

# **S.I. No. 17/1994 — European Communities (Amendment of Cruelty To Animals Act 1876) Regulations, 1994.**

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The Minister for Health, in exercise of the powers conferred on him by section 3 of the European Communities Act, 1972 (No. 27 of 1972), for the purpose of giving full effect to the Council Directive No. 86/609/EEC<sup>(1)</sup> of 24 November, 1986 on the Protection of Animals used for experimental and other Scientific Purposes hereby makes the following Regulations:—

1. These Regulations may be cited as the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations, 1994.

2. The Cruelty to Animals Act 1876, 39 & 40 Vict., Ch. 77, 1876 is hereby amended by the insertion after section 12 of the following section:

"12A. In particular, the following provisions shall be observed in relation to experiments provided for under this Act:

(1) Experiments using animals considered as endangered under Appendix 1 of the convention on International Trade in Endangered Species of Flora and Fauna and C.1. of Regulation (EEC) No. 3626 82 (1)<sup>(2)</sup> are prohibited unless they are in conformity with the above Regulations and the objectives of the experiment are—

— research aimed at the preservation of the species in question, or

— essential biomedical purposes where the species in question exceptionally proves to be the only one suitable for those purposes.

(2) An experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available.

(1)OJ No. L358, 18/12/86p. 1-6.

(2)OJ No. L384, 31/12/82p. 1.

(3) Where an experiment has to be performed, the choice of species shall be carefully considered and, where necessary, explained to the Minister for Health. In a choice between experiments, 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 which are most likely to provide satisfactory results shall be selected.

(4) As far as the general care and accommodation of animals is concerned:—

(i) All experimental animals shall be provided with housing, an environment, at least some freedom of movement, food, water and care which are appropriate to their health and well-being.

(ii) Any restriction on the extent to which an experimental animal can satisfy its physiological and ethological needs shall be limited to the absolute minimum.

(iii) The environmental conditions in which experimental animals are bred, kept or used must be checked daily.

(iv) The well-being and state of health of experimental animals shall be observed by a competent person to prevent pain or avoidable suffering, distress or lasting harm.

(v) Arrangements shall be made to ensure that any defect or suffering discovered is eliminated as quickly as possible.

(5) (i) Experiments shall be performed solely by competent authorised persons, or under the direct responsibility of such a person, or if the experimental or other scientific project concerned is authorised in accordance with the provisions of the Act.

(ii) An experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available.

(iii) When an experiment has to be performed the choice of species shall be carefully considered and where necessary, explained to the Minister for Health. In a choice between experiments, 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 which are most likely to provide satisfactory results shall be selected.

(iv) Experiments on animals taken from the wild may not be carried out unless experiments on other animals would not suffice for the aims of the experiment.

(v) All experiments shall be designed to avoid distress and unnecessary pain and suffering to the experimental animals. They shall be subject to the provisions laid down in section 6. The measures set out in section 7 shall be taken in all cases.

(6) (i) All experiments shall be carried out under general or local anaesthesia.

(ii) subsection (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.

(iii) 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.

(iv) 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 immediately be killed by a humane method.

(7) (i) At the end of any experiment, it shall be decided whether the animal shall be kept alive or killed by a humane method, subject to the condition that it shall not be kept alive if, even though it has been restored to normal health in all other respects, it is likely to remain in lasting pain or distress.

(ii) The decisions referred to in subsection (1) shall be taken by a competent person, preferably a veterinarian.

(iii) Where at the end of the experiment:

( a ) an animal is to be kept alive, it shall receive care appropriate to its state of health, be placed under the supervision of a veterinarian or other competent person and shall be kept under conditions conforming to the requirements of section 4. The conditions laid down in this section may, however, be waived where, in the opinion of a veterinarian, the animal would not suffer as a consequence of such exemption;

( b ) an animal is not to be kept alive or cannot benefit from the provisions of section 4 concerning its well-being, it shall be killed by a humane method as soon as possible.

(8) (i) Any re-use of animals in experiments shall be compatible with the provisions of these regulations.

(ii) In particular, an animal shall not be used more than once in experiments entailing severe pain, distress or equivalent suffering.

(9) Notwithstanding the other provisions of these regulations where it is necessary for the legitimate purposes of the experiment, the animal concerned may be set free, provided that the maximum possible care has been taken to safeguard the animal's well-being, as long as its state of health allows this to be done and there is no danger for public health and the environment.

(10) (i) The Minister shall establish procedures whereby experiments themselves or the details of persons conducting such experiments shall be notified in advance to the authority.

(ii) Where it is planned to subject the animal to an experiment in which it will or may experience severe pain which is likely to be prolonged, that experiment must be specifically declared and justified to, or specifically authorised by, the Minister for Health. The Minister shall take appropriate judicial or administrative action if he is not satisfied that the experiment is of sufficient importance for meeting the essential needs of man or animal.

(11) (i) On the basis of requests for authorisation and notifications received, and on the basis of the reports made, the Minister shall collect, and as far as possible make publicly available, the statistical information on the use of animals in experiments in respect of:

( a ) the number and kind of animals used in experiments;

( b ) the number of animals, in selected categories, used in the experiments referred to in Section 3 of the Act.

( c ) the number of animals, in selected categories used in experiments required by legislation.

(ii) The Minister shall take all the necessary steps to ensure that the confidentiality or commercially sensitive information communicated pursuant to these regulations is protected.

(12) Persons who carry out experiments or take part in them and persons who take care of animals used for experiments, including duties of a supervisory nature, shall have appropriate education and training.

In particular, persons carrying out or supervising the conduct of experiments shall have received instruction in a scientific discipline relevant to the experimental work being undertaken and be capable of handling and taking care of laboratory animals; they shall also have satisfied the Minister that they have attained a level of training sufficient for carrying out their tasks.

(13) Breeding and supplying establishments shall be approved by or registered with the Minister and comply with the requirements of section 4 and 12 unless an exemption is granted under section 15 (iv) or section 17. A supplying establishment shall obtain animals only from a breeding or other supplying establishment unless the animal has

been lawfully imported and is not a feral or stray animal. General or special exemption from this last provision may be granted to a supplying establishment under arrangements determined by the Minister.

The approval or the registration provided for shall specify the competent person responsible for the establishment entrusted with the task of administering, or arranging for the administration of, appropriate care of the animals bred or kept in the establishment and of ensuring compliance with the requirements of section 4 and 12.

(14) (i) Breeding and supplying establishments shall record the number and the species of animals sold or supplied, the dates on which they are sold or supplied, the name and address of the recipient and the number and species of animals dying while in the breeding or supplying establishment in question.

(ii) The Minister shall prescribe the records which are to be kept and made available to authorised representatives of the Minister by the person responsible for the establishments mentioned in subsection (i); such records shall be kept for a minimum of three years from the date of the last entry and shall undergo periodic inspection by authorised representatives of the Minister.

(iii) Each dog, cat or non-human primate in any breeding, supplying establishment shall, before it is weaned, be provided with an individual identification mark in the least painful manner possible except in the cases referred to in subsection (v).

(iv) Where an unmarked dog, cat or non-human primate is taken into an establishment for the first time after it has been weaned it shall be marked as soon as possible.

(v) Where a dog, cat or non-human primate is transferred from one establishment as referred to in subsection (iii) to another before it is weaned, and it is not practicable to mark it beforehand, a full documentary record, specifying in particular its mother, must be maintained by the receiving establishment until it can be so marked.

(vi) Particulars of the identity and origin of each dog, cat or non-human primate shall be entered in the records of each establishment.

(15) (i) User establishments shall be registered with, or approved by, the Minister. Arrangements shall be made for user establishments to have installations and equipment suited to the species of animal used and the performance of the experiments conducted there; their design, construction and method of functioning shall be such as to ensure that the experiments are performed as effectively as possible, with the object of obtaining consistent results with the minimum number of animals and the minimum degree of pain, suffering, distress or lasting harm.

(ii) In each user establishment:

( a ) the person or persons who are administratively responsible for the care of the animals and the functioning of the equipment shall be identified;

( *b* ) sufficient trained staff shall be provided;

( *c* ) adequate arrangements shall be made for the provision of veterinary advice and treatment;

( *d* ) a veterinarian or other competent person should be charged with advisory duties in relation to the well-being of the animals.

(iii) Experiments may, where authorised by the Minister, be conducted, outside user establishments.

(iv) In user establishments, only animals from breeding or supplying establishments shall be used unless a general or special exemption has been obtained under arrangements determined by the Minister. Bred animals shall be used whenever possible. Stray animals of domestic species shall not be used in experiments. A general exemption made under the conditions of this subsection may not extend to stray dogs and cats.

(v) User establishments shall keep records of all animals used and produce them whenever required to do so by the Minister. In particular, these records shall show the number and species of all animals acquired, from whom they were acquired and the date of their arrival. Such records shall be kept for a minimum of three years and shall be submitted to the authorised persons who asks for them. User establishments shall be subject to periodic inspection by representatives of the Minister.

(16) When user establishments breed animals for use in experiments on their own premises, only one registration or approval is needed for the purposes of section 14 or 15. However, the establishments shall comply with the relevant provisions of these regulations concerning breeding and user establishments.

(17) Animals belonging to the species listed in section 20 which are to be used in experiments shall be bred animals unless a general or special exemption has been obtained under arrangements determined by the Minister.

(18) (i) In order to avoid unnecessary duplication of experiments for the purpose of satisfying national or Community health and safety legislation, the Minister shall as far as possible recognise the validity of data generated by experiments carried out in the territory of another EC country unless further testing is necessary in order to protect public health and safety.

(ii) To this end, the Minister shall, where practicable and without prejudice to the requirements of existing Community Directives, furnish information to the Commission on national legislation and administrative practices relating to animal experiments, including requirements to be satisfied prior to the marketing of products; the Minister shall also supply factual information on experiments carried out in the national territory and on authorisations or any other administrative particulars pertaining to these experiments.

(19) The Minister will encourage research into the development and validation of

alternative techniques which could provide the same level of information as that obtained in experiments using animals but which involve fewer animals or which entail less painful procedures and shall take such other steps as he considers appropriate to encourage research in this field. The Minister shall monitor trends in experimental methods.

(20) List of animals belonging to the species referred to in section 17.

— Mouse	— <i>Mus musculus</i>
— Rat	— <i>Rattus norvegicus</i>
— Guinea Pig	— <i>Cavia porcellus</i>
— Golden Hamster	— <i>Mesocricetus auratus</i>
— Rabbit	— <i>Oryctolagus cuniculus</i>
— Non-human primates	
— Dog	— <i>Canis familiaris</i>
— Cat	— <i>Felis catus</i>
— Quail	— <i>Coturnix coturnix</i> "

GIVEN under the Official Seal of the Minister for Health, this 1st day of February,  
1994.

BRENDAN HOWLIN,

Minister for Health.

#### EXPLANATORY NOTE.

These Regulations implement EEC Directive No. 86/609. They amend The Cruelty to Animals Act, 1876 which deals with the prohibition of painful experiments on living animals except subject to restrictions imposed by the Act.