

2012 No. 3039

ANIMALS

The Animals (Scientific
Procedures) Act 1986
Amendment Regulations 2012

Made - - - - - 18th December 2012

Coming into force in accordance with regulation 1(2) to (4)



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The Secretary of State is designated^(a) for the purposes of section 2(2) of the European Communities Act 1972^(b) in relation to the protection of animals used for experimental and other scientific purposes.

The Secretary of State makes the following Regulations under the powers conferred by that section, as read with paragraph 1A of Schedule 2 to the 1972 Act.

These Regulations make provision for a purpose mentioned in that section and it appears to the Secretary of State that it is expedient for the references to an Annex to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes to be construed as a reference to the Annex as amended from time to time.

In accordance with paragraph 2(2) of Schedule 2 to the 1972 Act a draft of these Regulations was laid before Parliament and approved by a resolution of each House of Parliament.

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.

(a) S.I. 1993/595.

(b) 1972 c. 68.

Amendment of the Animals (Scientific Procedures) Act 1986

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

Protected animals

3. In section 1(b) (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(c) (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 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) 1986 c. 14.
(b) Section 4 was amended by S.I. 1993/2103.
(c) Section 2(6) was substituted by S.I. 2006/2407.

- (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(a);
 - (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—

(a) S.I. 2011/2159.

“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(a) (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”;

(a) Section 4 was amended by S.I. 1998/1974.

- (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(a) substitute—

(a) Section 10 was amended by S.I. 1998/1974 and S.I. 1993/2102.

“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).

(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(a) 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”.

(a) Section 14 was substituted by S.I. 1998/1974.

(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
- (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(a) (appropriate methods of humane killing) is amended as follows.

(a) Schedule 1 was amended by S.I. 1996/3278, S.I. 1997/226.

(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—

“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(a) (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—

(a) Section 332 of 2003 c.44, and section 2006 c. 45.

“(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(a)—

- (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.

(a) 2003 c. 44.

- (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(a) (prosecutions) in subsection (1)(b) for “designated establishment” substitute “place specified in a section 2C licence”.
- (14) In section 27(b) (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(e) (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”;
 - (ii) in sub-paragraph (a), for “the Assembly” substitute “the Northern Ireland Assembly”;

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

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

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

- (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(a), in the shoulder reference, for “Sections 2, 6, 7, 10, 15(1) and 18(3)” substitute “Sections 2 and 15A”.
- (18) In Schedule 2(b)—
- (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(c).

Other minor and consequential amendments etc

27. In section 5(4)(d) of the Dangerous Wild Animals Act 1976(e) (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(f) (harming a animal research organisation or intimidating a connected person: definition of “animal research organisation”) is amended as follows.

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- (a) Schedule 1 was amended by S.I. 1996/3278 and S.I. 1997/226.
(b) Schedule 2 was amended by S.I. 1993/2103 and S.I. 1998/1674.
(c) Schedule 2A was inserted by S.I. 1998/1974.
(d) Section 5(4) was amended by section 27(2) of 1986 c. 14.
(e) 1976 c.38.
(f) 2005 c. 15.

(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(a) (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(b) (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.

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

32. Article 3 of the Animals (Scientific Procedures) Act (Amendment) Order 1993(d) (*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(e) (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.

(a) 2006 c. 45.

(b) S.I. 1986/1911.

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

(d) S.I. 1993/2103.

(e) S.I. 1996/3090.

34. In the Schedule to the Animals (Scientific Procedures) Act 1986 (Amendment) Regulations 1998(a) (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(b) (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(c) (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(d) (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(e) (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(f) (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(g) (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”.

41.—(1) Section 52 of the Welfare of Animals Act (Northern Ireland) 2011(h) (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).

(a) S.I. 1998/1974.

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

(c) S.I.2006/2407.

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

(e) S.I. 2006/2702.

(f) S.I. 2006/2927.

(g) S.R. 2007/68.

(h) 2011 c. 16 (N.I.).

Transitional provision

42. Schedule 3 makes transitional provision.

Home Office
18th December 2012

Taylor of Holbeach
Parliamentary Under Secretary of State

SCHEDULE 1

Regulation 9(2)

Additional conditions for the grant of certain project licences

“SCHEDULE 2B

Section 5C(4)

**ADDITIONAL CONDITIONS FOR THE GRANT OF CERTAIN
PROJECT LICENCES**

Project licences authorising the use of endangered primates

1.—(1) A project licence that would authorise the application of regulated procedures to endangered primates must not be granted unless the Secretary of State has verified that the following conditions are met—

- (a) Condition 1 or 2; and
- (b) Condition 3.

(2) Condition 1 is that the programme of work to be specified in the licence is to be carried out—

- (a) for the purpose mentioned in paragraph (b)(i) or (c) of section 5C(3); and
- (b) for the purpose of the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in man.

(3) Condition 2 is that the programme of work to be specified in the licence is to be carried out for the purpose mentioned in paragraph (e) of section 5C(3).

(4) Condition 3 is that 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—

- (a) are not primates; and
- (b) are not of a species listed in Annex A to the Council Regulation.

Project licences authorising the use of non-endangered primates

2.—(1) A project licence that would authorise the application of regulated procedures to non-endangered primates must not be granted unless the Secretary of State has verified that the following conditions are met—

- (a) Condition 4 or 5; and
- (b) Condition 6.

(2) Condition 4 is that the programme of work to be specified in the licence is to be carried out—

- (a) for the purpose mentioned in paragraph (b)(i) or (c) of section 5C(3); and
- (b) for the purpose of the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in man.

(3) Condition 5 is that the programme of work to be specified in the licence is to be carried out for the purpose mentioned in paragraph (a) or (e) of section 5C(3).

(4) Condition 6 is that 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.

Project licences authorising the use of endangered animals that are not primates

3.—(1) A project licence that would authorise the application of regulated procedures to endangered animals other than primates must not be granted unless the Secretary of State has verified that conditions 7 and 8 are met.

(2) Condition 7 is that the programme of work to be specified in the licence is to be carried out for a purpose mentioned in paragraph (b)(i), (c) or (e) of section 5C(3).

(3) Condition 8 is that there is scientific justification to the effect 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 the Council Regulation.

Project licences authorising the use of cats, dogs and equidae

4.—(1) A project licence that would authorise the application of regulated procedures to cats, dogs or equidae must not be granted unless the Secretary of State has verified that Condition 9 is met.

(2) Condition 9 is that the purpose of the programme of work to be specified in the licence can be achieved—

- (a) only by the use of cats, dogs or equidae; or
- (b) only by the use of cats, dogs, equidae and other animals which it is not practicable to obtain.

Interpretation

5. In this Schedule—

“the Council Regulation” means Council Regulation (EC) No 338/97(a) on the protection of species of wild fauna and flora by regulating trade therein;

“debilitating clinical condition” means a condition which causes a reduction in a person’s normal physical or psychological ability to function;

“endangered animal” means an animal of a species which—

- (a) is listed in Annex A to the Council Regulation; and
- (b) is not within the scope of Article 7(1) of that Regulation;

and “endangered primate” and “non-endangered primate” are to be construed accordingly.”

(a) OJL 61, 3.3.1997, P.1.

SCHEDULE 2

Regulation 10(2)

Conditions in licences

“SCHEDULE 2C

Section 10(1)

CONDITIONS IN LICENCES

PART 1

Conditions in section 2C licences

1. A section 2C licence must include a condition requiring the holder to ensure that the activities carried on at the place specified in the licence are carried on in a manner that is consistent with the principles of replacement, reduction and refinement.

2.—(1) A section 2C licence must include conditions requiring the holder to keep a register for the purposes of section 15A(1)(c) which—

- (a) contains the names of persons who are competent to kill protected animals; and
- (b) specifies in relation to each person named the description of animal that the person is competent to kill and the methods of killing that the person is competent to use to kill that description of animal.

(2) A section 2C licence must include such conditions as the Secretary of State considers appropriate for the purpose of ensuring—

- (a) that a person is not registered in the register kept by the holder unless the person has been adequately educated and trained in the killing of animals;
- (b) that a person who is so registered is supervised when killing animals at the place specified in the licence until he or she has demonstrated the requisite competence;
- (c) that at all times the number of persons who are so registered and are present at the place specified in the licence is sufficient to enable any protected animal being kept at that place that needs to be killed to be killed expeditiously.

3. A section 2C licence must include such conditions as the Secretary of State considers appropriate for the purpose of ensuring that the Secretary of State—

- (a) is notified if any changes become necessary to the persons specified in the licence by virtue of subsection (5) of section 2C;
- (b) is notified of any changes falling within subsection (10) of that section.

4.—(1) A section 2C licence must include such conditions as the Secretary of State considers appropriate for ensuring that the installations and equipment at the place specified in the licence are suitable for—

- (a) the species of protected animals kept at that place; and
- (b) the regulated procedures, if any, carried out at that place.

(2) For the purposes of sub-paragraph (1)(b), the installations and equipment at a place specified in a section 2C licence are suitable for the regulated procedures carried out at that place only if the design, construction and method of functioning of the installations and equipment enable the regulated procedures to be performed in a manner that—

- (a) provides reliable results;
- (b) uses the minimum number of animals; and
- (c) causes the minimum degree of pain, suffering, distress and lasting harm to the animals used.

(3) The conditions included in a licence by virtue of this paragraph must be such as to ensure that any applicable standard in Annex 3 of the Animals Directive concerning installations and equipment is met.

(4) For the purposes of sub-paragraph (3) a standard set out in Annex 3 of the Animals Directive is not to be treated as being an applicable standard if the Annex specifies a date from which the standard is to have effect and that date has not been reached.

5. A section 2C licence must include such conditions as the Secretary of State considers appropriate to ensure—

- (a) that sufficient staff are provided at the place specified in the licence to care for the protected animals kept at that place;
- (b) that the staff are adequately educated and trained before they perform any function relating to the care of those protected animals;
- (c) that the staff are supervised when performing any such function until they have demonstrated the requisite competence.

6.—(1) A section 2C licence must include a condition requiring the holder to establish and maintain a body (to be known as an “Animal Welfare and Ethical Review Body”) which—

- (a) consists of the persons mentioned in sub-paragraph (2) and such other persons as are determined in accordance with the licence; and
- (b) carries out the tasks mentioned in paragraphs (a) to (e) of Article 27.1 of the Animals Directive and such other advisory and reviewing tasks as are specified in the licence.

(2) The persons referred to in sub-paragraph (1)(a) are—

- (a) the persons specified in the section 2C licence in pursuance of paragraphs (a) and (b) of section 2C(5); and
- (b) in a case where the section 2C licence authorises the holder to carry on an undertaking that involves the applying of regulated procedures to protected animals, a person with such scientific credentials as are specified in the licence.

(3) A section 2C licence must include a condition requiring the holder to ensure that whenever the Animal Welfare and Ethical Review Body established by the holder provides advice a record is made of the advice and of any decisions taken in response to the advice.

(4) A section 2C licence must include a condition requiring the holder to ensure that any such records are kept for a period of three years and are supplied to the Secretary of State upon request.

7. A section 2C licence which authorises the holder to carry on an undertaking which involves the activity mentioned in section 2B(2)(b) must include such conditions as the Secretary of State considers appropriate to ensure that primates are not bred at the place specified in the licence unless the holder of the licence has in place a strategy for increasing the proportion of primates bred from primates bred in captivity.

8. A section 2C licence must include conditions requiring the holder—

- (a) to maintain records of the information mentioned in paragraphs (a) to (g) of Article 30.1 of the Animals Directive;
- (b) to retain any such record for a period determined in accordance with the licence (being a period of at least five years); and
- (c) to make any such record that is being retained available to the Secretary of State upon request.

9.—(1) A section 2C licence must include conditions requiring the holder to ensure—

- (a) that if a dog, cat or non-human primate is bred at the place specified in the licence an individual history file is established in relation to the animal as soon as is reasonably practicable after its birth;
- (b) that if a dog, cat or non-human primate is transferred to the place specified in the licence an individual history file is established in relation to the animal as soon as is reasonably practicable after its transfer (unless the animal is transferred from a place specified in another section 2C licence and an individual history file previously established in relation to the animal is provided in accordance with conditions included in that other licence by virtue of paragraph (c));
- (c) that if a dog, cat or non-human primate kept at the place specified in the licence is transferred to a place specified in another section 2C licence, the individual history file kept in relation to the animal is provided to the holder of that other licence;
- (d) that if a dog, cat or non-human primate kept at the place specified in the licence is re-homed otherwise than at a place specified in another section 2C licence, the person with whom the animal is re-homed is provided with a copy of any veterinary and social information about the animal that is included in the individual history file kept in relation to the animal;
- (e) that if a dog, cat or non-human primate kept at the place specified in the licence dies at that place, is set free from that place or is re-homed otherwise than at a place specified in another section 2C licence, the individual history file for the animal is kept for a period of three years following the death, setting free or re-homing;
- (g) that where an individual history file is being kept by virtue of this paragraph, the information included within it is kept up to date;
- (h) that where an individual history file is being kept by virtue of this paragraph, a copy of it is provided to the Secretary of State upon request.

(2) An “individual history file” is a file kept in relation to a dog, cat or non-human primate which contains the following—

- (a) particulars of the animal’s identity;
- (b) particulars of the animal’s date and place of birth (if known);
- (c) a statement as to whether the animal was bred for use in regulated procedures;
- (d) any relevant reproductive, veterinary and social information about the animal;
- (e) a record of the programmes of work, if any, which have involved the use of the animal in regulated procedures; and
- (f) in the case of a primate, a statement as to whether the animal is the offspring of primates bred in captivity.

10.—(1) A section 2C licence must include conditions requiring the holder to ensure—

- (a) that before any unmarked dog, cat or non-human primate is weaned at the place specified in the licence the animal is provided with a permanent individual identification mark;
- (b) that before any unmarked dog, cat or non-human primate that has not been weaned is transferred from the place specified in the licence to a place specified in another section 2C licence, the animal is provided with a permanent individual identification mark unless it would not be reasonably practicable to do so;
- (c) that where an unmarked dog, cat or non-human primate that has not been weaned is transferred to the place specified in the licence from a place specified in another section 2C licence, a record of the animal’s mother is kept until the animal is provided with a permanent individual identification mark;
- (d) that where an unmarked dog, cat or non-human primate is taken into the place specified in the licence after being weaned it is provided as soon as is reasonably practicable with a permanent individual identification mark.

(2) A section 2C licence must include a condition requiring the holder to ensure that where a dog, cat or primate at the place specified in the licence is provided with a permanent individual identification mark it is provided in the least painful manner possible.

(3) A section 2C licence must include a condition requiring the holder to comply with any request made by the Secretary of State for an explanation of why any dog, cat or primate at the place specified in the licence has not been provided with a permanent individual identification mark.

(4) In this paragraph references to an “unmarked” animal are to an animal that has not been provided with a permanent individual identification mark.

11.—(1) A section 2C licence must include such conditions relating to the general care and accommodation of protected animals kept at the place specified in the licence as the Secretary of State considers appropriate to ensure—

- (a) that the environment, housing, freedom of movement, food, water and care provided for each such animal is appropriate for the animal’s health and well-being;
- (b) that the conditions under which any such animal is transported are appropriate for the animal’s health and well-being;
- (c) that any restrictions on the extent to which each such animal can satisfy its physiological and ethological needs are kept to the absolute minimum;
- (d) that the environmental conditions in which such animals are kept are checked daily;
- (e) that the well-being and state of health of such animals is monitored by a suitably qualified person in order to prevent pain or avoidable suffering, distress or lasting harm; and
- (f) that arrangements are made to ensure that any defect discovered and any avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible.

(2) The conditions included in a section 2C licence under sub-paragraph (1) must include conditions which ensure that at least the following standards are met—

- (a) any applicable standard concerning the care and accommodation of animals which is set out in Annex 3 of the Animals Directive;
- (b) any additional or higher standard concerning the care and accommodation of animals which is set out in any code of practice issued or approved under section 21 that was in force on 9 November 2010.

(3) For the purposes of sub-paragraph (2) a standard set out in Annex 3 of the Animals Directive is not to be treated as being an “applicable standard” if the Annex specifies a date from which the standard is to have effect and that date has not been reached.

(4) The conditions included in a section 2C licence by virtue of sub-paragraph (1)(a) and (2) do not have effect in so far as compliance with them would—

- (a) prevent the carrying out of a programme of work specified in a project licence; or
- (b) prevent the objectives of a programme of work specified in a project licence from being achieved.

(5) A section 2C licence may include other exemptions from the conditions included in it by virtue of sub-paragraph (1)(a) and (2) if the Secretary of State is satisfied that the exemptions are necessary for scientific, animal welfare or animal health reasons.

12. A section 2C licence must include conditions requiring the holder to give any necessary assistance to—

- (a) inspectors carrying out visits by virtue of section 18(2A)(b); and
- (b) experts of the European Commission carrying out duties under Article 35 of the Animals Directive.

PART 2

Conditions in personal licences

13. A personal licence must include a condition requiring the holder to act at all times in a manner that is consistent with the principles of replacement, reduction and refinement.

14. A personal licence must include—

- (a) a condition to the effect that the holder must not apply a regulated procedure to an animal if the procedure may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated;
- (b) a condition to the effect that the holder must not apply a regulated procedure to an animal unless the holder has taken precautions to prevent or reduce to the minimum consistent with the purposes of the procedure any pain, suffering, distress or discomfort that may be caused to the animal;
- (c) a condition to the effect that where the holder is applying a regulated procedure to an animal the holder must ensure that any unnecessary pain, suffering, distress or lasting harm that is being caused to the animal is stopped;
- (d) a condition to the effect that where the holder is applying or has applied a regulated procedure which is causing the animal severe pain, suffering or distress the holder must take steps to ameliorate that pain, suffering or distress;
- (e) a condition requiring the holder to ensure that where the holder applies a regulated procedure death as the end-point of the procedure is avoided as far as possible and is replaced by an early and humane end-point;
- (f) a condition to the effect that where the holder is applying or has applied a regulated procedure to an animal and the animal is in severe pain, suffering or distress which is likely to be long-lasting and cannot be ameliorated, the holder must ensure that the animal is immediately killed in accordance with section 15A.

15.—(1) A personal licence must include a condition to the effect that the holder may apply a regulated procedure without the use of general or local anaesthesia only if the holder is satisfied that—

- (a) the procedure will not inflict serious injuries capable of causing severe pain; and
- (b) the use of general or local anaesthesia would be more traumatic to the animal than the procedure itself or would frustrate the purposes of the procedure.

(2) A personal licence must include a condition to the effect that the holder must use analgesia or another appropriate method to ensure that the pain, suffering and distress caused by regulated procedures are kept to a minimum.

(3) A personal licence must include a condition to the effect that if the holder applies a regulated procedure to an animal with the use of general or local anaesthesia the holder must, unless it would frustrate the purpose of the procedure, use such analgesics or other pain-relieving methods as may be necessary to reduce any pain that the animal may experience once the anaesthesia wears off.

16. A personal licence must include conditions requiring the holder to give any necessary assistance to—

- (a) inspectors carrying out visits by virtue of section 18(2A)(b); and
- (b) experts of the European Commission carrying out duties under Article 35 of the Animals Directive.

PART 3

Conditions in project licences

17. A project licence must include a condition requiring the holder to ensure that the specified programme of work does not involve the application of any regulated procedure to which there is a scientifically satisfactory alternative method or testing strategy not entailing the use of a protected animal.

18.—(1) A project licence must include a condition requiring the holder to ensure that the regulated procedures applied as part of the specified programme of work are those which to the greatest extent meet the following requirements—

- (a) use the minimum number of animals;
- (b) involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;
- (c) cause the least pain, suffering, distress or lasting harm;
- (d) are most likely to provide satisfactory results.

(2) A project licence must include a condition requiring the holder to ensure that the regulated procedures applied as part of the specified programme of work are designed so as—

- (a) to result in the death of as few protected animals as possible; and
- (b) to reduce to the minimum possible the duration and intensity of suffering caused to those animals that die and, as far as possible, ensure a painless death.

19. A project licence must include such conditions as the Secretary of State considers appropriate for the purpose of ensuring that any person who applies regulated procedures as part of the specified programme of work does so under supervision until the person has demonstrated the requisite competence.

20. A project licence must include such conditions as the Secretary of State considers appropriate for the purpose of ensuring that a regulated procedure is not applied to an animal as part of a specified programme of work if the procedure may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

21. A project licence must include such conditions as the Secretary of State considers appropriate for the purpose of ensuring that where a regulated procedure is being applied to an animal as part of the specified programme of work, any unnecessary pain, suffering, distress or lasting harm that is being caused to the animal is stopped.

22. A project licence must include such conditions as the Secretary of State considers appropriate for the purpose of ensuring that where a regulated procedure is applied to an animal as part of the specified programme of work—

- (a) death as the end point of the procedure is avoided as far as possible and is replaced by an early and humane end point;
- (b) as soon as the purpose of the procedure has been achieved, the procedure is stopped and appropriate action is taken to minimise the suffering of the animal.

23.—(1) A project licence must include a condition requiring the holder to ensure that where a regulated procedure has been applied to an animal as part of the specified programme of work a suitably qualified person classifies the severity of the procedure as “non-recovery”, “mild”, “moderate” or “severe” using the criteria in Annex 8 of the Animals Directive.

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

24.—(1) A project licence must include such conditions as the Secretary of State considers appropriate for the purpose of ensuring that where a series of regulated

procedures are applied to an animal for a particular purpose the animal is killed at the end of the series unless a veterinary surgeon or other competent person has determined that the animal is not suffering and is not likely to suffer adverse effects.

(2) For the purposes of this paragraph a series of regulated procedures is to be treated as ending when no further observations are to be made for the purposes of the series.

25.—(1) Subject to sub-paragraph (3), a project licence must include—

- (a) a condition to the effect that a stray animal of a domestic species must not be subjected to a regulated procedure as part of the specified programme of work;
- (b) a condition to the effect that a feral animal of a domestic species must not be subjected to a regulated procedure as part of the specified programme of work;
- (c) a condition to the effect that an animal taken from the wild must not be subjected to a regulated procedure as part of the specified programme of work;
- (d) a condition to the effect that a marmoset must not be subjected to a regulated procedure as part of the specified programme of work unless it is the offspring of marmosets bred in captivity or it has been obtained from a self-sustaining colony of marmosets;
- (e) a condition to the effect that an animal of a description specified in Schedule 2 must not be subjected to a regulated procedure as part of the specified programme of work unless it has been bred for use in regulated procedures.

(2) A project licence may include an exemption from the condition mentioned in sub-paragraph (1)(b) in relation to a particular domestic species (“the exempted species”); but such an exemption may be included only if the Secretary of State is satisfied that there is scientific justification to the effect that the purposes of the specified programme of work can be achieved only by the application of regulated procedures to feral animals of the exempted species and that the specified programme of work consists of a study which is essential—

- (a) to protect the health or welfare of animals of the exempted species; or
- (b) to avoid a serious threat to human or animal health or the environment.

(3) A project licence is not required to include a condition mentioned in sub-paragraph (1)(c), (d) or (e) if the Secretary of State is satisfied that there is scientific justification to the effect that compliance with the condition would prevent the purposes of the programme of work specified in the licence from being achieved.

(4) A project licence that permits the application of regulated procedures to animals taken from the wild must include such conditions as the Secretary of State considers appropriate for the purpose of ensuring—

- (a) that the animals taken from the wild are captured by a competent person using a method which does not cause the animal avoidable pain, suffering, distress or lasting harm;
- (b) that an animal taken from the wild which is found to be injured or in poor health is not subjected to a regulated procedure unless and until—
 - (i) it has been examined by a veterinary surgeon or other competent person; and
 - (ii) action has been taken to minimise the suffering of the animal.

(5) But a project licence that permits the application of regulated procedures to animals taken from the wild is not required to include conditions for the purpose of ensuring the matter mentioned in sub-paragraph (4)(b)(ii) if the Secretary of State is satisfied that there is scientific justification to the effect that compliance with any such conditions would prevent the purposes of the programme of work specified in the licence from being achieved.

(6) For the purposes of sub-paragraph (1)(d) a colony of animals is a “self-sustaining colony” if—

- (a) the colony is kept in captivity in a way that ensures the animals are accustomed to humans;
- (b) the colony consists only of animals that have been bred in captivity; and
- (c) the colony is sustained only by animals being bred within the colony or animals being sourced from other colonies that meet paragraphs (a) and (b).

26.—(1) A project licence must include such conditions as the Secretary of State considers appropriate to ensure that regulated procedures are not applied to an animal as part of the specified programme of work if the data to be obtained from the application of those procedures is already available in a Member State and has been obtained there by procedures which satisfy any relevant regulatory requirements of the EU.

(2) A project licence may include exemptions from the conditions included in it by virtue of sub-paragraph (1) if the Secretary of State considers the exemptions are justified for the protection of public health, safety or the environment.

27. A project licence must include conditions requiring the holder to give any necessary assistance to—

- (a) inspectors carrying out visits by virtue of section 18(2A)(b); and
- (b) experts of the European Commission carrying out duties under Article 35 of the Animals Directive.

28. A project licence must include a condition to the effect that if the holder becomes aware of a failure to comply with any of the other conditions of the licence the holder must—

- (a) take appropriate steps to rectify the failure (if it is capable of being rectified); and
- (b) keep a record of the steps taken.”

SCHEDULE 3

Regulation 42

Transitional provision

PART 1

Existing certificates and licences, etc.

Interpretation

1.—(1) In this Schedule—

“the Act” means the Animals (Scientific Procedures) Act 1986 (and unless otherwise specified, references to a section are to a section of that Act);

“the Home Office guidance” means the guidance on the operation of the Act presented to Parliament by the Secretary of State for the Home Department under section 21 which was ordered to be printed by the House of Commons on 23 March 2000;

“named animal care and welfare officer” means the person specified in a section 2C licence pursuant to section 2C(5)(a);

“named information officer” means the person specified in a section 2C licence pursuant to section 2C(5)(c);

“named person responsible for compliance” means the person specified in a section 2C licence pursuant to section 2C(5)(e);

“named persons” means the persons specified in a section 2C licence pursuant to section 2C(5);

“named training and competency officer” means the person specified in a section 2C licence pursuant to section 2C(5)(d);

“named veterinary surgeon” means the person specified in a section 2C licence pursuant to section 2C(5)(b).

(2) Terms used in this Schedule which are defined in the Act have the same meaning in this Schedule as in the Act.

(3) Any reference in this Schedule to an Annex of the Animals Directive is a reference to the Annex as amended from time to time.

(4) For the purposes of Part 2 of this Schedule, in relation to a section 2C licence—

(a) “regulated activities” means such of the activities listed in section 2B(2) as are authorised by the licence, and

(b) “establishment” means a place specified in the licence as a place where regulated activities may be carried on.

(5) For the purposes of this Schedule, these Regulations come fully into force on 1 January 2013.

Scientific procedure establishments

2. Paragraphs 3 to 8 apply in relation to a certificate issued under section 6 (a “section 6 certificate”) which is in force immediately before these Regulations come fully into force.

3.—(1) The section 6 certificate is to be treated as a licence granted under section 2C to the holder of the certificate.

(2) The licence is to be treated as authorising the holder of the section 6 certificate to carry on an undertaking involving the activity mentioned in section 2B(2)(a) at the place designated in the section 6 certificate as a scientific procedure establishment.

(3) The person specified in the section 6 certificate pursuant to section 6(5)(a) is to be treated as the person specified in the licence pursuant to section 2C(5)(a).

(4) The person specified in the section 6 certificate pursuant to section 6(5)(b) is to be treated as the person specified in the licence pursuant to section 2C(5)(b).

(5) The holder of the section 6 certificate is to be treated as the person specified in the licence pursuant to section 2C(5)(c), (d) and (e).

(6) The Act applies to a licence arising under this paragraph as it applies to a licence granted under section 2C.

4.—(1) The licence arising under paragraph 3 is to be treated as including the conditions in Part 2 of this Schedule (the “deemed conditions”).

(2) The following existing conditions of the section 6 certificate cease to have effect—

(a) the conditions which correspond to the conditions set out in Appendix B of the Home Office guidance (standard conditions for designated scientific procedure establishments), and

(b) any additional conditions which authorise an exception from, or otherwise relate to, one of those conditions.

(3) If any of the deemed conditions is inconsistent with an existing condition which does not cease to have effect under sub-paragraph (2), the deemed condition prevails.

(4) For the purposes of this paragraph the existing conditions of the certificate are the conditions contained in the certificate by virtue of section 10 immediately before these Regulations come fully into force.

(5) The Act applies to the deemed conditions as it applies to conditions included in a licence by virtue of section 10.

5.—(1) This paragraph applies to conditions 4(3) and 4(7) in Part 2 of this Schedule (standards of care and accommodation etc).

(2) Nothing contained in the section 6 certificate immediately before these Regulations come fully into force is to be treated as authorising an exception from the condition.

(3) The Secretary of State may under this paragraph authorise an exception from the condition if he or she is satisfied of the matters specified in paragraph 11(5) of Schedule 2C to the Act.

(4) The Act applies to an authorisation under this paragraph as if the authorisation were included in the licence arising under paragraph 3.

(5) This paragraph is without prejudice to the Secretary of State's power to authorise an exception from the condition by variation of the licence after these Regulations come fully into force.

6.—(1) Until the Secretary of State publishes guidance about Animal Welfare and Ethical Review Bodies, condition 6 in Part 2 of this Schedule applies with the following modifications.

(2) Sub-paragraph (2)(c) of the condition does not apply; but in selecting any members of the Animal Welfare and Ethical Review Body additional to those required by sub-paragraph (2)(a) and (b) of the condition the licence holder must have regard to the principles in paragraph 5 of Appendix J of the Home Office guidance (persons to be involved in ethical review process).

(3) The reference to guidance in paragraph (3) of the condition is to be treated as a reference to paragraphs 6 to 8 of that Appendix (operation of ethical review process).

7.—(1) This paragraph applies where the section 6 certificate specifies in relation to a description of animal a method of killing (an "alternative method") which is not a method appropriate to that description of animal under Schedule 1 to the Act.

(2) The licence arising under paragraph 3 is to be treated as if it did not specify the alternative method, unless—

- (a) the Secretary of State authorises the use of that method under this paragraph, or
- (b) the licence is varied after these Regulations come fully into force and the use of that method is authorised in the licence as varied.

(3) The Secretary of State may authorise the use of the alternative method under this paragraph only if he or she is satisfied of the matters specified in section 15A(6).

(4) The Act applies to an authorisation under this paragraph as if the authorisation were included in the licence arising under paragraph 3.

8.—(1) Any proceedings under section 12 which are underway in relation to the section 6 certificate when these Regulations come fully into force may be continued in relation to the licence arising under paragraph 3.

(2) If immediately before these Regulations come fully into force the section 6 certificate is suspended under section 13, the suspension continues to have effect in relation to the licence arising under paragraph 3.

9.—(1) An application for a certificate under section 6 which is made but not determined before these Regulations come fully into force may be treated by the Secretary of State as an application for a section 2C licence; and any proceedings under section 12 which are underway in relation to such an application when these Regulations come fully into force may be continued accordingly.

(2) Any enactment or instrument passed or made before these Regulations come fully into force has effect, so far as is necessary or appropriate in consequence of these Regulations, as if—

- (a) references to a certificate issued by the Secretary of State under section 6 were to a section 2C licence authorising the holder to carry on an undertaking involving the activity mentioned in section 2B(2)(a), and
- (b) references to a designated scientific procedure establishment were to a place specified in such a licence.

Breeding and supplying establishments

10. Paragraphs 11 to 17 apply in relation to a certificate issued under section 7 (a “section 7 certificate”) which is in force immediately before these Regulations come fully into force.

11.—(1) The section 7 certificate has effect as if it were a licence granted under section 2C to the holder of the certificate.

(2) If the section 7 certificate designates a place as a breeding establishment, the licence is to be treated as authorising the holder of the section 7 certificate to carry on an undertaking involving the activity mentioned in section 2B(2)(b) at the place designated in the section 7 certificate as a breeding establishment (subject to paragraph 12(1)).

(3) If the section 7 certificate designates a place as a supplying establishment, the licence is to be treated as authorising the holder of the section 7 certificate to carry on an undertaking involving the activity mentioned in section 2B(2)(c) at the place designated in the section 7 certificate as a supplying establishment (subject to paragraph 12(2)).

(4) The person specified in the section 7 certificate pursuant to section 7(5)(a) is to be treated as the person specified in the licence pursuant to section 2C(5)(a).

(5) The person specified in the section 7 certificate pursuant to section 7(5)(b) is to be treated as the person specified in the licence pursuant to section 2C(5)(b).

(6) The holder of the section 7 certificate is to be treated as the person specified in the licence pursuant to section 2C(5)(c), (d) and (e).

(7) The Act applies to a licence arising under this paragraph as it applies to a licence granted under section 2C.

12.—(1) If the section 7 certificate designates a place as a breeding establishment, the licence arising under paragraph 11 does not authorise carrying out the activity mentioned in section 2B(2)(b) in relation to a new relevant protected animal, unless—

- (a) carrying out that activity in relation to such an animal is authorised by the Secretary of State under this paragraph, or
- (b) the licence is varied after these Regulations come fully into force and carrying out that activity in relation to such an animal is authorised in the licence as varied.

(2) If the section 7 certificate designates a place as a supplying establishment, the licence arising under paragraph 11 does not authorise carrying out the activity mentioned in section 2B(2)(c) in relation to a new relevant protected animal, unless—

- (a) carrying out that activity in relation to such an animal is authorised by the Secretary of State under this paragraph, or
- (b) the licence is varied after these Regulations come fully into force and carrying out that activity in relation to such an animal is authorised in the licence as varied.

(3) In this paragraph a “new relevant protected animal” means a protected animal which is a relevant protected animal by virtue of regulation 26(18)(h).

(4) The Act applies to an authorisation under this paragraph as if the authorisation were included in the licence arising under paragraph 11.

13.—(1) The licence arising under paragraph 11 is to be treated as including the conditions set out in Part 2 of this Schedule (the “deemed conditions”).

(2) The following existing conditions of the section 7 certificate cease to have effect—

- (a) the conditions which correspond to the conditions set out in Appendix C of the Home Office guidance (standard conditions for designated breeding and supplying establishments), and
- (b) any additional conditions which authorise an exception from, or otherwise relate to, one of those conditions.

(3) If any of the deemed conditions is inconsistent with an existing condition which does not cease to have effect under sub-paragraph (2), the deemed condition prevails.

(4) For the purposes of this paragraph the existing conditions of the certificate are the conditions contained in the certificate by virtue of section 10 immediately before these Regulations come fully into force.

(5) The Act applies to the deemed conditions as it applies to conditions included in a licence by virtue of section 10.

14.—(1) This paragraph applies to conditions 4(3) and 4(7) in Part 2 of this Schedule (standards of care and accommodation etc).

(2) Nothing contained in the section 7 certificate immediately before these Regulations come fully into force is to be treated as authorising an exception from the condition.

(3) The Secretary of State may under this paragraph authorise an exception from the condition if he or she is satisfied of the matters specified in paragraph 11(5) of Schedule 2C to the Act.

(4) The Act applies to an authorisation under this paragraph as if the authorisation were included in the licence arising under paragraph 11.

(5) This paragraph is without prejudice to the Secretary of State's power to authorise an exception from the condition by variation of the licence after these Regulations come fully into force.

15.—(1) Until the Secretary of State publishes guidance about Animal Welfare and Ethical Review Bodies, condition 6 in Part 2 of this Schedule applies with the following modifications.

(2) Sub-paragraph (2)(c) of the condition does not apply; but in selecting any members of the Animal Welfare and Ethical Review Body additional to those required by sub-paragraph (2)(a) and (b) of the condition the licence holder must have regard to the principles in paragraph 5 of Appendix J of the Home Office guidance (persons to be involved in ethical review process).

(3) The reference to guidance in paragraph (3) of the condition is to be treated as a reference to paragraphs 6 to 8 of that Appendix (operation of ethical review process).

16.—(1) This paragraph applies where the section 7 certificate specifies in relation to a description of animal a method of killing (an "alternative method") which is not a method appropriate to that description of animal under Schedule 1 to the Act.

(2) The licence arising under paragraph 11 is to be treated as if it did not specify the alternative method, unless—

(a) the Secretary of State authorises the use of that method under this paragraph, or

(b) the licence is varied after these Regulations come fully into force and the use of that method is authorised in the licence as varied.

(3) The Secretary of State may authorise the use of the alternative method under this paragraph only if he or she is satisfied of the matters specified in section 15A(6).

(4) The Act applies to an authorisation under this paragraph as if the authorisation were included in the licence arising under paragraph 11.

17.—(1) Any proceedings under section 12 which are underway in relation to the section 7 certificate when these Regulations come fully into force may be continued in relation to the licence arising under paragraph 11.

(2) If immediately before these Regulations come fully into force the section 7 certificate is suspended under section 13, the suspension continues to have effect in relation to the licence arising under paragraph 11.

18.—(1) An application for a certificate under section 7 which is made but not determined before these Regulations come fully into force may be treated by the Secretary of State as an application for a section 2C licence; and any proceedings under section 12 which are underway in relation to such an application when these Regulations come fully into force may be continued accordingly.

(2) Any enactment or instrument passed or made before these Regulations come fully into force has effect, so far as is necessary or appropriate in consequence of these Regulations, as if—

- (a) references to a certificate issued by the Secretary of State under section 7(1) were to a section 2C licence authorising the holder to carry on an undertaking involving the activity mentioned in section 2B(2)(b),
- (b) references to a designated breeding establishment were to a place specified in such a licence,
- (c) references to a certificate issued by the Secretary of State under section 7(2) were to a section 2C licence authorising the holder to carry on an undertaking involving the activity mentioned in section 2B(2)(c), and
- (d) references to a designated supplying establishment were to a place specified in such a licence.

Personal licences

19.—(1) This paragraph applies in relation to a personal licence granted under section 4 which is in force immediately before these Regulations come fully into force.

(2) The licence is to be treated as including the conditions in Part 3 of this Schedule (the “deemed conditions”).

(3) The existing conditions of the licence which correspond to the conditions set out in Appendix E of the Home Office guidance (standard conditions for personal licences) cease to have effect.

(4) If any of the deemed conditions is inconsistent with an existing condition which does not cease to have effect under sub-paragraph (3), the deemed condition prevails.

(5) For the purposes of this paragraph the existing conditions of the licence are the conditions contained in the licence by virtue of section 10 immediately before these Regulations come fully into force.

(6) The Act applies to the deemed conditions as it applies to conditions included in a licence by virtue of section 10.

Project licences

20. Paragraphs 21 to 28 apply in relation to a project licence granted under section 5 which is in force immediately before these Regulations come fully into force.

21. Except as provided by this Part of this Schedule, the amendments made by regulation 9 do not apply in relation to the licence.

22. Section 5E(2) to (4) (termination of licence on death of licence holder) applies to the licence as it applies to a licence granted after these Regulations come fully into force.

23.—(1) Where the licence classifies the severity of a regulated procedure specified in the licence as “unclassified”, it is to be treated as classifying the severity of that procedure as “non-recovery”.

(2) Where the licence classifies the severity of a regulated procedure specified in the licence as “substantial”, it is to be treated as classifying the severity of that procedure as “severe”.

24.—(1) The licence is to be treated as including the conditions set out in Part 4 of this Schedule (the “deemed conditions”).

(2) The following existing conditions of the licence cease to have effect—

- (a) the conditions which correspond to the conditions set out in Appendix D of the Home Office guidance (standard conditions for project licences), and
- (b) any additional conditions which authorise an exception from, or otherwise relate to, one of those conditions (subject to paragraph 29(4)).

(3) If any of the deemed conditions is inconsistent with an existing condition which does not cease to have effect under sub-paragraph (2), the deemed condition prevails.

(4) For the purposes of this paragraph the existing conditions of the licence are the conditions contained in the licence by virtue of section 10 immediately before these Regulations come fully into force.

(5) The Act applies to the deemed conditions as it applies to conditions included in a licence by virtue of section 10.

25.—(1) This paragraph applies to condition 13 in Part 4 of this Schedule (restrictions on use of certain descriptions of animal).

(2) Nothing contained in the licence immediately before these Regulations come fully into force is to be treated as authorising an exception from the condition.

(3) The Secretary of State may under this paragraph authorise an exception from the condition if he or she is satisfied of the matters specified in paragraph 25(2) or (3) of Schedule 2C to the Act (whichever is relevant).

(4) The Act applies to an authorisation under this paragraph as if the authorisation were included in the licence.

(5) This paragraph is without prejudice to the Secretary of State's power to authorise an exception from the condition by variation of the licence after these Regulations come fully into force.

26.—(1) The following requirements apply in relation to the licence (despite anything to the contrary in the licence).

(2) The licence holder must meet the requirements in section 5C(2)(a) to (c).

(3) The programme of work specified in the licence may only be carried out for one of the purposes specified in section 5C(3)(a) to (g).

(4) Regulated procedures must not be applied to any of the following unless authorised by the Secretary of State under paragraph 27—

- (a) endangered primates,
- (b) non-endangered primates,
- (c) endangered animals other than primates.

(5) Regulated procedures must not be applied to great apes.

(6) Section 15A applies as if in subsection (3)(b), at the end there were inserted “and 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.”

(7) A neuromuscular blocking agent must not be used unless authorised by the Secretary of State under paragraph 27.

(8) The Act applies to the requirements imposed by this paragraph as if they were provisions of the Act.

27.—(1) The Secretary of State may authorise the application of regulated procedures to endangered primates only if he or she has verified that the following conditions are met—

- (a) Condition 1 or 2 of Schedule 2B to the Act, and
- (b) Condition 3 of that Schedule.

(2) The Secretary of State may authorise the application of regulated procedures to non-endangered primates only if he or she has verified that the following conditions are met—

- (a) Condition 4 or 5 of Schedule 2B to the Act, and
- (b) Condition 6 of that Schedule.

(3) The Secretary of State may authorise the application of regulated procedures to endangered animals other than primates only if he or she has verified that the following conditions are met—

- (a) Condition 7 of Schedule 2B to the Act, and
- (b) Condition 8 of that Schedule.

(4) The Secretary of State may authorise the use of a neuromuscular blocking agent only if he or she is satisfied of the matters specified in section 17(2).

(5) The Act applies to an authorisation under this paragraph as if the authorisation were included in the licence.

28.—(1) This paragraph applies if the Secretary of State is considering—

(a) a variation of the licence, or

(b) if the licence was granted for a period of less than 5 years, its renewal.

(2) The following provisions apply in relation to the licence as proposed to be varied or renewed as they apply in relation to a project licence granted after these Regulations come fully into force—

(a) section 5C (restrictions on grant of project licence);

(b) section 15A(7) (methods of killing not specified in Schedule 1 to the Act);

(c) section 17(2) (neuromuscular blocking agents).

(3) Accordingly, on the variation or renewal of the licence paragraph 26 ceases to apply in relation to it.

Re-use of protected animals

29.—(1) This paragraph applies to any consent given by the Secretary of State under section 14 which has effect immediately before these Regulations come fully into force.

(2) The consent continues to have effect after these Regulations come fully into force, subject to sub-paragraph (3).

(3) In a case to which section 14(6) applies, the consent does not continue to have effect after these Regulations come fully into force unless it was given under section 14(6) by virtue of regulation 1(3)(a).

(4) Where a consent to which this paragraph applies takes the form of an existing additional condition of a project licence (within the meaning of paragraph 24), paragraph 24(2)(b) does not apply in relation to that condition.

30. In the application of section 14(4) to a project licence granted before these Regulations come fully into force, paragraph (b) applies as if for “was classified by the Secretary of State under section 5B(3)(c)” there were substituted “is classified in the project licence”.

Setting free and re-homing protected animals

31. In section 17A(1)(a), the reference to the Secretary of State’s consent does not include a consent given before these Regulations come fully into force, unless it was given under section 17A by virtue of regulation 1(3)(b).

PART 2

Conditions in section 2C licences

1. The licence holder shall ensure that the regulated activities carried on at the establishment are carried on in a manner that is consistent with the principles of replacement, reduction and refinement.

2.—(1) The licence holder shall ensure that a register is maintained of those who are competent to kill protected animals. A person’s name shall not be included in the register unless the person has been adequately educated and trained in the killing of animals.

(2) The register must specify, in relation to each person named, the descriptions of animals that the person is competent to kill and the methods of killing that the person is competent to use to kill each such animal.

(3) The licence holder shall ensure that each person so registered is supervised when killing animals at the establishment until he or she has demonstrated the requisite competence.

(4) The licence holder shall ensure that at all times the number of persons who are so registered and are present at the establishment is sufficient to enable any protected animal being kept at that place that needs to be killed to be killed expeditiously.

(5) The register shall, on request, be submitted to the Secretary of State or made available to an Inspector.

3. The licence holder shall notify the Secretary of State of any proposed change in:

- (a) the full name of the holder; or
- (b) the full name and qualifications of the named person responsible for compliance; or
- (c) the full name and qualifications of the named animal care and welfare officer; or
- (d) the full name and qualifications of the named veterinary surgeon; or
- (e) the full name and qualifications of the named information officer; or
- (f) the full name and qualifications of the named training and competency officer; or
- (g) the areas appearing on the schedule of premises for the establishment or the class of use within those areas; or
- (h) the types of protected animals to be held and/or used in regulated activities at the establishment.

4.—(1) All protected animals must at all times be provided with adequate care and accommodation appropriate to their type or species.

(2) Any restrictions on the extent to which such an animal can satisfy its physiological and ethological needs shall be kept to the absolute minimum.

(3) Unless otherwise authorised by the Secretary of State an environment, housing, freedom of movement, food and water appropriate for the health and well-being of each protected animal shall be provided.

(4) The licence holder shall ensure that the installations and equipment at the establishment are suitable for the species of protected animals kept at the establishment and for the regulated procedures, if any, carried out at the establishment. The design, construction and method of functioning of the installations and equipment must be such as to enable regulated procedures to be performed in a manner that provides reliable results, uses the minimum number of animals and causes the minimum degree of pain, suffering, distress and lasting harm to the animals used.

(5) The health and well-being of protected animals, and the environmental conditions in all parts of the establishment where protected animals are kept, shall be checked at least once daily by competent persons. Arrangements shall be made to ensure that any defect discovered and any avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible.

(6) The holder shall ensure that the conditions under which any protected animal is transported are appropriate for the animal's health and well-being.

(7) Unless otherwise authorised by the Secretary of State the licence holder shall ensure that at least the following standards are met—

- (a) any applicable standard concerning the care and accommodation of animals or installations and equipment, which is set out in Annex 3 of the Animals Directive;
- (b) any additional or higher standard concerning the care and accommodation of animals which is set out in any code of practice issued or approved under section 21 that was in force on 9 November 2010.

(8) For the purposes of subparagraph (7)(a) a standard set out in Annex 3 of the Animals Directive is not to be treated as being an “applicable standard” if the Annex specifies a date from which the standard is to have effect and that date has not been reached.

5. The licence holder shall ensure that the establishment shall be appropriately staffed at all times to ensure the well-being of the protected animals. Staff shall be adequately educated and

trained before they perform any function relating to the care of the protected animals and shall be supervised when performing any such function until they have demonstrated the requisite competence.

6.—(1) The licence holder is required to have established, and to maintain, an Animal Welfare and Ethical Review Body.

(2) The Animal Welfare and Ethical Review Body must consist at least of—

- (a) the named animal welfare officer and named veterinary surgeon,
- (b) if this licence authorises the application of regulated procedures to protected animals at the establishment, the holder of a project licence which specifies the establishment as a place where regulated procedures may be carried out, or another person with suitable scientific credentials acceptable to the Secretary of State, and
- (c) such other persons as may be specified in guidance issued by the Secretary of State.

(3) The Animal Welfare and Ethical Review Body must carry out the tasks mentioned in Article 27.1 of the Animals Directive and any other advisory and reviewing tasks specified in this licence or in guidance issued by the Secretary of State.

(4) The licence holder shall ensure that whenever the Animal Welfare and Ethical Review Body provides advice a record is made of the advice and of any decisions taken in response to the advice. Such records shall be kept for a minimum period of three years and shall, on request, be submitted to the Secretary of State or made available to an Inspector.

7. If this licence authorises the breeding of protected animals, the holder is not authorised to breed, at the establishment, non-human primates from any animal not bred in captivity unless the holder has in place a strategy acceptable to the Secretary of State for increasing the proportion of primates bred from animals bred in captivity. Any substantial changes to the strategy that are proposed shall be submitted to the Secretary of State for approval.

8.—(1) Records shall be maintained, in a format acceptable to the Secretary of State, of the source, use and final disposal of all protected animals bred, kept or used at the establishment for any regulated activities.

(2) Such records shall include at least the following information—

- (a) the number and the species of animals bred, acquired, supplied, used in procedures, or discharged from the control of the Act;
- (b) the origin of the animals, including whether they are bred for use in procedures;
- (c) the dates on which the animals are acquired, supplied, or discharged from the control of the Act;
- (d) from whom the animals are acquired;
- (e) the name and address of the recipient of animals;
- (f) the number and species of animals which died or were killed in each establishment. For animals that have died, the cause of death shall, when known, be noted; and
- (g) where this licence authorises the applying of regulated procedures to protected animals, the projects in which animals are used.

(3) Such records shall be kept for a minimum of five years from the date of final disposal of the animal and, on request, be submitted to the Secretary of State or made available to an Inspector.

(4) The licence holder shall, on request, submit to the Secretary of State a summary report, in a form specified by the Secretary of State, of the source, use and final disposal of all protected animals bred, kept, or used at the establishment for any regulated activities.

9.—(1) For the purposes of this condition, an “individual history file” is a file kept in relation to a dog, cat or non-human primate which contains particulars of the animal’s identity; particulars of the animal’s date and place of birth (if known); a statement as to whether the animal was bred for use in regulated procedures; any relevant reproductive, veterinary and social information about the animal; a record of the programmes of work, if any, which have involved the use of the animal in

regulated procedures; and in the case of a primate, a statement as to whether the animal is the offspring of primates bred in captivity.

(2) The licence holder shall ensure that for each dog, cat and non-human primate held at the establishment an individual history file is established and kept up to date. In the case of such an animal bred at the establishment the individual history file shall be established as soon as is reasonably practicable after the animal's birth. Where such an animal is transferred to the establishment an individual history file shall be established in relation to the animal as soon as is reasonably practicable after its transfer (unless the animal is transferred from a place specified in another section 2C licence and an individual history file previously established in relation to the animal is provided in accordance with conditions included in that other licence).

(3) The licence holder shall ensure that if a dog, cat or non-human primate kept at the establishment is transferred to a place specified in another section 2C licence, the individual history file kept in relation to the animal is provided to the holder of that other licence.

(4) The licence holder shall ensure that if a dog, cat or non-human primate kept at the establishment is transferred otherwise than to a place specified in another section 2C licence, the person to whom the animal is transferred is provided with a copy of any veterinary and social information about the animal that is included in the animal's individual history file.

(5) The licence holder shall ensure that if a dog, cat or non-human primate kept at the establishment dies at that place, is set free from that place or is transferred otherwise than to a place specified in another section 2C licence, the individual history file for the animal is kept for a period of three years following its death, setting free or transfer.

(6) A copy of any individual history file required to be kept by this condition shall, on request, be submitted to the Secretary of State or made available to an Inspector.

10.—(1) The licence holder shall ensure that before any unmarked dog, cat or non-human primate is weaned at the place specified in the licence the animal is marked. The licence holder shall ensure that before any unmarked dog, cat or non-human primate that has not been weaned is transferred from the establishment to a place specified in another section 2C licence, the animal is marked unless it would not be reasonably practicable to do so. Where an unmarked dog, cat or non-human primate that has not been weaned is transferred to the establishment, the establishment shall maintain records attesting the identity and origin of the animal's mother until the animal is marked.

(2) The holder shall ensure that any unmarked cat, dog or non-human primate which is taken into the establishment after weaning shall be marked as soon as possible.

(3) The holder shall ensure that where a dog, cat or primate at the establishment is marked it is done in the least painful manner possible.

(4) The holder shall comply with any request made by the Secretary of State for an explanation of why any dog, cat or primate at the establishment has not been marked.

(5) For the purpose of this condition, "marked" means provided with a permanent means of individual identification and "unmarked" refers to an animal that has not been provided with a permanent individual identification mark.

11.—(1) Inspectors shall be provided with access at all reasonable times to all parts of the establishment which are concerned with the use, holding, breeding or care of protected animals.

(2) The licence holder must give any necessary assistance to inspectors carrying out visits by virtue of section 18(2A)(b); and to experts of the European Commission carrying out duties under Article 35 of the Animals Directive.

12. Unless authorised by the Secretary of State, there shall be no variation of the use of the approved areas of the establishment in the licence that may have adverse consequences for the welfare of the protected animals held.

13. Unless otherwise authorised by the Secretary of State—

- (a) only the types of protected animals specified in the licence may be kept in the place or places specified in the licence for the purpose of the regulated activities specified in the licence; and
- (b) for the purpose of the regulated activities specified in the licence, these animals may only be kept, bred and used in the areas listed in the schedule to the licence.

14. Records shall be maintained, in a format acceptable to the Secretary of State and under the supervision of the named veterinary surgeon, relating to the health of all protected animals bred, kept or used at the establishment for any regulated activities. Records shall, on request, be submitted to the Secretary of State or made available to an Inspector.

15. The licence holder shall nominate and be responsible for the performance of named persons, acceptable to the Secretary of State, as required by section 2C(5) .

16. Arrangements to ensure that animals are given adequate care must be made in the event that the named persons referred to in condition 15 above are not available for any reason.

17. Adequate security measures shall be maintained to prevent the escape of protected animals and to prevent intrusions by unauthorised persons.

18. Quarantine and acclimatisation facilities shall be provided and used as necessary.

19. Adequate precautions against fire shall be maintained at all times.

20. If this licence authorises the applying of regulated procedures to protected animals, the holder shall take all reasonable steps to prevent the performance of unauthorised procedures in the establishment.

21. The licence holder shall make adequate and effective provision for regular and effective liaison with and between those entrusted with responsibilities under the Act and with others who have responsibility for the welfare of the protected animals kept at the establishment.

22. Where this licence authorises the applying of regulated procedures to protected animals, the licence holder shall notify the Secretary of State of the death of a project licence holder within seven days of its coming to his or her knowledge when, unless the Secretary of State directs otherwise, the project licence shall continue in force for 28 days from the date of notification. The section 2C licence holder will, during that period, assume responsibility for ensuring compliance with the terms and conditions of the project licence.

23.—(1) This condition applies where this licence authorises the applying of regulated procedures to protected animals.

(2) A protected animal which, having been subjected to a completed series of regulated procedures, is kept alive shall continue to be kept at the establishment under the supervision of a veterinary surgeon or other suitably qualified person unless—

- (a) it is moved, with the authority of the Secretary of State, to another establishment;
- (b) the Secretary of State consents under section 17A to the animal no longer being kept at the establishment; or
- (c) its re-use in another procedure is authorised by the Secretary of State.

24. A copy of these conditions shall be readily available for consultation by all licence holders and named persons in the establishment.

25. The licence remains the property of the Secretary of State, and shall be surrendered to him on request.

PART 3

Conditions in personal licences

- 1.** In exercising his or her responsibilities, the licence holder shall act at all times in a manner that is consistent with the principles of replacement, reduction and refinement.
- 2.** The licence holder is entrusted with primary responsibility for the welfare of the animals on which he or she has performed regulated procedures; the licence holder must ensure that animals are properly monitored and cared for.
- 3.** The licence holder must not apply a regulated procedure to an animal if the procedure may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.
- 4.** The licence holder must not apply a regulated procedure to an animal unless the holder has taken precautions to prevent or reduce to the minimum consistent with the purposes of the procedure any pain, suffering, distress or discomfort that may be caused to the animal.
- 5.** Where the licence holder is applying a regulated procedure to an animal the holder must ensure that any unnecessary pain, suffering, distress or lasting harm that is being caused to the animal is stopped.
- 6.** Where the licence holder is applying or has applied a regulated procedure which is causing the animal severe pain, suffering or distress the holder must take steps to ameliorate that pain, suffering or distress.
- 7.** The licence holder shall ensure that where the holder applies a regulated procedure death as the end-point of the procedure is avoided as far as possible and is replaced by an early and humane end-point.
- 8.** In all circumstances where an animal which is being, or has been, subjected to a regulated procedure is in severe pain, suffering or distress which is likely to be long-lasting and cannot be ameliorated, the licence holder must ensure that the animal is immediately killed in accordance with section 15A.
- 9.** The licence holder may apply a regulated procedure without the use of general or local anaesthesia only if the holder is satisfied that—
 - (a) the procedure will not inflict serious injuries capable of causing severe pain; and
 - (b) the use of general or local anaesthesia would be more traumatic to the animal than the procedure itself or would frustrate the purposes of the procedure.
- 10.** When anaesthesia (whether general or local) is used, it shall be of sufficient depth to prevent the animal from being aware of pain arising during the procedure.
- 11.** If the licence holder applies a regulated procedure to an animal with the use of general or local anaesthesia the holder must, unless it would frustrate the purpose of the procedure, use such analgesics or other pain-relieving methods as may be necessary to reduce any pain that the animal may experience once the anaesthesia wears off.
- 12.** The licence holder must use analgesia or another appropriate method to ensure that the pain, suffering and distress caused by regulated procedures are kept to a minimum.
- 13.** It is the responsibility of the personal licence holder to notify the project licence holder as soon as possible when it appears either that the severity limit of any procedure listed in the project licence or that the constraints upon adverse effects described in the project licence have been or are likely to be exceeded.
- 14.** The licence holder shall ensure that suitable arrangements exist for the care and welfare of animals during any period when the personal licence holder is not in attendance.

15. The licence holder shall ensure that, whenever necessary, veterinary advice and treatment are obtained for the animals in his or her care.

16. The licence holder shall ensure that all cages, pens or other enclosures are clearly labelled. The labelling must be such as to enable Inspectors, named veterinary surgeons and named animal care and welfare officers to identify the number of the project licence authorising the procedures, the project licence protocol in which the animals are being used, the date the protocol was started, and the responsible personal licence holder.

17. In order to ensure that regulated procedures are performed competently, the licence holder shall not apply regulated procedures unless given the appropriate level of supervision by the project licence holder or an experienced personal licence holder deputed by him/her for such time as may be needed to achieve competence.

18. The licence holder is authorised to delegate to assistants, who do not themselves possess the requisite personal licence authority but are under his or her control, the delegable tasks which form an integral part of the regulated procedures the licence holder is authorised to perform by this licence. The tasks must not require technical knowledge or skill, and delegation shall be in accordance with any relevant guidance published by the Secretary of State under section 21.

19. The licence holder must take all reasonable steps to ensure appropriate personal and project licence authorities exist before performing regulated procedures. The licence holder must be aware of the nature of the authorities given by this licence and the project licence, and of the conditions of issue attached to the licences.

20. The licence holder shall maintain a record of all animals on which procedures have been carried out, including details of supervision and declarations of competence by the project licence holder as appropriate. This record shall be retained for at least five years and shall, on request, be submitted to the Secretary of State or made available to an Inspector.

21. The licence holder must give any necessary assistance to inspectors carrying out visits by virtue of section 18(2A)(b) ; and to experts of the European Commission carrying out duties under Article 35 of the Animals Directive.

22. The licence remains the property of the Secretary of State, and shall be surrendered to him on request.

PART 4

Conditions in project licences

1. The licence holder is responsible for the overall implementation of the programme of work specified in this licence and for ensuring that the programme of work is carried out in compliance with the conditions of the licence.

2. The licence holder shall ensure that the specified programme of work does not involve the application of any regulated procedure to which there is a scientifically satisfactory alternative method or testing strategy not entailing the use of a protected animal.

3. The licence holder shall ensure that regulated procedures are not applied to an animal as part of the specified programme of work if the data to be obtained from the application of those procedures is already available in a Member State and has been obtained there by procedures which satisfy any relevant regulatory requirements of the EU.

4. The licence holder shall ensure that the regulated procedures applied as part of the programme of work specified in this licence are those which to the greatest extent use the minimum number of animals; involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm; cause the least pain, suffering, distress or lasting harm; and are most likely to provide satisfactory results.

5. The licence holder shall ensure that the regulated procedures applied as part of the programme of work specified in this licence are designed so as to result in the death of as few protected animals as possible; and to reduce to the minimum possible the duration and intensity of suffering caused to those animals that die and, as far as possible, ensure a painless death.

6. The licence holder shall ensure that the appropriate level of supervision is provided for all personal licensees carrying out regulated procedures under the authority of this licence.

7. The licence holder shall ensure that a regulated procedure is not applied to an animal as part of the programme of work specified in this licence if the procedure may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

8. The licence holder shall ensure that where a regulated procedure is being applied to an animal as part of the programme of work specified in this licence, any unnecessary pain, suffering, distress or lasting harm that is being caused to the animal shall be stopped.

9. The licence holder shall ensure that where a regulated procedure is applied to an animal as part of the specified programme of work, death as the end point of the procedure is avoided as far as possible and is replaced by an early and humane end point; and as soon as the purpose of the procedure has been achieved, the procedure is stopped and appropriate action is taken to minimise the suffering of the animal.

10. The licence holder shall ensure that where a regulated procedure has been applied to an animal as part of the programme of work specified in this licence, a suitably qualified person classifies the severity of the procedure as “non-recovery”, “mild”, “moderate” or “severe” using the criteria in Annex 8 of the Animals Directive. For the purposes of this condition, a series of regulated procedures applied to an animal for a particular purpose is to be treated as constituting a single regulated procedure.

11. Where a series of regulated procedures are applied to an animal for a particular purpose the licence holder shall ensure that the animal is killed at the end of the series unless a veterinary surgeon or other competent person has determined that the animal is not suffering and is not likely to suffer adverse effects, as a result of the regulated procedures.

12. Regulated procedures shall not be carried out on any stray animal of a domestic species as part of the programme of work specified in this licence.

13. Except with the authorisation of the Secretary of State, regulated procedures shall not be carried out as part of the programme of work specified in this licence on any of the following type of animal—

- (a) any feral animal of a domestic species;
- (b) any animal taken from the wild;
- (c) a marmoset unless it is the offspring of marmosets bred in captivity or has been obtained from a self-sustaining colony of marmosets;
- (d) any animal of a description specified in Schedule 2 to the Act unless it has been bred for use in procedures.

14. If the application of regulated procedures to animals taken from the wild is authorised in this licence the holder shall ensure—

- (a) that animals taken from the wild are captured by a competent person using a method which does not cause the animal avoidable pain, suffering, distress or lasting harm; and
- (b) that an animal taken from the wild which is found to be injured or in poor health is not subjected to a regulated procedure unless and until it has been examined by a veterinary surgeon or other competent person; and, unless the Secretary of State has agreed otherwise, action has been taken to minimise the suffering of the animal.

15. The licence holder must give any necessary assistance to inspectors carrying out visits by virtue of section 18(2A)(b); and to experts of the European Commission carrying out duties under Article 35 of the Animals Directive.

16. If the licence holder becomes aware of a failure to comply with any conditions of the licence the holder must take appropriate steps to rectify the failure (if it is capable of being rectified); and keep a record of the steps taken.

17. All authorised procedures shall be carried out under general or local anaesthesia unless—

- (a) anaesthesia would be more traumatic to the animal concerned than the procedures themselves; or
- (b) anaesthesia would be incompatible with the purposes of the procedures.

18. The licence holder shall ensure adherence to the severity limits as specified in the project licence and observance of any other controls described in the licence. If these constraints appear to have been, or are likely to be, breached, the holder shall ensure that the Secretary of State is notified as soon as possible.

19. The licence holder shall maintain a contemporaneous record of all animals on which procedures have been carried out under the authority of the project licence. This record shall show the procedures used and the names of personal licensees who have carried out the procedures. The record shall, on request, be submitted to the Secretary of State or made available to an Inspector.

20. The licence holder shall send to the Secretary of State, before 31 January each year (and within 28 days of the licence having expired or been revoked), a report in a form specified by the Secretary of State, giving details of the number of procedures and animals used, and the nature and purpose of the procedures performed under the authority of the project licence during the calendar year.

21. The licence holder shall maintain a list of publications resulting from the licensed programme of work and a copy of any such publication shall be made available to the Secretary of State on request. The list shall, on request, be submitted to the Secretary of State or made available to an Inspector, and it shall be submitted to the Secretary of State when the licence is returned to him on expiry or for revocation.

22. The project licence holder shall submit such other reports as the Secretary of State may from time to time require.

23. The project licence holder shall ensure that details of the programme of work and regulated procedures specified in the licence, and any additional conditions imposed on those procedures, are known to—

- (a) all personal licensees performing those procedures;
- (b) the named person responsible for compliance;
- (c) the named animal care and welfare officers responsible for the day to day care of the animals;
- (d) the named veterinary surgeon, on request; and
- (e) the named information officer and named training and competency officer, on request.

24. The licence holder must obtain the permission of the Secretary of State before—

- (a) any animal undergoing regulated procedures is moved from a place specified in one section 2C licence to a place specified in another section 2C licence; or
- (b) any animal is released for slaughter,

unless this is already explicitly authorised by the project licence.

25. The licence remains the property of the Secretary of State, and shall be surrendered to him on request.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These regulations amend the Animals (Scientific Procedures) Act 1986 (“the Act”) to transpose EC Directive 2010/63/EU on the protection of animals used for scientific purposes (“the Directive”). The Directive replaces Directive 86/609/EEC which is repealed.

Regulation 3 lengthens the period of gestation that must have elapsed before an animal in a foetal, larval or embryonic form becomes a “protected animal” for the purposes of the Act. Regulation 3 also extends protection to cephalopods.

Regulation 4 amends the definition of a ‘regulated procedure’ in section 2 of the Act so as to include, amongst other things, the modification of an animal’s genes in particular circumstances.

Regulation 5 inserts a new section 2A requiring the Secretary of State to exercise his or her functions with a view to ensuring compliance with the principles of replacement, reduction and refinement. Regulation 5 also inserts definitions of these terms.

Regulations 6, 7 and 8 change the licensing system; the certificates of designation of premises for breeding, supplying and scientific research are now amalgamated into one licence; project and personal licences remain part of the licensing system but there are minor amendments to personal licences to remove the current requirement for the place where regulated procedures are performed to be specified in the personal licence. This will enable personal licence holders to carry out regulated procedures at any place specified in the project licence that authorises the procedures and will obviate the need to amend the personal licence before working at additional places; in addition the holder of a personal licence will be authorised to apply categories of techniques rather than specified individual techniques.

Regulation 9 replaces section 5 of the Act and amongst other things provides that project licences may specify multiple generic projects as set out in article 40.4 of the Directive. There is also a requirement for the applicant for a project licence to provide the Secretary of State with a non-technical summary of the proposed project which will be published if the application is successful. Regulation 9 also provides timescales for acknowledging applications and making decisions whether to grant a project licence. In addition some programmes of work will now be subject to a retrospective assessment regarding whether the severity level of the procedures have been correctly assessed.

Regulation 10 replaces section 10 of the Act relating to the conditions to be included in licences granted under the Act. Regulation 10 also inserts a new Schedule 2C into the Act which sets out certain conditions that must be included in licences granted under the Act. Schedule 2C is divided into three parts: Part 1 sets out the requirements for the conditions to be applied to section 2C licences; Part 2 sets out the requirements for the conditions to be applied to personal licences; Part 3 sets out the requirements for the conditions to be applied to project licences.

Regulations 11, 12 and 13 deal with failure to comply with licence conditions and the right of the licence holder to appeal, regulation 11 inserts a new section 11 which allows Secretary of State to issue a compliance notice and variation, suspension or revocation of a licence.

Regulation 14 replaces section 14 of the Act; the new section provides that an animal that has already been subjected to one or more procedures must not be re-used unless the Secretary of State consents to the re-use and certain conditions are met.

Regulation 15 inserts new section 15A which sets out detailed requirements relating to the killing of animals, protected animals as defined in the Directive have to be killed using a particular method unless the Secretary of State has authorised another method or the animal has been caught in the wild and is killed for its organs or tissues.

Regulation 17 replaces section 17 of the Act to prohibit the use of a neuromuscular blocking agent in the course of a regulated procedure unless (a) the person is expressly authorised to do so by the personal licence and the project licence under which the procedure is carried out; and (b) the agent is used in combination with such level of anaesthesia or analgesia as is determined in accordance

with the project licence. It also stipulates that the Secretary of State must not grant a project licence that authorises the use of a neuromuscular blocking agent unless he or she is satisfied, on the basis of a scientific justification, that the purposes of the programme of work specified in the licence cannot be achieved without the use of such an agent.

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

Regulation 19 amends section 18 of the Act relating to the duties and functions of inspectors. In relation to visits of inspection the regulation introduces a requirement on the Secretary of State to determine an appropriate risk-based inspection programme to be followed by the Inspectorate.

Regulation 20 replaces sections 19 and 20 of the Act dealing with the Animal Procedures Committee which is to be replaced with a new committee to be known as the Committee for the Protection of Animals Used for Scientific Purposes.

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

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

Regulation 23 inserts new section 21A which deals with the publication of annual statistics in which there is now a requirement to report on the actual severity of the regulated procedures; the origin and the species of any primates used in regulated procedures; and on methods of killing specified which are used but which are not specified in Annex IV to the Directive. (Annex IV methods are set out in Schedule 1 to the Act.).

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

Regulations 24 and 25 provide penalties and deal with powers of entry under the Act.

Regulations 26 to 41 make minor and consequential amendments to the Act and other legislation; schedule 2 to the Act is amended to include frogs (*Rana* and *Xenopus* species) and zebra fish in the list of animals that will be “relevant protected animals” for the purposes of new section 2B. Regulation 42 introduces Schedule 3 to the regulations which sets out transitional provisions.

The regulations insert a new schedule 2B into the Act This Schedule provides for additional conditions which must be met before the Secretary of State grants certain project licences. These relate to conditions which must be satisfied before authorisation can be given for the use of endangered and non-endangered primates, the use of endangered animals that are not primates and the use of cats, dogs and equidae.

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Published by TSO (The Stationery Office) and available from:

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www.tsoshop.co.uk

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