

This 'consolidated' version of the Animals (Scientific Procedures) Act 1986 has been prepared from the draft Animals (Scientific Procedures) Act 1986 Amendment Regulations dated 26 July 2012 to show the changes that would be effected by those Regulations

New and altered text is shown in the document in black type; existing text is shown in blue type to enable changes to be distinguishable in both colour and monochrome printing.

For each section or sub-section of the Act, the Regulation effecting the change has been identified together with the Article of the Directive that it transposes.

Animals (Scientific Procedures) Act 1986

1986 CHAPTER 14

An Act to make new provision for the protection of animals used for experimental or other scientific purposes. (20th May 1986)

BE IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:-

Preliminary

1. (1) Subject to the provisions of this section, "a protected animal" for the purposes of this Act means any living vertebrate other than man and any living cephalopod.

(2) Any such vertebrate in its foetal, larval or embryonic form is a protected animal only from the stage of its development when-

- (a) in the case of a mammal, bird or reptile, two thirds of the gestation or incubation period for the relevant species has elapsed; and
- (b) in any other case, it becomes capable of independent feeding.

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

(3) The Secretary of State may by order-

- (a) extend the definition of protected animal so as to include any description of invertebrates other than cephalopods;
- (b) alter the stage of development specified in subsection (2) above;
- (c) make provision in lieu of subsection (2) above as respects any animal which becomes a protected animal by virtue of an order under paragraph (a) above.

(4) For the purposes of this section an animal shall be regarded as continuing to live until the permanent cessation of circulation or the destruction of its brain.

(5) In this Section "vertebrate" means any animal of the Sub-phylum Vertebrata of the Phylum Chordata and "invertebrate" means any animal not of that Sub-phylum.

Regulations 3(a) & 3(c) amend sections 1(1) and 1(2A) to transpose Article 1.3(b).

Section 1(2)(a) is amended by Regulation 3(b) to transpose Article 1.3(a) and to retain protection of foetal forms of birds and reptiles during the last third of their development (aligning protection with that for mammals).

Section 3(a) is amended consequentially by Regulation 3(d).

2. (1) Subject to the provisions of this Section, "a regulated procedure" for the purposes of this Act means any 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.

(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.

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

- (a) it is part of a series or combination of such procedures (whether the same or different) applied to the same animal; and
- (ab) each of the other procedures in the series or combination is applied for a qualifying purpose; and
- (b) the series or combination may have the effect mentioned in subsection (1) above; and
- (c) the animal is a protected animal throughout the series or combination or in the course of it attains the stage of its development when it becomes such an animal.

(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).

(3) Anything done for the purpose of, or liable to result in, the birth or hatching of a protected animal is also a regulated procedure if it may as respects that animal have the effect mentioned in subsection (1) above.

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

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

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

- (a) the animal is bred from an animal whose genes have been modified or from a descendant of an animal whose genes have 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 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.

Regulation 4(2) amends subsection (1) for Article.1.5(f) and 3.1

Regulation 4(3) inserts new section (1A) for Articles. 1.1 and 3.1

Regulations 4(4)(a), (b) & (c) amend subsection (2) for Article 3.1

Regulation 4(5) inserts new subsection (2A) for Articles 1.4 and 3.1

Regulation 4(6) inserts new subsections (3A) and (3B) for Article 3.1 subparagraph 2

Section 2. (continued)

(4) In determining whether any procedure may have the effect mentioned in subsection (1) above the use of an anaesthetic or analgesic, decerebration and any other procedure for rendering an animal insentient shall be disregarded; and the administration of an anaesthetic or analgesic to a protected animal, or decerebration or any other such procedure applied to such an animal, for the purposes of any experimental or other scientific procedure shall itself be a regulated procedure.

(5) [Deleted]

(6) [Deleted]

(7) Killing a protected animal is a regulated procedure only if it is killed for experimental or other scientific use, the place where it is killed is a place that is specified in a licence granted under section 2C and the method employed is not an appropriate method within the meaning given by section 15A.

(8) Notwithstanding anything in this section, none of the following are regulated procedures—

- (a) non-experimental agricultural practices;
- (b) non-experimental clinical veterinary practices;
- (c) practices undertaken for the purposes of recognised animal husbandry;
- (d) veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product;
- (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.

(9) Schedule 1 to this Act may be amended by orders made by the Secretary of State.

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.

Article 1.2 para 3

Regulation 4(7) deletes subsections (5) & (6). Procedures exempted from regulation now all set out in amended Section 2(8)

Regulation 4(8) amends subsection (7) for Article 3.1 sub-para 2.

Regulation 4(9) replaces existing subsection (8) with new subsections (8) & (8A).
(8)(a) is for Article 1.5(a)
(8)(b) is for Article 1.5(b)
(8)(c) is for Article 1.5(d)

(8)(d) is for Article 1.5(c)

(8)(e) is for Article 1.5(e)

(8A) is for Article 3.1

Regulation 5 inserts new Section 2A for Articles 4.1-4.3

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
 - (iii) breeding other animals from them primarily for purposes within subparagraph (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 take steps to ensure that it 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).

Regulation 6 inserts new Section 2B for Article 20.1

Regulation 6 inserts new Section 2C
(1) is for Article 20.1 para 1

(2) is for Article 20.1 para 2

(3) is for Article 20.1 para 2

(4) is for Articles 20.2, 24.1 & 25

(5) is for Article 20.2
(5)(a) is for Article 24.1(a)

(5)(b) is for Article 25

(5)(c) is for Article. 24.1(b)

(5)(d) is for Article. 24.1(c)

(5)(e) is for Article. 20.2

(6) is for Article 24.1

(7) = Duty of NACWO & NVS retained as higher welfare standard from current ASPA sections 6(6) & 7(6)

2C Licensing of undertakings (continued)

(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 but the Secretary of State shall review each licence granted by him or her at intervals not exceeding five years and may for that purpose require the holder to furnish the Secretary of State with such information as he or she may require.

(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).

(8) = Duty of NACWO & NVS retained as higher welfare standard from current ASPA sections 6(7) & 7(7)

(9) is for Article 20.1 discretion

(10) is for Article 20.4

Personal and project licences

3. No person shall personally apply a regulated procedure to an animal unless-

- (a) he holds a personal licence qualifying him to apply a regulated procedure of that description to an animal of that description;
- (b) the procedure is applied as part of a programme of work specified in a project licence authorising the application, as part of that programme, of a regulated procedure of that description to an animal of that description; and
- (c) the place where the procedure is carried out is a place specified in ~~the personal licence and~~ the project licence.

4. (1) A personal licence is a licence granted by the Secretary of State qualifying the holder personally to apply regulated procedures of specified descriptions to animals of specified descriptions ~~at a specified place or specified places.~~

(2) An application for a personal licence shall be made to the Secretary of State in such form and shall be supported by such information as he may reasonably require.

(3) Except where the Secretary of State dispenses with the requirements of this subsection any such application shall be endorsed by a person who-

- (a) is for the time being specified in a relevant section 2C licence by virtue of section 2C(5)(d); and
- (b) has knowledge of the education, training, experience and character of the applicant;

~~and the person endorsing an application shall, if practicable, be a person occupying a position of authority at a place where the applicant is to be authorised by the licence to carry out the procedures specified in it.~~

(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.

(4) No personal licence shall be granted to a person under the age of eighteen.

(4A) The Secretary of State shall not grant a personal licence to a person unless he is satisfied that the person-

- (a) has appropriate education and training ~~(including instruction in a relevant scientific discipline)~~ for the purpose of applying the regulated procedures that the licence would qualify the person to apply; and
- (b) is competent to apply those procedures in accordance with the conditions which are to be included in the licence and to handle and take care of laboratory animals.

(5) A personal licence shall continue in force until revoked but the Secretary of State shall review each personal licence granted by him at intervals not exceeding five years and may for that purpose require the holder to furnish him with such information as he may reasonably require.

Regulation 7(2) amends Section 3.
3(a) is for Article 23.2(a)

3(b) is for Article 36.1

3(c) is for Article.12.1
Regulation 7(3) removes from section3(c) the requirement for a personal licence to specify places.

Regulation 8(2) amends subsection (1) (see note re Section 3(c) above).

Regulation 8(3) amends subsection (3) for Article .

Regulation 8(4) inserts new subsection 3A

Regulation 8(5) amends subsection (4A)(a) for Article.23.2

Amended section 4 is for Article 23.2(a) and subsequent paragraphs

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.

Regulation 9 replaces existing Section 5.

(1) is for Article 12.2

(2) & (3) are for Articles 12.1 and 40.2(c)

(4) is for Article 40.4

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) explains the programme of work specified in the application and the objectives of the programme;
 - (b) explains the regulated procedures specified in the application;
 - (c) sets out the descriptions of animal specified in the application and estimates the number of animals of each description that would be subjected to regulated procedures as part of the programme of work;
 - (d) predicts the benefits that would be gained, and the harm to animals that would be caused, by carrying out the programme of work;
 - (e) demonstrates that the 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) must not contain the name or address of the applicant or any other person.
- (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.

Regulation 9 inserts new Section 5A

(1) – (3) are for Article 37

(4) is for Article 41.4

5A (continued)

(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.

Regulation 9 inserts new Section 5A.

(6) is for Article 41.3

(7) is for Article 41.1

(8) & (9) are for Article 41.2

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;
- (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 1A or paragraph 26(2) or (3) of Schedule 2A) to the question of whether or on what terms a project licence may be granted in respect of the programme of work;

Regulation 9 inserts new Section 5B

(1) is for Article 36.2

(2) is for Article 38.1

(3) is for Article 38.2

5B(3) (continued)

- (f) assess whether carrying out the programme of work would give rise to any scientific reason for an exemption under paragraph 11(5) of Schedule 2A;
- (g) 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 and transparent manner.

Regulation 9 inserts new Section 5B

(4) is for Article 38.3

(6) is for Article 15.1

(7) is for Article 39.2

(8) is for Articles 38.1 and 38.4

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 1A (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.

Regulation 9 inserts new Section 5C

(1) is for Article 40.2(a)

(2) is for Article 23.2

(3) is for Article 5

(4) is for Articles 7 & 8 retains existing protection for 'special species'

(5) is for Article 8.3 and places a ban on the face of the Act

5D Granting a project licence

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

Regulation 9 inserts new Section 5D

(2)(a) is for Article 40.2(b)

(2)(b) is for Article 23.2

(3) is for Article 40.2(a)

(4) is for Article 15 and to enable Article 16

(5) is for Article 40.2(d)

(6) & (7) are for Article 43

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 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.

Regulation 9 inserts new Section 5E

(1) is for Article 40.3

(2)- (4) are existing measures retained.

(5) & (6) are for Article 44

5F Retrospective assessment of programme of work

Regulation 9 inserts new Section 5F for Article 39

- (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)(g) 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)(g), 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

Regulation 9 inserts new Section 5G for Article 45

- (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.

[Sections 6 & 7 deleted]

Licences: general provisions

8. The holder of a section 2C licence shall pay such periodical fees to the Secretary of State as may be prescribed by or determined in accordance with an order made by him.

9. (1) Before granting a section 2C licence or a project licence under this Act the Secretary of State shall consult one of the inspectors appointed under this Act and may also consult an independent assessor or the Committee for the Protection of Animals Used for Scientific Purposes established by this Act.

(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.

(2) Where the Secretary of State proposes to consult an independent assessor he shall notify the applicant of that fact, and in selecting the assessor he shall have regard to any representations made by the applicant.

10 Conditions

(1) Schedule 2A 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).

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,
- (b) a provision of this Act, or
- (c) a provision concerned with the welfare of animals that is contained in or made under any other 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 must 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 must suspend or revoke the licence.

Consequential deletion by Regulation 26(1)
Consequential amendments by Regulations 26(2) and 26(3)
Regulation 26(5) amends subsection (1) to remove the requirement for the Secretary of State to consult an inspector before granting a personal licence in every case.
Regulation 10 replaces existing Section 10 and introduces new Schedule 2A, which sets out the requirements for conditions to be included in licences.
Regulation 11 replaces existing Section 11. This is for Articles 21.1, 23.2 paragraph 4, 44.4 and 60.

11 (continued)

(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,
- (b) a provision of this Act, or
- (c) a provision concerned with the welfare of animals that is contained in or made under any other 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 must 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 must suspend or revoke the licence.

(6) A licence under this Act may be also be suspended, revoked or varied by the Secretary of State in any case in which it appears to the Secretary of State that 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.

12. (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; or
- (d) to issue a compliance notice to the holder of a licence under this Act.,
he shall serve on the applicant or the holder a notice of his intention to do so.

(2) The notice shall state the reasons for which the Secretary of State proposes to act and give particulars of the rights conferred by subsection (3) below.

(3) A person on whom a notice is served under subsection (1) above may make written representations and, if desired, oral representations to a person appointed for that purpose by the Secretary of State if before such date as is specified in the notice (not being less than twenty-eight days after the date of service) he notifies the Secretary of State of his wish to do so.

Regulation 11 replaces existing Section 11. This is for Articles 21.1, 23.2 paragraph 4, 44.4 and 60.

Regulation 12 makes a series of minor and consequential amendments to Section 12, including deletion of references to “certificates” and includes reference to “suspension” covered in the amended Section 11

12. (Continued)

(4) The holder of a licence who is dissatisfied with any condition contained in it may, if he notifies the Secretary of State of his wish to do so, make written representations and, if desired, oral representations to a person appointed for that purpose by the Secretary of State; but the making of such representations shall not affect the operation of any condition unless and until it is varied under Section 11 above.

(5) The person appointed to receive any representations under this Section shall be a person who holds or has held judicial office in the United Kingdom or a barrister, solicitor or advocate of at least seven years' standing and the Secretary of State may, if he thinks fit, appoint a person with scientific or other appropriate qualifications to assist the person receiving the representations in his consideration of them.

(6) The person appointed to receive any such representations shall after considering them make a report to the Secretary of State; and the Secretary of State shall furnish a copy of the report to the person who made the representations and take it into account in deciding whether to refuse the application or to revoke, suspend or vary the licence or to issue the compliance notice, as the case may be.

(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.

(7) The Secretary of State may by order make rules with respect to the procedure to be followed in the making and consideration of representations under this Section, including, provision requiring any such representations to be made within a specified time.

(8) A notice under subsection (1) above may be served either personally or by post.

13. (1) If it appears to the Secretary of State to be urgently necessary for the welfare of any protected animals that a licence under this Act should cease to have effect forthwith he shall by notice served on the holder suspend its operation for a period not exceeding three months.

(2) If during that period a notice of proposed variation or revocation of the licence is served under Section 12 above but at the end of that period-

(a) the time for notifying the Secretary of State under subsection (3) of that Section has not expired; or

(b) representations are to be or are being made in accordance with that subsection; or

(c) such representations have been made but the Secretary of State has not received or has not completed his consideration of the report of the person to whom the representations were made,

he may by notice served on the holder further suspend the licence until he is able to decide whether to vary or revoke it but no suspension shall be for longer than three months at a time.

(3) A notice under this Section may be served personally or by post.

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.

Regulation 12 makes a series of minor and consequential amendments to Section 12, including deletion of references to “certificates” and includes reference to “suspension” covered in the amended Section 11

Minor and consequential amendments are made to Section 13 by Regulation 26(6) (deletion of references to “certificates”. This covers Articles 21.1, 23.2 paragraph 4 & 44.3

Regulation 13 inserts new Section 13A for Articles 21.1 & 44.4

Additional controls

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 24 of Schedule 2A, and
 - (b) in a case where more than one regulated procedure has previously been applied to the animal, the actual severity of no more than one of those procedures has been classified as “severe”.
- (3) The second condition is that a veterinary surgeon with knowledge of the lifetime experience of the animal has advised that the animal’s general state of health and well-being has been fully restored following the application of the previous procedure or procedures.
- (4) The third condition is that—
- (a) the further procedure is to be applied as part of a programme of work specified in a project licence; and
 - (b) the likely severity of the further procedure is classified as “non-recovery”, “mild” or “moderate” (using the criteria in Annex 8 of the Animals Directive) by a person of a description specified in the licence for the purposes of this section.
- (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 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.

15. (1) Where a protected animal-

- (a) has been subjected to a series of regulated procedures for a particular purpose; and
- (b) at the conclusion of the series is suffering or likely to suffer adverse effects, the person who applied those procedures, or the last of them, shall ensure that the animal is immediately killed in accordance with section 15A.

(2) Subsection (1) above is without prejudice to any condition of a project licence requiring an animal to be killed at the conclusion of a regulated procedure in circumstances other than those mentioned in that subsection.

Regulation 14 replaces existing Section 14 for Article 16

Consequential amendment is made to subsection (1) by Regulation 26(7) to refer to new Section 15A. This is for Article 17.

15A Manner in which protected animals are to be killed

Regulation 15 inserts new Section 15A for Article 6 and Annex IV

(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 as being competent to kill animals of that description using that method.

For further provision about registers of the sort mentioned in paragraph (c), see paragraph 2 of Schedule 2A.

(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; and
- (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.

(5) An animal is also killed using an appropriate method if—

- (a) the method is applied to the animal while it is unconscious; and
- (b) the animal does not subsequently regain consciousness.

(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.

15A (continued)

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

16. (1) No person shall carry out any regulated procedure as an exhibition to the general public or carry out any such procedure which is shown live on television for general reception.

(2) No person shall publish a notice or advertisement announcing the carrying out of any regulated procedure in a manner that would contravene subsection (1) above.

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.

17A Setting free and re-homing protected animals

(1) A person who holds a licence under this Act must not set free or 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 setting free or re-homing of the animal.

(2) 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.

(3) 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.

(4) For the purposes of this section—

- (a) “relevant protected animal” has the same meaning as in section 15A;
- (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.

Regulation 15 inserts new Section 15A for Article 6 and Annex IV

Section 16 remains unchanged.

Regulation 17 replaces existing Section 17 for Article 14.3

Regulation 18 inserts new Section 17A for Article 19

The inspectorate and the committee

18. (1) The Secretary of State shall, with the consent of the Treasury as to numbers and remuneration, appoint as inspectors for the purposes of this Act persons having such medical or veterinary qualifications as he thinks requisite.

(2) It shall be the duty of an inspector-

(a) to advise the Secretary of State on applications for licences under this Act, on requests for their variation or revocation and on their periodical review;

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

(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 throughout the year 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.

(3) If an inspector considers that a protected animal is undergoing excessive suffering he may require it to be immediately killed in accordance with section 15A.

Regulation 19(2)(a) makes a consequential amendment to subsection (2)(a) to cover all licence assessment.

Regulations 19(2)(b) and 19(3) replace existing subsections (2)(b) to (2)(e) with new subsections (2)(b) and 2A – 2E to cover all inspection requirements of Article 34

Consequential amendment is made to subsection (3) by Regulation 26(8)

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) 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.
- (3) 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 new Schedule 2A;

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

Miscellaneous and supplementary

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.

Regulation 20 replaces existing Sections 19 and 20 for Article 49.

Regulation 20 replaces existing Sections 19 and 20 for Article 49.

Regulation 21 inserts new Section 20A for Article 18

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 or lasting harm caused to protected animals.

21. (1) The Secretary of State shall publish information to serve as guidance with respect to the manner in which he proposes to exercise his power to grant licences under this Act and with respect to the conditions which he proposes to include in such licences.

(2) The Secretary of State shall issue codes of practice as to the care of protected animals and their use for regulated procedures and may approve such codes issued by other persons.

(3) The Secretary of State shall consult the Committee for the Protection of Animals Used for Scientific Purposes before publishing or altering any information under subsection (1) above or issuing, approving, altering or approving any alteration in any code issued or approved under subsection (2) above.

(4) A failure on the part of any person to comply with any provision of a code issued or approved under subsection (2) above shall not of itself render that person liable to criminal or civil proceedings but-

- (a) any such code shall be admissible in evidence in any such proceedings; and
- (b) if any of its provisions appears to the court conducting the proceedings to be relevant to any question arising in the proceedings it shall be taken into account in determining that question.

(5) The Secretary of State shall lay before Parliament-

- (a) copies of any information published or code issued by him under subsection (1) or (2) above and of any alteration made by him in any such information or code; and
- (b) copies of any code approved by him under subsection (2) above and of any alteration approved by him in any such code;

and if either House of Parliament passes a resolution requiring the information, code or alteration mentioned in paragraph (a) above or the approval mentioned in paragraph (b) above, to be withdrawn the Secretary of State shall withdraw it accordingly; and where he withdraws information published or a code issued by him or his approval of a code he shall publish information or issue or approve a code, as the case may be, in substitution for the information or code previously published, issued or approved.

(6) No resolution shall be passed by either House under subsection (5) above in respect of any information, code or alteration after the end of the period of forty days beginning with the day on which a copy of the information, code or alteration was laid before that House; but for the purpose of this subsection no account shall be taken of any time during which Parliament is dissolved or prorogued or during which both Houses are adjourned for more than four days.

Regulation 22 inserts new Section 20B for Article 47

Regulation 26(9) makes a consequential amendments to subsection (3) to cover the change of name of the ‘National Committee’ and remove references to “certificates”.

21A Statistics and reporting

Regulation 23 inserts new Section 21A for Article 54.

- (1) The Secretary of State must in each year collect, publish and lay before Parliament statistical information on the use of protected animals in regulated procedures during the previous year.
- (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 by 10 November 2015 send to the European Commission the statistical information collected; and every year thereafter the Secretary of State must send to the Commission any further statistical information collected.
- (4) 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).
- (5) The Secretary of State must by 10 November 2018, and every five years 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).

22. (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—

Regulations 24(2) and 24(3)(a) inserts new subsections (A1) and (3)(za) into Section 22 to make contravention of new section 2B a criminal offence. This is for Article 60

- (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.

(1) Any person who contravenes Section 3 above 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, to imprisonment for a term not exceeding six months or to a fine not exceeding the statutory maximum or to both.

(2) Any person who, being the holder of a project licence-

- (a) procures or knowingly permits a person under his control to carry out a regulated procedure otherwise than as part of the programme specified in the licence; or
 - (b) procures or knowingly permits a person under his control to carry out a regulated procedure otherwise than in accordance with that person's personal licence,
- shall be guilty of an offence and liable to the penalties specified in subsection (1) above.

(3) Any person who-

- (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);
- (a) contravenes Section 14, 15, 16 or 17 above or
 - (b) fails to comply with a requirement imposed on him under Section 18(3) above,
- shall be guilty of an offence and liable on summary conviction to imprisonment for a term not exceeding three months or to a fine not exceeding the fourth level on the standard scale or to both.

Regulation 24(3)(b) makes a consequential amendment to subsection (3)(a) to remove reference to (the now deleted) Section 7.

22. (continued)

(3A) If an individual contravenes section 15A above—

- (a) the individual is guilty of an offence, and
- (b) if the contravention takes place in the course of the individual's employment with the holder of a section 2C licence, the holder of the licence is guilty of an offence.

(3B) A person who contravenes section 17A above shall be guilty of an offence.

(3C) A person guilty of an offence by virtue of subsection (3A) or (3B) above shall be 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.

(4) A person shall not be guilty of an offence under Section 3 or 17 above by reason only that he acted without the authority of a project licence if he shows that he reasonably believed, after making due enquiry, that he had such authority.

(4A) An individual who kills an animal in contravention of section 15A above shall not be guilty of an offence by virtue of subsection (3A)(a) above if the individual 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).

(4B) The holder of a section 2C licence shall not be guilty of an offence by virtue of subsection (3A)(b) above if the holder shows—

- (a) that the individual by whom the animal in question was killed did not know and had no reason to believe that the animal was a relevant protected animal (within the meaning of section 15A); or
- (b) that all reasonable steps were taken and all due diligence exercised to avoid contravention of section 15A by the holder's employees.

(5) A person guilty of an offence under Section 1 of the Protection of Animals Act 1911 or Section 1 of the Protection of Animals (Scotland) Act 1912 in respect of an animal at a place specified in a section 2C licence shall be liable to the penalties specified in subsection (1) above.

[Regulation 23(6): In relation to an offence committed before the commencement of paragraph 3 of Schedule 27 to the Criminal Justice Act 2003, —

(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 (3C)(a) of that section (inserted by paragraph (4) above) is to be read as a reference to three months.]

[NB this provision is reproduced here for reference only. It does not amend the Animals (Scientific Procedures) Act itself]

23. (1) A person is guilty of an offence if for the purpose of obtaining or assisting another person to obtain a licence under this Act he furnishes information which he knows to be false or misleading in a material particular or recklessly furnishes information which is false or misleading in a material particular.

(2) A person guilty of an offence under this Section shall be liable on summary conviction to imprisonment for a term not exceeding three months or to a fine not exceeding the fourth level on the standard scale or to both.

Regulation 24(4) inserts new subsections (3A)-(3C)

Minor consequential amendment to subsection (4) by Regulation 26(10)(a)

Regulation 24(5) inserts new subsection (4A)

Consequential amendment to subsection (5) by Regulation 26(10)(b)

Regulation 26(11) makes a consequential amendment to subsection (1) to remove reference to "certificates"

24. (1) A person is guilty of an offence if otherwise than for the purpose of discharging his functions under this Act he discloses any information which has been obtained by him in the exercise of those functions and which he knows or has reasonable grounds for believing to have been given in confidence.

(2) A person guilty of an offence under this Section shall be 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, to imprisonment for a term not exceeding six months or to a fine not exceeding the statutory maximum or to both.

25. (1) If a justice of the peace or in Scotland a sheriff is satisfied by information on oath that there are reasonable grounds for believing that an offence under this Act has been or is being committed at any place, he may issue a warrant authorising a constable to enter that place if need be by such force as is reasonably necessary, to search it and to require any person found there to give his name and address.

(2) A warrant under subsection 1 may authorise a constable to be accompanied by an inspector appointed under this Act and shall require him to be accompanied by such an inspector if the place in question is a designated establishment.

(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.

(3) Any person who-

(a) intentionally obstructs a constable or inspector in the exercise of his powers under this Section;

(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

(b) refuses on demand to give his name and address or gives a false name or address,

shall be guilty of an offence and liable on summary conviction to imprisonment for a term not exceeding three months or to a fine not exceeding the fourth level on the standard scale or to both.

26. (1) No proceedings for-

(a) an offence under this Act; or

(b) an offence under Section 1 of the Protection of Animals Act 1911 which is alleged to have been committed in respect of an animal at a place specified in a section 2C licence,

shall be brought in England and Wales except by or with the consent of the Director of Public Prosecutions.

(2) Summary proceedings for an offence under this Act may (without prejudice to any jurisdiction exercisable apart from this subsection) be taken against any person at any place at which he is for the time being.

No change to current section 24

(24/7/12) Regulation 25 inserts new subsections (2A), (2B) and (3)(aa) to enable the Secretary of State to take action to safeguard animal welfare as required by new/amended sections 11(4) and 13A.

Regulation 26(14) makes a consequential amendment to subsection (1)(b)

26. (continued)

(3) Notwithstanding anything in Section 127(1) of the Magistrates' Courts Act 1980, an information relating to an offence under this Act which is triable by a magistrates' court in England and Wales may be so tried if it is laid at any time within three years after the commission of the offence and within six months after the date on which evidence sufficient in the opinion of the Director of Public Prosecutions to justify the proceedings comes to his knowledge.

(4) Notwithstanding anything in Section 331 of the Criminal Procedure (Scotland) Act 1975, summary proceedings for an offence under this Act may be commenced in Scotland at any time within three years after the commission of the offence and within six months after the date on which evidence sufficient in the opinion of the Lord Advocate to justify the proceedings comes to his knowledge; and subsection (3) of that Section shall apply for the purposes of this subsection as it applies for the purposes of that Section.

(5) For the purposes of subsections (3) and (4) above a certificate of the Director of Public Prosecutions or, as the case may be, the Lord Advocate as to the date on which such evidence as is there mentioned came to his knowledge shall be conclusive evidence of that fact.

27. (1) The Cruelty to Animals Act 1876 is hereby repealed.

(2) The enactments mentioned in Schedule 3 to this Act shall have effect with the amendments there specified, being amendments consequential on the provisions of this Act.

(3) The Breeding of Dogs Act 1973 shall not apply to the breeding of dogs for use in regulated procedures if they are bred at a place specified in a section 2C licence by virtue of section 2B(2)(b).

(4) Schedule 4 to this Act shall have effect with respect to the transitional matters there mentioned.

(5) The Secretary of State may by order make such further transitional provisions as he considers necessary or expedient.

28. (1) Any power of the Secretary of State to make an order under this Act shall be exercisable by statutory instrument.

(2) A statutory instrument containing an order under any of the foregoing provisions of this Act shall be subject to annulment in pursuance of a resolution of either House of Parliament.

29. (1) This Act applies to Northern Ireland with the following modifications.

(2) For any reference to the Secretary of State in any provision of this Act except Sections 19 and 20(1) there shall be substituted a reference to the Department of Health and Social Services for Northern Ireland; and for the reference in Section 18(1) above to the Treasury there shall be substituted a reference to the Department of Finance and Personnel for Northern Ireland.

(3) The functions of the Secretary of State under Sections 19 and 20(1) shall be exercisable by him jointly with the Department of Health and Social Services for Northern Ireland; and any notice under Section 19(4) or advice under Section 20(1) may be given to either of them.

(4) In Section 21 above-

(a) for the references to Parliament or either House of Parliament there shall be substituted references to the Northern Ireland Assembly;

(b) in subsection (5) after the word "if" there shall be inserted the words "within the statutory period (within the meaning of the Interpretation Act (Northern Ireland) 1954)"; and

(c) subsection (6) shall be omitted.

Regulation 26(14) makes a consequential amendment to subsection (1)(b)

Regulation 26(13) makes a consequential amendment to subsection (3).

Regulation 26(14) makes consequential amendments to Section 29

29. (continued)

(4A) In section 21A(1) above for the reference to Parliament there shall be substituted a reference to the Northern Ireland Assembly.

(5) In Sections 22(5) and 26(1)(b) above for the references to Section 1 of the Protection of Animals Act 1911 there shall be substituted references to Sections 13 and 14 of the Welfare of Animals Act (Northern Ireland) 1972.

(6) In section 25 above for the references to information on oath there shall be substituted references to a complaint on oath.

(7) In Section 26 above-

(a) in subsections (1) and (3) for the words "England and Wales" there shall be substituted the words "Northern Ireland";

(b) in subsections (1), (3) and (5) for the references to the Director of Public Prosecutions there shall be substituted references to the Director of Public Prosecutions for Northern Ireland; and

(c) in subsection (3) for the reference to Section 127(1) of the Magistrates' Courts Act 1980 there shall be substituted a reference to Article 19(1) of the Magistrates' Courts (Northern Ireland) Order 1981.

(8) In Section 27(3) above for the reference to the Breeding of Dogs Act 1973 there shall be substituted a reference to Articles 12, 13 and 43 of the Dogs (Northern Ireland) Order 1983.

(9) Section 28 above shall not apply and any order made by the Department of Health and Social Services for Northern Ireland under this Act shall be a statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979 and shall be subject to negative resolution within the meaning of Section 41(6) of the Interpretation Act (Northern Ireland) 1954.

30. (1) This Act may be cited as the Animals (Scientific Procedures) Act 1986.

(2) In this Act-

"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;

"personal licence" means a licence granted under Section 4 above;

"place" includes any place within the seaward limits of the territorial waters of the United Kingdom, including any vessel other than a ship which is not a British ship;

"project licence" means a licence granted under Section 5 above;

"protected animal" has the meaning given in Section 1 above but subject to any order under subsection (3) of that Section;

"regulated procedure" has the meaning given in Section 2 above.

"section 2C licence" means a licence granted under section 2C.

(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.

(3) This Act shall come into force on such date as the Secretary of State may by order appoint; and different dates may be appointed for different provisions or different purposes.

Regulation 26(14) makes consequential amendments to Section 29

Regulation 26(15) amends subsection (2) to delete the definition of "designated", and to insert definitions of "the Animals Directive" and "section 2C licence"; and inserts new subsection (2A) to clarify that references to Annexes of the Animals Directive are ambulatory.

SCHEDULE 1

APPROPRIATE METHODS OF HUMANE KILLING

Section 15A

1. The methods of humane killing listed in Tables A and B below are appropriate for the animals listed in the corresponding entries in those tables only if the process of killing is completed by one of the methods listed in subparagraphs (a) to (f) below:

- (a) confirmation of permanent cessation of the circulation
- (b) destruction of the brain
- (c) dislocation of the neck
- (d) exsanguination
- (e) confirming the onset of *rigor mortis*
- (f) instantaneous destruction of the body in a macerator.

~~2. Paragraph 1 above does not apply in those cases where Table A specifies one of the methods listed in that paragraph as an appropriate method of humane killing.~~

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.

For Article 6 & Annex IV

Regulation 26(16) makes minor consequential amendments to the sub-heading

Regulation 16(3) amends Schedule 1 to delete paragraph to clarify that when completing the process of killing the means of doing so should be different from the method of killing. New paragraph 3 is inserted to provide for the use of prior sedation or anaesthesia when in the welfare interests of the animal.

A.Methods for animals other than foetal, larval and embryonic forms	Animals for which appropriate
1.Overdose of an anaesthetic using a route and an anaesthetic agent appropriate for the size and species of animal	All animals
2.Exposure to carbon dioxide gas in a rising concentration	Birds and Rodents up to 1.5 kg (but not neonatal rodents)
3.Dislocation of the neck (with the prior use of a sedative or anaesthetic in the case of rodents and rabbits over 150 g and birds over 250 g)	Rodents up to 500g Rabbits up to 1kg Birds up to 1kg
4.Concussion of the brain by striking the cranium	Rodents and Rabbits up to 1kg Birds up to 5kg Amphibians and reptiles (with destruction of the brain before the return of consciousness) up to 1kg Fishes (with destruction of the brain before the return of consciousness)
5.One of the recognised methods of slaughter set out below which is appropriate to the animal and is performed by a registered veterinary surgeon, or, in the case of the methods described in paragraph (ii) below, performed by the holder of a current licence granted under the Welfare of Animals (Slaughter or Killing) Regulations 1995 (a) i) Destruction of the brain by free bullet using appropriate rifles, guns and ammunition, or ii) captive bolt or electrical stunning followed by destruction of the brain or exsanguination before return of consciousness.	Ungulates
B. Methods for foetal, larval and embryonic forms	Animals for which appropriate
1. Overdose of an anaesthetic using a route and anaesthetic agent appropriate for the size, stage of development and species of animal	All animals
2. Refrigeration, or disruption of membranes, or maceration in apparatus approved under appropriate slaughter legislation, or exposure to carbon dioxide in near 100% concentration until they are dead	Birds Reptiles
3. Cooling of foetuses followed by immersion in cold tissue fixative	Mice, Rats and Rabbits
4. Decapitation	Mammals and Birds up to 50g

Regulation 16(4) amends Table A:

(a) to remove rabbits from the list of animals for which carbon dioxide exposure is appropriate in accordance with Annex IV;

(b) to transpose the Annex IV requirement for sedation or anaesthesia prior to dislocation of the neck but subject to Paragraph 3 above;

(c) to reduce the bodyweight limit of birds that may be killed by dislocation of the neck to 1kg in accordance with Annex IV;

(d) to increase the bodyweight of birds that may be killed by concussion (percussion) in accordance with Annex IV; and

(e) to amend the wording of the recognised slaughter methods and to remove percussion as a permissible method, both to transpose Annex IV.

(a) S.I. 1995/731

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 paragraphs (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 the following conditions 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.

Schedule 1A is inserted by Regulation 9(2)

1 is for Article 8.2

2 is for Article 8.1

3 is for Article 7.1

SCHEDULE 1A (continued)

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 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.

Schedule 1A is inserted by Regulation 9(2)

Paragraph 4 retains special protection for cats, dogs and horses as currently provided by Section 5(6) of ASPA.

SCHEDULE 2

ANIMALS THAT ARE “RELEVANT PROTECTED ANIMALS” FOR THE PURPOSES OF SECTION 2B

Section 2B

Mouse
Rat
Guinea-pig
Hamster
Rabbit
Dog
Cat
Primate
Ferrets
Gerbils

Any frog of the species *Xenopus laevis*, *Xenopus tropicalis*, *Rana temporaria* or *Rana pipiens*
Zebra fish.

Regulation 26(17) amends Schedule 2 to transpose Annex I of the Directive by including frogs (*Rana* and *Xenopus* spp) and zebra fish.

Ferrets are to be retained in Schedule 2 as per the Government Response to the consultation.

SCHEDULE 2A

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 principle 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.

Schedule 2A is inserted by
Regulation 10(2)

1 is for Article 4

2 is for Articles 6 & 23.2

3(a) is for Article 20.4

3(b) is for Article 20.3

4 is for Article 22 (and 33.2)

Schedule 2A Part 1 Paragraph 4 continued

(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) (subject to sub-paragraph (3)) 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) If information published under section 21(1) so specifies, a condition under sub-paragraph (1) may allow the tasks mentioned in paragraphs (a) to (e) of Article 27.1 of the Animals Directive to be carried out, in the case of an undertaking that is a small business (as defined in the information), in a manner specified in the information rather than by the Animal Welfare and Ethical Review Body.

(4) 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.

(5) 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.

5 is for Article 23.1 & 23.2

6 is for Articles 26 & 27

7 is for Article 28

8 is for Article 30.1

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;

9 is for Article 31

10 is for Article 32

Schedule 2A Part 1 Paragraph 10 continued

(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 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.

11 (1) is for Article 33.1

11(2) is for Article 33.2

11(3) is for Article 33.2 & Annex III

11(4) & 11(5) are for Article 33.3

Schedule 2A Part 1 continued

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.

12(a) is for Article 34

12(b) is for Article 35

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.

13 is for Article 4

14.—(1) A personal licence must include a condition requiring the holder to ensure that the regulated procedures the holder applies are those which to the greatest extent meet the following requirements—

14 is for Article 13

- (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 personal licence must include a condition requiring the holder to ensure that the regulated procedures the holder applies are designed so as—

- (a) to result in the death of as few protected animals as possible;
- (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.

15. 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;
- (e) 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;
- (f) 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 human end-point;
- (g) a condition specifying circumstances in which a protected animal that is being or has been subjected to a regulated procedure by the holder must in every case be immediately killed in accordance with section 15A.

15 (a) is for Article 15.2

15(b) is for Article 4.3

15(c) is for Article 24.2(a)

15(e) is for Article 15.2

15(f) is for Article 13.3

15(g) is for Article 17

16.—(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—

- (a) the holder uses analgesia or another appropriate method to ensure that the pain, suffering and distress caused by the procedure is kept to a minimum; and
- (b) the holder is satisfied that—
 - (i) the procedure will not inflict serious injuries capable of causing severe pain; and
 - (ii) 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 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.

17. 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

18. A project licence must include a condition requiring the holder to ensure that the specified programme of work is carried out in a manner that is consistent with the principles of replacement, reduction and refinement.

19.—(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.

20. 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.

21. 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.

16 is for Article 14

17(a) is for Article 34

17(b) is for Article 35

18 is for Article 4

19 is for Article 13

20 is for Article 23.2 paragraph 3

21 is for Article 15.2

Schedule 2A Part 3 continued

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 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 is for Article 24.2(a)

23. 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—

23 is for Articles 13.3 and 14.5

- (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.

24.—(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 a 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.

24 is to enable Article 54.2 and is also for Article 16 in relation to Article 15.1

(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.

25.—(1) A project licence must include such conditions as the Secretary of State considers appropriate for the purpose of ensuring—

25 is for Article 17

- (a) that where an animal has been subjected to a series of regulated procedures for a particular purpose, a decision is taken at the end of the series by a veterinary surgeon or other competent person as to whether the animal should be kept alive or killed;
- (b) that, if that person considers that the animal is likely to remain in moderate or severe pain, suffering or distress or is likely to experience lasting harm, the animal is killed; and
- (c) that where the animal is to be kept alive it receives care and accommodation appropriate to its state of health.

(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.

26.—(1) Subject to sub-paragraphs (2) and (3), a project licence must include—

26(1)(a) & (b) are for Article 11

- (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.

26(1)(c) is for Article 9

26(1)(d) is for Article 10.1 paragraph 2

26(1)(e) is for Article 10.1 paragraph 1

Schedule 2A Part 3 Paragraph 26

(2) A project licence is not required to include the condition mentioned in sub-paragraph (1)(b) if the Secretary of State is satisfied that there is scientific justification to the effect that the purposes of the programme of work specified in the licence can be achieved only by the application of regulated procedures to feral animals of a domestic species and the programme of work consists of—

- (a) an essential study into the health or welfare of a domestic species; or
- (b) an essential study into 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 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).

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.

26(2) is for Article 11

26(3) is for Articles 9 & 10

26(4) & (5) are for Article 9

26(6) is for Article 10.1 paragraph 3

27(a) is for Article 34

27(b) is for Article 35

28 is for Article 24.2(b)