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		
Article 2	Stricter national measures		
Article 3	Definitions		
Article 4	Principle of replacement, reduction and refinement		
Article 5	Purposes of procedures		
Article 6	Methods of killing		
	CHAPTER II		
PROVI	SIONS ON THE USE OF CERTAIN ANIMALS IN PROCEDURES		
Article 7	Endangered species		
Article 8	Non-human primates		
Article 9	Animals taken from the wild		

CHAPTER III

PROCEDURES

Article 12	Procedures
Article 13	Choice of methods
Article 14	Anaesthesia
Article 15	Classification of severity of procedures
Article 16	Reuse
Article 17	End of the procedure
Article 18	Sharing organs and tissues
Article 19	Setting free of animals and rehoming

Animals bred for use in procedures

Stray and feral animals of domestic species

Article 10

Article 11

CHAPTER IV

AUTHORISATION

Section 1

Requirements for breeders, suppliers and users

Article 20	Authorisation of breeders, suppliers and users
Article 21	Suspension and withdrawal of authorisation
Article 22	Requirements for installations and equipment

Article 23 Article 24 Article 25 Article 26 Article 27 Article 28 Article 29 Article 30 Article 31 Article 32 Article 33	Competence of personnel Specific requirements for personnel Designated veterinarian Animal-welfare body Tasks of the animal-welfare body Breeding strategy for non-human primates Scheme for rehoming or setting free of animals Animal records Information on dogs, cats and non-human primates Marking and identification of dogs, cats and non-human primates Care and accommodation
	Section 2
	Inspections
Article 34 Article 35	Inspections by the Member States Controls of Member State inspections
	Section 3
	Requirements for projects
Article 36 Article 37 Article 38 Article 39 Article 40 Article 41 Article 42 Article 43 Article 44 Article 45	Project authorisation Application for project authorisation Project evaluation Retrospective assessment Granting of project authorisation Authorisation decisions Simplified administrative procedure Non-technical project summaries Amendment, renewal and withdrawal of a project authorisation Documentation
	CHAPTER V
AVOID	ANCE OF DUPLICATION AND ALTERNATIVE APPROACHES
Article 46 Article 47 Article 48 Article 49	Avoidance of duplication of procedures Alternative approaches Union Reference Laboratory National committees for the protection of animals used for scientific purposes
	CHAPTER VI
	FINAL PROVISIONS
Article 50 Article 51 Article 52 Article 53 Article 54	Adaptation of Annexes to technical progress Exercise of the delegation Revocation of the delegation Objections to delegated acts Reporting

Article 55	Safeguard clauses
Article 56	Committee
Article 57	Commission report
Article 58	Review
Article 59	Competent authorities
Article 60	Penalties
Article 61	Transposition
Article 62	Repeal
Article 63	Amendment of Regulation (EC) No 1069/2009
Article 64	Transitional provisions
Article 65	Entry into force
Article 66	Addressees
	Signature

ANNEX I

LIST OF ANIMALS REFERRED TO IN ARTICLE 10

Mouse (Mus musculus) Rat (Rattus norvegicus) Guinea pig (Cavia porcellus)...

ANNEX II

ANNEX III

REQUIREMENTS FOR ESTABLISHMENTS AND FOR THE CARE AND ACCOMMODATION OF ANIMALS

Section A:

General section

- 1. The physical facilities
 - 1.1. Functions and general design
 - (a) All facilities shall be constructed so as to provide an...
 - (b) Establishments shall have an active maintenance programme to prevent and...
 - 1.2. Holding rooms
 - (a) Establishments shall have a regular and efficient cleaning schedule for...
 - (b) Walls and floors shall be surfaced with a material resistant...
 - (c) Species that are incompatible, for example predator and prey, or...
 - 1.3. General and special purpose procedure rooms
 - (a) Establishments shall, where appropriate, have available laboratory facilities for the...
 - (b) Facilities shall be provided to enable newly-acquired animals to be...
 - (c) There shall be accommodation for the separate housing of sick...
 - 1.4. Service rooms

- (a) Store-rooms shall be designed, used and maintained to safeguard the...
- (b) The cleaning and washing areas shall be large enough to...
- (c) Establishments shall provide for the hygienic storage and safe disposal...
- (d) Where surgical procedures under aseptic conditions are required there shall...

2. The environment and control thereof

- 2.1. Ventilation and temperature
 - (a) Insulation, heating and ventilation of the holding room shall ensure...
 - (b) Temperature and relative humidity in the holding rooms shall be...
 - (c) Animals shall not be restricted to outdoor areas under climatic...
- 2.2. Lighting
 - (a) Where natural light does not provide an appropriate light/dark cycle,...
 - (b) Illumination shall satisfy the needs for the performance of husbandry...
 - (c) Regular photoperiods and intensity of light adapted to the species...
 - (d) When keeping albino animals, the lighting shall be adjusted to...
- 2.3. Noise
 - (a) Noise levels including ultrasound, shall not adversely affect animal welfare....
 - (b) Establishments shall have alarm systems that sound outside the sensitive...
 - (c) Holding rooms shall where appropriate be provided with noise insulation...
- 2.4. Alarm systems
 - (a) Establishments relying on electrical or mechanical equipment for environmental control...
 - (b) Heating and ventilation systems shall be equipped with monitoring devices...
 - (c) Clear instructions on emergency procedures shall be prominently displayed.

3. Care of animals

- 3.1. Health
 - (a) Establishments shall have a strategy in place to ensure that...
 - (b) Animals shall be checked at least daily by a competent...
- 3.2. Animals taken from the wild
 - (a) Transport containers and means of transport adapted to the species...
 - (b) Special consideration shall be given and appropriate measures taken for...
- 3.3. Housing and enrichment
 - (a) Housing
 - (b) Enrichment
 - (c) Animal enclosures
- 3.4. Feeding
 - (a) The form, content and presentation of the diet shall meet...
 - (b) The animals' diet shall be palatable and non-contaminated. In the...
 - (c) Packing, transport and storage shall be such as to avoid...
 - (d) Each animal shall be able to access the food, with...
- 3.5. Watering
 - (a) Uncontaminated drinking water shall always be available to all animals....
 - (b) When automatic watering systems are used, they shall be regularly...

- (c) Provision shall be made to adapt the water supply for...
- 3.6. Resting and sleeping areas
 - (a) Bedding materials or sleeping structures adapted to the species shall...
 - (b) Within the animal enclosure, as appropriate to the species, a...
- 3.7. Handling

Section B:

Species-specific section

- 1. Mice, rats, gerbils, hamsters and guinea pigs
 - Table 1. Mice
 - Table 1. Rats
 - Table 1. Gerbils
 - Table 1. Hamsters
 - Table 1. Suinea pigs
- 2. Rabbits
 - Table 2. Rabbits over 10 weeks of age
 - Table 2. Doe plus litter
 - Table 2. Rabbits less than 10 weeks of age
 - Table 2. Rabbits: Optimal dimensions for raised areas for enclosures having the...
- 3. Cats
 - Table 3. Cats
- 4. Dogs
 - Table 4. Dogs
 - Table 4. Dogs post-weaned stock
- 5. Ferrets
 - Table 5. Ferrets
- 6. Non-human primates
 - Table 6. Marmosets and tamarins
 - Table 6. Squirrel monkeys
- 7. Farm animals
 - Table 7. Cattle
 - Table 7. Sheep and goats
 - Table 7. Prigs and minipigs
 - Table 7. Equines
- 8. Birds
 - Table 8. Domestic fowl
 - Table 8. Domestic turkeys
 - Table 8. Quails
 - Table 8. Ducks and geese
 - Table 8. Pigeons
 - Table 8. Zebra finches
- 9. Amphibians
 - Table 9. Aquatic urodeles

Table 9. Semi-aquatic anurans
Table 9. Semi-terrestrial anurans
Table 9. Arboreal anurans

10. Reptiles

Table 10Alquatic chelonians
Table 10I2rrestrial snakes

11. Fish

- 11.1. Water supply and quality
- 11.2. Oxygen, nitrogen compounds, pH, and salinity
- 11.3. Temperature, lighting, noise
- 11.4. Stocking density and environmental complexity
- 11.5. Feeding and handling

ANNEX IV

METHODS OF KILLING ANIMALS

- 1. In the process of killing animals, methods listed in the...
- 2. The killing of animals shall be completed by one of...
- 3. Table

Requirements

- 1. Shall, where appropriate, be used with prior sedation.
- 2. Only to be used on large reptiles.
- 3. Only to be used in gradual fill. Not to be...
- 4. Only to be used for birds under 1 kg. Birds over...
- 5. Only to be used for rodents under 1 kg. Rodents over...
- 6. Only to be used for rabbits under 1 kg. Rabbits over...
- 7. Only to be used for birds under 5 kg.
- 8. Only to be used for rodents under 1 kg.
- 9. Only to be used for rabbits under 5 kg.
- 10. Only to be used on neonates.
- 11. Only to be used for birds under 250 g.
- 12. Only to be used if other methods are not possible....
- 13. Specialised equipment required.
- 14. Only to be used on pigs.
- 15. Only to be used in field conditions by experienced marksmen....
- 16. Only to be used in field conditions by experienced marksmen...

ANNEX V

LIST OF ELEMENTS REFERRED TO IN ARTICLE 23(3)

National legislation in force relevant to the acquisition, husbandry, care...

ANNEX VI LIST OF ELEMENTS REFERRED TO IN ARTICLE 37(1)(c)

Relevance and justification of the following: use of animals including...

ANNEX VII DUTIES AND TASKS OF THE UNION REFERENCE LABORATORY

- 1. The Union Reference Laboratory referred to in Article 48 is...
- 2. The Union Reference Laboratory shall be responsible, in particular, for:...
- 3. The Union Reference Laboratory shall participate in the validation of...

ANNEX VIII SEVERITY CLASSIFICATION OF PROCEDURES

The severity of a procedure shall be determined by the...

Section I:

Severity categories

	Non-recovery:	
	Mild:	
	Moderate:	
	Severe:	
		Section II:
		Assignment criteria
		Section III:
	2011	
1.	Mild:	
2.	Moderate:	
3.	Severe:	

Status: This is the original version (as it was originally adopted).

- (1) OJ C 277, 17.11.2009, p. 51.
- (2) Position of the European Parliament of 5 May 2009 (OJ C 212 E, 5.8.2010, p. 170), position of the Council of 13 September 2010 (not yet published in the Official Journal) and position of the European Parliament of 8 September 2010 (not yet published in the Official Journal).
- (**3**) OJ L 358, 18.12.1986, p. 1.
- (4) OJ L 222, 24.8.1999, p. 29.
- (5) OJ L 197, 30.7.2007, p. 1.
- (6) OJ L 184, 17.7.1999, p. 23.
- (7) OJ L 300, 14.11.2009, p. 1.