

Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance)

CHAPTER IV
AUTHORISATION

Section 1

Requirements for breeders, suppliers and users

Article 20

Authorisation of breeders, suppliers and users

1 Member States shall ensure that all breeders, suppliers and users are authorised by, and registered with, the competent authority. Such authorisation may be granted for a limited period.

Authorisation shall be granted only if the breeder, supplier or user and its establishment is in compliance with the requirements of this Directive.

2 The authorisation shall specify the person responsible for ensuring compliance with the provisions of this Directive and the person or persons referred to in Article 24(1) and in Article 25.

3 Renewal of the authorisation shall be required for any significant change to the structure or the function of an establishment of a breeder, supplier or user that could negatively affect animal welfare.

4 Member States shall ensure that the competent authority is notified of any changes of the person or persons referred to in paragraph 2.

Article 21

Suspension and withdrawal of authorisation

1 Where a breeder, supplier or user no longer complies with the requirements set out in this Directive, the competent authority shall take appropriate remedial action, or require such action to be taken, or suspend or withdraw its authorisation.

2 Member States shall ensure that, where the authorisation is suspended or withdrawn, the welfare of the animals housed in the establishment is not adversely affected.

Article 22

Requirements for installations and equipment

1 Member States shall ensure that all establishments of a breeder, supplier or user have installations and equipment suited to the species of animals housed and, where procedures are carried out, to the performance of the procedures.

2 The design, construction and method of functioning of the installations and equipment referred to in paragraph 1 shall ensure that the procedures are carried out as effectively as possible, and aim at obtaining reliable results using the minimum number of animals and causing the minimum degree of pain, suffering, distress or lasting harm.

3 For the purposes of implementation of paragraphs 1 and 2, Member States shall ensure that the relevant requirements as set out in Annex III are complied with.

Article 23

Competence of personnel

1 Member States shall ensure that each breeder, supplier and user has sufficient staff on site.

2 The staff shall be adequately educated and trained before they perform any of the following functions:

- a carrying out procedures on animals;
- b designing procedures and projects;
- c taking care of animals; or
- d killing animals.

Persons carrying out the functions referred to in point (b) shall have received instruction in a scientific discipline relevant to the work being undertaken and shall have species-specific knowledge.

Staff carrying out functions referred to in points (a), (c) or (d) shall be supervised in the performance of their tasks until they have demonstrated the requisite competence.

Member States shall ensure, through authorisation or by other means, that the requirements laid down in this paragraph are fulfilled.

3 Member States shall publish, on the basis of the elements set out in Annex V, minimum requirements with regard to education and training and the requirements for obtaining, maintaining and demonstrating requisite competence for the functions set out in paragraph 2.

4 Non-binding guidelines at the level of the Union on the requirements laid down in paragraph 2 may be adopted in accordance with the advisory procedure referred to in Article 56(2).

Article 24

Specific requirements for personnel

- 1 Member States shall ensure that each breeder, supplier and user has one or several persons on site who shall:
 - a be responsible for overseeing the welfare and care of the animals in the establishment;
 - b ensure that the staff dealing with animals have access to information specific to the species housed in the establishment;
 - c be responsible for ensuring that the staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence.
- 2 Member States shall ensure that persons specified in Article 40(2)(b) shall:
 - a ensure that any unnecessary pain, suffering, distress or lasting harm that is being inflicted on an animal in the course of a procedure is stopped; and
 - b ensure that the projects are carried out in accordance with the project authorisation or, in the cases referred to in Article 42, in accordance with the application sent to the competent authority or any decision taken by the competent authority, and ensure that in the event of non-compliance, the appropriate measures to rectify it are taken and recorded.

Article 25

Designated veterinarian

Member States shall ensure that each breeder, supplier and user has a designated veterinarian with expertise in laboratory animal medicine, or a suitably qualified expert where more appropriate, charged with advisory duties in relation to the well-being and treatment of the animals.

Article 26

Animal-welfare body

- 1 Member States shall ensure that each breeder, supplier and user sets up an animal-welfare body.
- 2 The animal-welfare body shall include at least the person or persons responsible for the welfare and care of the animals and, in the case of a user, a scientific member. The animal-welfare body shall also receive input from the designated veterinarian or the expert referred to in Article 25.
- 3 Member States may allow small breeders, suppliers and users to fulfil the tasks laid down in Article 27(1) by other means.

Article 27

Tasks of the animal-welfare body

- 1 The animal-welfare body shall, as a minimum, carry out the following tasks:
 - a advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;
 - b advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement;
 - c establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment;
 - d follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement; and
 - e advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed.
- 2 Member States shall ensure that the records of any advice given by the animal-welfare body and decisions taken regarding that advice are kept for at least 3 years.

The records shall be made available to the competent authority upon request.

Article 28

Breeding strategy for non-human primates

Member States shall ensure that breeders of non-human primates have a strategy in place for increasing the proportion of animals that are the offspring of non-human primates that have been bred in captivity.

Article 29

Scheme for rehoming or setting free of animals

Where Member States allow rehoming, the breeders, suppliers and users from which animals are intended to be rehomed shall have a rehoming scheme in place that ensures socialisation of the animals that are rehomed. In the case of wild animals, where appropriate, a programme of rehabilitation shall be in place before they are returned to their habitat.

Article 30

Animal records

- 1 Member States shall ensure that all breeders, suppliers and users keep records of at least the following:
 - a the number and the species of animals bred, acquired, supplied, used in procedures, set-free or rehomed;

- b the origin of the animals, including whether they are bred for use in procedures;
- c the dates on which the animals are acquired, supplied, released or rehomed;
- d from whom the animals are acquired;
- e the name and address of the recipient of animals;
- f the number and species of animals which died or were killed in each establishment. For animals that have died, the cause of death shall, when known, be noted; and
- g in the case of users, the projects in which animals are used.

2 The records referred to in paragraph 1 shall be kept for a minimum of 5 years and made available to the competent authority upon request.

Article 31

Information on dogs, cats and non-human primates

1 Member States shall ensure that all breeders, suppliers and users keep the following information on each dog, cat and non-human primate:

- a identity;
- b place and date of birth, when available;
- c whether it is bred for use in procedures; and
- d in the case of a non-human primate, whether it is the offspring of non-human primates that have been bred in captivity.

2 Each dog, cat and non-human primate shall have an individual history file, which follows the animal as long as it is kept for the purposes of this Directive.

The file shall be established at birth or as soon as possible thereafter and shall cover any relevant reproductive, veterinary and social information on the individual animal and the projects in which it has been used.

3 The information referred to in this Article shall be kept for a minimum of 3 years after the death or rehoming of the animal and shall be made available to the competent authority upon request.

In the case of rehoming, relevant veterinary care and social information from the individual history file referred to in paragraph 2 shall accompany the animal.

Article 32

Marking and identification of dogs, cats and non-human primates

1 Each dog, cat or non-human primate shall be provided, at the latest at the time of weaning, with a permanent individual identification mark in the least painful manner possible.

2 Where a dog, cat or non-human primate is transferred from one breeder, supplier or user to another before it is weaned, and it is not practicable to mark it beforehand, a record, specifying in particular its mother, must be maintained by the receiver until it is marked.

3 Where an unmarked dog, cat or non-human primate, which is weaned, is received by a breeder, supplier or user it shall be permanently marked as soon as possible and in the least painful manner possible.

4 The breeder, supplier and user shall provide, at the request of the competent authority, reasons for which the animal is unmarked.

Article 33

Care and accommodation

1 Member States shall, as far as the care and accommodation of animals is concerned, ensure that:

- a all animals are provided with accommodation, an environment, food, water and care which are appropriate to their health and well-being;
- b any restrictions on the extent to which an animal can satisfy its physiological and ethological needs are kept to a minimum;
- c the environmental conditions in which animals are bred, kept or used are checked daily;
- d arrangements are made to ensure that any defect or avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible; and
- e animals are transported under appropriate conditions.

2 For the purposes of paragraph 1, Member States shall ensure that the care and accommodation standards set out in Annex III are applied from the dates provided for therein.

3 Member States may allow exemptions from the requirements of paragraph 1(a) or paragraph 2 for scientific, animal-welfare or animal-health reasons.