

S.I. No. 566/2002 — European Communities (Amendment of Cruelty To Animals Act 1876) Regulations 2002

STATUTORY INSTRUMENT

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DUBLIN

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The Minister for Health and Children, in exercise of powers conferred on him by section 3 of the European Communities Act 1972 (No. 27 of 1972), as amended by the European Communities (Amendment) Act 1993 (No. 25 of 1993), and for the purpose of giving full effect to the Council Directive No. 86/609/EEC of 24 November 1986 hereby makes the following regulations:

- 1.—These Regulations may be cited as the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2002.
- 2.—The Cruelty to Animals Act 1876, 39 & 40 Vict., Ch.77, 1876, as amended by the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 1994, is further amended as follows:
 - (a) by striking out every reference to “calculated to inflict pain” or “calculated to give pain”;
 - (b) by inserting the following after section 1:

“Interpretation.

1A.—(1) In this Act, unless the context otherwise requires—

‘animal’ means any live non-human vertebrate, including free-living larval and reproducing larval forms but excluding fetal or embryonic forms;

‘Authority’ has the meaning given by subsection (3) of this section;

‘bred animal’ means any animal specially bred for use in experiments in an establishment registered under this Act;

‘breeding establishment’ means any establishment where an animal is bred with a view to its use in an experiment;

‘Directive’ means Council Directive No. 86/609/EEC of 24 November 1986 on the Protection of Animals used for Experimental and other Scientific Purposes;

‘endangered animal’ means an animal considered as endangered under Appendix 1 of the Convention on International Trade in Endangered Species of Fauna and Flora and Annex C.I. of Regulation (EEC) No. 3626/82 (1);

‘establishment’ means any installation, building, group of buildings or other premises, including—

(a) a place that is not wholly enclosed or covered, and

(b) a mobile facility;

‘experiment’ means any use or re-use of an animal for experimental or other scientific purposes that may cause it pain, suffering, distress or lasting harm, including any course of action intended, or liable, to result in the birth of an animal in any such condition, but excluding—

(a) the least painful methods accepted in modern practice (humane methods) of killing or marking an animal, and

- (b) non-experimental, agricultural or clinical veterinary practices;

‘experimental animal’ means an animal used or to be used in experiments;

‘farm animal’ means any animal (including fish, reptiles and amphibians) bred or kept for draught or sport purposes or for the production of food, hide, feathers or fur, but does not include any species listed in section 2(3);

‘humane method’, in relation to the killing of an animal, means the killing of the animal with the minimum of physical and mental suffering, depending on the species;

‘inspector’ means a person who holds an appointment as, or is assigned the duties of, an inspector or special inspector under section 10;

‘licensee’ means a person who holds a valid licence granted under this Act;

‘mobile facility’ includes—

- (a) a ship or other vessel,
- (b) a railway wagon or any other vehicle, and
- (c) a container;

‘operator’, in relation to a breeding establishment, supplying establishment or user establishment means—

- (a) the owner, manager or other person in charge of the establishment, or
- (b) any person purporting to act in the capacity of a person referred to in paragraph (a);

‘properly anaesthetised’ means deprived of sensation by methods of anaesthesia as effective as those used in good veterinary practice;

‘registered establishment’ means any establishment registered under this Act, whether as a breeding establishment, supplying establishment or user establishment or as one or more of those establishments, and includes an establishment that was so registered before the day on which this definition came into operation;

‘supplying establishment’ means any establishment, other than a breeding establishment, from which animals are supplied with a view to their use in experiments;

‘suitably qualified person’ means a person qualified to provide advice or treatment, or both, relating to the health and welfare of experimental animals;

‘user establishment’ means any establishment where animals are used for experiments;

‘veterinary surgeon’ means a person who is registered in the register established under the Veterinary Surgeons Act 1931 .

(2) For the purposes of this Act—

- (a) an experiment starts when an animal is first prepared for use in the experiment and ends when no further observations are to be made for that experiment, and
- (b) the elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia or analgesia or other methods does not place an animal outside the scope of the definition of ‘experiment’.

(3) The Minister for Health and Children, being the successor to the minister to whom the functions of the Minister for Justice in respect of this Act as the successor to the Chief Secretary to the Lord Lieutenant of Ireland were transferred by Statutory Instrument No. 138 of 1950 , is designated as the Authority for the purposes of the Directive and this Act, and a reference in this Act to ‘the Authority’ or the ‘Secretary of

State' is to be read as a reference to the Minister for Health and Children.

(4) A word or expression that is used both in this Act and in the Directive has, unless the context otherwise requires, the same meaning in this Act as it has in the Directive.

(5) In this Act—

(a) a reference to a section is to a section of this Act unless it is indicated that a reference to some other enactment is intended,

(b) a reference to a subsection or paragraph is to a subsection or paragraph of the provision in which the reference occurs unless it is indicated that a reference to some other provision is intended, and

(c) a reference to a certificate is to a certificate in the applicable form set out in the Schedule to this Act.”;

(c) by substituting the following for sections 2 and 3:

“Restrictions on use of animals in experiments.

2.— (1) A person shall not perform an experiment except subject to the restrictions imposed by this Act.

(2) The following restrictions apply:

(a) an experiment shall not be performed except for one of the following purposes:

(i) the development, manufacture, quality, effectiveness and safety testing of drugs, foodstuffs and other substances or products for—

(A) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants, or

(B) the assessment, detection, regulation or

modification of physiological conditions in human beings, animals or plants;

(ii) the protection of the natural environment in the interests of the health or welfare of human beings or animals;

(iii) the illustration of lectures in medical schools, hospitals, colleges or elsewhere;

(b) 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;

(c) an experiment shall not be performed on an animal taken from the wild unless experiments on other animals would not suffice for the aims of the experiment;

(d) an experiment shall not be performed on an animal belonging to a species listed in subsection (3) unless the animal is a bred animal;

(e) when an experiment has to be performed, the person proposing to perform the experiment shall carefully consider the choice of species and, in the application for a licence to perform the experiment, explain the choice to the Authority;

(f) in a choice between experiments, the ones selected shall be those that—

(i) use the minimum number of animals,

(ii) involve animals with the lowest degree of neurophysiological sensitivity,

(iii) cause the least pain, suffering, distress or lasting harm, and

(iv) are most likely to provide satisfactory results;

- (g) an experiment shall not be performed except—
 - (i) by a person who holds a valid licence granted under section 8 authorizing the licensee to perform the specified experiment on an animal of the specified description in accordance with the restrictions imposed by this Act or, if specifically authorised by the licence, by a person under the supervision and direct responsibility of such licensee, and
 - (ii) at a place that is specified on the licence and is registered under section 7 as a user establishment or, if specifically authorized by the licence, elsewhere than in a user establishment;
- (h) an experiment shall not be performed as an illustration of a lecture in a medical school, hospital, college or elsewhere unless a certificate (Certificate C) has been given in advance under this Act certifying that the proposed experiment is absolutely necessary for instructing those to whom the lecture is to be given with a view to their acquiring physiological knowledge or knowledge that will be useful to them for saving or prolonging life or alleviating suffering;
- (i) experiments shall be designed to avoid distress and unnecessary pain and suffering to experimental animals;
- (j) an animal shall not be subjected to an experiment in which it will or may experience severe pain that is likely to be prolonged unless a certificate (Certificate G) has been given in advance under this Act certifying that the proposed experiment is of sufficient importance for meeting the essential needs of human beings or animals;
- (k) subject to subsection (4) and section 5, experiments shall be performed only when the animal is properly anaesthetised by means of—
 - (i) a general anaesthetic, or
 - (i) if a certificate has been given in advance, a local anaesthetic;

- (l) at the end of any experiment, a veterinary surgeon or other suitably qualified person shall, subject to subsections (7) to (9), decide whether the animal shall be kept alive or killed by a humane method;

 - (m) an animal that is to be kept alive shall, subject to subsection (12)—
 - (i) receive the care appropriate to its state of health,

 - (ii) be placed under the supervision of a veterinary surgeon or other suitably qualified person, and

 - (iii) be kept under conditions conforming to the requirements of section 5A;

 - (n) an animal that is not to be kept alive or that cannot benefit from the provisions of section 5A shall be killed by a humane method as soon as possible;

 - (o) an animal shall not be used more than once in experiments entailing severe pain, distress or equivalent suffering.
- (3) For the purposes of subsection (2)(d), the following species are listed:
- (a) mouse (*mus musculus*);

 - (b) rat (*rattus norvegicus*);

 - (c) guinea pig (*cavia porcellus*);

 - (d) golden hamster (*mesocricetus auratus*);

 - (e) rabbit (*oryctolagus cuniculus*);

 - (f) non-human primates;

(g) dog (*canis familiaris*);

(h) cat (*felix catus*);

(i) quail (*coturnix coturnix*).

(4) Subject to subsection (6) the requirement of subsection (2)(k) that an experiment be performed under anaesthesia does not apply when—

(a) a certificate has been given in advance under this Act certifying that anaesthesia is considered to be more traumatic to the animal than the experiment itself, or

(b) anaesthesia is incompatible with the object of the experiment and the required certificate or certificates have been given in advance under this Act certifying that insensibility cannot be produced without necessarily frustrating the object of the proposed experiment.

(5) For the purposes of subsection (2)(k)(ii), subsection (4) and section 5,

(a) Certificate A is the required certificate for any species of animal, and

(b) in addition to that certificate, Certificate E is required for the purposes of section 5 if the animal is a dog or cat.

(6) Anaesthesia should be used in the case of serious injuries that may cause severe pain.

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

(8) If the pain is likely to continue after the anaesthesia has worn off or if any serious injury has been inflicted on the animal, the animal shall be killed before it recovers from the influence of the anaesthesia.

(9) Subsection (8) does not apply if—

- (a) the required certificate or certificates have been given in advance under this Act certifying that killing the animal before it recovers from the influence of the anaesthesia would necessarily frustrate the object of the proposed experiment, and
- (b) the animal is killed as soon as the object of the experiment is attained.

(10) For the purposes of subsection (9)—

- (a) Certificate B is the required certificate for any species of animal, and
- (b) in addition to that certificate, Certificate EE is required if the animal is a dog or cat.

(11) If such action is compatible with the object of the experiment, an anaesthetized animal that suffers considerable pain once anaesthesia has worn off —

- (a) shall be treated in good time with pain relieving means, or
- (b) where this is not possible, shall be immediately killed by a humane method.

(12) Subsection (2)(m) does not apply if, in the opinion of a veterinary surgeon, the animal would not suffer as a result of the exemption.

(13) Notwithstanding any other provision of this Act, where a certificate (Certificate D) has been given in advance under this Act to a licensee certifying that the setting free of the animal is necessary for the legitimate purposes of a proposed experiment, the licensee may set the animal free but only if an inspector is satisfied that —

- (a) the licensee has taken the maximum possible care to safeguard the animal's well-being,
- (b) the animal's state of health allows it to be set free, and
- (c) the setting free of the animal poses no danger to public health or the environment.

- (14) For the purposes of section 5, Certificate F is the required certificate for an experiment on a horse, ass or mule.

Experiments on endangered animals.

3.— Notwithstanding any other provision of this Act, a person shall not perform an experiment using an endangered animal unless the experiment conforms with Regulation (EEC) No. 3626/82 (1) and the object of the experiment is—

- (a) research aimed at preserving the species in question, or
- (b) essential biomedical purposes where the species in question exceptionally proves to be the only one suitable for those purposes.”;
- (d) in section 5 by substituting “Subject to section 2(6) but notwithstanding any other provision of this Act,” for “Notwithstanding anything in this Act contained,”;
- (e) by inserting the following after section 5:

“General requirements about care and accommodation of experimental animals.

5A.— (1) The operator of each registered establishment and the person specified under section 7(5) in its registration shall ensure that the following general care and accommodation standards are met in the establishment:

- (a) all experimental animals shall be provided with housing, an environment, at least some freedom of movement, food water and care that are appropriate to their health and well being;
- (b) any restriction on the extent to which an experimental animal can satisfy its physiological and ethological needs shall be limited to the absolute minimum;
- (c) the environmental conditions in which experimental animals are bred, kept or housed shall be checked daily;

- (d) the well-being and state of health of experimental animals shall be observed by a veterinary surgeon or other suitably qualified person in order to prevent pain or avoidable suffering, distress or lasting harm;
 - (e) arrangements shall be made to ensure that any defect or suffering discovered is eliminated as quickly as possible.
- (2) Subsection (1) applies also to animals in the establishment that are used for breeding experimental animals.
- (3) Each person responsible for ensuring compliance with the requirements of subsection (1)(a) and (b) in relation to experimental animals or animals referred to in subsection (2) shall, for that purpose, pay regard to the guidelines set out in Annex II of the Directive.

Standards relating to dogs, cats and non-human primates.

5B.— The operator of each registered establishment and the person specified under section 7(5) in its registration shall ensure that the following standards are met in the establishment:

- (a) subject to paragraph (b), each dog, cat or non-human primate in the establishment shall be provided, before it is weaned, with an individual identification mark in the least painful manner possible;
- (b) if an unmarked dog, cat or non-human primate is transferred to the establishment from another establishment before the animal is weaned and it is not practicable to mark the animal beforehand, a full documentary record, specifying in particular its mother, shall be maintained by the receiving establishment until the transferred animal can be so marked;
- (c) if an unmarked dog, cat or non-human primate is taken into the establishment for the first time after it is weaned, it shall be provided as soon as possible with an individual identification mark in the manner described in paragraph (a);
- (d) particulars of the identity and origin of each dog, cat or non-human primate shall be entered in the record of the establishment.

Standards for user establishments.

5C.— (1) The operator of each user establishment shall ensure that the standards set out in subsections (2) to (5) are met in that establishment.

(2) In each user establishment—

- (a) sufficient trained staff shall be provided,
- (b) adequate arrangements shall be made for the provision of advice and treatment by a veterinary surgeon, and
- (c) a veterinary surgeon or other suitably qualified person shall be charged with advisory duties in relation to the well-being of the animals.

(3) Subject to section 2(2)(c) or a general exemption granted under section 8(5), only animals from breeding or supplying establishments shall be used for experiments in a user establishment.

(4) Subject to section 2(2)(d), bred animals shall be used in experiments wherever possible.

(5) Each user establishment shall—

- (a) keep records of all animals used in experiments, and in particular shall record the following information:
 - (i) the number and species of all animals acquired by the establishment;
 - (ii) the person or persons from whom the animals are acquired,
 - (iii) the date of their arrival at the establishment,
- (b) keep the records referred to in paragraph (a) and those required under section 5B(b) and (d) for not less than three years after the date on which the establishment first recorded the information, and

- (c) make the records referred to in paragraph (b) available to the Authority or an inspector at the request of either.

Standards for breeding and supplying establishments.

- 5D.—(1) The operator of each breeding establishment or supplying establishment shall ensure that the applicable standards set out in subsections (2) and (3) are met in that establishment.
- (2) A supplying establishment shall obtain animals only from a breeding establishment or another supplying establishment unless the animal—
 - (a) has been imported, and
 - (b) is not a feral or stray animal.
 - (3) Each breeding establishment and each supplying establishment shall —
 - (a) record the following information:
 - (i) the number and species of animals sold or supplied by the establishment;
 - (ii) the dates on which they are sold or supplied;
 - (iii) the name and address of the recipient;
 - (iv) the number and species of animals dying while in the establishment,
 - (b) keep the records referred to in paragraph (a) and those recorded under section 5B(b) and (d) for not less than three years after the date on which it first recorded the information, and
 - (c) make the records referred to in paragraph (b) available to the Authority or an inspector at the request of either.

Offences and penalties.

5E.—(1) A person is guilty of an offence if he or she —

- (a) performs or takes part in performing an experiment in contravention of section 2, 3 or 5,
- (b) provides in an application under this Act information that the person knows is false or misleading in a material respect,
- (c) forges a signature or other entry on a certificate, application or other document or record required under this Act,
- (d) intentionally obstructs, interferes with or impedes an inspector or a member of the Garda Síochána who is exercising a power conferred on the inspector or member by section 10 or by a warrant issued under that section,
- (e) fails or refuses to comply with a request or requirement of, or to answer a question asked by, an inspector or member of the Garda Síochána under section 10,
- (f) in purported compliance with such a request or requirement or in answer to such question, provides information that the person knows is false or misleading in a material respect, or
- (g) contravenes section 11A.

(2) A person is guilty of an offence if the person —

- (a) contravenes section 5A, 5B or 5C, or
- (b) operates a breeding establishment, supplying establishment or user establishment in contravention of section 7(1).

(3) Where an offence under subsection (2) is committed by a body corporate and is proved to have been so committed with the consent, connivance or approval of or to be attributable to any neglect on the part of a person who, at the relevant time, was a director, manager, secretary or other officer of the body corporate or was acting or purporting to act in any such capacity, that person, as well as the body corporate, is guilty of the offence.

(4) A person who is guilty of an offence under this section is liable on summary conviction to a fine not exceeding €2,000 or to imprisonment for a term not exceeding three months or, at the discretion of the court, to both such fine and such imprisonment.”;

(f) by substituting the following for section 7:

“Registry for breeding, supplying and user establishments.

7.—(1) Subject to subsection (12), a person shall not operate a breeding establishment, supplying establishment or user establishment unless the establishment is registered with the Authority.

(2) An application for the registration of a breeding establishment, supplying establishment or user establishment must—

(a) be made to the Authority in the form directed by the Authority,

(b) identify the person who is to be responsible—

(i) for the day-to-day care of the animals in the establishment and, in the case of a user establishment, for the functioning of the equipment, and

(ii) for ensuring compliance with the requirements of sections 5A and 5D that are applicable to the establishment, and

(c) be accompanied by the applicable fee set under section 8A.

(3) The applicant shall as a condition of registration satisfy the Authority that—

(a) in the case of a breeding, supplying or user establishment, the persons who are to take care of the animals or to supervise this task have the appropriate education and training, and

(a) in the case of a user establishment, the establishment has installations and equipment—

(i) that are suited to the species of animal to be used and

the experiments to be performed there, and

- (ii) whose design, construction and method of functioning will ensure that the experiment is performed as effectively as possible, with the object of obtaining results with the minimum number of animals and the minimum degree of pain, suffering or distress.
- (4) The Authority may require the applicant to supply any further information or documents that may reasonably be necessary for performing the Authority's functions under this Act.
- (5) Where an establishment is registered under this Act, the registration shall specify—
- (a) the person identified in accordance with subsection (2)(b), and
 - (b) the conditions subject to which the registration continues in force.
- (6) The operator of a registered establishment must promptly notify the Authority if the responsibilities of the person specified under subsection (5) in its registration are transferred to another person.
- (7) The registration of an establishment continues in force until suspended or revoked under subsection (8).
- (8) The Authority may, by notice served on the operator of a registered establishment, suspend or revoke its registration if—
- (a) the standards applicable under this Act to that establishment are not met, or
 - (b) it appears necessary for the welfare of the animals in the establishment to do so.
- (9) Subsection (8) applies whether the registration was granted before or after this section comes into operation.
- (10) Any registration granted under this Act must be in the form set out in the Schedule to this Act.
- (11) If, after considering an application under this section, the Authority decides to refuse to register an establishment, the Authority shall inform the applicant in writing of that decision and the reasons.

(12) Where a registered user establishment breeds animals for use in experiments on its own premises or supplies animals to other establishments with a view to their use in experiments, or does both of those things, the establishment need only be registered as a user establishment, but in every other respect that establishment shall be operated in compliance with the relevant provisions of this Act concerning—

(a) user establishments, and

(b) each type of establishment for which, but for this provision, registration would otherwise be required.”;

(g) by renumbering section 8 as section 8(1) and inserting the following:

“(2) Any person who proposes to perform an experiment on an animal shall make a written application in advance to the Authority for a licence authorizing the person to perform that experiment.

(3) The application must—

(a) be in the form directed by the Authority,

(b) be signed as required by section 11,

(c) specify whether, in addition to the licence, one or more certificates are required under this Act for the proposed experiment and specify the reason why each certificate is required,

(d) specify the user establishment where the experiment is to be performed,

(e) specify whether an authorisation or general exemption under subsection (5) is requested, and

(f) be accompanied by the applicable fee set under section 8A.

(4) The applicant shall, as a condition of the granting of the licence,

satisfy the Authority about the following:

(a) that the person who is to perform, or supervise the performance of, all or part of the experiment specified in the application —

(i) has the appropriate education and training (including instruction in a relevant scientific discipline) for the task,

(ii) is competent to perform the task in accordance with the conditions specified in the licence, and

(iii) has the appropriate competence to handle and take care of the experimental animals specified in the application;

(b) that the experiment is not prohibited by section 2, 3 or 5.

(5) If satisfied that the authorisation or exemption is requested in respect of farm animals, the Authority may, on granting a licence to the applicant—

(a) authorise the applicant to perform experiments elsewhere than in a user establishment as described in section 2(2)(g) (ii), or

(b) grant the applicant a general exemption from section 5C(3) allowing the use of farm animals in experiments performed by the applicant in a user establishment.

(6) The Authority may require the applicant to supply any further information or documents that may reasonably be necessary for performing the Authority's functions under this Act.

(7) Any licence granted under this Act must be in the form set out in the Schedule to this Act.

(8) If, after considering an application, the Authority decides to refuse to grant the applicant a licence, the Authority shall inform the applicant in writing of that decision and the reasons.”;

(h) by inserting the following after section 8:

“Fees and forms.

8A.— (1) The Authority may set fees to be paid by applicants, not exceeding the expense the Authority is likely to incur in considering applications, including the expense incurred in inspecting registered establishments.

(2) The Authority may, by regulation, amend or replace any form of certificate, licence or registration set out in the Schedule to this Act. ;

(i) in section 10 by substituting “registered establishments” for “registered places”, by renumbering section 10 as section 10(1) and by inserting the following:

“(2) A person is not eligible to be appointed as or assigned the duties of an inspector unless the person has the medical or veterinary qualifications that the Authority considers appropriate.

(3) An inspector shall—

(a) on being appointed, be provided with a warrant of appointment, and

(b) on being so requested while exercising a power conferred by this Act, produce the warrant for inspection by any person affected.

(4) An inspector has the following functions:

(a) to advise the Authority on applications under section 7 for the registration of establishments and on the suspension or revocation of registrations;

(b) to advise the Authority on—

(i) applications under section 8 for licences,

- (ii) the revocation of licences,
 - (iii) authorisations and exemptions under section 8(5),
and
 - (iv) the disallowance or suspension of certificates;
 - (c) to visit registered establishments at the intervals required under subsection (1) for the purpose of securing compliance with this Act;
 - (d) to visit establishments and other locations where experiments are performed for the purpose of determining whether—
 - (i) the experiments are authorised by the requisite licences and certificates issued under this Act,
 - (ii) the conditions of the licences have been and are being complied with, and
 - (iii) the conditions set out in paragraphs (a) to (c) of section 2(13) are being complied with by licensees given a certificate under this Act certifying that it is necessary for the legitimate purposes of a proposed experiment that an experimental animal be set free;
 - (e) to inspect periodically records required under this Act to be kept by registered establishments;
 - (f) to report to the Authority any case in which this Act, or any condition of a licence or certificate issued under this Act, has not been or is not being complied with and to advise the Authority on the action to be taken in that case.
- (5) An inspector who considers that an experimental animal is experiencing excessive pain or suffering may require that the animal be immediately killed by a humane method.
- (6) For the purposes of this Act, an inspector may do one or more of the following:

- (a) subject to subsection (8), enter at all reasonable times and where necessary by the use of reasonable force any establishment if the inspector has reasonable grounds for believing that—
 - (i) an experimental animal is at the establishment,
 - (ii) any trade, business or activity connected with the use of animals in experiments, or with the breeding or supply of animals with a view to their use in experiments, is being or has been carried on at the establishment,
 - (iii) records relating to such a trade, business or activity are located at the establishment;
- (b) at an establishment entered under this section, inspect and take copies of or of extracts from, any books and records referred to in paragraph (a)(iii);
- (c) remove any books or records referred to in paragraph (a)(iii) from the establishment and detain them for the period that the inspector reasonably considers necessary for performing his or her functions under this section;
- (d) carry out, or have carried out, the tests, examinations, inspections and checks of any of the following that the inspector reasonably considers necessary for performing his or her functions under this section:
 - (i) the establishment entered under this section;
 - (ii) any animal at that establishment;
 - (iii) any article, reagent or other substance at that establishment that is used in experiments or in the breeding or supply of animals with a view to their use in experiments;
 - (iv) any equipment or machinery at that

establishment;

(e) require any person at or employed at that establishment or the owner or person in charge of the establishment—

(i) to give the inspector any assistance and information,

(ii) to produce to the inspector any books or records in the person's power or procurement and, if those records are stored in non-legible form, to produce to the inspector a legible reproduction of them,

that the inspector may reasonably require for the purposes of performing the inspector's functions;

(f) if the inspector has reasonable grounds to believe that this Act has been contravened in relation to an animal at the establishment, direct that the animal not be removed from the establishment without the inspector's consent;

(g) for the period that the inspector reasonably considers necessary for the purposes of this Act, secure for later inspection all or part of any establishment in which is found or ordinarily kept any animal or any article, reagent or other substance that is used in experiments or in the breeding or supply of animals with a view to their use in experiments.

(7) When performing functions under this Act, an inspector may, subject to any warrant issued under subsection (9), be accompanied by the number of inspectors or members of the Garda Síochána that the inspector considers appropriate.

(8) An inspector shall not enter a dwelling except—

(a) with the consent of the occupier, or

(b) in accordance with a warrant issued under subsection (9).

(9) On the application of an inspector, a judge of the District Court who is satisfied as to the matters specified in subsection (10) may

issue a warrant authorising a named inspector, accompanied by such other inspectors or members of the Garda Síochána as may be necessary, to enter, at any time or times within one month after the date of issue of the warrant, a specified dwelling and perform any of the functions conferred on an inspector under subsection (4) (c) to (e) or (6)(b) to (g).

(10) A warrant may not be issued under subsection (9) unless the judge is satisfied that there are reasonable grounds to believe that —

- (a) an experimental animal is in the dwelling,
- (b) an article, reagent or other substance that is used in experiments, or in the breeding or supply of animals with a view to their use in experiments, is located in the dwelling,
- (c) books or records relating to any trade, business or activity connected with the use of animals in experiments, or with the breeding or supply of animals with a view to their use in experiments, are located in the dwelling, or
- (d) all or part of the dwelling is occupied by an undertaking engaged in using animals in experiments or in the breeding or supply of animals with a view to their use in experiments.

(11) An inspector who has reasonable grounds to believe that a person has committed an offence under this Act may require that person to provide the inspector with the person's name and the address at which he or she ordinarily resides.

(12) In this section 'record' includes—

- (a) a document, and
- (b) anything recorded in legible or non-legible form.”;

(j) by inserting the following after section 11:

“Licensee's duty to record information and retain records.

11A.— (1) Each licensee shall record the following information in respect

of each experiment performed under the licence;

- (a) the date on which the experiment was performed;
- (b) the address of the establishment where the experiment was performed;
- (c) the nature, purpose and duration of the experiment;
- (d) the number of animals used in the experiment;
- (e) the species and strain of each animal used in the experiment;
- (f) whether the animal was obtained from a breeding establishment, a supplying establishment or another source;
- (g) whether anaesthesia, analgesic or another method was used to relieve the animal's pain, distress or suffering and, if so, the type of anaesthesia, analgesic or method;
- (h) whether the animal had been used in a previous experiment;
- (i) whether the animal was kept alive, set free or killed at the end of the experiment;
- (j) if the animal was killed, the final disposition of the carcass.

(2) The licensee shall keep the records referred to in subsection (1) for not less than three years after the date on which the information was first recorded.”;

(k) by repealing section 12A;

(l) by inserting the following:

“Statistical information.

12B. — On the basis of applications for licences and certificates and of reports made under section 9, the Authority shall collect and shall, as far as possible, periodically make publicly available the following statistical information:

- (a) the number and kinds of animals used in experiments;
- (b) the number of animals, in selected categories, used in experiments performed for the purposes specified in section 2(2)(a);
- (c) the number of animals, in selected categories, used in experiments required by legislation.

Confidentiality of information.

12C.—(1) A person shall not disclose any commercially sensitive information obtained by him or her while performing functions as —

- (a) an inspector,
- (b) an officer or employee of the Authority, or
- (c) a member of a committee established under this Act, except for the purpose of performing those functions.

(2) For the purposes of this section, “commercially sensitive information” includes financial, commercial, scientific, technical or other information the disclosure of which could—

- (a) reasonably be expected to result in a material financial loss or gain to the person to whom the information relates,
- (b) prejudice the competitive position of that person in the conduct of his or her profession or business or otherwise in his or her occupation, or
- (c) prejudice the conduct or outcome of contractual or other negotiations of that person.

Authority to supply information to Commission.

12D.—The Authority shall supply to the Commission—

- (a) where practicable and without prejudice to the requirements of existing Community Directives, information on national legislation and administrative practice relating to animal experiments, including requirements to be satisfied before the marketing of products, and
- (b) factual information on experiments carried out in the national territory and on authorizations or any other administrative particulars pertaining to those experiments.

Advisory committee.

12E.—The Authority may—

- (a) establish one or more committees consisting of persons having the qualifications or experience that the Authority considers appropriate, including persons with expertise in veterinary medicine, medicine, biology or other relevant disciplines, to advise the Authority concerning—
 - (i) the implementation of the Directive,
 - (ii) research into the development and validation of alternative techniques that could provide the same level of information as that obtained in using animals but that involve fewer animals or entail less painful procedures, and
 - (iii) trends in experimental methods,
- (b) determine each committee's terms of reference, and
- (c) regulate each committee's procedure.”;

(m) in section 13 by substituting “establishment” for “place” and by

substituting “is guilty of an offence and shall be liable on summary conviction to a penalty not exceeding €2000” for “shall be liable to a penalty not exceeding five pounds”;

(n) by renumbering section 19 as section 19(1) and adding the following subsection:

“(2) Subsection (1) does not apply in respect an offence under section 5E of this Act.”;

(o) by adding the attached Schedule after section 22.

3. The European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 1994 are revoked.

Given under the Official Seal of
the Minister for Health and
Children this 5th day of December
2002.

Micheál Martin

Minister for Health and Children

Explanatory Memorandum

(This note is not part of the Regulations and does not purport to be a legal interpretation)

These Regulations give effect to Council Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes. They amend The Cruelty to Animals Act 1876 which prohibits painful experiments on living animals except subject to the restrictions imposed by the Act.

The Regulations also revoke the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations, 1994.