

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 I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1 This Directive establishes measures for the protection of animals used for scientific or educational purposes.

To that end, it lays down rules on the following:

- a the replacement and reduction of the use of animals in procedures and the refinement of the breeding, accommodation, care and use of animals in procedures;
- b the origin, breeding, marking, care and accommodation and killing of animals;
- c the operations of breeders, suppliers and users;
- d the evaluation and authorisation of projects involving the use of animals in procedures.

2 This Directive shall apply where animals are used or intended to be used in procedures, or bred specifically so that their organs or tissues may be used for scientific purposes.

This Directive shall apply until the animals referred to in the first subparagraph have been killed, rehomed or returned to a suitable habitat or husbandry system.

The elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia, analgesia or other methods shall not exclude the use of an animal in procedures from the scope of this Directive.

3 This Directive shall apply to the following animals:

- a live non-human vertebrate animals, including:
 - (i) independently feeding larval forms; and
 - (ii) foetal forms of mammals as from the last third of their normal development;
- b live cephalopods.

4 This Directive shall apply to animals used in procedures, which are at an earlier stage of development than that referred to in point (a) of paragraph 3, if the animal is to be allowed to live beyond that stage of development and, as a result of the procedures performed, is likely to experience pain, suffering, distress or lasting harm after it has reached that stage of development.

5 This Directive shall not apply to the following:

- a non-experimental agricultural practices;
- b non-experimental clinical veterinary practices;
- c veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product;
- d practices undertaken for the purposes of recognised animal husbandry;

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- e practices undertaken for the primary purpose of identification of an animal;
- f practices not likely to cause pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

6 This Directive shall apply without prejudice to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products⁽¹⁾.

Article 2

Stricter national measures

1 Member States may, while observing the general rules laid down in the TFEU, maintain provisions in force on 9 November 2010, aimed at ensuring more extensive protection of animals falling within the scope of this Directive than those contained in this Directive.

Before 1 January 2013 Member States shall inform the Commission about such national provisions. The Commission shall bring them to the attention of other Member States.

2 When acting pursuant to paragraph 1, a Member State shall not prohibit or impede the supply or use of animals bred or kept in another Member State in accordance with this Directive, nor shall it prohibit or impede the placing on the market of products developed with the use of such animals in accordance with this Directive.

Article 3

Definitions

For the purposes of this Directive the following definitions shall apply:

1. 'procedure' means any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition, but excludes the killing of animals solely for the use of their organs or tissues;

2. 'project' means a programme of work having a defined scientific objective and involving one or more procedures;
3. 'establishment' means any installation, building, group of buildings or other premises and may include a place that is not wholly enclosed or covered and mobile facilities;
4. 'breeder' means any natural or legal person breeding animals referred to in Annex I with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, or breeding other animals primarily for those purposes, whether for profit or not;
5. 'supplier' means any natural or legal person, other than a breeder, supplying animals with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, whether for profit or not;

6. 'user' means any natural or legal person using animals in procedures, whether for profit or not;
7. 'competent authority' means an authority or authorities or bodies designated by a Member State to carry out the obligations arising from this Directive.

Article 4

Principle of replacement, reduction and refinement

- 1 Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure.
- 2 Member States shall ensure that the number of animals used in projects is reduced to a minimum without compromising the objectives of the project.
- 3 Member States shall ensure refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals.
- 4 This Article shall, in the choice of methods, be implemented in accordance with Article 13.

Article 5

Purposes of procedures

Procedures may be carried out for the following purposes only:

- (a) basic research;
- (b) translational or applied research with any of the following aims:
 - (i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants;
 - (ii) the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants; or
 - (iii) the welfare of animals and the improvement of the production conditions for animals reared for agricultural purposes;
- (c) for any of the aims in point (b) in the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products;
- (d) protection of the natural environment in the interests of the health or welfare of human beings or animals;
- (e) research aimed at preservation of the species;
- (f) higher education, or training for the acquisition, maintenance or improvement of vocational skills;
- (g) forensic inquiries.

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Article 6

Methods of killing

1 Member States shall ensure that animals are killed with minimum pain, suffering and distress.

2 Member States shall ensure that animals are killed in the establishment of a breeder, supplier or user, by a competent person.

However, in the case of a field study an animal may be killed by a competent person outside of an establishment.

3 In relation to the animals covered by Annex IV, the appropriate method of killing as set out in that Annex shall be used.

4 Competent authorities may grant exemptions from the requirement in paragraph 3:

- a to allow the use of another method provided that, on the basis of scientific evidence, the method is considered to be at least as humane; or
- b when, on the basis of scientific justification, the purpose of the procedure cannot be achieved by the use of a method of killing set out in Annex IV.

5 Paragraphs 2 and 3 shall not apply where an animal has to be killed in emergency circumstances for animal-welfare, public-health, public-security, animal-health or environmental reasons.

CHAPTER II

PROVISIONS ON THE USE OF CERTAIN ANIMALS IN PROCEDURES

Article 7

Endangered species

1 Specimens of those endangered species listed in Annex A to Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein⁽²⁾, which do not fall within the scope of Article 7(1) of that Regulation, shall not be used in procedures, with the exception of those procedures meeting the following conditions:

- a the procedure has one of the purposes referred to in points (b)(i), (c) or (e) of Article 5 of this Directive; and
- b there is scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than those listed in that Annex.

2 Paragraph 1 shall not apply to any species of non-human primates.

Article 8

Non-human primates

1 Subject to paragraph 2, specimens of non-human primates shall not be used in procedures, with the exception of those procedures meeting the following conditions:

- a the procedure has one of the purposes referred to in
 - (i) points (b)(i) or (c) of Article 5 of this Directive and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings; or
 - (ii) points (a) or (e) of Article 5;
- and
- b there is scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than non-human primates.

A debilitating clinical condition for the purposes of this Directive means a reduction in a person's normal physical or psychological ability to function.

2 Specimens of non-human primates listed in Annex A to Regulation (EC) No 338/97, which do not fall within the scope of Article 7(1) of that Regulation, shall not be used in procedures, with the exception of those procedures meeting the following conditions:

- a the procedure has one of the purposes referred to in:
 - (i) points (b)(i) or (c) of Article 5 of this Directive and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings; or
 - (ii) Article 5(e);
- and
- b there is scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than non-human primates and by the use of species not listed in that Annex.

3 Notwithstanding paragraphs 1 and 2, great apes shall not be used in procedures, subject to the use of the safeguard clause in Article 55(2).

Article 9

Animals taken from the wild

1 Animals taken from the wild shall not be used in procedures.

2 Competent authorities may grant exemptions from paragraph 1 on the basis of scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of an animal which has been bred for use in procedures.

3 The capture of animals in the wild shall be carried out only by competent persons using methods which do not cause the animals avoidable pain, suffering, distress or lasting harm.

Any animal found, at or after capture, to be injured or in poor health shall be examined by a veterinarian or another competent person and action shall be taken to minimise the suffering of the animal. Competent authorities may grant exemptions from the requirement of taking action to minimise the suffering of the animal if there is scientific justification.

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Article 10

Animals bred for use in procedures

1 Member States shall ensure that animals belonging to the species listed in Annex I may only be used in procedures where those animals have been bred for use in procedures.

However, from the dates set out in Annex II, Member States shall ensure that non-human primates listed therein may be used in procedures only where they are the offspring of non-human primates which have been bred in captivity or where they are sourced from self-sustaining colonies.

For the purposes of this Article a 'self-sustaining colony' means a colony in which animals are bred only within the colony or sourced from other colonies but not taken from the wild, and where the animals are kept in a way that ensures that they are accustomed to humans.

The Commission shall, in consultation with the Member States and stakeholders, conduct a feasibility study, which shall include an animal health and welfare assessment, of the requirement laid down in the second subparagraph. The study shall be published no later than 10 November 2017. It shall be accompanied, where appropriate, by proposals for amendments to Annex II.

2 The Commission shall keep under review the use of sourcing non-human primates from self-sustaining colonies and, in consultation with the Member States and stakeholders, conduct a study to analyse the feasibility of sourcing animals only from self-sustaining colonies.

The study shall be published no later than 10 November 2022.

3 Competent authorities may grant exemptions from paragraph 1 on the basis of scientific justification.

Article 11

Stray and feral animals of domestic species

1 Stray and feral animals of domestic species shall not be used in procedures.

2 The competent authorities may only grant exemptions from paragraph 1 subject to the following conditions:

- a there is an essential need for studies concerning the health and welfare of the animals or serious threats to the environment or to human or animal health; and
- b there is scientific justification to the effect that the purpose of the procedure can be achieved only by the use of a stray or a feral animal.

CHAPTER III

PROCEDURES

Article 12

Procedures

- 1 Member States shall ensure that procedures are carried out in a user's establishment. The competent authority may grant an exemption from the first subparagraph on the basis of scientific justification.
- 2 Procedures may be carried out only within the framework of a project.

Article 13

Choice of methods

- 1 Without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under the legislation of the Union.
- 2 In choosing between procedures, those which to the greatest extent meet the following requirements shall be selected:
 - a use the minimum number of animals;
 - b involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;
 - c cause the least pain, suffering, distress or lasting harm;and are most likely to provide satisfactory results.
- 3 Death as the end-point of a procedure shall be avoided as far as possible and replaced by early and humane end-points. Where death as the end-point is unavoidable, the procedure shall be designed so as to:
 - a result in the deaths of as few animals as possible; and
 - b reduce the duration and intensity of suffering to the animal to the minimum possible and, as far as possible, ensure a painless death.

Article 14

Anaesthesia

- 1 Member States shall ensure that, unless it is inappropriate, procedures are carried out under general or local anaesthesia, and that analgesia or another appropriate method is used to ensure that pain, suffering and distress are kept to a minimum.

Procedures that involve serious injuries that may cause severe pain shall not be carried out without anaesthesia.

- 2 When deciding on the appropriateness of using anaesthesia, the following shall be taken into account:

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- a whether anaesthesia is judged to be more traumatic to the animal than the procedure itself; and
- b whether anaesthesia is incompatible with the purpose of the procedure.

3 Member States shall ensure that animals are not given any drug to stop or restrict their showing pain without an adequate level of anaesthesia or analgesia.

In these cases, a scientific justification shall be provided, accompanied by the details of the anaesthetic or analgesic regimen.

4 An animal, which may suffer pain once anaesthesia has worn off, shall be treated with pre-emptive and post-operative analgesics or other appropriate pain-relieving methods provided that it is compatible with the purpose of the procedure.

5 As soon as the purpose of the procedure has been achieved appropriate action shall be taken to minimise the suffering of the animal.

Article 15

Classification of severity of procedures

1 Member States shall ensure that all procedures are classified as ‘non-recovery’, ‘mild’, ‘moderate’, or ‘severe’ on a case-by-case basis using the assignment criteria set out in Annex VIII.

2 Subject to the use of the safeguard clause in Article 55(3), Member States shall ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

Article 16

Reuse

1 Member States shall ensure that an animal already used in one or more procedures, when a different animal on which no procedure has previously been carried out could also be used, may only be reused in a new procedure provided that the following conditions are met:

- a the actual severity of the previous procedures was ‘mild’ or ‘moderate’;
- b it is demonstrated that the animal’s general state of health and well-being has been fully restored;
- c the further procedure is classified as ‘mild’, ‘moderate’ or ‘non-recovery’; and
- d it is in accordance with veterinary advice, taking into account the lifetime experience of the animal.

2 In exceptional circumstances, by way of derogation from point (a) of paragraph 1 and after a veterinary examination of the animal, the competent authority may allow reuse of an animal, provided the animal has not been used more than once in a procedure entailing severe pain, distress or equivalent suffering.

Article 17

End of the procedure

1 A procedure shall be deemed to end when no further observations are to be made for that procedure or, as regards new genetically modified animal lines, when the progeny are no longer observed or expected to experience pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle.

2 At the end of a procedure, a decision to keep an animal alive shall be taken by a veterinarian or by another competent person. An animal shall be killed when it is likely to remain in moderate or severe pain, suffering, distress or lasting harm.

3 Where an animal is to be kept alive, it shall receive care and accommodation appropriate to its state of health.

Article 18

Sharing organs and tissues

Member States shall facilitate, where appropriate, the establishment of programmes for the sharing of organs and tissues of animals killed.

Article 19

Setting free of animals and rehoming

Member States may allow animals used or intended to be used in procedures to be rehomed, or returned to a suitable habitat or husbandry system appropriate to the species, provided that the following conditions are met:

- (a) the state of health of the animal allows it;
- (b) there is no danger to public health, animal health or the environment; and
- (c) appropriate measures have been taken to safeguard the well-being of the animal.

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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

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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.

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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

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- 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;

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- 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.

[^{F12} 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.]

[^{F24} 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 \(Text with EEA relevance\).](#)

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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.

CHAPTER V

AVOIDANCE OF DUPLICATION AND ALTERNATIVE APPROACHES

Article 46

Avoidance of duplication of procedures

Each Member State shall accept data from other Member States that are generated by procedures recognised by the legislation of the Union, unless further procedures need to be carried out regarding that data for the protection of public health, safety or the environment.

Article 47

Alternative approaches

1 The Commission and the Member States shall contribute to the development and validation of alternative approaches which could provide the same or higher levels of information as those obtained in procedures using animals, but which do not involve the use of animals or use fewer animals or which entail less painful procedures, and they shall take such other steps as they consider appropriate to encourage research in this field.

2 Member States shall assist the Commission in identifying and nominating suitable specialised and qualified laboratories to carry out such validation studies.

3 After consulting the Member States, the Commission shall set the priorities for those validation studies and allocate the tasks between the laboratories for carrying out those studies.

4 Member States shall, at national level, ensure the promotion of alternative approaches and the dissemination of information thereon.

5 Member States shall nominate a single point of contact to provide advice on the regulatory relevance and suitability of alternative approaches proposed for validation.

6 The Commission shall take appropriate action with a view to obtaining international acceptance of alternative approaches validated in the Union.

Article 48

Union Reference Laboratory

1 The Union Reference Laboratory and its duties and tasks shall be those referred to in Annex VII.

2 The Union Reference Laboratory may collect charges for the services it provides that do not directly contribute to the further advancement of replacement, reduction and refinement.

3 Detailed rules necessary for the implementation of paragraph 2 of this Article and Annex VII may be adopted in accordance with the regulatory procedure referred to in Article 56(3).

Article 49

National committees for the protection of animals used for scientific purposes

1 Each Member State shall establish a national committee for the protection of animals used for scientific purposes. It shall advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice.

2 The national committees referred to in paragraph 1 shall exchange information on the operation of animal-welfare bodies and project evaluation and share best practice within the Union.

CHAPTER VI

FINAL PROVISIONS

Article 50

Adaptation of Annexes to technical progress

In order to ensure that the provisions of Annexes I and III to VIII reflect the state of technical or scientific progress, taking into account the experience gained in the implementation of this Directive, in particular through the reporting referred to in Article 54(1), the Commission may adopt, by means of delegated acts in accordance with Article 51 and subject to the conditions laid down in Articles 52 and 53, modifications of those Annexes, with the exception of provisions of Sections I and II of Annex VIII. The dates referred to in Section B of Annex III shall not be brought forward. When adopting such delegated acts, the Commission shall act in accordance with the relevant provisions of this Directive.

Article 51

Exercise of the delegation

1 The power to adopt delegated acts referred to in Article 50 shall be conferred on the Commission for a period of 8 years beginning on 9 November 2010. The Commission shall make a report in respect of the delegated power at the latest 12 months before the end of the 8-year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 52.

2 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 52 and 53.

Article 52

Revocation of the delegation

1 The delegation of power referred to in Article 50 may be revoked at any time by the European Parliament or by the Council.

2 The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated power which could be subject to revocation and possible reasons for a revocation.

3 The decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 53

Objections to delegated acts

1 The European Parliament or the Council may object to a delegated act within a period of 2 months from the date of notification.

At the initiative of the European Parliament or the Council this period shall be extended by 2 months.

2 If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force at the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3 If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 54

[^{F1}Information on implementation and provision of statistical data

1 Member States shall by 10 November 2023, and every five years thereafter, send the information on the implementation of this Directive and in particular of Article 10(1) and Articles 26, 28, 34, 38, 39, 43 and 46 to the Commission.

Member States shall submit and publish that data, by electronic transfer in a format established by the Commission in accordance with paragraph 4.

No later than six months after the submission by Member States of the data referred to in the second subparagraph, the Commission services shall publish and regularly update a Union-wide overview on the basis of that data.

2 Member States shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures.

Member States shall submit that statistical information to the Commission, at the latest by 10 November of the following year, by electronic transfer, in a non-summarised format established by the Commission in accordance with paragraph 4.

The Commission shall establish and maintain a searchable, open access database containing that statistical information. On an annual basis, the Commission services shall make publicly available the statistical information submitted by the Member States in accordance with this paragraph and a summary report thereof.]

3 Member States shall submit to the Commission, on annual basis, detailed information on exemptions granted under Article 6(4)(a).

[^{F14} The Commission shall, by means of implementing acts, establish a common format and information content for submitting the information referred to in paragraphs 1, 2 and 3

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of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56(3).]

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).

Article 55

Safeguard clauses

1 Where a Member State has scientifically justifiable grounds for believing it is essential to use non-human primates for the purposes referred to in Article 8(1)(a)(i) with regard to human beings, but where the use is not undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions, it may adopt a provisional measure allowing such use, provided the purpose cannot be achieved by the use of species other than non-human primates.

2 Where a Member State has justifiable grounds for believing that action is essential for the preservation of the species or in relation to an unexpected outbreak of a life-threatening or debilitating clinical condition in human beings, it may adopt a provisional measure allowing the use of great apes in procedures having one of the purposes referred to in points (b)(i), (c) or (e) of Article 5; provided that the purpose of the procedure cannot be achieved by the use of species other than great apes or by the use of alternative methods. However, the reference to Article 5(b)(i) shall not be taken to include the reference to animals and plants.

3 Where, for exceptional and scientifically justifiable reasons, a Member State deems it necessary to allow the use of a procedure involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated, as referred to in Article 15(2), it may adopt a provisional measure to allow such procedure. Member States may decide not to allow the use of non-human primates in such procedures.

4 A Member State which has adopted a provisional measure in accordance with paragraph 1, 2 or 3 shall immediately inform the Commission and the other Member States thereof, giving reasons for its decision and submitting evidence of the situation as described in paragraphs 1, 2 and 3 on which the provisional measure is based.

The Commission shall put the matter before the Committee referred to in Article 56(1) within 30 days of receipt of the information from the Member State and shall, in accordance with the regulatory procedure referred to in Article 56(3), either:

- a authorise the provisional measure for a time period defined in the decision; or
- b require the Member State to revoke the provisional measure.

Article 56

Committee

- 1 The Commission shall be assisted by a Committee.
 - 2 Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
 - 3 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
- The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.

^{F3}Article 57

[^{F3}Commission report]

.....

Textual Amendments

- F3** Deleted 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 58

Review

The Commission shall review this Directive by 10 November 2017, taking into account advancements in the development of alternative methods not entailing the use of animals, in particular of non-human primates, and shall propose amendments, where appropriate.

The Commission shall, where appropriate, and in consultation with the Member States and stakeholders, conduct periodic thematic reviews of the replacement, reduction and refinement of the use of animals in procedures, paying specific attention to non-human primates, technological developments, and new scientific and animal-welfare knowledge.

Article 59

Competent authorities

- 1 Each Member State shall designate one or more competent authorities responsible for the implementation of this Directive.

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Member States may designate bodies other than public authorities for the implementation of specific tasks laid down in this Directive only if there is proof that the body:

- a has the expertise and infrastructure required to carry out the tasks; and
- b is free of any conflict of interests as regards the performance of the tasks.

Bodies thus designated shall be considered competent authorities for the purposes of this Directive.

2 Each Member State shall communicate details of a national authority serving as contact point for the purposes of this Directive to the Commission by 10 February 2011, as well as any update to such data.

The Commission shall make publicly available the list of those contact points.

Article 60

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 10 February 2013, and shall notify the Commission without delay of any subsequent amendment affecting them.

Article 61

Transposition

1 Member States shall adopt and publish, by 10 November 2012, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 January 2013.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The method of making such reference shall be laid down by Member States.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 62

Repeal

1 Directive 86/609/EEC is repealed with effect from 1 January 2013 with the exception of Article 13, which shall be repealed with effect from 10 May 2013.

2 References to the repealed Directive shall be construed as references to this Directive.

Article 63

Amendment of Regulation (EC) No 1069/2009

Point (a)(iv) of Article 8 of Regulation (EC) No 1069/2009 is replaced by the following:

- (iv) animals used in a procedure or procedures defined in Article 3 of 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⁽³⁾, in cases where the competent authority decides that such animals or any of their body parts have the potential to pose serious health risks to humans or to other animals, as a result of that procedure or those procedures without prejudice to Article 3(2) of Regulation (EC) No 1831/2003;

Article 64

Transitional provisions

1 Member States shall not apply laws, regulations and administrative provisions adopted in accordance with Articles 36 to 45 to projects which have been approved before 1 January 2013 and the duration of which does not extend beyond 1 January 2018.

2 Projects which have been approved before 1 January 2013 and the duration of which extends beyond 1 January 2018 shall obtain project authorisation by 1 January 2018.

Article 65

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 66

Addressees

This Directive is addressed to the Member States.

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- (1) [OJ L 262, 27.9.1976, p. 169](#). Directive recast by Regulation (EC) No 1223/2009 of the European Parliament and the Council of 30 November 2009 on cosmetic products ([OJ L 342, 22.12.2009, p. 59](#)), which applies as from 11 July 2013.
- (2) [OJ L 61, 3.3.1997, p. 1](#).
- (3) [OJ L 276, 20.10.2010, p. 33](#)'.