

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 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:

- 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.