COUNCIL DIRECTIVE of 24 November 1986 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 (86/609/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,
Having regard to the proposal from the Commission (1),
Having regard to the opinion of the European Parliament (2),
Having regard to the opinion of the Economic and Social Committee (3),
Whereas there exist between the national laws at present in force for the protection of animals used for certain experimental purposes disparities which may affect the functioning of the common market;
Whereas, in order to eliminate these disparities, the laws of the Member States should be harmonized; whereas such harmonization should ensure that the number of animals used for experimental or other scientific purposes is reduced to a minimum, that such animals are adequately cared for, that no pain, suffering, distress or lasting harm are inflicted unnecessarily and ensure that, where unavoidable, these shall be kept to the minimum;
Whereas, in particular, unnecessary duplication of experiments should be avoided,
(1) OJ N° C 351, 31. 12. 1985, p. 16.
(2) OJ N° C 255, 13. 10. 1986, p. 250.
(3) OJ N° C 207, 18. 8. 1986, p. 3.
HAS ADOPTED THIS DIRECTIVE:

Article 1
The aim of this Directive is to ensure that where animals are used for experimental or other scientific purposes the provisions laid down by law, regulation or administrative provisions in the Member States for their protection are approximated so as to avoid affecting the establishment and functioning of the common market, in particular by distorsions of competition or barriers to trade.

Article 2
For the purposes of this Directive the following definitions shall apply:
(a)
'animal' unless otherwise qualified, means any live non-human vertebrate, including free-living larval and/or reproducing larval forms, but excluding foetal or embryonic forms;
(b)
'experimental animals' means animals used or to be used in experiments;
(c)
'bred animals' means animals specially bred for use in experiments in facilities approved by, or registered with, the authority;
(d)
'experiment' means any use of an animal for experimental or other scientific purposes which 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 the least painful methods accepted in modern practice (i.e. 'humane' methods) of killing or marking an animal; an experiment starts when an animal is first prepared for use
and ends when no further observations are to be made for that experiment; the elimination of pain, suffering,
distress or lasting harm by the successful use of anaesthesia or analgesia or other methods does

not place the use of an animal outside the scope of this definition. Non experimental, agricultural or clinical veterinary practices are excluded;
(e)
'authority' means the authority or authorities designated by each Member State as being responsible for supervising the experiments within the meaning of this Directive;
(f)
'competent person' means any person who is considered by a Member State to be competent to perform the relevant function described in this Directive;
(g)
'establishment' means any installation, building, group of buildings or other premises and may include a place which is not wholly enclosed or covered and mobile facilities;
(h)
'breeding establishment' means any establishment where animals are bred with a view to their use in experiments;
(i)
'supplying establishment' means any establishment, other than a breeding establishment, from which animals are supplied with a view to their use in experiments;
(j)
'user establishment' means any establishment where animals are used for experiments;
(k)
'properly anaesthetized' means deprived of sensation by methods of anaesthesia (whether local or general) as effective as those used in good veterinary practice;
(l)
'humane method of killing' means the killing of an animal with a minimum of physical and mental suffering, depending on the species.

Article 3
This Directive applies to the use of animals in experiments which are undertaken for one of the following purposes:
(a)
the development, manufacture, quality, effectiveness and safety testing of drugs, foodstuffs and other substances or products:
(i)
for the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in man, animals or plants;
(ii)
for the assessment, detection, regulation or modification of physiological conditions in man, animals or plants;
(b)
the protection of the natural environment in the interests of the health or welfare of man or animal.

Article 4
Each Member State shall ensure that experiments using animals considered as endangered under Appendix I of the Convention on International Trade in Endangered Species of Fauna and Flora and Annex C.I. of Regulation (EEC) N° 3626/82 (1) are prohibited unless they are in conformity with the above Regulation and the objects of the experiment are:
- research aimed at 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.

Article 5
Member States shall ensure that, as far as the general care and accommodation of animals is concerned:
(a) 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;
(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 used must be checked daily;
(d) 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;
(e) arrangements are made to ensure that any defect or suffering discovered is eliminated as quickly as possible.
For the implementation of the provisions of paragraphs (a) and (b), Member States shall pay regard to the guidelines set out in Annex II.

Article 6
1. Each Member State shall designate the authority or authorities responsible for verifying that the provisions of this Directive are properly carried out.
2. In the framework of the implementation of this Directive, Member States shall adopt the necessary measures in order that the designated authority mentioned in paragraph 1 above may have the advice of experts competent for the matters in question.
(1) OJ N° L 384, 31. 12. 1982, p. 1.

Article 7
1. Experiments shall be performed solely by competent authorized persons, or under the direct responsibility of such a person, or if the experimental or other scientific project concerned is authorized in accordance with the provisions of national legislation.
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.
3. When an experiment has to be performed, the choice of species shall be carefully considered and, where necessary, explained to the authority. 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.
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.
4. 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 Article 8. The measures set out in Article 9 shall be taken in all cases.

Article 8
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 anaesthetized 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.

Article 9
1. 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.
2. The decisions referred to in paragraph 1 shall be taken by a competent person, preferably a veterinarian.
3. Where, at the end of an experiment:
(a) an animal is to be kept alive, it shall receive the 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 Article 5. The conditions laid down in this subparagraph 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 Article 5 concerning its well-being, it shall be killed by a humane method as soon as possible.

Article 10
Member States shall ensure that any re-use of animals in experiments shall be compatible with the provisions of this Directive.
In particular, an animal shall not be used more than once in experiments entailing severe pain, distress or equivalent suffering.

Article 11
Notwithstanding the other provisions of this Directive, where it is necessary for the legitimate purposes of the experiment, the authority may allow the animal concerned to be set free, provided that it is satisfied 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.

Article 12
1. Member States shall establish procedures whereby experiments themselves or the details of persons conducting such experiments shall be notified in advance to the authority.
2. Where it is planned to subject an 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 authorized by, the authority. The authority shall take appropriate judicial or administrative action if it is not satisfied that the experiment is of sufficient importance for meeting the essential needs of man or animal.

Article 13
1. On the basis of requests for authorization and notifications received, and on the basis of the reports made, the authority in each Member State shall collect, and as far as possible periodically make publicly available, the statistical information on the use of animals in experiments in respect of:
(a) the number and kinds of animals used in experiments;
(b) the number of animals, in selected categories, used in the experiments referred to in Article 3;
(c) the number of animals, in selected categories, used in experiments required by legislation.

2. Member States shall take all necessary steps to ensure that the confidentiality of commercially sensitive information communicated pursuant to this Directive is protected.

Article 14

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 authority that they have attained a level of training sufficient for carrying out their tasks.

Article 15

Breeding and supplying establishments shall be approved by or registered with, the authority and comply with the requirements of Articles 5 and 14 unless an exemption is granted under Article 19 (4) or Article 21. 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 authority.

Article 16

The approval or the registration provided for in Article 15 shall specify the competent person responsible for the establishment entrusted with the task of administering, or arranging for the administration of, appropriate care to the animals bred or kept in the establishment and of ensuring compliance with the requirements of Articles 5 and 14.

Article 17

1. 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.
2. Each authority shall prescribe the records which are to be kept and made available to it by the person responsible for the establishments mentioned in paragraph 1; such records shall be kept for a minimum of three years from the date of the last entry and shall undergo periodic inspection by officers of the authority.

Article 18

1. Each dog, cat or non-human primate in any breeding, supplying or user 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 paragraph 3.
2. 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.
3. Where a dog, cat or non-human primate is transferred from one establishment as referred to in paragraph 1 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.
4. Particulars of the identity and origin of each dog, cat or non-human primate shall be entered in the records of each establishment.

Article 19

1. User establishments shall be registered with, or approved by, the authority. Arrangements

shall be made for user establishments to have installations and equipment suited to the species of animals 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.
2. 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.
3. Experiments may, where authorized by the authority, be conducted outside user establishments.
4. 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 authority. 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 paragraph may not extend to stray dogs and cats.
5. User establishments shall keep records of all animals used and produce them whenever required to do so by the authority. 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 authority which asks for them. User establishments shall be subject to periodic inspection by representatives of the authority.

Article 20
When user establishments breed animals for use in experiments on their own premises, only one registration or approval is needed for the purposes of Article 15 and 19. However, the establishments shall comply with the relevant provisions of this Directive concerning breeding and user establishments.

Article 21
Animals belonging to the species listed in Annex I 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 authority.

Article 22
1. In order to avoid unnecessary duplication of experiments for the purposes of satisfying national or
Community health and safety legislation, Member States shall as far as possible recognize the validity of data generated by experiments carried out in the territory of another Member State unless further testing is necessary in order to protect public health and safety.
2. To that end, Member States shall, where practicable and without prejudice to the requirements of existing Community Directives, furnish information to the Commission on their legislation and administrative practice relating to animal experiments, including requirements to be satisfied prior to the marketing of products; they shall also supply factual information on experiments carried out in their territory and on authorizations or any other administrative particulars pertaining to these experiments.
3. The Commission shall establish a permanent consultative committee within which the

Member States would be represented, which will assist the Commission in organizing the exchange of appropriate information, while respecting the requirements of confidentiality, and which will also assist the Commission in the other questions raised by the application of this Directive.

Article 23
1. The Commission and Member States should 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 they consider appropriate to encourage research in this field. The Commission and Member States shall monitor trends in experimental methods.
2. The Commission shall report before the end of 1987 on the possibility of modifying tests and guidelines laid down in existing Community legislation taking into account the objectives referred to in paragraph 1.

Article 24
This Directive shall not restrict the right of the Member States to apply or adopt stricter measures for the protection of animals used in experiments or for the control and restriction of the use of animals for experiments. In particular, Member States may require a prior authorization for experiments or programmes of work notified in accordance with the provisions of Article 12 (1).

Article 25
1. Member States shall take the measures necessary to comply with this Directive by 24 November 1989. They shall forthwith inform the Commission thereof.
2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

Article 26
At regular intervals not exceeding three years, and for the first time five years following notification of this Directive, Member States shall inform the Commission of the measures taken in this area and provide a suitable summary of the information collected under the provisions of Article 13. The Commission shall prepare a report for the Council and the European Parliament.

Article 27
This Directive is addressed to the Member States.

Done at Brussels, 24 November 1986.
For the Council
The President
W. WALDEGRAVE