

Status: Point in time view as at 01/01/2013.

Changes to legislation: There are currently no known outstanding effects for the Animals (Scientific Procedures) Act 1986, SCHEDULE 2C. (See end of Document for details)

SCHEDULES

[^{F1}SCHEDULE 2C

Section 10(1)

CONDITIONS IN LICENCES

Textual Amendments

- F1** Sch. 2C inserted (1.1.2013) by [The Animals \(Scientific Procedures\) Act 1986 Amendment Regulations 2012 \(S.I. 2012/3039\)](#), regs. 1(2), 10(2), **Sch. 2** (with Sch. 3)

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—

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- (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.

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- (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;

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- (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;

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- (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;

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- (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—

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- (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.

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- (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

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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.]

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