 5” substitute “specified in a licence granted under section 2C”.

**39.** In article 71(3)(c) of the Avian Influenza and Influenza of Avian Origin in Mammals (Wales) (No. 2) Order 2006(**30**) (measures on suspicion or confirmation of avian influenza: designation of premises to which things may be moved), for “licensed under sections 4 or 5” substitute “specified in a licence granted under section 2C”.

**40.** In regulation 71(3)(c) of the Avian Influenza and Influenza of Avian Origin in Mammals (Northern Ireland) Regulations 2007(**31**) (measures on suspicion or confirmation of avian influenza: designation of premises to which things may be moved), for “licensed under sections 4 or 5” substitute “specified in a licence granted under section 2C”.

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(22) Was substituted by Schedule 4 paragraph 6(a) to 2011 c. 16.

(23) S.I. 1993/2103.

(24) S.I. 1996/3090.

(25) S.I. 1998/1974.

(26) S.I. 2004/1993 (N.I.16).

(27) S.I.2006/2407.

(28) S.S.I. 2006/336.

(29) S.I. 2006/2702.

(30) S.I. 2006/2927.

(31) S.R. 2007/68.

**41.**—(1) Section 52 of the Welfare of Animals Act (Northern Ireland) 2011(**32**) (application of the Act: exceptions for places and animals used for scientific procedures etc) is amended as follows.

(2) In subsection (2), for the words from “which is” to the end substitute “which is specified in a licence granted under section 2C of the Animals (Scientific Procedures) Act 1986 (licensing of undertakings involving the use of animals for scientific procedures).”

(3) In subsection (3), for paragraphs (a) to (d) substitute—

“(a) is being kept at a place specified in a licence granted under section 2C of the Animals (Scientific Procedures) Act 1986, and

(b) is being so kept for the purposes of, or in connection with, an activity mentioned in section 2B(2) of that Act that is pursued at that place in the course of carrying on the undertaking authorised by the licence.”

(4) Omit subsection (4).

### **Transitional provision**

**42.** Schedule 3 makes transitional provision.

Address  
Date

*Name*  
Parliamentary Under Secretary of State  
Department