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2 Member States shall ensure that, where the authorisation is suspended or withdrawn, the welfare of the animals housed in the establishment is not adversely affected.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

Section 2

Inspections

Article 34

Inspections by the Member States

1 Member States shall ensure that the competent authorities carry out regular inspections of all breeders, suppliers and users, including their establishments, to verify compliance with the requirements of this Directive.

2 The competent authority shall adapt the frequency of inspections on the basis of a risk analysis for each establishment, taking account of:

a the number and species of animals housed;

b the record of the breeder, supplier or user in complying with the requirements of this Directive;

c the number and types of projects carried out by the user in question; and

d any information that might indicate non-compliance.

3 Inspections shall be carried out on at least one third of the users each year in accordance with the risk analysis referred to in paragraph 2. However, breeders, suppliers and users of non-human primates shall be inspected at least once a year.

4 An appropriate proportion of the inspections shall be carried out without prior warning.

5 Records of all inspections shall be kept for at least 5 years.

Article 35

Controls of Member State inspections

1 The Commission shall, when there is due reason for concern, taking into account, inter alia, the proportion of inspections carried out without prior warning, undertake controls of the infrastructure and operation of national inspections in Member States.

2 The Member State in the territory of which the control referred to in paragraph 1 is being carried out shall give all necessary assistance to the experts of the Commission in carrying out their duties. The Commission shall inform the competent authority of the Member State concerned of the results of the control.

3 The competent authority of the Member State concerned shall take measures to take account of the results of the control referred to in paragraph 1.

Section 3

Requirements for projects

Article 36

Project authorisation

1 Member States shall ensure, without prejudice to Article 42, that projects are not carried out without prior authorisation from the competent authority, and that projects are carried out in accordance with the 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.

2 Member States shall ensure that no project is carried out unless a favourable project evaluation by the competent authority has been received in accordance with Article 38.

Article 37

Application for project authorisation

1 Member States shall ensure that an application for project authorisation is submitted by the user or the person responsible for the project. The application shall include at least the following:

a the project proposal;

b a non-technical project summary; and

c information on the elements set out in Annex VI.

2 Member States may waive the requirement in paragraph 1(b) for projects referred to in Article 42(1).

Article 38

Project evaluation

1 The project evaluation shall be performed with a degree of detail appropriate for the type of project and shall verify that the project meets the following criteria:

a the project is justified from a scientific or educational point of view or required by law;

b the purposes of the project justify the use of animals; and

c the project is designed so as to enable procedures to be carried out in the most humane and environmentally sensitive manner possible.

2 The project evaluation shall consist in particular of the following:

a an evaluation of the objectives of the project, the predicted scientific benefits or educational value;

b an assessment of the compliance of the project with the requirement of replacement, reduction and refinement;

c an assessment and assignment of the classification of the severity of procedures;

d a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment;

e an assessment of any justification referred to in Articles 6 to 12, 14, 16 and 33; and

f a determination as to whether and when the project should be assessed retrospectively.

3 The competent authority carrying out the project evaluation shall consider expertise in particular in the following areas:

a the areas of scientific use for which animals will be used including replacement, reduction and refinement in the respective areas;

b experimental design, including statistics where appropriate;

c veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;

d animal husbandry and care, in relation to the species that are intended to be used.

4 The project evaluation process shall be transparent.

Subject to safeguarding intellectual property and confidential information, the project evaluation shall be performed in an impartial manner and may integrate the opinion of independent parties.

Article 39

Retrospective assessment

1 Member States shall ensure that when determined in accordance with Article 38(2)(f), the retrospective assessment shall be carried out by the competent authority which shall, on the basis of the necessary documentation submitted by the user, evaluate the following:

a whether the objectives of the project were achieved;

b the harm inflicted on animals, including the numbers and species of animals used, and the severity of the procedures; and

c any elements that may contribute to the further implementation of the requirement of replacement, reduction and refinement.

2 All projects using non-human primates and projects involving procedures classified as 'severe', including those referred to in Article 15(2), shall undergo a retrospective assessment.

3 Without prejudice to paragraph 2 and by way of derogation from Article 38(2)(f), Member States may exempt projects involving only procedures classified as 'mild' or 'non-recovery' from the requirement for a retrospective assessment.

Article 40

Granting of project authorisation

1 The project authorisation shall be limited to procedures which have been subject to:
- a a project evaluation; and
- b the severity classifications assigned to those procedures.

2 The project authorisation shall specify the following:
- a the user who undertakes the project;
- b the persons responsible for the overall implementation of the project and its compliance with the project authorisation;
- c the establishments in which the project will be undertaken, where applicable; and
- d any specific conditions following the project evaluation, including whether and when the project shall be assessed retrospectively.

3 Project authorisations shall be granted for a period not exceeding 5 years.

4 Member States may allow the authorisation of multiple generic projects carried out by the same user if such projects are to satisfy regulatory requirements or if such projects use animals for production or diagnostic purposes with established methods.

Article 41

Authorisation decisions

1 Member States shall ensure that the decision regarding authorisation is taken and communicated to the applicant 40 working days at the latest from the receipt of the complete and correct application. This period shall include the project evaluation.

2 When justified by the complexity or the multi-disciplinary nature of the project, the competent authority may extend the period referred to in paragraph 1 once, by an additional period not exceeding 15 working days. The extension and its duration shall be duly motivated and shall be notified to the applicant before the expiry of the period referred to in paragraph 1.

3 Competent authorities shall acknowledge to the applicant all applications for authorisations as quickly as possible, and shall indicate the period referred to in paragraph 1 within which the decision is to be taken.

4 In the case of an incomplete or incorrect application, the competent authority shall, as quickly as possible, inform the applicant of the need to supply any additional documentation and of any possible effects on the running of the applicable time period.

Article 42

Simplified administrative procedure

1 Member States may decide to introduce a simplified administrative procedure for projects containing procedures classified as 'non-recovery', 'mild' or 'moderate' and not using non-human primates, that are necessary to satisfy regulatory requirements, or which use animals for production or diagnostic purposes with established methods.

2 When introducing a simplified administrative procedure, Member States shall ensure that the following provisions are met:

a the application specifies elements referred to in Article 40(2)(a), (b) and (c);

b a project evaluation is performed in accordance with Article 38; and

c that the period referred to in Article 41(1) is not exceeded.

3 If a project is changed in a way that may have a negative impact on animal welfare, Member States shall require an additional project evaluation with a favourable outcome.

4 Article 40(3) and (4), Article 41(3) and Article 44(3), (4) and (5) shall apply mutatis mutandis to projects that are allowed to be carried out in accordance with this Article.

Article 43

Non-technical project summaries

1 Subject to safeguarding intellectual property and confidential information, the non-technical project summary shall provide the following:

a information on the objectives of the project, including the predicted harm and benefits and the number and types of animals to be used;

b a demonstration of compliance with the requirement of replacement, reduction and refinement.

The non-technical project summary shall be anonymous and shall not contain the names and addresses of the user and its personnel.

[F1 2 Member States may require the non-technical project summary to specify whether a project is to undergo a retrospective assessment and, if so, set out the deadline. In such a case, from 1 January 2021, Member States shall ensure that the non-technical project summary is updated within six months of the completion of the retrospective assessment with the results thereof.

3 Member States shall, until 31 December 2020, publish the non-technical project summaries of authorised projects and any updates thereto. From 1 January 2021, Member States shall submit for publication the non-technical project summaries, at the latest within six months of authorisation, and any updates thereto, by electronic transfer to the Commission.**]**

[F2 4 The Commission shall, by means of implementing acts, establish a common format for submitting the information referred to in paragraphs 1 and 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56(3). The Commission services shall establish and maintain a searchable, open access database on non-technical project summaries and any updates thereto.**]**

Textual Amendments

F1 Substituted by Regulation (EU) 2019/1010 of the European Parliament and of the Council of 5 June 2019 on the alignment of reporting obligations in the field of legislation related to the environment, and amending Regulations (EC) No 166/2006 and (EU) No 995/2010 of the European Parliament and of the Council, Directives 2002/49/EC, 2004/35/EC, 2007/2/EC, 2009/147/EC and 2010/63/EU of the European Parliament and of the Council, Council Regulations (EC) No 338/97 and (EC) No 2173/2005, and Council Directive 86/278/EEC (Text with EEA relevance).

F2 Inserted by Regulation (EU) 2019/1010 of the European Parliament and of the Council of 5 June 2019 on the alignment of reporting obligations in the field of legislation related to the environment, and amending Regulations (EC) No 166/2006 and (EU) No 995/2010 of the European Parliament and of the Council, Directives 2002/49/EC, 2004/35/EC, 2007/2/EC, 2009/147/EC and 2010/63/EU of the European Parliament and of the Council, Council Regulations (EC) No 338/97 and (EC) No 2173/2005, and Council Directive 86/278/EEC (Text with EEA relevance).

Article 44

Amendment, renewal and withdrawal of a project authorisation

1 Member States shall ensure that amendment or renewal of the project authorisation is required for any change of the project that may have a negative impact on animal welfare.

2 Any amendment or renewal of a project authorisation shall be subject to a further favourable outcome of the project evaluation.

3 The competent authority may withdraw the project authorisation where the project is not carried out in accordance with the project authorisation.

4 Where a project authorisation is withdrawn, the welfare of the animals used or intended to be used in the project must not be adversely affected.

5 Member States shall establish and publish conditions for amendment and renewal of project authorisations.

Article 45

Documentation

1 Member States shall ensure that all relevant documentation, including project authorisations and the result of the project evaluation is kept for at least 3 years from the expiry date of the authorisation of the project or from the expiry of the period referred to in Article 41(1) and shall be available to the competent authority.

2 Without prejudice to paragraph 1, the documentation for projects which have to undergo retrospective assessment shall be kept until the retrospective assessment has been completed.