

SCHEDULE 1

Regulation 9(2)

Additional conditions for the grant of certain project licences

“SCHEDULE 2B

Section 5C(4)

ADDITIONAL CONDITIONS FOR THE GRANT OF CERTAIN PROJECT LICENCES

Project licences authorising the use of endangered primates

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

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

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

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

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

(4) Condition 3 is that there is scientific justification to the effect that the purpose of the programme of work to be specified in the licence cannot be achieved by the use of animals which—

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

Project licences authorising the use of non-endangered primates

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

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

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

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

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

(4) Condition 6 is that there is scientific justification to the effect that the purpose of the programme of work to be specified in the licence cannot be achieved by the use of animals which are not primates.

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

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

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

(3) Condition 8 is that there is scientific justification to the effect the purpose of the programme of work to be specified in the licence cannot be achieved by the use of animals which are not of a species listed in Annex A to the Council Regulation.

Project licences authorising the use of cats, dogs and equidae

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

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

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

Interpretation

5. In this Schedule—

“the Council Regulation” means Council Regulation (EC) No 338/97(1) 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.”

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

SCHEDULE 2

Regulation 10(2)

Conditions in licences

“SCHEDULE 2C

Section 10(1)

CONDITIONS IN LICENCES

PART 1

Conditions in section 2C licences

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

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

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

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

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

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

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

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

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

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

- (a) provides reliable results;

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

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

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

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

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

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

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

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

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

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

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

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

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

- (a) to maintain records of the information mentioned in paragraphs (a) to (g) of Article 30.1 of the Animals Directive;
- (b) to retain any such record for a period determined in accordance with the licence (being a period of at least five years); and

- (c) to make any such record that is being retained available to the Secretary of State upon request.

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

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

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

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

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

- (a) that before any unmarked dog, cat or non-human primate is weaned at the place specified in the licence the animal is provided with a permanent individual identification mark;
- (b) that before any unmarked dog, cat or non-human primate that has not been weaned is transferred from the place specified in the licence to a place specified in another section 2C licence, the animal is provided with a permanent individual identification mark unless it would not be reasonably practicable to do so;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PART 2

Conditions in personal licences

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

14. A personal licence must include—

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

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

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

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

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

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

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

PART 3

Conditions in project licences

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

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

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

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

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

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

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

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

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

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

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

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

24.—(1) A project licence must include such conditions as the Secretary of State considers appropriate for the purpose of ensuring that where a series of regulated procedures are applied to an animal for a particular purpose the animal is killed at the end of the series unless a veterinary surgeon or other competent person has determined that the animal is not suffering and is not likely to suffer adverse effects.

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

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

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

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

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

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

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

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

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

- (6) For the purposes of sub-paragraph (1)(d) a colony of animals is a “self-sustaining colony” if—
- (a) the colony is kept in captivity in a way that ensures the animals are accustomed to humans;
 - (b) the colony consists only of animals that have been bred in captivity; and
 - (c) the colony is sustained only by animals being bred within the colony or animals being sourced from other colonies that meet paragraphs (a) and (b).

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

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

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

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

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

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

SCHEDULE 3

Regulation 42

Transitional provision

PART 1

Existing certificates and licences, etc.

Interpretation

1.—(1) In this Schedule—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Scientific procedure establishments

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Breeding and supplying establishments

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Personal licences

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

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

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

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

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

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

Project licences

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(6) Section 15A applies as if in subsection (3)(b), at the end there were inserted “and there is a scientific justification that the purposes of the programme of work specified in the licence cannot be achieved if a method of killing appropriate to that description of animal under Schedule 1 is used.”

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

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

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

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

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

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

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

- (a) Condition 7 of Schedule 2B to the Act, and

(b) Condition 8 of that Schedule.

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

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

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

(a) a variation of the licence, or

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

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

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

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

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

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

Re-use of protected animals

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

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

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

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

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

Setting free and re-homing protected animals

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

PART 2

Conditions in section 2C licences

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5. The licence holder shall ensure that the establishment shall be appropriately staffed at all times to ensure the well-being of the protected animals. Staff shall be adequately educated and trained before they perform any function relating to the care of the protected animals and shall be supervised when performing any such function until they have demonstrated the requisite competence.

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

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

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

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

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

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

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

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

- (a) the number and the species of animals bred, acquired, supplied, used in procedures, or discharged from the control of the Act;
- (b) the origin of the animals, including whether they are bred for use in procedures;
- (c) the dates on which the animals are acquired, supplied, or discharged from the control of the Act;
- (d) from whom the animals are acquired;
- (e) the name and address of the recipient of animals;

- (f) the number and species of animals which died or were killed in each establishment. For animals that have died, the cause of death shall, when known, be noted; and
- (g) where this licence authorises the applying of regulated procedures to protected animals, the projects in which animals are used.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13. Unless otherwise authorised by the Secretary of State—

(a) only the types of protected animals specified in the licence may be kept in the place or places specified in the licence for the purpose of the regulated activities specified in the licence; and

(b) for the purpose of the regulated activities specified in the licence, these animals may only be kept, bred and used in the areas listed in the schedule to the licence.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PART 3

Conditions in personal licences

1. In exercising his or her responsibilities, the licence holder shall act at all times in a manner that is consistent with the principles of replacement, reduction and refinement.

2. The licence holder is entrusted with primary responsibility for the welfare of the animals on which he or she has performed regulated procedures; the licence holder must ensure that animals are properly monitored and cared for.

3. The licence holder must not apply a regulated procedure to an animal if the procedure may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

4. The licence holder must not apply a regulated procedure to an animal unless the holder has taken precautions to prevent or reduce to the minimum consistent with the purposes of the procedure any pain, suffering, distress or discomfort that may be caused to the animal.

5. Where the licence holder is applying a regulated procedure to an animal the holder must ensure that any unnecessary pain, suffering, distress or lasting harm that is being caused to the animal is stopped.

6. Where the licence holder is applying or has applied a regulated procedure which is causing the animal severe pain, suffering or distress the holder must take steps to ameliorate that pain, suffering or distress.

7. The licence holder shall ensure that where the holder applies a regulated procedure death as the end-point of the procedure is avoided as far as possible and is replaced by an early and humane end-point.

8. In all circumstances where an animal which is being, or has been, subjected to a regulated procedure is in severe pain, suffering or distress which is likely to be long-lasting and cannot be ameliorated, the licence holder must ensure that the animal is immediately killed in accordance with section 15A.

9. The licence holder may apply a regulated procedure without the use of general or local anaesthesia only if the holder is satisfied that—

- (a) the procedure will not inflict serious injuries capable of causing severe pain; and

- (b) the use of general or local anaesthesia would be more traumatic to the animal than the procedure itself or would frustrate the purposes of the procedure.
- 10.** When anaesthesia (whether general or local) is used, it shall be of sufficient depth to prevent the animal from being aware of pain arising during the procedure.
- 11.** If the licence holder applies a regulated procedure to an animal with the use of general or local anaesthesia the holder must, unless it would frustrate the purpose of the procedure, use such analgesics or other pain-relieving methods as may be necessary to reduce any pain that the animal may experience once the anaesthesia wears off.
- 12.** The licence holder must use analgesia or another appropriate method to ensure that the pain, suffering and distress caused by regulated procedures are kept to a minimum.
- 13.** It is the responsibility of the personal licence holder to notify the project licence holder as soon as possible when it appears either that the severity limit of any procedure listed in the project licence or that the constraints upon adverse effects described in the project licence have been or are likely to be exceeded.
- 14.** The licence holder shall ensure that suitable arrangements exist for the care and welfare of animals during any period when the personal licence holder is not in attendance.
- 15.** The licence holder shall ensure that, whenever necessary, veterinary advice and treatment are obtained for the animals in his or her care.
- 16.** The licence holder shall ensure that all cages, pens or other enclosures are clearly labelled. The labelling must be such as to enable Inspectors, named veterinary surgeons and named animal care and welfare officers to identify the number of the project licence authorising the procedures, the project licence protocol in which the animals are being used, the date the protocol was started, and the responsible personal licence holder.
- 17.** In order to ensure that regulated procedures are performed competently, the licence holder shall not apply regulated procedures unless given the appropriate level of supervision by the project licence holder or an experienced personal licence holder deputed by him/her for such time as may be needed to achieve competence.
- 18.** The licence holder is authorised to delegate to assistants, who do not themselves possess the requisite personal licence authority but are under his or her control, the delegable tasks which form an integral part of the regulated procedures the licence holder is authorised to perform by this licence. The tasks must not require technical knowledge or skill, and delegation shall be in accordance with any relevant guidance published by the Secretary of State under section 21.
- 19.** The licence holder must take all reasonable steps to ensure appropriate personal and project licence authorities exist before performing regulated procedures. The licence holder must be aware of the nature of the authorities given by this licence and the project licence, and of the conditions of issue attached to the licences.
- 20.** The licence holder shall maintain a record of all animals on which procedures have been carried out, including details of supervision and declarations of competence by the project licence holder as appropriate. This record shall be retained for at least five years and shall, on request, be submitted to the Secretary of State or made available to an Inspector.
- 21.** The licence holder must give any necessary assistance to inspectors carrying out visits by virtue of section 18(2A)(b) ; and to experts of the European Commission carrying out duties under Article 35 of the Animals Directive.
- 22.** The licence remains the property of the Secretary of State, and shall be surrendered to him on request.

PART 4

Conditions in project licences

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

unless this is already explicitly authorised by the project licence.

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