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;

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.

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.

(**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.