NB: Unofficial translation
Legally binding texts are those in Finnish and Swedish

Government Decree on the Protection of Animals Used for Scientific or Educational Purposes (564/2013)

Chapter 1 – **Requirements concerning establishments and care and keeping of animals**

Section 1 – *Requirements set for an establishment*

(1) An establishment shall have adequate and appropriate facilities and premises for the animals required for the type of activity of the establishment for the receipt and dispatch, breeding and rearing, keeping and care of animals as well as performing procedures and killing as well as separating injured and sick animals and newly-acquired animals from other animals.
(2) An establishment shall have adequate and appropriate service rooms for keeping, cleaning and maintenance of installations and equipment and for keeping feed, bedding and other substances as well as dead animals and waste.
(3) Storage facilities shall be designed, used and maintained in a way that the quality of the animal feed and bedding is safeguarded. Prevention of vermin and insects shall be taken care of in the facilities. A separate storage facility shall be available for substances which may be contaminated or otherwise present a hazard to animals or staff. The facilities for cleaning installations and equipment shall be large enough to accommodate the installations needed in the cleaning. The facilities shall be such that clean and used equipment can be kept separate.
(4) Where necessary, an establishment shall have appropriate laboratory premises in which simple diagnostic tests and post-mortem examinations can be carried out and laboratory samples taken. Where necessary, an establishment shall have available separate rooms for performing procedures and observation of animals. For surgical procedures an establishment shall have suitable premises for aseptic work and care of animals after an operation.
(5) The facilities of an establishment shall be designed and managed in a way that access by unauthorised persons and the ingress or escape of animals is prevented. An establishment shall have a plan for the management and maintenance of the animal holding rooms. An establishment shall have the necessary rescue and fire prevention equipment.

Section 2 – *General requirements for animal premises*

(1) Animal premises shall be such that they are suitable for satisfying the physiological and ethological needs of the animals. Animal premises shall offer adequate possibilities for an animal to avoid other animals or hide from them.
(2) The materials, structures and other properties of animal premises shall be such that the risk of injury to the animal is minimised. The structure and material of the floor shall be adapted to the animals kept in them. Animal premises shall be easy to clean.
(3) Animal premises shall be kept clean and in good condition so that they do not injure the animal or present a hazard to their health and welfare.

Section 3 – *Conditions in animal holding rooms*

(1) Ventilation of holding rooms shall be such that the air circulation and humidity are adapted to the animals and dust levels and gas concentrations do not present a hazard to the welfare of an animal. Temperature shall be adapted to the animals housed in the holding rooms. The

temperature of the holding rooms shall be measured and logged on a daily basis. Animals shall not be restricted to outdoor areas under weather conditions which may cause them distress.

(2) In animal premises for fish or other aquatic animals the oxygen level, quality, replacement frequency and circulation of the water shall be adapted to them.

(3) Animal holding rooms shall have adequate illumination for husbandry procedures and inspection of the animals. Lighting shall have regular photoperiods of light and dark and intensity of light shall be adapted to the species housed. Where natural light does not provide an appropriate light/dark cycle, controlled lighting shall be provided to satisfy the biological requirements of animals. When keeping albino animals the lighting shall be adjusted to take into account their sensitivity to light.

(4) Noise levels in the animal holding room including ultrasound shall not adversely affect animal welfare. Alarm systems shall sound outside the sensitive hearing range of the animals, where this nor conflict with their audibility to human beings. Where appropriate, holding rooms shall be provided with noise insulation and absorption materials.

(5) In animal holding rooms relying on electrical or mechanical equipment for environmental control and protection there shall be a possibility to maintain essential services for animal welfare and emergency lighting as well as ensure the operation of alarm systems even during failure of the equipment. Mechanical heating, ventilation and water replacement systems shall be equipped with monitoring systems and alarms if animal welfare depends on the operation of these systems. Instructions on emergency procedures shall be prominently displayed.

Section 4 – *Enrichment and bedding*

(1) Animals shall be provided with space of sufficient complexity to allow expression of a wide range of normal behavioural needs. Animals shall be able to control their environment and make choices concerning it. Enrichment shall be provided to animals that is adapted to the species and individual needs of the animals. The practices for enrichment for animals shall be regularly reviewed and updated.

(2) Bedding or sleeping structures adapted to the species shall always be provided to the animals. In sleeping areas there shall be enough space for all animals to rest at the same time. Sleeping areas shall be kept clean and dry. For breeding animals suitable nesting structures or materials shall be provided.

Section 5 – *Monitoring animal welfare*

(1) The welfare of animals shall be inspected at least once a day. Special attention shall be given to inspection when significant changes take place in the care or circumstances of animals or procedures are performed on animals which may interfere with or alter their normal physiological conditions.

(2) In the inspection it shall be ensured that animals that are sick, injured or otherwise in distress are detected. If unforeseen irregularities in the state of health or welfare of an animal are observed in the inspection, action shall be taken without delay to correct the irregularities. As regards animals involved in a project the person responsible for implementing the project shall be notified of the matter without delay.

Section 6 – *Handling and treatment*

(1) Animals shall be habituated and trained for the handling and housing conditions if this is to be considered appropriate as regards the animals, procedures performed on them and length of the project.

(2) Animals, except those which are naturally solitary, shall be socially housed in stable groups of compatible individuals. In cases where single housing is allowed in accordance with section

9(1) the duration shall be limited to the minimum and the animal shall have, whenever possible, visual, auditory, olfactory or tactile contact to individuals of the same species.

(3) When animals are put together to form a group or new animals are introduced to a group special attention is required to avoid any behavioural problems. If animals injure each other or fight immediate action shall be taken to prevent this.

(4) Species that are incompatible, for example predator and prey, or animals requiring different environmental conditions shall not be housed in the same room. Predator and prey shall not be housed within sight, smell or sound of each other.

Section 7 – *Watering and feeding*

(1) Feeding shall be organised so that competition between animals can be avoided. Unless feed is available at all times, all animals shall be able to feed at the same time

(2) Feed provided to animals shall be palatable, nutritious and balanced. The composition and presentation of the feed shall meet the behavioural needs of the animal.

(3) Unnecessary contamination shall be avoided. Feed and watering utensils shall be regularly cleaned and, if necessary, sterilised.

(4) Clean drinking water shall always be available to animals. Automatic watering systems shall be regularly checked and serviced. In solid-bottomed cages care shall be taken that water does not pile up on the floor in harmful quantities.

Section 8 – *Specific requirements for animal premises and care*

(1) The minimum requirements for animal premises and care in Annex I shall be complied with. When the purpose of the project requires that the animals are kept under similar conditions to those under which commercial farm animals or horses are kept, the species-specific animal protection requirements concerning them shall be complied with.

(2) Special consideration shall be given for the acclimatisation, quarantine, housing, husbandry and care of animals taken from the wild to safeguard the well-being of animals.

Section 9 – *Exemptions from requirements concerning animal premises and care*

(1) In a project authorisation or operation authorisation an exemption may be granted from the requirements concerning animal premises and care if there is a scientific, animal welfare or animal health reason for this.

(2) An exemption from the requirements concerning animal premises and care for an individual animal may be allowed if there is an animal welfare or animal health reason for this.

Chapter 2 – **Animals**

Section 10 – *Purpose-bred animals*

(1) Mice (*Mus musculus*), rats (*Rattus norvegicus*), guinea pigs (*Cavia porcellus*), Syrian (golden) hamsters (*Mesocricetus auratus*), Chinese hamsters (*Cricetulus griseus*), gerbils (*Meriones unguiculatus*), rabbits (*Oryctolagus cuniculus*) all species of non-human primates, dogs (*Canis familiaris*), cats (*Felis catus*), frogs (*Xenopus laevis*, *Xenopus tropicalis*, *Rana temporaria* and *Rana pipiens*), zebra fish (*Danio rerio*) and quails (*Coturnix coturnix*) used for scientific or educational purposes shall be bred for these purposes.

Section 11 – *Non-human primates*

(1) Procedures may be performed on non-human primates only if there is scientific justification that the purpose of the project cannot be achieved by the use of species other than non-human primates; and:
   1) the project is carried out for a purpose referred to in paragraph 1 or 5 of section 12 of the Act on the Protection of Animals Used for Scientific or Educational Purposes; or
   2) the purpose of the project is to achieve an aim referred to in paragraph 2(a) or 3 of section 12 of the Act with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical condition in humans.

(2) Non-human primates listed in Annex A to Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein may be used in a project only if the purpose of the project cannot be achieved by the use of non-human primates other than those listed in the Annex. However, procedures for a purpose referred to in paragraph 1 of section 12 of the Act on the Protection of Animals Used for Scientific or Educational Purposes may not be performed on non-human primates listed in the said Annex which do not fall within the scope of Article 7(1) of the Regulation.

(3) A procedure involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated may not be performed on a non-human primate.

(4) No procedures may be performed on great apes.

Section 12 – *Animals taken from the wild*

(1) An animal of species considered as threatened under Appendix I of the Convention on International Trade in Endangered Species of Wild Fauna and Flora and Annex A to Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein may be used in a project only if:
   1) the project is in accordance with the Regulation and the objective is scientific research with the aim to preserve the animal species concerned; or
   2) the animal species concerned is the only animal species suitable for a project carried out for an essential biomedical purpose.

(2) In addition, the provisions in the second paragraph of Article 10(1) and Article 10(3) of Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes apply to the use of non-human primates taken from the wild. The project authorisation board functions as the competent authority referred to in Article 10(3).

Section 13 – *Preparing for transport of an animal taken from the wild*

(1) When animals are taken from the wild, means of transport adapted to the species concerned shall be available at the capture site in case animals need to be moved for examination or treatment.

Section 14 – *Marking and identification of animals*

(1) Each animal or group of animals shall be marked or it shall be otherwise identifiable except for an animal taken from the wild to be set free to the wild immediately after the procedure. An animal shall be identifiable either by providing it with an identification mark or so that it is identifiable by appearance or by a marking made in the animal premises where it is kept.

(2) Each dog, cat or non-human primate shall be provided, at least at the time of weaning, with a permanent individual identification mark in the least painful manner possible. Where a dog, cat or non-human primate is transferred from one operator to another before weaning and it is not practicable to mark it beforehand, the receiver shall maintain a record concerning the animal and specifying its mother until it is marked.

(3) Where an operator receives an unmarked dog, cat or non-human primate which is weaned it shall be permanently marked as soon as possible.

Section 15 – *Use of analgesia in a procedure*

(1) If a medicine is given to an animal in a procedure which stops or restricts its showing pain a scientific justification shall be provided for the need to use the medicine and details of the anaesthetic or analgesic regimen shall be stated in the project authorisation application.
(2) 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 for an adequately long time if this is possible without compromising the purpose of the procedure.

Section 16 – *Rehoming of animals*

(1) If animals used in a project or intended for this are rehomed, the operator shall have a written scheme on the rehabilitation of the animals to be rehomed to their new environment.
(2) Before rehoming an animal used in a project, the designated veterinarian shall, where necessary, examine the animal and ensure that the general state of health and well-being of the animal allow it to be rehomed.
(3) Where an animal is delivered to another operator, it shall be accompanied by the records referred to in section 29(1) and (2). Where an animal is rehomed, it shall be accompanied with information referred to in paragraphs 2, 5 and 6 of section 29(1).

Section 17 – *Killing of animals*

(1) In killing animals referred to in Annex 2 the methods of killing set out in the Annex shall be used.
(2) Where an animal has to be killed in emergency circumstances for animal health or welfare, public health, public security or environmental reasons it may also be killed by a method other than those referred to in subsection 1 but in a way that no unnecessary distress is caused to the animal.
(3) An exemption from subsection 1 may be granted in the project authorisation if 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 2. An exemption may also be granted if on the basis of scientific evidence the other method may be considered to be at least as humane as the method of killing set out in Annex 2.

Chapter 3 – **Staff**

Section 18 – *Competence requirements of staff*

(1) Persons designing projects, performing procedures on animals, taking care of animals and killing animals shall have the necessary knowledge and skills on the following topic areas:
    1) national legislation on the acquisition, breeding, care and use of animals used for scientific purposes;
    2) ethics related to the use of animals for scientific purposes;
    3) principle of replacement, reduction and refinement;
    4) anatomy, physiological characteristics, reproduction biology, reproduction, genetics and gene technology and breeding of animals;
    5) behaviour, care, environmental factors and enrichment of animals;
    6) species-specific handling methods and procedures;

7) maintaining the welfare and health of animals as well as hygiene and advance prevention of ill-health;
8) identification of pain, suffering and distress in animal species the most commonly used for scientific or educational purposes;
9) anaesthesia, analgesia methods and killing of animals;
10) justification for the killing of an animal, removal from a project or suspension of procedures during a project; and
11) design of procedures and projects.

(2) The guidelines referred to in Article 23(4) of Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes shall be taken into account in the organisation of education and training for and assessing the competence of persons designing projects, performing procedures on animals, taking care of animals and killing animals.

(3) Persons performing procedures on animals, taking care of animals and killing animals shall be supervised in their work until they have adequate knowledge and skills to work on their own. The maintenance of the professional competence of the staff shall be ensured.

Section 19 – *Person responsible for the activity*

(1) The task of the person responsible for the activity referred to in section 7(2) of the Act on the Protection of Animals Used for Scientific or Educational Purposes is to:
1) see that the requirements laid down for the activity are fulfilled;
2) take immediate action to remedy any defects and shortcomings in the activity which may adversely affect the welfare of animals;
3) see that projects are implemented in accordance with the legislation and project authorisation;
4) see that the staff dealing with animals have adequate education, training and qualifications; and
5) see that the designated veterinarian and expert, person or persons responsible for the establishment and animal welfare body have the opportunity to manage their tasks in accordance with the legislation and authorisation conditions.

Section 20 – *Person responsible for the establishment*

(1) The person responsible for the establishment referred to in section 7(3) of the Act on the Protection of Animals Used for Scientific or Educational Purposes shall possess adequate knowledge and skills required for the tasks on the care, treatment, handling and killing of the animals kept in the establishment.

(2) For implementing the tasks referred to in section 7(3) of the Act on the Protection of Animals Used for Scientific or Educational Purposes the task of the person responsible for the establishment is to:
1) ensure that the requirements laid down for the keeping, care and use in projects of animals kept in the establishment are complied with;
2) provide the staff dealing with animals with the necessary instructions on the care and killing of animals kept in the establishment, their use in projects and action in special situations and emergencies;
3) ensure that the staff working in the establishment have the necessary competence; and
4) see that the staff dealing with animals are supervised in a way referred to in section 18(3).

Section 21 – *Person responsible for implementing the project*

(1) The person responsible for implementing the project referred to in section 25(2) of the Act on the Protection of Animals Used for Scientific or Educational Purposes shall possess adequate knowledge and skills required for the tasks on the care, treatment, handling and killing of the animals used in the project.
(2) The person responsible for implementing the project shall ensure that:
    1) projects are carried out in accordance with the project authorisation and requirements laid down for the project are complied with in its implementation;
    2) remedial action is taken where necessary and such action is recorded; and
    3) medicines administered to animals for research purposes are entered to the records referred to in section 26.

Section 22 – *Animal welfare body*

(1) For implementing the tasks referred to in section 9(2) and 28(2) of the Act on the Protection of Animals Used for Scientific or Educational Purposes the animal welfare body:
    1) advises the care and research staff in matters related to the welfare of animals in relation to their acquisition, keeping and use;
    2) advises on the application of the principle of replacement, reduction and refinement to the breeding, keeping and use of animals;
    3) informs the care and research staff of technical and scientific development relating to the application of the principle of replacement, reduction and refinement;
    4) reviews and develops internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals;
    5) follows the severity of procedures performed on animals and the assessment of severity and advises on action needed to promote the principle of replacement, reduction and refinement;
    6) draws up the written scheme referred to in section 16(1) on the rehabilitation of animals to their new environment; and
    7) keeps a record on its decisions, activity and advice given, follows the impacts of its activity and prepares a report on its activity on a regular basis.

Chapter 4 – **Veterinary care and advice**

Section 23 – *Veterinary care*

(1) The operator shall organise appropriate veterinary care for the control of the state of health, medication, treatment and advance prevention of illness and ensuring the welfare of animals kept in the establishment. The operator shall see to the appropriate keeping, storage and disposal of medicines used in the activity and that no medicines past their expiry date are kept in storage.
(2) The designated veterinarian referred to in section 7(4) of Act on the Protection of Animals Used for Scientific or Educational Purposes shall see to the veterinary care of animals and provide veterinary advice relating to the activity.
(3) The designated veterinarian shall draw up a veterinary care plan which shall include:
    1) a health care plan for advance prevention of illness in animals;
    2) plan on veterinary advice relating to the activity;
    3) plan on the acquisition and use of medicines used for the health care and treatment of illness in animals; and
    4) instructions concerning the reuse of animals.
(4) The veterinary care plan shall be kept up-to- date.
(5) The health care plan referred to above in paragraph 1 of subsection 3 shall include:
    1) specification of the requirements set for animal welfare;

2) regular monitoring of the health and welfare of animals;
3) where necessary, a microbiological surveillance programme;
4) plan for dealing with health and welfare problems;
5) actions for isolation and quarantine of animals introduced to the establishment; and
6) hygiene practices relating to disease prevention.

Section 24 – *Advice relating to welfare and treatment of animals*

(1) The designated veterinarian or expert referred to in section 7(4) of Act on the Protection of Animals Used for Scientific or Educational Purposes shall provide guidance, advice and assistance in:
1) monitoring the welfare of animals;
2) design and performance of procedures on animals;
3) care of animals after procedures;
4) matters relating to the welfare of animals and promoting it as well as the facilities, care and environment of animals;
5) returning of animals to a suitable husbandry system, rehoming or release to a suitable habitat; and
6) other tasks in which expertise in the welfare of animals is needed.

Section 25 – *Records concerning veterinary care and care and conditions of animals*

(1) For appropriate implementation of veterinary care records shall be kept at the establishment on:
1) care of animals and any failures in this;
2) visits by the veterinarian designated for veterinary care;
3) measures suggested by the veterinarian to remedy the defects and their implementation;
4) problems affecting the welfare of animals and cases of animals falling ill which have arisen in procedures, and care and other measures these have caused;
5) environmental conditions specified in the conditions of the operation authorisation and any failures in these; and
6) operation and maintenance of care equipment and installations of the establishment, any failures in these and measures taken to remedy the defects.

Section 26 – *Records on the medication of animals*

(1) Both the medicines used in the care of the health of animals and treatment of illness and medicines administered to animals for research purposes shall be entered to the records on the medication of animals.
(2) The records shall show at least the following information:
1) identification information of the animal or group of animals;
2) date of administering the medicine;
3) name of the medicine;
4) dosage of the medicine and duration of the treatment;
5) cause for the medication or diagnosis made;
6) withdrawal period established for the medicine if the animal concerned is a food-producing animal; and
7) person who administered the medication.

Chapter 5 – **Authorisations needed for the activity**

Section 27 – *Applying for an operation authorisation*

(1) An application for an operation authorisation referred to in section 21(3) of the of Act on the Protection of Animals Used for Scientific or Educational Purposes shall show:
   1) name, address, domicile and business ID of the applicant;
   2) any business name used in the activity;
   3) where and what kind of activity the applicant intends to practise and when the activity is to be started;
   4) name of the person responsible for the activity referred to in section 7(2) of the Act and an account of his or her qualifications as regards the requirements set for the activity;
   5) name of the person or names of the persons responsible for the establishment referred to in section 7(3) of the Act and an account of their qualifications for their tasks;
   6) an account of the competence of persons in the staff who perform procedures on animals, design procedures and projects, care for animals and kill animals;
   7) name of the designated veterinarian or other qualified expert referred to in section 7(4) of the Act and an account of their competence;
   8) an account of the organisation of veterinary care in the establishment;
   9) an account of the composition of the animal welfare body or other manner by which the operator fulfils the obligations set for the animal welfare body in section 9 of the Act;
   10) information on the facilities, installations and equipment relating to the activity and floor plans of the applicant's establishments;
   11) an account of the animal species used in the activity, as well as of the numbers of animals intended to be housed in the establishments at the same time by animal species;
   12) an account of the environmental conditions of the establishments used for the care and housing of animals by animal species; and
   13) if the applicants is a company, cooperative or other corporation or a foundation, a copy of the articles of association or bylaws and extract of company registration.

(2) In addition to the provisions in subsection 1, breeders of non-human primates shall present a breeding strategy for increasing the proportion of animals in the activity that are the offspring of non-human primates that have been bred in captivity.

Section 28 – *Applying for a project authorisation*

(1) An application for a project authorisation referred to in section 24(2) of the Act on the Protection of Animals Used for Scientific or Educational Purposes shall show at least the following:
   1) name and contact information or domicile and business ID of the applicant and person responsible for implementing the project;
   2) information on establishments of the user or other locations where the project is to be implemented;
   3) information on the competence referred to in section 8(1) of the Act of the person who designs the project and account of the competence of the other persons participating in the project;
   4) project proposal; and
   5) non-technical project summary.

(2) The project proposal referred to in paragraph 4 of subsection 1 above shall show at least the following, with justification:
   1) use of animals in the project, justification for the duplication of a procedure, where necessary, and estimate of the expected benefit from the results of the project;
   2) an account of the possibility to use methods replacing, reducing or refining the use of animals in the project;
   3) an account of performing the procedures in a way that ensures the minimisation of the number of animals used, by means of test arrangements and statistical planning, and of the adverse welfare impacts caused by the procedures or environmental factors;

4) an account of the animal species to be used, origin of animals, age, welfare problems caused by the genotype of animal populations or lines, procedures performed earlier on the animals to be used as well as breeding and care conditions of the animals;
5) an account of the procedures to be performed on animals and their method of implementation;
6) an estimate of the numbers of animals used by animal species and procedures;
7) a description of the harm to be inflicted on the animals and proposal for the severity classification of the procedures, where necessary also taking account of the reuse of the animal and other lifetime experience of the animal;
8) an account of the methods to be used in anaesthesia, sedation and analgesia;
9) an account of the monitoring of animal welfare and action taken with the aim to avoid or relieve pain, suffering, distress and lasting harm caused to animals;
10) humane end-points applied in the project;
11) information on killing animals and methods of killing or rehoming of animals or returning animals to a suitable husbandry system or release of animals taken from the wild; and
12) where necessary, an account of the implementation of the project elsewhere than in the establishment of the user.

(3) The non-technical summary referred to in paragraph 5 of subsection 1 above shall show information on objectives of the project, including the predicted harm and benefits, number and species of animals to be used and an account of how the principle of replacement, reduction and refinement has been complied with in the project plan. The summary shall not contain the names and addresses of any persons. Information shall be stated in a way that intellectual property rights are protected and confidential information is not disclosed.

Chapter 6 – **Records and statistics on animals**

Section 29 – *Records on individual animals*

(1) An operator shall keep records on each individual dog, cat and non-human primate he or she keeps. The keeping of records shall be started as soon as possible after birth and the following information shall be entered to them:
1) identification information of the animal;
2) date and place of birth of the animal, if known;
3) information on whether the animal was bred for the purpose;
4) information concerning reproduction;
5) veterinary information;
6) information concerning rehabilitation; and
7) information on projects where the animal has been used.

(2) In addition to the provisions in subsection 1, for each non-human primate an entry in the records shall be made on whether it is an offspring of non-human primates that have been bred in captivity.

Section 30 –*Statistics on animals*

(1) The statistics referred to in section 10(3) of the Act on the Protection of Animals Used for Scientific or Educational Purposes shall be drawn up using the common format established for the submission of information in accordance with Annex 2 to the Commission Implementing Decision pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.

Chapter 7 – **Control plan**

Section 31 – *Content of the control plan*

(1) The control plan of the Regional State Administrative Agency referred to in section 38(1) of the Act on the Protection of Animals Used for Scientific or Educational Purposes shall include an inspection plan on the basis of which at least one-third of the users, based on risk assessment, and all breeders, suppliers and users of non-human primates are inspected annually.
(2) Information on the inspections is kept for at least five years from performing the inspection.

Section 32 – *Risk assessment*

(1) Risk assessment relating to the control plan referred to in section 31 above shall take account of the following:
    1) number and species of animals kept by the operator;
    2) number and type of projects implemented by the user;
    3) information on how the operator has earlier complied with the requirements in the legislation concerning animals used for scientific or educational purposes; and
    4) any information that may indicate non-compliance with the relevant provisions.

Chapter 8 – **Miscellaneous provisions**

Section 33 – *Assignment of procedures to severity categories*

(1) Provisions on the assignment of procedures to the severity categories are laid down in Annex 3. The grounds laid down in the Annex shall be complied with in assigning procedures to categories.

Section 34 – *Retrospective assessment of a project*

(1) For retrospective assessment referred to in section 29 of the Act on the Protection of Animals Used for Scientific or Educational Purposes the person responsible for implementing the project shall provide the following information to the Regional State Administrative Agency:
    1) objectives of the project and assessment of how well they were achieved;
    2) information on the species and numbers of animals used in the project and the actual severity of the procedures performed; and
    3) any elements that on the basis of experiences gained from the project may contribute to the implementation of the principle of replacement, reduction and refinement.

Section 35 – *Entry into force and transitional provision*

(1) This Decree enters into force on 1 August 2013. However, Chapter 2 of Annex 1 shall not be applicable until 1 January 2017.

Annex 1

SPECIES-SPECIFIC REQUIREMENTS CONCERNING ANIMAL PREMISES AND CARE

Chapter 1

1. Cats

Cats shall not be single-housed for more than 24 hours at a time. Cats that are repeatedly aggressive towards other cats shall be housed singly only if a compatible companion cannot be found. Females in the last two weeks of pregnancy may be housed singly, and so may females with kittens under four weeks of age.

Social stress in all pair- or group-housed individuals shall be monitored at least weekly.

2. Dogs

Dogs shall, where possible, be provided with outside runs. Dogs shall not be single-housed for more than four hours at a time.

3. Non-human primates

Young non-human primates shall not be separated from their mothers until they are, depending on the species, 6 to 12 months old. For marmosets, tamarins, macaques, vervets and baboons separation from their mother shall not take place before 8 months of age. For squirrel monkeys, separation from the mother shall not take place before 6 months of age.

The premises for non-human primates shall enable them to carry out a complex daily programme of activity. The premises shall allow non-human primates to adopt as wide a behavioural repertoire as possible, provide it with a sense of security, and a suitably complex environment to allow them to run, walk, climb and jump.

4. Fish

Adequate water supply of suitable quality shall be provided at all times. Water flow in re-circulatory systems or filtration within tanks shall be sufficient to ensure that water quality parameters are maintained within acceptable levels. Water supply shall be filtered or treated to remove substances harmful to fish, where necessary. Water-quality parameters shall at all times be within the acceptable range that sustains normal activity and physiology for a given species and stage of development. The water flow shall be appropriate to enable fish to swim correctly and to maintain normal behaviour. Fish shall be given an appropriate time for acclimatisation and adaptation to changes in water-quality conditions.

Oxygen concentration of the water shall be appropriate to the species and to the context in which the fish are held. Where necessary, supplementary aeration of tank water shall be provided. The concentrations of nitrogen compounds shall be kept low. The pH level of the water shall be adapted to the species and kept as stable as possible. The salinity shall be adapted to the requirements of the fish species and to the life stage of the fish. Changes in salinity shall take place gradually.

Water temperature shall be maintained within the optimal range for the fish species concerned and kept as stable as possible. Changes in temperature shall take place gradually. Fish shall be maintained on an appropriate photoperiod. Noise levels shall be kept to a minimum and, where possible, equipment causing noise or vibration, such as power generators or filtration systems, shall be separate from the fish-holding tanks.

The stocking density of fish shall be based on the total needs of the fish in respect of environmental conditions, health and welfare. Fish shall have sufficient water volume for normal swimming, taking account of their size, age, health and feeding method. Fish shall be provided with an appropriate environmental enrichment, such as hiding places or bottom substrate, unless behavioural traits suggest none is required.

Fish shall be fed a diet suitable for the fish at an appropriate feeding rate and frequency. Particular attention shall be given to feeding of larval fish during any transition from live to artificial diets. Handling of fish shall be kept to a minimum.

Chapter 2

1. Mice

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)[1)]
In stock and during procedures	up to 20 over 20 to 25 over 20 to 30 over 30	330 330 330 330	60 70 80 100	12 12 12 12
Breeding		330[2)]		12
Stock and breeders[3)] Enclosure size 950 cm²	less than 20	950	40	12
Enclosure size 1 500 cm²	less than 20	1500	30	12

1) Minimum enclosure height means the vertical distance between the enclosure floor and the top of the enclosure and this height applies over more than 50 % of the minimum enclosure floor area prior to the addition of enrichment devices.
2) For a monogamous pair (outbred/inbred) or a trio (inbred). For each additional female and litter 180 cm² shall be added.
3) Post-weaned mice may be kept at these higher stocking densities for the short period after weaning, provided that the animals are housed in larger enclosures with adequate enrichment, and these housing conditions do not cause any welfare deficit such as increased levels of aggression, morbidity or mortality, stereotypes or other behavioural deficits, weight loss, or other physiological or behavioural stress responses.

When designing procedures, consideration shall be given to the potential growth of the animals to ensure adequate space is provided for the duration of the study.

2. Rats

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm) [1)]
In stock and during procedures[2)]	up to 200 over 200 to 300 over 300 to 400 over 400 to 600 over 600	800 800 800 800 1500	200 250 350 450 600	18 18 18 18 18
Breeding		800[3)]		18

Stock at breeders[4)] Enclosure size 1500 cm²	up to 50 over 50 to 100 over 100 to 150 over 150 to 200	1 500 1 500 1 500 1 500	100 125 150 175	18 18 18 18
Stock at breeders[4)] Enclosure size 2500 cm²	up to 100 over 100 to 150 over 150 to 200	2 500 2 500 2 500	100 125 150	18 18 18

1) Minimum enclosure height means the vertical distance between the enclosure floor and the top of the enclosure and this height applies over more than 50 % of the minimum enclosure floor area prior to the addition of enrichment devices.
2) In long-term studies, if space allowances per individual animal fall below those indicated above towards the end of such studies, priority shall be given to maintaining stable social structures.
3) Mother and litter. For each additional adult animal permanently added to the enclosure add 400 cm².
4) Post-weaned rats may be kept at these higher stocking densities for the short period after weaning, provided that the animals are housed in larger enclosures with adequate enrichment, and these housing conditions do not cause any welfare deficit such as increased levels of aggression, morbidity or mortality, stereotypes or other behavioural deficits, weight loss, or other physiological or behavioural stress responses.

When designing procedures, consideration shall be given to the potential growth of the animals to ensure adequate space is provided for the duration of the study.

3. Gerbils

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm) [1)]
In stock and during procedures	up to 40 over 40	1 200 1 200	150 250	18 18
Breeding		1 200[2)]		18

1) Minimum enclosure height means the vertical distance between the enclosure floor and the top of the enclosure and this height applies over more than 50 % of the minimum enclosure floor area prior to the addition of enrichment devices.
2) Monogamous pair or trio with offspring.

When designing procedures, consideration shall be given to the potential growth of the animals to ensure adequate space is provided for the duration of the study.

4. Hamsters

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm) [1)]
In stock and during procedures	up to 60 over 60 to 100 over 100	800 800 800	150 200 250	14 14 14
Breeding		800[2)]		14
Stock at breeders[3)]	less than 60	1 500	100	14

1) Minimum enclosure height means the vertical distance between the enclosure floor and the top of the enclosure and this height applies over more than 50 % of the minimum enclosure floor area prior to the addition of enrichment devices.
2) Mother and monogamous pair with litter.
3) Post-weaned hamsters may be kept at these higher stocking densities for the short period after weaning, provided that the animals are housed in larger enclosures with adequate enrichment, and these housing conditions do not cause any welfare deficit such as increased levels of aggression, morbidity or mortality, stereotypes or other behavioural deficits, weight loss, or other physiological or behavioural stress responses.

When designing procedures, consideration shall be given to the potential growth of the animals to ensure adequate space is provided for the duration of the study.

5. Guinea pigs

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)[1)]
In stock and during procedures	up to 200 over 200 to 300 over 300 to 450 over 450 to 700 over 700	1 800 1 800 1 800 2 500 2 500	200 350 500 700 900	23 23 23 23 23
Breeding		2 500[2)]		23

1) Minimum enclosure height means the vertical distance between the enclosure floor and the top of the enclosure and this height applies over more than 50 % of the minimum enclosure floor area prior to the addition of enrichment devices.
2) Pair with litter. For each additional breeding female add 1 000 cm².

When designing procedures, consideration shall be given to the potential growth of the animals to ensure adequate space is provided for the duration of the study.

6. Rabbits

A raised area shall be provided within the enclosure. This raised area must allow the animal to lie and sit and easily move underneath, and shall not cover more than 40 % of the floor space. When for scientific or veterinary reasons a raised area cannot be used, the enclosure shall be 33 % larger for a single rabbit and 60 % larger for two rabbits. Where a raised area is provided for rabbits of less than 10 weeks of age, the size of the raised area shall be at least of 55 cm by 25 cm and the height above the floor shall be such that the animals can make use of it.

6.1 Rabbits over 10 weeks of age

Table 6.1 is to be used for both cages and pens. The additional floor area is a minimum of 3 000 cm² per rabbit for the third, the fourth, the fifth and the sixth rabbit, while 2 500 cm² as a minimum shall be added for each additional rabbit above the number of six.

Final body weight (kg)	Minimum floor area for one or two socially harmonious animals (cm^2)	Minimum height (cm)
less than 3 from 3 to 5 over 5	3 500 4 200 5 400	45 45 60

6.2 Doe plus litter

Doe weight	Minimum enclosure	Addition for nest boxes	Minimum height

(kg)	size (cm^2)	(cm^2)	(cm)
less than 3 from 3 to 5 over 5	3 500 4 200 5 400	1 000 1 200 1 400	45 45 60

6.3 Rabbits less than 10 weeks of age

Table 6.3 is to be used for both cages and pens.

Age	Minimum enclosure size (cm^2)	Minimum floor area per animal (cm^2)	Minimum height (cm)
Weaning to 7 weeks From 7 to 10 weeks	4 000 4 000	800 1 200	40 40

7. Cats

	Floor[1)] (m^2)	Shelves (m^2)	Height (m)
Minimum for one adult animal	1,5	0,5	2
For each additional animal add	0,75	0,25	–

1) Floor area excluding shelves.

The minimum space in which a queen and litter may be held is the space for a single cat, which shall be gradually increased so that by 4 months of age litters have been rehoused following the space requirements for adults. Cats kept in a cage during procedures shall be allowed out of the cage for exercise at least once a day, provided that this is compatible with the purpose of the project.

Areas for feeding and for litter trays shall not be less than 0,5 metres apart and shall not be interchanged.

8. Dogs

The internal enclosure shall represent at least 50 % of the minimum space to be made available to the dogs, as detailed in Table 8.1. The internal enclosure shall not have a grid floor, unless this is required for the project. If a dog is kept on a grid floor, the floor of the sleeping area shall be solid. Dogs kept outdoors on a permanent basis shall have access to shelter from inclement weather.

The space allowances detailed in the table are based on the requirements of beagles, but giant breeds such as St Bernards or Irish wolfhounds shall be provided with allowances significantly in excess of those detailed in Table 8.1. For breeds other than the laboratory beagle, space allowances shall be determined in consultation with veterinary staff.

Weight (kg)	Minimum enclosure size (m^2)	Minimum floor area for one or two animals (m^2)	For each additional animal add a minimum of (m^2)	Minimum height (m)
up to 20 over 20	4 8	4 8	2 4	2 2

Dogs that are pair or group housed may each be constrained to half the total space provided (2 m^2 for a dog under 20 kg, 4 m^2 for a dog over 20 kg) while they are undergoing procedures, if this separation is essential for scientific purposes. The period for which a dog is so constrained shall not exceed 4 hours at a time. The space shall not have a grid floor, unless this is required for the project.

A nursing bitch and litter shall have the same space allowance as a single bitch of equivalent weight. The whelping pen shall be designed so that the bitch can move to an additional compartment or raised area away from the puppies.

8.1 Post-weaned dogs

Weight of dog (kg)	Minimum enclosure size (m^2)	Minimum floor area/animal (m^2)	Minimum height (m)
up to 5	4	0,5	2
over 5 to 10	4	1,0	2
over 10 to 15	4	1,5	2
over 15 to 20	4	2	2
over 20	8	4	2

9. Ferrets

	Minimum enclosure size (cm^2)	Minimum floor area per animal (cm^2)	Minimum height (cm)
Animals up to 600 g	4 500	1 500	50
Animals over 600 g	4 500	3 000	50
Adult males	6 000	6 000	50
Jill and litter	5 400	5 400	50

10. Non-human primates

10.1 Marmosets and tamarins

	Minimum floor area of enclosures for 1[1)] or 2 animals plus offspring up to 5 months old (m^2)	Minimum volume per additional animal over 5 months (m^3)	Minimum enclosure height (m)[2)]
Marmosets	0,5	0,2	1,5
Tamarins	1,5	0,2	1,5

1) Animals shall be kept singly only in exceptional circumstances.
2) The top of the enclosure shall be at least 1,8 metres from the floor.

10.2 Squirrel monkeys

Minimum floor area for 1[1)] or 2 animals (m^2)	Minimum volume per additional animal over 6 months of age (m^3)	Minimum enclosure height (m)
2,0	0,5	1,8

1) Animals shall be kept singly only in exceptional circumstances.

10.3 Macaques and vervets[1)]

	Minimum enclosure size (m^2)	Minimum enclosure volume (m^3)	Minimum volume per animal (m^3)	Minimum enclosure height (m)
Animals less than 3 yrs of age[2)]	2,0	3,6	1,0	1,8
Animals from 3 yrs of age[3)]	2,0	3,6	1,8	1,8

Animals held for breeding purposes[4)]			3,5	2,0

1) Animals shall be kept singly only in exceptional circumstances.
2) An enclosure of minimum dimensions may hold up to three animals.
3) An enclosure of minimum dimensions may hold up to two animals.
4) In breeding colonies no additional space/volume allowance is required for young animals up to 2 years of age housed with their mother.

10.4 Baboons[1)]

	Minimum enclosure size (m^2)	Minimum enclosure volume (m^3)	Minimum volume per animal (m^3)	Minimum enclosure height (m)
Animals less than 4 yrs of age[2)]	4,0	7,2	3,0	1,8
Animals from 4 yrs of age[2)]	7,0	12,6	6,0	1,8
Animals held for breeding purposes[3)]			12,0	2,0

1) Animals shall be kept singly only in exceptional circumstances.
2) An enclosure of minimum dimensions may hold up to 2 animals.
3) In breeding colonies no additional space/volume allowance is required for young animals up to 2 years of age housed with their mother.

11. Farm animals

11.1 Cattle

Body weight (kg)	Minimum enclosure size (m^2)	Minimum floor area/animal (m^2/animal)	Trough space for *ad-libitum* feeding of polled cattle (m/animal)	Trough space for restricted feeding of polled cattle (m/animal)
up to 100	2,50	2,30	0,10	0,30
over 100 to 200	4,25	3,40	0,15	0,50
over 200 to 400	6,00	4,80	0,18	0,60
over 400 to 600	9,00	7,50	0,21	0,70
over 600 to 800	11,00	8,75	0,24	0,80
over 800	16,00	10,00	0,30	1,00

11.2 Sheep and goats

Body weight (kg)	Minimum enclosure size (m^2)	Minimum floor area/animal (m^2/animal)	Minimum partition height (m)	Trough space for *ad-libitum* feeding (m/animal)	Trough space for restricted feeding (m/animal)
less than 20	1,0	0,7	1,0	0,10	0,25
over 20 to 35	1,5	1,0	1,2	0,10	0,30
over 35 to 60	2,0	1,5	1,2	0,12	0,40
over 60	3,0	1,8	1,5	0,12	0,50

11.3 Pigs and minipigs

Live weight (kg)	Minimum enclosure size (m^2)[1)]	Minimum floor area per animal (m^2/animal)	Minimum lying space per animal (in thermoneutral conditions) (m^2/animal)
up to 5	2,0	0,20	0,10
over 5 to10	2,0	0,25	0,11
over 10 to 20	2,0	0,35	0,18
over 20 to 30	2,0	0,50	0,24
over 30 to 50	2,0	0,70	0,33
over 50 to 70	3,0	0,80	0,41
over 70 to 100	3,0	1,00	0,53
over 100 to 150	4,0	1,35	0,70
over 150	5,0	2,50	0,95
Adult (conventional) boars	7,5		1,30

1) Pigs may be confined in smaller enclosures for short periods of time, for example by partitioning the main enclosure using dividers, when justified on veterinary or experimental grounds, for example where individual food consumption is required.

11.4 Equines

Wither height (m)	Minimum floor area/animal (m^2/animal)			Minimum enclosure height (m)
	For each animal held singly or in groups of up to 3 animals	For each animal held in groups of 4 or more animals	Foaling box/mare with foal	
1,00 to 1,40	9,0	6,0	16	3,00
over 1,40 to 1,60	12,0	9,0	20	3,00
over 1,60	16,0	$(2 \times WH)^{2}$ [1)]	20	3,00

1) To ensure adequate space is provided, space allowance for each individual animal shall be based on height to withers (WH).

The shortest side shall be a minimum of 1,5 times the wither height of the animal. The height of indoor enclosures shall allow animals to rear to their full height.

12. Birds

12.1 Domestic fowl

Body mass (g)	Minimum enclosure size (m^2)	Minimum area per bird (m^2)	Minimum height (cm)	Minimum length of feed trough per bird (cm)
up to 200	1,00	0,025	30	3
over 200 to 300	1,00	0,03	30	3
over 300 to 600	1,00	0,05	40	7
over 600 to 1200	2,00	0,09	50	15
over 1200 to 1800	2,00	0,11	75	15
over 1800 to 2400	2,00	0,13	75	15
over 2400	2,00	0,21	75	15

Where these minimum enclosure sizes cannot be provided for scientific reasons, the duration of the confinement shall be justified by the experimenter in consultation with veterinary staff. In such circumstances, birds can be housed in smaller enclosures containing appropriate enrichment and with a minimum floor area of 0,75 m^2.

12.2 Domestic turkeys

Body mass (kg)	Minimum enclosure size (m^2)	Minimum area per bird (m^2)	Minimum height (cm)	Minimum length of feed trough per bird (cm)
up to 0,3	2,00	0,13	50	3
over 0,3 to 0,6	2,00	0,17	50	7
over 0,6 to 1	2,00	0,30	100	15
over 1to 4	2,00	0,35	100	15
over 4 to 8	2,00	0,40	100	15
over 8 to 12	2,00	0,50	150	20
over 12 to 16	2,00	0,55	150	20
over 16 to 20	2,00	0,60	150	20
over 20	3,00	1,00	150	20

All enclosure sides shall be at least 1,5 m long. Where these minimum enclosures sizes cannot be provided for scientific reasons, the duration of the confinement shall be justified by the experimenter in consultation with veterinary staff. In such circumstances, birds can be housed in smaller enclosures containing appropriate enrichment and with a minimum floor area of 0,75 m² and a minimum height of 50 cm for birds below 0,6 kg, 75 cm for birds below 4 kg, and 100 cm for birds over 4 kg. These can be used to house small groups of birds in accordance with the space allowances given in table 12.2.

12.3 Quails

Body mass (g)	Minimum enclosure size (m^2)	Area per bird pair-housed (m^2)	Area per additional bird group-housed (m^2)	Minimum height (cm)	Minimum length of trough per bird (cm)
up to 150	1,00	0,5	0,10	20	4
over 150	1,00	0,6	0,15	30	4

12.4 Ducks and geese

Body mass (g)	Minimum enclosure size (m^2)	Area per bird (m^2)[1)]	Minimum height (cm)	Minimum length of feed trough per bird (cm)
Ducks				
up to 300	2,00	0,10	50	10
over 300 to 1 200[2)]	2,00	0,20	200	10
over 1 200 to 3 500	2,00	0,25	200	15
over 3 500	2,00	0,50	200	15
Geese				
up to 500	2,00	0,20	200	10
over 500 to 2 000	2,00	0,33	200	15
over 2 000	2,00	0,50	200	15

1) This shall include a pond of minimum area 0,5 m^2 per 2 m^2 enclosure with a minimum depth of 30 cm. The pond may contribute up to 50 % of the minimum enclosure size.
2) Pre-fledged birds may be held in enclosures with a minimum height of 75 cm.

Where these minimum enclosures sizes cannot be provided for scientific reasons, the duration of the confinement shall be justified by the experimenter in consultation with veterinary staff. In such circumstances, birds can be housed in smaller enclosures containing appropriate enrichment and with a

minimum floor area of 0,75 m^2. These can be used to house small groups of birds in accordance with the space allowances given in table 12.4.

Minimum pond sizes

	Area (m^2)	Depth (cm)
Ducks	0,5	30
Geese	0,5	from 10 to 30

Pond sizes are per 2 m^2 enclosure. The pond may contribute up to 50 % of the minimum enclosure size.

12.5 Pigeons

Group size	Minimum enclosure size (m^2)	Minimum height (cm)	Minimum length of food trough per bird (cm)	Minimum length of perch per bird (cm)
up to 6	2	200	5	30
from 7 to 12	3	200	5	30
for each additional bird above 12	0,15		5	30

Enclosures shall be long and narrow (for example 2 m by 1 m) rather than square to allow birds to perform short flights.

12.6 Zebra finches

Group size	Minimum enclosure size (m^2)	Minimum height (cm)	Minimum number of feeders
up to 6	1,0	100	2
7 to 12	1,5	200	2
13 to 20	2,0	200	3
for each additional bird above 20	0,05		1 per 6 birds

Enclosures shall be long and narrow (for example 2 m by 1 m) to enable birds to perform short flights. For breeding studies, pairs may be housed in smaller enclosures containing appropriate enrichment with a minimum floor area of 0,5 m^2 and a minimum height of 40 cm. The duration of the confinement shall be justified by the experimenter in consultation with veterinary staff.

13. Amphibians

13.1 Aquatic urodoles

Body length[1)] (cm)	Minimum water surface area (cm^2)	Minimum water surface area for each additional animal in group-holding (cm^2)	Minimum water depth (cm)
up to 10	262,5	50	13
over 10 to 15	525	110	13
over 15 to 20	875	200	15
over 20 to 30	1 837,5	440	15
over 30	3 150	800	20

1) Measured from snout to vent.

13.2 Aquatic anurans[1)]

Body length[2)] (cm)	Minimum water surface area (cm^2)	Minimum water surface area for each additional animal in group-holding (cm^2)	Minimum water depth (cm)
less than 6	160	40	6
from 6 to 9	300	75	8
over 9 to 12	600	150	10
over 12	920	230	12,5

1) These conditions apply to holding (i.e. husbandry) tanks but not to those tanks used for natural mating and super-ovulation for reasons of efficiency, as the latter procedures require smaller individual tanks. Space requirements determined for adults in the indicated size categories; juveniles and tadpoles shall either be excluded, or dimensions altered according to the scaling principle.
2) Measured from snout to vent.

13.3 Semi-aquatic anurans

Body length[1)] (cm)	Minimum enclosure size[2)] (cm^2)	Minimum area for each additional animal in group-holding (cm^2)	Minimum enclosure height[3)] (cm)	Minimum water depth (cm)
up to 5,0	1 500	200	20	10
over 5,0 to 7,5	3 500	500	30	10
over 7,5	4 000	700	30	15

1) Measured from snout to vent.
2) One-third land division, two-thirds water division sufficient for animals to submerge.
3) Measured from the surface of the land division up to the inner part of the top of the terrarium; furthermore, the height of the enclosures shall be adapted to the interior design.

13.4 Semi-terrestrial anurans

Body length[1)] (cm)	Minimum enclosure size[2)] (cm^2)	Minimum area for each additional animal in group-holding (cm^2)	Minimum enclosure height[3)] (cm)	Minimum water depth (cm)
up to 5,0	1 500	200	20	10
over 5,0 to 7,5	3 500	500	30	10
over 7,5	4 000	700	30	15

1) Measured from snout to vent.
2) Two-thirds land division, one-third water division sufficient for animals to submerge.
3) Measured from the surface of the land division up to the inner part of the top of the terrarium; furthermore, the height of the enclosures shall be adapted to the interior design.

13.5 Arboreal anurans

Body length[1)] (cm)	Minimum enclosure size[2)] (cm^2)	Minimum area for each additional animal	Minimum enclosure height[3)] (cm)

		in group-holding (cm^2)	
up to 3,0	900	100	30
over 3,0	1500	200	30

1) Measured from snout to vent.
2) Two-thirds land division, one-third pool division sufficient for animals to submerge.
3) Measured from the surface of the land division up to the inner part of the top of the terrarium; furthermore, the height of the enclosures shall be adapted to the interior design.

14. Reptiles

14.1 Aquatic chelonians

Body length[1] (cm)	Minimum water surface area (cm^2)	Minimum water surface area for each additional animal in group-holding (cm^2)	Minimum water depth (cm)
up to 5	600	100	10
over 5 to 10	1 600	300	15
over 10 to 15	3 500	600	20
over 15 to 20	6 000	1 200	30
over 20 to 30	10 000	2 000	35
over 30	20 000	5 000	40

1) Measured in a straight line from the front edge to the back of the shell.

14.2 Terrestrial snakes

Body length[1] (cm)	Minimum floor area (cm^2)	Minimum area for each additional animal in group-holding (cm^2)	Minimum enclosure height[2] (cm)
up to 30	300	150	10
over 30 to 40	400	200	12
over 40 to 50	600	300	15
over 50 to 75	1 200	600	20
over 75	2 500	1 200	28

1) Measured from snout to tail.
2) Measured from the surface of the land division up to the inner part of the top of the terrarium; furthermore, the height of the enclosure shall be adapted to the interior design.

Annex 2

METHODS OF KILLING ANIMALS

1. In the process of killing animals, methods listed in Table 3 shall be used.
Methods other than those listed in the table may be used:
(a) on unconscious animals, providing the animal does not regain consciousness before death;
(b) on animals used in agricultural research, when the aim of the project requires that the animals are kept under similar conditions to those under which commercial farm animals are kept; these animals may be killed in accordance with the requirements laid down in Annex I to Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing.

2. The killing of animals shall be completed by one of the following methods:
(a) confirmation of permanent cessation of the circulation;
(b) destruction of the brain;
(c) dislocation of the neck;
(d) exsanguination; or
(e) confirmation of the onset of *rigor mortis*.

3. Table

Animals - remarks/ methods	Fish	Amphibians	Reptiles	Birds	Rodents	Rabbits	Dogs, cats, ferrets and foxes	Large mammals	Non-human primates
Anaesthetic overdose	x[1)]	x[1)]	x[1)]	x[1)]	x[1)]	x[1)]	x[1)]	x[1)]	x[1)]
Captive bolt			x[2)]			x		x	
Carbon dioxide				x	x[3)]				
Cervical dislocation				x[4)]	x[5)]	x[6)]			
Concussion/ percussive blow to the head	x	x	x	x[7)]	x[8)]	x[9)]	x[10)]		
Decapitation				x[11)]	x[12)]				
Electric stunning		x[13)]					x[14)]	x[14)]	
Inertia gases (Ar, N_2)				x	x			x[15)]	
Shooting with a free bullet with appropriate rifles, guns and ammunition			x[16)]				x[17)]	x[16)]	

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 used for foetal and neonate rodents.
4. Only to be used for birds under 1 kg. Birds over 250 g shall be sedated.

5. Only to be used for rodents under 1 kg. Rodents over 150 g shall be sedated.
6. Only to be used for rabbits under 1 kg. Rabbits over 150 g shall be sedated.
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. Only to be used for amphibians under 40 g.
14. Specialised equipment required.
15. Only to be used on pigs.
16. Only to be used in field conditions by experienced marksmen.
17. Only to be used in field conditions by experienced marksmen when other methods are not possible.

Annex 3

SEVERITY CLASSIFICATION OF PROCEDURES

1. Severity categories

Non-recovery:
Procedures which are performed entirely under general anaesthesia from which the animal shall not recover consciousness shall be classified as ‘non-recovery’.

Mild:
Procedures on animals as a result of which the animals are likely to experience short-term mild pain, suffering or distress, as well as procedures with no significant impairment of the well-being or general condition of the animals shall be classified as ‘mild’.

Moderate:
Procedures on animals as a result of which the animals are likely to experience short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as procedures that are likely to cause moderate impairment of the well-being or general condition of the animals shall be classified as ‘moderate’.

Severe:
Procedures on animals as a result of which the animals are likely to experience severe pain, suffering or distress, or long- lasting moderate pain, suffering or distress as well as procedures, that are likely to cause severe impairment of the well-being or general condition of the animals shall be classified as ‘severe’.

2. Assignment criteria

The assignment of the severity category shall take into account any intervention or manipulation of an animal within a defined procedure. It shall be based on the most severe effects likely to be experienced by an individual animal after applying pain-relieving methods and all appropriate refinement techniques.

When assigning a procedure to a particular category, the type of procedure and a number of other factors shall be taken into account. All these factors shall be considered on a case-by-case basis.
The factors related to the procedure shall include
- type of manipulation, handling,
- nature of pain, suffering, distress or lasting harm caused by (all elements of) the procedure, and its intensity, the duration, frequency and multiplicity of techniques employed,
- cumulative suffering within a procedure,
- prevention from expressing natural behaviour including restrictions on the housing, husbandry and care standards.

Examples are given in Section III of procedures assigned to each of the severity categories on the basis of factors related to the type of the procedure alone. They shall provide the first indication as to what classification would be the most appropriate for a certain type of procedure.

However, for the purposes of the final severity classification of the procedure, the following additional factors, assessed on a case-by-case basis, shall also be taken into account:
- type of species and genotype,
- maturity, age and gender of the animal,
- training experience of the animal with respect to the procedure,
- if the animal is to be reused, the actual severity of the previous procedures,
- the methods used to reduce or eliminate pain, suffering and distress, including refinement of housing, husbandry and care conditions,
- humane end-points.

3. Examples of different types of procedure assigned to each of the severity categories on the basis of factors related to the type of the procedure

1. Mild
(a) administration of anaesthesia except for the sole purpose of killing;
(b) pharmacokinetic study where a single dose is administered and a limited number of blood samples are taken (totalling < 10 % of circulating volume) and the substance is not expected to cause any detectable adverse effect;
(c) non-invasive imaging of animals (e.g. MRI) with appropriate sedation or anaesthesia;
(d) superficial procedures, e.g. ear and tail biopsies, non-surgical subcutaneous implantation of mini-pumps and transponders;
(e) application of external telemetry devices that cause only minor impairment to the animals or minor interference with normal activity and behaviour;
(f) administration of substances by subcutaneous, intramuscular, intraperitoneal routes, gavage and intravenously via superficial blood vessels, where the substance has no more than mild impact on the animal, and the volumes are within appropriate limits for the size and species of the animal;
(g) induction of tumours, or spontaneous tumours, that cause no detectable clinical adverse effects (e.g. small, subcutaneous, non-invasive nodules);
(h) breeding of genetically altered animals, which is expected to result in a phenotype with mild effects;
(i) feeding of modified diets, that do not meet all of the animals' nutritional needs and are expected to cause mild clinical abnormality within the time-scale of the study;
(j) short-term (< 24h) restraint in metabolic cages;
(k) studies involving short-term deprivation of social partners, short-term solitary caging of adult rats or mice of sociable strains;
(l) models which expose animals to noxious stimuli which are briefly associated with mild pain, suffering or distress, and which the animals can successfully avoid;
(m) a combination or accumulation of the following examples may result in classification as 'mild':
(i) assessing body composition by non-invasive measures and with minimal restraint;
(ii) monitoring ECG with non-invasive techniques with minimal or no restraint of habituated animals;
(iii) application of external telemetry devices that are expected to cause no impairment to socially adapted animals and do not interfere with normal activity and behaviour;
(iv) breeding genetically altered animals which are expected to have no clinically detectable adverse phenotype;
(v) adding inert markers in the diet to follow passage of digesta;
(vi) withdrawal of food for < 24h in adult rats;
(vii) open field testing.

2. Moderate
(a) frequent application of test substances which produce moderate clinical effects, and withdrawal of blood samples (> 10 % of circulating volume) in a conscious animal within a few days without volume replacement;
(b) acute dose-range finding studies, chronic toxicity/carcinogenicity tests, with non-lethal end-points;
(c) surgery under general anaesthesia and appropriate analgesia, associated with post surgical pain, suffering or impairment of general condition. Examples include: thoracotomy, craniotomy, laparotomy, orchidectomy, lymphadenectomy, thyroidectomy, orthopaedic surgery with effective stabilisation and wound management, organ transplantation with effective management of rejection, surgical implantation of catheters, or biomedical devices (e.g. telemetry transmitters, minipumps, etc.);

(d) models of induction of tumours, or spontaneous tumours, that are expected to cause moderate pain or distress or moderate interference with normal behaviour;
(e) irradiation or chemotherapy with a sublethal dose, or with an otherwise lethal dose but with reconstitution of the immune system. Adverse effects would be expected to be mild or moderate and would be short-lived (< 5 days);
(f) breeding of genetically altered animals which are expected to result in a phenotype with moderate effects;
(g) creation of genetically altered animals through surgical procedures;
(h) use of metabolic cages involving moderate restriction of movement over a prolonged period (up to 5 days);
(i) studies with modified diets that do not meet all of the animals' nutritional needs and are expected to cause moderate clinical abnormality within the time-scale of the study;
(j) withdrawal of food for 48 hours in adult rats;
(k) evoking escape and avoidance reactions where the animal is unable to escape or avoid the stimulus, and are expected to result in moderate distress.

3. Severe
(a) toxicity testing where death is the end-point, or fatalities are to be expected and severe pathophysiological states are induced. For example, single dose acute toxicity testing (see OECD testing guidelines);
(b) testing of device where failure may cause severe pain, distress or death of the animal (e.g. cardiac assist devices);
(c) vaccine potency testing characterised by persistent impairment of the animal's condition, progressive disease leading to death, associated with long-lasting moderate pain, distress or suffering;
(d) irradiation or chemotherapy with a lethal dose without reconstitution of the immune system, or reconstitution with production of graft versus host disease;
(e) models with induction of tumours, or with spontaneous tumours, that are expected to cause progressive lethal disease associated with long-lasting moderate pain, distress or suffering. For example tumours causing cachexia, invasive bone tumours, tumours resulting in metastatic spread, and tumours that are allowed to ulcerate;
(f) surgical and other interventions in animals under general anaesthesia which are expected to result in severe or persistent moderate postoperative pain, suffering or distress or severe and persistent impairment of the general condition of the animals. Production of unstable fractures, thoracotomy without adequate analgesia, or trauma to produce multiple organ failure;
(g) organ transplantation where organ rejection is likely to lead to severe distress or impairment of the general condition of the animals (e.g. xenotransplantation);
(h) breeding animals with genetic disorders that are expected to experience severe and persistent impairment of general condition, for example Huntington's disease, Muscular dystrophy, chronic relapsing neuritis models;
(i) use of metabolic cages involving severe restriction of movement over a prolonged period;
(j) inescapable electric shock (e.g. to produce learned helplessness);
(k) complete isolation for prolonged periods of social species e.g. dogs and non-human primates;
(l) immobilisation stress to induce gastric ulcers or cardiac failure in rats;
(m) forced swim or exercise tests with exhaustion as the end-point.