

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 [FN 1],

Having regard to the opinion of the European Parliament [FN 2],

Having regard to the opinion of the Economic and Social Committee [FN 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,

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 distortions 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) No 3626/82 [FN 4] 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 11.

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.

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. WALDEGPAVE

FN 1: OJ No C 351, 31. 12. 1985, p. 16.

FN 2: OJ No C 255, 13. 10. 1986, p. 250.

FN 3: OJ No C 207, 18. 8. 1986, p. 3.

FN 4: OJ No L 384, 31. 12. 1982, p. 1.

ANNEX I

LIST OF EXPERIMENTAL ANIMALS COVERED BY THE PROVISIONS OF ARTICLE 21

- Mouse - *mus musculus*
- Rat - *Rattus norvegicus*
- Guinea Pig - *Cavia porcellus*
- Golden Hamster - *Mesocricetus auratus*
- Rabbit - *Oryctolagus cuniculus*
- Non-human Primates
- Dog - *Canis familiaris*

- Cat - Felis catus

- Quail - Coturnix coturnix

ANNEX II

GUIDELINES FOR ACCOMMODATION AND CARE OF ANIMALS

(Article 5 of the Directive)

INTRODUCTION

1. The Council of the European Economic Community has decided that the aim of the Directive is to harmonize the laws of the Member States for the protection of animals used for experimental and other scientific purposes in order to eliminate disparities which at present may affect the functioning of the common market. Harmonization should ensure that such animals are adequately cared for, that no pain, suffering, distress or lasting harm are inflicted unnecessarily and that where unavoidable the latter shall be kept to the minimum.

2. It is true that some experiments are conducted under field conditions on free-living, self-supporting, wild animals, but such experiments are relatively few in number. The great majority of animals used in experiments must for practical reasons be kept under some sort of physical control in facilities ranging from outdoor corrals to cages for small animals in a laboratory animal house. This is a situation where there are highly conflicting interests. On the one hand, the animal whose needs in respect of movement, social relations and other manifestations of life must be restricted, on the other hand, the experimenter and his assistants who demand full control of the animal and its environment. In this confrontation of interests the animal may sometimes be given secondary consideration.

3. Therefore, the Directive provides in Article 5 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'.

4. This Annex draws up certain guidelines based on present knowledge and practice for the accommodation and care of animals. It explains and supplements the basic principles adopted in Article 5. The object is thus to help authorities, institutions and individuals in their pursuit of the aims of the Directive in this matter.

5. Care is a word which, when used in connection with animals intended for or in actual use in experiments covers all aspects of the relationship between animals and man. Its substance is the sum of material and non-material resources mobilized by man to obtain and maintain an animal in a physical and mental state where it suffers least and performs best in experiments. It starts from the moment the animal is destined to be used in experiments and continues until it is killed by a humane method or otherwise disposed of by the establishment in accordance with Article 9 of the Directive after the close of the experiment.

6. This Annex aims to give advice about the design of appropriate animal quarters. There are, however, several methods of breeding and keeping laboratory animals that differ chiefly in the degree of control of the microbiological environment. It has to be borne in mind that the staff concerned will sometimes have to judge from the character and condition of the animals where the recommended standards of space may not be sufficient, as with especially aggressive animals. In applying the guidelines described in this Annex the requirements of each of these situations should be taken into account. Furthermore, it is necessary to make clear the status of these guidelines. Unlike the provisions of the Directive itself, they are not mandatory; they are recommendations to be used with discretion, designed as guidance to the practices and standards which all concerned should conscientiously strive to achieve. It is for this reason that the term 'should' has had to be used throughout the text even where 'must' might seem to be the more appropriate word. For example, it is self-evident that food and water *must* be provided (see 3.7.2 and 3.8).

7. Finally, for practical and financial reasons, existing animal quarters equipment should not need to be replaced before it is worn out, or has otherwise become useless. Pending replacement with equipment conforming with the present guidelines, these should as far as practicable be complied with by adjusting the numbers and sizes of animals placed in existing cages and pens.

DEFINITIONS

In this Annex, in addition to the definitions contained in Article 2 of the Directive:

(a) '*holding rooms*' mean rooms where animals are normally housed, either for breeding and stocking or during the conduct of an experiment;

(b) '*cage*' means a permanently fixed or movable container that is closed by solid walls and, at least on one side, by bars or meshed wire or, where appropriate, nets and in which one or more animals are kept or transported; depending on the stocking density and the size of the container, the freedom of movement of the animals is relatively restricted;

(c) '*pen*' means an area enclosed, for example, by walls, bars or meshed wire in which one or more animals are kept; depending on the size of the enclosure and the stocking density the freedom of movement of the animals is usually less restricted than in a cage;

(d) '*run*' means an area closed, for example, by fences, walls, bars or meshed wire and frequently situated outside permanently fixed buildings in which animals kept in cages or pens can move freely during certain periods of time in accordance with their ethological and physiological needs, such as exercise;

(e) '*stall*' means a small enclosure with three sides, usually a feed-rack and lateral separations, where one of two animals may be kept tethered.

I. THE PHYSICAL FACILITIES

1. 1. Functions and general design

1. 1. 1. Any facility should be so constructed as to provide a suitable environment for the species housed. It should also be designed to prevent access by unauthorized persons.

Facilities that are part of a larger building complex should also be protected by proper building measures and arrangements that limit the number of entrances and prevent unauthorized traffic.

1.1.2. It is recommended that there should be a maintenance programme for the facilities in order to prevent any defect of equipment.

1.2. Holding rooms

1.2.1. All necessary measures should be taken to ensure regular and efficient cleaning of the rooms and the maintenance of a satisfactory hygienic standard. Ceilings and walls should be damage-resistant with a smooth, impervious and easily washable surface. Special attention should be paid to junctions with doors, ducts, pipes and cables. Doors and windows, if any, should be constructed or protected so as to keep out unwanted animals. Where appropriate, an inspection window may be fitted in the door. Floors should be smooth, impervious and have a non-slippery, easily washable surface which can carry the weight of racks and other heavy equipment without being damaged. Drains, if any, should be adequately covered and fitted with a barrier which will prevent animals from gaining access.

1.2.2. Rooms where the animals are allowed to run freely should have walls and floors with a particularly resistant surface material to stand up to the heavy wear and tear caused by the animals and the cleaning process. The material should not be detrimental to the health of the animals and be such that the animals cannot hurt themselves. Drains are desirable in such rooms. Additional protection must be given to any equipment or fixtures so that they may not be damaged by the animals or hurt the animals themselves. Where outdoor exercise areas are provided measures should be taken when appropriate to prevent access by the public and animals.

1.2.3. Rooms intended for the holding of farm animals (cattle, sheep, goats, pigs, horses, poultry, etc.) should at least conform with the standards laid down in the European Convention for the Protection of Animals kept for Farming Purposes and by national veterinary and other authorities.

1.2.4. The majority of holding rooms are usually designed to house rodents. Frequently such rooms may also be used to house larger species. Care should be taken not to house together species which are incompatible.

1.2.5. Holding rooms should be provided with facilities for carrying out minor experiments and manipulations, where appropriate.

1.3. Laboratories and general and special purpose experiment rooms

1.3.1. At breeding or supplying establishments suitable facilities for making consignments of animals ready for dispatch should be made available.

1.3.2. All establishments should also have available as a minimum laboratory facilities for the carrying out of simple diagnostic tests, post-mortem examinations, and/ or the collection of samples which are to be subjected to more extensive laboratory investigations elsewhere.

1.3.3. Provision should be made for the receipt of animals in such a way that incoming animals do not put at risk animals already present in the facility, for example by quarantining. General and special purpose experiment rooms should be available for situations where it is undesirable to carry out the experiments or observations in the holding room.

1.3.4. There should be appropriate accommodation for enabling animals which are ill or injured to be housed separately.

1.3.5. Where appropriate, there should be provision for one or more separate operating rooms suitably equipped for the performance of surgical experiments under aseptic conditions. There should be facilities for post-operative recovery where this is warranted.

1.4. Service rooms

1.4.1. Store rooms for food should be cool, dry, vermin and insect proof and those for bedding, dry, vermin and insect proof. Other materials, which may be contaminated or present a hazard, should be stored separately.

1.4.2. Store rooms for clean cages, instruments and other equipment should be available.

1.4.3. The cleaning and washing room should be large enough to accommodate the installations necessary to decontaminate and clean used equipment. The cleaning process should be arranged so as to separate the flow of clean and dirty equipment to prevent the contamination of newly cleaned equipment. Walls and floors should be covered with a suitably resistant surface material and the ventilation system should have ample capacity to carry away the excess heat and humidity.

1.4.4. Provision should be made for the hygienic storage and disposal of carcasses and animal waste. If incineration on the site is not possible or desirable, suitable arrangements should be made for the safe disposal of such material having regard to local regulations and by-laws. Special precautions should be taken with highly toxic or radioactive waste.

1.4.5. The design and construction of circulation areas should correspond to the standards of the holding rooms. The corridors should be wide enough to allow easy circulation of movable equipment.

2. THE ENVIRONMENT IN THE HOLDING ROOMS AND ITS CONTROL

2.1. Ventilation

2.1.1. Holding rooms should have an adequate ventilation system which should satisfy the requirements of the species housed. The purpose of the ventilation system is to provide fresh air and to keep down the level of odours, noxious gases, dust and infectious agents of any kind. It also provides for the removal of excess heat and humidity.

2.1.2. The air in the room should be renewed at frequent intervals. A ventilation rate of 15-20 air changes per hour is normally adequate. However, in some circumstances, where stocking density is low, 8-10 air changes per hour may suffice or mechanical ventilation may not even be needed at all. Other circumstances may necessitate a much higher rate of air change. Recirculation of untreated air should be avoided. However, it should be emphasized that even the most efficient system cannot compensate for poor cleaning routines or negligence.

2.1.3. The ventilation system should be so designed as to avoid harmful draughts.

2.1.4. Smoking in rooms where there are animals should be forbidden.

2.2. Temperature

2.2.1. Table 1 gives the range within which it is recommended that the temperature should be maintained. It should also be emphasized that the figures apply only to adult, normal animals.

Newborn and young animals will often require a much higher temperature level. The temperature of the premises should be regulated according to possible changes in the animals' thermal regulation which may be due to special physiological conditions or to the effects of the experiment.

2.2.2. Under the climatic conditions prevailing in Europe it may be necessary to provide a ventilation system having the capacity both to heat and to cool the air supplied.

2.2.3. In user establishments a precise temperature control in the holding rooms may be required, because the environmental temperature is a physical factor which has a profound effect on the metabolism of all animals.

2.3. Humidity

Extreme variations in relative humidity (RH) have an adverse effect on the health and well-being of animals. It is therefore recommended that the RH level in holding rooms should be appropriate to the species concerned and should ordinarily be maintained at $55\% \pm 10\%$. Values below 40% and above 70% RH for prolonged periods should be avoided.

2.4. Lighting

In windowless rooms, it is necessary to provide controlled lighting both to satisfy the biological requirements of the animals and to provide a satisfactory working environment. It is also necessary to have a control of the intensity and of the light-dark cycle. When keeping albino animals, one should take into account their sensitivity to light (see also 2.6).

2.5. Noise

Noise can be an important disturbing factor in the animal quarters. Holding rooms and experiment rooms should be insulated against loud noise sources in the audible and in the higher frequencies in order to avoid disturbances in the behaviour and the physiology of the animals. Sudden noises may lead to considerable change in organ functions but, as they are often unavoidable, it is sometimes advisable to provide holding and experiment rooms with a continuous sound of moderate intensity such as soft music.

2.6. Alarm systems

A facility housing a large number of animals is vulnerable. It is therefore recommended that the facility is duly protected by the installation of devices to detect fires and the intrusion of unauthorized persons. Technical defects or a breakdown of the ventilation system is another hazard which could cause distress and even the death of animals, due to suffocation and overheating or, in less serious cases, have such negative effects on an experiment that it will be a failure and have to be repeated. Adequate monitoring devices should therefore be installed in connection with the heating and ventilation plant to enable the staff to supervise its operation in general. If warranted, a stand-by generator should be provided for the maintenance of life support systems for the animals and lighting in the event of a breakdown or the withdrawal of supply. Clear instructions on emergency procedures should be prominently displayed. Alarms for fish tanks are recommended in case of failure of the water supply. Care should be taken to ensure that the operation of an alarm system causes as little disturbance as possible to the animals.

3. CARE

3.1. Health

3.1.1. The person in charge of the establishment should ensure regular inspection of the animals and supervision of the accommodation and care by a veterinarian or other competent person.

3.1.2. According to the assessment of the potential hazard to the animals, appropriate attention should be paid to the health and hygiene of the staff.

3.2. Capture

Wild and feral animals should be captured only by humane methods and by experienced persons who have a thorough knowledge of the habits and habitats of the animals to be caught. If an anaesthetic or any other drug has to be used in the capturing operation, it should be administered by a veterinarian or other competent person. Any animal which is seriously injured should be presented as soon as possible to a veterinarian for treatment. If the animal, in the opinion of the veterinarian, can only go on living with suffering or pain it should be killed at once by a humane method. In the absence of a veterinarian, any animal which may be seriously injured should be killed at once by a humane method.

3.3. Packing and transport conditions

All transportation is undoubtedly, for the animals, a stressful experience, which should be mitigated as far as possible. Animals should be in good health for transportation and it is the duty of the sender to ensure that they are so. Animals which are sick or otherwise out of condition should never be subjected to any transport which is not necessary for therapeutic or diagnostic reasons. Special care should be exercised with female animals in an advanced state of pregnancy. Female animals which are likely to give birth during the transport or which have done so within the preceding forty-eight hours, and their offspring, should be excluded from transportation. Every precaution should be taken by sender and carrier in packing, stowing and transit to avoid unnecessary suffering through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. The receiver should be properly informed about the transport details and documentary particulars to ensure quick handling and reception in the place of arrival. It is recalled that, as far as international transport of animals is concerned, Directives 77/489/EEC and 81/389/EEC apply; strict observance of national laws and regulations as well as of the regulations for live animals of the International Air Transport Association and the Animal Air Transport Association is also recommended.

3.4. Reception and unpacking

The consignments of animals should be received and unpacked without avoidable delay. After inspection, the animals should be transferred to clean cages or pens and be supplied with feed and water as appropriate. Animals which are sick or otherwise out of condition should be kept under close observation and separately from other animals. They should be examined by a veterinarian or other competent person as soon as possible and, where necessary, treated. Animals which do not have any chance to recover should be killed at once by a humane method. Finally, all animals received must be registered and marked in accordance with the provisions of Articles 17, 18, 19 (5) of the Directive. Transport boxes should be destroyed immediately if proper decontamination is impossible.

3.5. Quarantine, isolation and acclimatization

3.5.1. The objects of quarantine are:

- (a) to protect other animals in the establishment;
- (b) to protect man against zoonotic infection;
- (c) to foster good scientific practice.

Unless the state of health of animals introduced into an establishment is satisfactory, it is recommended that they should undergo a period of quarantine. In some cases, that of rabies, for example, this period may be laid down in the national regulations of the Member State. In others, it will vary and should be determined by a competent person, according to the circumstances, normally the veterinarian appointed by the establishment (see also Table 2).

Animals may be used for experiments during the quarantine period as long as they have become acclimatized to their new environment and they present no significant risk to other animals or man.

3.5.2. It is recommended that facilities should be set aside in which to isolate animals showing signs of or suspected of ill-health and which might present a hazard to man or to other animals.

3.5.3. Even when the animals are seen to be in sound health it is good husbandry for them to undergo a period of acclimatization before being used in an experiment. The time required depends on several factors, such as the stress to which the animals have been subjected which in turn depends on several factors such as the duration of the transportation and the age of the animal. This time shall be decided by a competent person.

3.6. Caging

3.6.1. It is possible to make a distinction between two broad systems of housing animals.

Firstly, there is the system found in breeding, supplying and user establishments in the bio-medical field designed to accommodate animals such as rodents, rabbits, carnivores, birds and non-human primates, sometimes also ruminants, swine and horses. Suggested guidelines for cages, pens, runs, and stalls suitable for such facilities are presented in Tables 3 to 13. Supplementary guidance on minimum cage areas is found in Figures 1 to 7. Furthermore, a corresponding guidance for the appraisal of the stocking density in cages is presented in Figures 8 to 12. Secondly, there is the system frequently found in establishments conducting experiments only on farm or similar large animals. The facilities in such establishments should not be less than those required by current veterinary standards.

3.6.2. Cages and pens should not be made out of material that is detrimental to the health of the animals, and their design should be such that the animals cannot injure themselves and, unless they are disposable, they should be made from a resistant material adapted to cleaning and decontamination techniques. In particular, attention should be given to the design of cage and pen floors which should vary according to the species and age of the animals and be designed to facilitate the removal of excreta.

3.6.3. Pens should be designed for the well-being of the species. They should permit the satisfaction of certain ethological needs (for example the need to climb, hide or shelter temporarily) and be designed for efficient cleaning and freedom from contact with other animals.

3.7. Feeding

3.7.1. In the selection, production and preparation of feed, precautions should be taken to avoid chemical, physical and microbiological contamination. The feed should be packed in tight, closed bags, stamped with the production date when appropriate. Packing, transport and storing should also be such as to avoid contamination, deterioration or destruction. Store rooms should be cool, dark, dry, and vermin and insect proof. Quickly perishable feed like greens, vegetables, fruit, meat, fish, etc. should be stored in cold rooms, refrigerators or freezers.

All feed hoppers, troughs or other utensils used for feeding should be regularly cleaned and if necessary sterilized. If moist feed is used or if the feed is easily contaminated with water, urine, etc., daily cleaning is necessary.

3.7.2. The feed distribution process may vary according to the species but it should be such as to satisfy the physiological needs of the animal. Provision should be made for each animal to have access to the feed.

3.8. Water

3.8.1. Uncontaminated drinking water should always be available to all animals. During transport, it is acceptable to provide water as part of a moist diet. Water is however a vehicle of micro-organisms and the supply should therefore be so arranged that the hazard involved is minimized. Two methods are in common use, bottles and automatic systems.

3.8.2. Bottles are often used with small animals like rodents and rabbits. When bottles are used, they should be made from translucent material in order to enable their contents to be monitored. The design should be wide-mouthed for easy and efficient cleaning and, if plastic material is used, it should not be leachable. Caps, stoppers and pipes should also be sterilizable and easy to clean. All bottles and accessories should be taken to pieces, cleaned and sterilized at appropriate and regular periods. It is preferable that the bottles should be replaced by clean, sterilized ones rather than be refilled in the holding rooms.

3.8.3. Automatic drinking systems should be regularly checked, serviced and flushed to avoid accidents and the spread of infections. If solid-bottom cages are used, care should be taken to minimize the risk of flooding. Regular bacteriological testing of the system is also necessary to monitor the quality of the water.

3.8.4. Water received from public waterworks contains some micro-organisms which are usually considered to be harmless unless one is dealing with microbiologically defined animals. In such cases, the water should be treated. Water supplied by public waterworks is usually chlorinated to reduce the growth of micro-organisms. Such chlorination is not always enough to keep down the growth of certain potential pathogens, as for example *Pseudomonas*. As an additional measure, the level of chlorine in the water could be increased or the water could be acidified to achieve the desired effect.

3.8.5. In fishes, amphibians and reptiles, tolerance for acidity, chlorine and many other chemicals differs widely from species to species. Therefore provision should be made to adapt the water supply for aquariums and tanks to the needs and tolerance limits of the individual species.

3.9. Bedding

Bedding should be dry, absorbent, non-dusty, non-toxic and free from infectious agents or vermin, or any other form of contamination. Special care should be taken to avoid using sawdust

or bedding material derived from wood which has been treated chemically. Certain industrial by-products or waste, such as shredded paper, may be used.

3.10. Exercising and handling

3.10.1. It is advisable to take every possible opportunity to let animals take exercise.

3.10.2. The performance of an animal during an experiment depends very much on its confidence in man, something which has to be developed. The wild or feral animal will probably never become an ideal experimental animal. It is different with the domesticated animal born and raised in contact with man. The confidence once established should however be preserved. It is therefore recommended that frequent contact should be maintained so that the animals become familiar with human presence and activity. Where appropriate, time should be set aside for talking, handling and grooming. The staff should be sympathetic, gentle and firm when associating with the animals.

3.11. Cleaning

3.11.1. The standard of a facility depends very much on good hygiene. Clear instructions should be given for the changing of bedding in cages and pens.

3.11.2. Adequate routines for the cleaning, washing, decontamination and, when necessary, sterilization of cages and accessories, bottles and other equipment should be established. A very high standard of cleanliness and order should also be maintained in holding, washing and storage rooms.

3.11.3. There should be regular cleaning and, where appropriate, renewal of the material forming the ground surface in outdoor pens, cages and runs to avoid them becoming a source of infection and parasite infestation.

3.12. Humane killing of animals

3.12.1. All humane methods of killing animals require expertise which can only be attained by appropriate training.

3.12.2. A deeply unconscious animal can be exsanguinated but drugs which paralyse muscles before unconsciousness occurs, those with curariform effects and electrocution without passage of current through the brain, should not be used without prior anaesthesia.

Carcass disposal should not be allowed until *rigor mortis* occurs.

TABLE 1

Guidelines for room temperature

(animals kept in cages, pens or indoor runs)

Species or groups of species	Optimal range in °C
------------------------------	------------------------

Non-human New World primates	20 - 28
Mouse	20 - 24
Rat	20 - 24
Syrian hamster	20 - 24
Gerbil	20 - 24
Guinea pig	20 - 24
Non-human Old World primates	20 - 24
Quail	20 - 24
Rabbit	15 - 21
Cat	15 - 21
Dog	15 - 21
Ferret	15 - 21
Poultry	15 - 21
Pigeon	15 - 21
Swine	10 - 24
Goat	10 - 24
Sheep	10 - 24
Cattle	10 - 24
Horse	10 - 24

Note: In special cases, for example when housing very young or hairless animals, higher room temperatures than those indicated may be required.

TABLE 2

Guidelines for local quarantine periods

Introductory note: For imported animals, all quarantine periods should be subject to the Member States' national regulations. In regard to local quarantine periods, the period should be determined by a competent person according to circumstances, normally, a veterinarian appointed by the establishment.

Species	Days
Mouse	5 - 15
Rat	5 - 15
Gerbil	5 - 15
Guinea pig	5 - 15
Syrian hamster	5 - 15
Rabbit	20 - 30
Cat	20 - 30
Dog	20 - 30
Non-human primates	40 - 60

TABLE 3

Guidelines for caging small rodents and rabbits

(in stock and during experiments)

Species	Minimum cage floor area cm ²	Minimum cage height cm
Mouse	180	12
Rat	350	14
Syrian hamster	180	12
Guinea pig	600	18
Rabbit 1 kg	1400	30
2 kg	2000	30
3 kg	2500	35
4 kg	3000	40
5 kg	3600	40

Note: 'Cage height' means the vertical distance between the cage floor and the upper horizontal part of the lid or cage.

When designing experiments, consideration should be given to the potential growth of the animals to ensure adequate room according to this table in all phases of the experiments.

See also Figures 1 to 5 and 8 to 12.

TABLE 4

Guidelines for caging small rodents in breeding

Species	Minimum cage floor area for mother and litter cm ²	Minimum cage height cm
Mouse	200	12
Rat	800	14
Syrian hamster	650	12
Guinea pig	1200	18

Note: For definition of 'cage height' see note to Table 3.

TABLE 5

Guidelines for caging breeding rabbits

Weight of doe	Minimum cage floor area per doe and litter	Minimum cage height	Minimum nest box floor
kg	m ²	cm	m ²
1	0,30	30	0,10
2	0,35	30	0,10
3	0,40	35	0,12
4	0,45	40	0,12
5	0,50	40	0,14

Note: For definition of 'cage height' see note to Table 3.

The minimum cage floor area per doe and litter includes the area of the nest box floor.

See also Figure 6.

TABLE 6

Guidelines for housing cats

(during experiments and breeding)

Weight of cat	Minimum cage floor area per cat	Minimum cage height	Minimum cage floor area per queen and litter	Minimum pen floor area per queen and litter
kg	m ²	cm	m ²	m ²

0,5 - 1	0,2	50	-	-
1 - 3	0,3	50	0,58	2
3 - 4	0,4	50	0,58	2
4 - 5	0,6	50	0,58	2

Note: The housing of cats in cages should be strictly limited. Cats confined in this way should be let out for exercising at least once a day, where it does not interfere with the experiment. Cat pens should be equipped with dirt trays, ample shelf room for resting and objects suitable for climbing and claw-trimming.

'Cage height' means the vertical distance between the highest point on the floor and the lowest point in the top of the cage.

For the purpose of calculating the minimum floor area, the shelf area may be included. The minimum cage floor area per queen and litter includes the 0,18 m² area of the kittening box.

See also Figure 7.

TABLE 7

Guidelines for housing dogs in cages

(during experiments)

Height of dog to point of shoulder	Minimum cage floor area per dog	Minimum height of cage
cm	m ²	cm
30	0,75	60
40	1,00	80
70	1,75	140

Note: Dogs should not be kept in cages any longer than is absolutely necessary for the purpose of the experiment. Caged dogs should be let out for exercise at least once a day unless it is incompatible with the purpose of the experiment. A time-limit should be set beyond which a dog should not be confined without daily exercise. Exercise areas should be large enough to allow the dog freedom of movement. Grid floors should not be used in dog cages unless the experiment requires it.

In the light of the great differences in height and the limited interdependence of height and weight of various breeds of dogs, the cage height should be based on the body height to the

shoulder of the individual animal. As a general rule the minimum cage height should be twice the height to the shoulder.

For definition of 'cage height', see note to Table 6.

TABLE 8

Guidelines for housing dogs in pens

(in stock and during experiments and breeding)

Weight of dog	Minimum pen floor area per dog	Minimum adjacent exercise area per dog	
		up to 3 dogs	more than 3 dogs
kg	m ²	m ²	m ²
< 6	0,5	0,5 (1,0)	0,5 (1,0)
6 - 10	0,7	1,4 (2,1)	1,2 (1,9)
10 - 20	1,2	1,6 (2,8)	1,4 (2,6)
20 - 30	1,7	1,9 (3,6)	1,6 (3,3)
> 30	2,0	2,0 (4,0)	1,8 (3,8)

Note: Figures in brackets give the total area per dog, that is, the pen floor area plus the adjacent exercise area. Dogs kept permanently outdoors should have access to a sheltered place to find protection against unfavourable weather conditions. Where dogs are housed on grid floors, a solid area should be provided for sleeping. Grid floors should not be used unless the experiment requires it. Partitions between pens should be such as to prevent dogs from injuring each other.

All pens should have adequate drainage.

TABLE 9

Guidelines for caging non-human primates

(in stock and during experiments and breeding)

Introductory note: Because of the wide variation in sizes and characteristics of primates, it is especially important to match the shape and internal fittings as well as the dimensions of their cages to their particular needs. The total volume of the cage is just as important to primates as the floor area. As a general principle, the height of a cage, at least for apes and other simians, should be its greatest dimension. Cages should be high enough at least to allow the animals to

stand up erect. The minimum cage height for brachiators should be such as to allow them to swing in full extension from the ceiling without their feet touching the cage floor. Where appropriate, perches should be fitted to allow the primates to use the upper part of the cage.

Compatible primates may be kept two to a cage. Where they cannot be kept in pairs, their cages should be so placed that they can see one another, but it should also be possible to prevent this when required.

Subject to these observations, the following table constitutes a general guideline for caging the groups of species most commonly used (superfamilies *Ceboidea* and *Cercopithecoidea*).

Weight of primate kg	Minimum cage floor area for one or two animals m ²	Minimum cage height cm
< 1	0,25	60
1 - 3	0,35	75
3 - 5	0,50	80
5 - 7	0,70	85
7 - 9	0,90	90
9 - 15	1,10	125
15 - 25	1,50	125

Note: For definition of 'cage height' see note to Table 6.

TABLE 10

Guidelines for caging pigs

(in stock and during experiments)

Weight of pig kg	Minimum cage floor area per pig m ²	Minimum cage height cm
5 - 15	0,35	50
15 - 25	0,55	60
25 - 40	0,80	80

Note: The table would also apply to piglets. Pigs should not be kept in cages unless absolutely necessary for the purpose of the experiment and then only for a minimum period of time.

For definition of 'cage height' see note to Table 6.

TABLE 11

Guidelines for accommodating farm animals in pens

(in stock and during experiments in user establishments)

Species and weights kg	Minimum pen floor area m ²	Minimum pen length m	Minimum pen partition height m	Minimum pen floor area for groups m ² /animal	Minimum length of feed rack per head m
Pigs 10 - 30	2	1,6	0,8	0,2	0,20
30 - 50	2	1,8	1,0	0,3	0,25
50 - 100	3	2,1	1,2	0,8	0,30
100 - 150	5	2,5	1,4	1,2	0,35
> 150	5	2,5	1,4	2,5	0,40
Sheep < 70	1,4	1,8	1,2	0,7	0,35
Goats < 70	1,6	1,8	2,0	0,8	0,35
Cattle < 60	2,0	1,1	1,0	0,8	0,30
60 - 100	2,2	1,8	1,0	1,0	0,30
100 - 150	2,4	1,8	1,0	1,2	0,35
150 - 200	2,5	2,0	1,2	1,4	0,40
200 - 400	2,6	2,2	1,4	1,6	0,55
> 400	2,8	2,2	1,4	1,8	0,65
Adult horses	13,5	4,5	1,8	-	-

TABLE 12

Guidelines for accommodating farm animals in stalls

(in stock and during experiments in user establishments)

Species and weights kg	Minimum stall area m ²	Minimum stall length m	Minimum stall partition height m
Pigs 100 - 150	1,2	2,0	0,9
> 150	2,5	2,5	1,4
Sheep < 70	0,7	1,0	0,9
Goats < 70	0,8	1,0	0,9
Cattle 60 - 100	0,6	1,0	0,9
100 - 150	0,9	1,4	0,9
150 - 200	1,2	1,6	1,4
200 - 350	1,8	1,8	1,4
350 - 500	2,1	1,9	1,4
> 500	2,6	2,2	1,4
Adult horses	4,0	2,5	1,6

Note: Stalls should be sufficiently wide to allow an animal to lie comfortably.

TABLE 13

Guidelines for caging birds

(in stock and during experiments in user establishments)

Species and weights g	Minimum area for one bird cm ²	Minimum area for 2 birds cm ² /bird	Minimum area for 3 birds or more cm ² /bird	Minimum cage height cm	Minimum length of feed trough per bird cm
Chickens 100 - 300	250	200	150	25	3
	500	400	300	35	7
- 600	300 1000	600	450	45	10
	1200	700	550	45	12
- 1200	600 1400	850	650	45	12
1800	1200 - 1800	1200	1000	60	15
	1800 - 350	250	200	15	4

2400
(Adult males)

> 2400

Quails 120 -
140

Note: 'Area' means the product of cage length and cage width measurement internally and horizontally. *Not* the product of the floor length and floor width.

For definition of 'cage height' see note to Table 6.

Mesh size in grid floors should not be greater than 10 x 10 mm for young chicks, and 25 x 25 mm for pullets and adults. The wire thickness should be at the least 2 mm. The sloping gradient should not exceed 14% (8°). Water troughs should be of the same length as the feed troughs. If nipples or cups are provided, each bird should have access to two. Cages should be fitted with perches and allow birds in single cages to see each other.

FIGURE 1

Mice

(in stock and during experiments)

Minimum cage floor area

Given the weight of a mouse, the full-drawn line, EU-EU, gives the minimum area that it should be allocated.

[image omitted]

FIGURE 2

Rats

(in stock and during experiments)

Minimum cage floor area

Given the weight of a rat, the full-drawn line, EU-EU, gives the minimum area that is should be allocated.

[image omitted]

FIGURE 3

Syrian hamsters

(in stock and during experiments)

Minimum cage floor area

Given the weight of a Syrian hamster, the full-drawn line, EU-EU, gives the minimum area that is should be allocated.

[image omitted]

FIGURE 4

Guinea pigs

(in stock and during experiments)

Minimum cage floor area

Given the area of a guinea pig, the full-drawn line, EU-EU, gives the minimum area that it should be allocated.

[image omitted]

FIGURE 5

Rabbits

(in stock and during experiments)

Minimum cage floor area

Given the weight of a rabbit, the full-drawn line, EU-EU, gives the minimum area that it should be allocated.

[image omitted]

FIGURE 6

Rabbits

(in breeding)

Minimum cage floor area for doe with unweaned liter

Given the weight of a doe, the full-drawn line, EU-EU, gives the minimum area that it should be allocated.

[image omitted]

FIGURE 7

Cats

(in stock and during experiments)

Minimum cage floor area

Given the weight of a cat, the full-drawn line, EU-EU, gives the minimum area that it should be allocated.

[image omitted]

FIGURE 8

Guide to the relationship between number of mice per cage and cage floor area

(in stock and during experiments)

The lines represent the average weights and correspond to the line EU-EU in Figure 1.

[image omitted]

FIGURE 9

Guide to the relationship between number of rats per cage and cage floor area

(in stock and during experiments)

The lines represent the average weights and correspond to the line EU-EU in Figure 2.

[image omitted]

FIGURE 10

Guide to the relationship between number of hamsters per cage and cage floor area

(in stock and during experiments)

The lines represent the average weights and correspond to the EU-EU in Figure 3.

[image omitted]

FIGURE 11

Guide to the relationship between number of guinea pigs per cage and cage floor area

(in stock and during experiments)

The lines represent the average weights and correspond to the line EU-EU in Figure 4.

[image omitted]

FIGURE 12

Guide to the relationship between number of rabbits per cage and cage floor area

(in stock and during experiments)

The lines represent the average weights and correspond to the line EU-EU in Figure 5.

[image omitted]