

*Draft Regulations laid before Parliament under paragraph 2(2) of Schedule 2 to the European Communities Act 1972, for approval by resolution of each House of Parliament.*

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DRAFT STATUTORY INSTRUMENTS

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**1998 No.**

**ANIMALS**

**Animals (Scientific Procedures) Act  
1986 (Amendment) Regulations 1998**

<i>Made</i>	- - - -	<i>1998</i>
<i>Coming into force</i>	- -	<i>1998</i>

The Secretary of State, being a Minister designated<sup>(1)</sup> for the purposes of section 2(2) of the European Communities Act 1972<sup>(2)</sup> in relation to measures relating to the protection of animals used for experimental and other scientific purposes, in exercise of the powers conferred on him by that section, hereby makes the following Regulations, a draft of which has been approved by a resolution of each House of Parliament:

**Citation and commencement**

1. These Regulations may be cited as the Animals (Scientific Procedures) Act 1986 (Amendment) Regulations 1998 and shall come into force 28 days after the day on which they are made.

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

2. The amendments made by the Schedule to these Regulations shall have effect.

Home Office  
1998

One of Her Majesty's Principal Secretaries of  
State

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(1) S.I.1993/595.  
(2) 1972 c. 68.

## SCHEDULE

Regulation 2

## AMENDMENTS TO THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

1. The Animals (Scientific Procedures) Act 1986<sup>(3)</sup> shall be amended as follows.
2. In section 4 (personal licences), after subsection (4) there shall be inserted—
  - “(4A) The Secretary of State shall not grant a personal licence to a person unless he is satisfied that the person—
    - (a) has appropriate education and training (including instruction in a relevant scientific discipline) for the purpose of applying the regulated procedures to be specified in the licence; and
    - (b) is competent to apply those procedures in accordance with the conditions which are to be included in the licence and to handle and take care of laboratory animals.”.
3. In section 5 (project licences), for subsection (5) there shall be substituted—
  - “(5) The Secretary of State shall not grant a project licence unless he is satisfied—
    - (a) that the purpose of the programme to be specified in the licence cannot be achieved satisfactorily by any other reasonably practicable method not entailing the use of protected animals; and
    - (b) that the regulated procedures to be used are those which use the minimum number of animals, involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm, and are most likely to produce satisfactory results.”.
- 4.—(1) Section 10 (conditions) shall be amended as follows.
  - (2) After subsection (2) there shall be inserted—
    - “(2A) Without prejudice to subsection (2)(a) above, the conditions of a personal licence shall include such conditions as the Secretary of State considers appropriate to ensure that the authorised procedures are carried out in accordance with Article 8 of Council Directive No.86/609/EEC<sup>(4)</sup>, the text of which is set out in Schedule 2A to this Act.”.
  - (3) In subsection (3)—
    - (a) after paragraph (c)<sup>(5)</sup> there shall be inserted—
      - “and
      - (d) that no protected animal taken from the wild shall be used under the licence;”;
    - (b) after the words “paragraph (a)” there shall be inserted the words “or (d)”.
  - (4) After subsection (3A)<sup>(6)</sup> there shall be inserted—
    - “(3B) Where a project licence authorises the setting free of a protected animal in the course of a series of regulated procedures, that licence shall include a condition requiring the prior consent of the Secretary of State to the setting free of the animal.
    - (3C) The Secretary of State shall not give his consent to the setting free of an animal in pursuance of a condition included in a project licence under subsection (3B) above unless he is satisfied—

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(3) 1986 c. 14.

(4) OJ No. L358, 18.12.86, p.1.

(5) Sub-paragraph (c) was inserted by S.I. 1993/2102.

(6) Subsection (3A) was inserted by S.I. 1993/2102.

- (a) that the maximum possible care has been taken to safeguard the animal's well-being;
  - (b) that the animal's state of health allows it to be set free; and
  - (c) that the setting free of the animal poses no danger to public health or the environment.
- (3D) The conditions of a project licence shall include such conditions as the Secretary of State considers appropriate to ensure—
- (a) that where a protected animal has been subjected to a series of regulated procedures for a particular purpose, at the conclusion of the series a veterinary surgeon or, if none is available, another suitably qualified person determines whether the animal should be killed or kept alive;
  - (b) that, if that person considers that it is likely to remain in lasting pain or distress, the animal is killed by a method appropriate to the animal under Schedule 1 to this Act, or by such other method as may be authorised by the personal licence of the person by whom the animal is killed; and
  - (c) that where the animal is to be kept alive, it is kept at a designated establishment (subject to subsection (6D) below).”.
- (5) After subsection (5) there shall be inserted—
- “(5A) The conditions of a certificate issued under section 6 above shall include such conditions as the Secretary of State considers appropriate to ensure—
- (a) that sufficient trained staff are provided at the establishment; and
  - (b) that the persons who take care of protected animals at the establishment and those who supervise such persons have appropriate education and training.”.
- (6) After subsection (6), there shall be inserted—
- “(6A) The conditions of a certificate issued under section 6 or 7 above shall, if the certificate permits dogs, cats or primates to be kept or bred at the establishment in question, include conditions requiring the holder of the certificate to ensure—
- (a) that particulars of the identity and origin of each dog, cat or primate kept or bred at the establishment are entered in the records referred to in subsection (6)(b) above;
  - (b) that before it is weaned, every dog, cat or primate in the establishment not falling within paragraph (c) below is provided with an individual identification mark in the least painful manner possible;
  - (c) that where a dog, cat or primate is transferred from one establishment to another before it is weaned and it is not practicable to mark it beforehand, the records kept by the establishment receiving the animal identify that animal's mother until the animal is provided with an individual identification mark; and
  - (d) that any unmarked dog, cat or primate which is taken into the establishment after being weaned is provided as soon as possible thereafter with an individual identification mark.
- (6B) The conditions of a certificate issued under section 6 or 7 above shall include such conditions relating to the general care and accommodation of protected animals bred, kept or used at the establishment as the Secretary of State considers appropriate in order to ensure—
- (a) that the environment, housing, freedom of movement, food, water and care provided for each such animal are appropriate for the animal's health and well-being;

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

(6C) When considering what conditions are appropriate to ensure the matters specified in subsection (6B)(a) and (b) above, the Secretary of State shall have regard to the guidance in Annex II to Council Directive No. [86/609/EEC](#).

(6D) The conditions of a certificate issued under section 6 or 7 above shall include such conditions as the Secretary of State considers appropriate to ensure that any animal kept alive after being subjected to a series of regulated procedures will continue to be kept at the establishment under the supervision of a veterinary surgeon or other suitably qualified person unless it is moved to another designated establishment or a veterinary surgeon certifies that it will not suffer if it ceases to be kept at a designated establishment.”.

5. For section 14 (re-use of protected animals) there shall be substituted—

**“14 Re-use of protected animals**

(1) Where—

- (a) a protected animal has been subjected to a series of regulated procedures for a particular purpose; and
- (b) any of those procedures has caused severe pain or distress to that animal,

that animal shall not be used for any further regulated procedures which will entail severe pain or distress.

(2) Where a protected animal has been subjected to a series of regulated procedures for a particular purpose and has been given a general anaesthetic for any of those procedures and been allowed to recover consciousness, that animal shall not be used for any further regulated procedures unless the Secretary of State has given his consent to such further use and—

- (a) the procedure, or each procedure, for which the anaesthetic was given consisted only of surgical preparation essential for a subsequent procedure; or
- (b) the anaesthetic was administered solely to immobilise the animal; or
- (c) the animal will be under general anaesthesia throughout the further procedures and will not be allowed to recover consciousness.

(3) Without prejudice to subsections (1) and (2) above, where a protected animal has been subjected to a series of regulated procedures for a particular purpose it shall not be used for any further regulated procedures except with the consent of the Secretary of State.

(4) Any consent for the purposes of this section may relate to a specified animal or to animals used in specified procedures or specified circumstances.”.

6. After Schedule 2 there shall be inserted the following Schedule—

“SCHEDULE 2A

Section 10(2A).

ARTICLE 8 OF COUNCIL DIRECTIVE No. 86/609/EEC

1. All experiments shall be carried out under general or local anaesthesia.
2. Paragraph 1 above does not apply when:
  - (a) anaesthesia is judged to be more traumatic to the animal than the experiment itself;
  - (b) anaesthesia is incompatible with the object of the experiment. In such cases appropriate legislative and/or administrative measures shall be taken to ensure that no such experiment is carried out unnecessarily.

Anaesthesia should be used in the case of serious injuries which may cause severe pain.

3. If anaesthesia is not possible, analgesics or other appropriate methods should be used in order to ensure as far as possible that pain, suffering, distress or harm are limited and that in any event the animal is not subject to severe pain, distress or suffering.

4. Provided such action is compatible with the object of the experiment, an anaesthetised animal, which suffers considerable pain once anaesthesia has worn off, shall be treated in good time with pain-relieving means or, if this is not possible, shall be immediately killed by a humane method.”

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**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

The Schedule to these Regulations amends the Animals (Scientific Procedures) Act 1986 in order to give effect to certain community obligations arising under Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ No. L358, 18.12.86, p.1).

Article 5 of the Directive imposes requirements with respect to the general care and accommodation of animals used for scientific procedures. Subsections (6B) and (6C) are added to section 10 of the Act to require certificates designating scientific procedure, breeding and supplying establishments to contain conditions ensuring that those requirements are met.

Article 7(1) of the Directive requires that scientific procedures are performed solely by competent persons; Article 14 imposes requirements as to the education and training of those who carry out experiments or take care of animals used for scientific procedures; and Article 19(2)(b) requires that sufficient trained staff are provided in scientific procedure establishments. These requirements are implemented by a new section 4(4A) as respects personal licence holders and a new section 10(5A) as respects designated establishments.

Article 7(2) and (3) of the Directive sets out criteria to be applied in considering whether to permit experiments to be carried out, and imposes a restriction on the use of animals taken from the wild. A new section 5(5) is substituted to reflect those criteria, and a new section 10(3)(d) imposes that restriction.

Article 8 of the Directive imposes requirements as to the use of anaesthesia in scientific procedures. A new section 10(2A) requires personal licences to contain conditions appropriate to ensure that the requirements of that article, the text of which is set out in a new Schedule 2A to the Act, are fulfilled.

Article 9 of the Directive deals with the treatment of animals at the end of scientific procedures. A new section 10(3D) requires project licences to include conditions requiring a decision to be taken as to whether an animal should be kept alive and a new section 10(6D) requires an animal which is kept alive to be kept at a designated establishment unless it would not otherwise suffer.

Article 10 of the Directive imposes restrictions on the re-use of animals in regulated procedures. A new section 14 prohibits the grant of consent to the use of an animal more than once in procedures which entail severe pain, distress or equivalent suffering.

Article 11 of the Directive permits animals to be set free in certain circumstances, and this is implemented by a new section 10(3B) and (3C).

Article 18 imposes requirements in respect of the marking of animals which are implemented by a new section 10(6A).