Republic of Latvia

Cabinet
Regulation No. 52
Adopted 22 January 2013

# Regulations Regarding the Protection of Animals Used for Scientific Purposes

*Issued pursuant to*
*Section 10, Clause 4 and Section 24.[2]*
*of the Animal Protection Law*

## I. General Provisions

1. This Regulation prescribes:

1.1. the procedures for the registration of a breeder, supplier and user of experimental animals and for the cancellation thereof;

1.2 the requirements for breeders, suppliers and users of experimental animals;

1.3 the procedures for the issuing or cancelling an experimental project authorisation to a person responsible for an experimental project;

1.4 the procedures by which an experimental project authorisation shall be issued, amended, renewed and cancelled;

1.5. the welfare requirements for the acquisition, marking, breeding, keeping, care, supply and use of an experimental animal;

1.6 the list of such animals which are bred in order to use them in procedures;

1.7 the procedures for the assessment of an experimental project;

1.8 the requirements for premises, facilities, inventory, equipment of a breeder, supplier and user of experimental animals;

1.9 the requirements for staff members of a breeder, supplier and user of experimental animals;

1.10 the requirements for the animal-welfare body and the tasks of the body;

1.11 the methods of killing experimental animals;

1.12. the procedures by which documents shall be submitted in order to receive an experimental project authorisation for the use of an animal in a procedure;

1.13. the requirements for the classification of severity of procedures;

1.14. the requirements for reusing of experimental animals in a procedure;

1.15. the procedures for the registering and collecting information and reporting, as well as storing documents; and

1.16. the procedures by which animals taken from the wild, non-human primates and endangered animal species shall be used in procedures.

2. The following terms are used in this Regulation:

2.1. establishment – any fixed or mobile facilities, building, group of buildings or other premises and may include a place which is not wholly enclosed or covered;

2.2. self-sustaining colony – non-human primates which are bred only within the colony or sourced from other colonies but not taken from the wild, and where the animals are kept in a way that ensures that they are accustomed to humans;

2.3. field study – a study conducted within an experimental project outside the premises of the establishment;

2.4. animal-welfare body – an advisory institution which advises the breeder, supplier and user of experimental animals on matters related to the welfare and protection of experimental animals.

3. This Regulation shall apply in cases when animals are used or intended to be used in procedures (including elimination of pain, suffering, distress or lasting harm by using anaesthesia, analgesia or other methods), or bred specifically so that their organs or tissues may be used for scientific purposes until these animals have been killed, rehomed or returned to a suitable habitat or husbandry system.

4. This Regulation shall apply to:

4.1. live non-human vertebrae animals, including:

4.1.1. independently feeding larval forms;

4.1.2. foetal forms of mammals as from the last third of their normal development;

4.2. live cephalopods;

4.3. animals used in procedures, which are at an earlier stage of development than that referred to in Sub-paragraph 4.1.1 or 4.1.2 of this Regulation, if the animal is 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 Regulation shall not apply to:

5.1. non-experimental agricultural practices;

5.2. non-experimental clinical veterinary practices;

5.3. veterinary clinical trials required for the registration of a veterinary medicinal product;

5.4. practices undertaken for the purposes of recognised animal husbandry;

5.5. practices undertaken for the primary purpose of identification of animals;

5.6. 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. Specimens of the endangered species listed in Annex A to Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (hereinafter – Regulation No 338/97), which do not fall within the scope of Article 7(1) of that Regulation, shall not be used in procedures unless authorised by the Food and Veterinary Service when the following conditions are met:

6.1. the procedure has one of the following purposes:

6.1.1. translational or applied research aimed at avoiding, preventing, diagnosing or treating disease, ill-health or other abnormality or their effects in human beings, animals or plants;

6.1.2. translational or applied research aimed at developing, manufacturing or testing the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products;

6.1.3. research aimed at preservation of the species;

6.2. there is scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than those listed in Annex A to Regulation No 338/97.

 

7. The Service may authorise the use of non-human primates (except those primates referred to in Paragraph 8 of this Regulation) in procedures meeting the following conditions:

7.1. the procedure has one of the following purposes:

7.1.1. translational or applied research aimed at avoiding, preventing, diagnosing or treating disease, ill-health or other abnormality or their effects in human beings, animals or plants, and the procedure is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings;

7.1.2. translational or applied research aimed at developing, manufacturing or testing the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products, and the procedure is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings;

7.1.3. basic research;

7.1.4. research aimed at preservation of the species;

7.2. there is scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than non-human primates.

8. The Service may authorise the use of non-human primates listed in Annex A to Regulation No 338/97, which do not fall within the scope of Article 7(1) of that Regulation, in procedures meeting the following conditions:

8.1. the procedure has one of the following purposes:

8.1.1. translational or applied research aimed at avoiding, preventing, diagnosing or treating disease, ill-health or other abnormality or their effects in human beings, animals or plants, and the procedure is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings;

8.1.2. translational or applied research aimed at developing, manufacturing or testing the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products, and the procedure is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings;

8.1.3. research aimed at preservation of the species;

8.2. there is scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than non-human primates and by the use of species not listed in Annex A to Regulation No 338/97.

9. The Service may authorise the use of animals taken from the wild in procedures on the basis of scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of an animal which has been bred for use in procedures.

10. Where the Service has scientifically justifiable grounds for believing it is essential to use non-human primates for the purpose referred to in Sub-paragraph 7.1.1 of this Regulation with regard to human beings, it may authorise the use of great apes in procedures, but where the use is not undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions, the Service may authorise such use provided the purpose cannot be achieved by the use of species other than non-human primates.

11. Where the Service has justifiable grounds for believing that action is essential for the preservation of the species or in relation to an unexpected outbreak of a life-threatening or debilitating clinical condition in human beings, it may authorise the use of great apes in

procedures for the purposes stipulated in Section 25, Clause 2, Sub-clause "a", as well as Clauses 3 and 5 of the Animal Protection Law provided that the purpose of the procedure cannot be achieved by the use of species other than great apes or by the use of alternative methods. However, the reference to Section 25, Clause 2, Sub-clause "a" of the Animal Protection Law shall not be taken to include the reference to animals and plants.

12. Where, for exceptional and scientifically justifiable reasons, it is required to perform a procedure involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated, the Service may allow such procedure. The Service may decide not to allow the use of non-human primates in such procedures.

13. The procedures shall be allowed with:

13.1. experimental animals acquired from a registered breeder and supplier of experimental animals;

13.2. animals listed in Annex 1 of this Regulation if these animals are bred for use in procedures;

13.3. non-human primates listed in Annex 2 of this Regulation where they are the offspring of non-human primates which have been bred in captivity or where they are sourced from self-sustaining colonies, starting from the date indicated in Annex 2 of this Regulation.

14. The Service may, on the basis of scientific justification, authorise the use of animals not listed in Sub-paragraphs 13.2 and 13.3 of this Regulation in an experimental project.

15. The Service shall notify the European Commission about a procedure envisaged in accordance with the requirements laid down in Paragraphs 7 and 8 of this Regulation if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

16. Breeders of experimental non-human primates shall have a strategy in place for increasing the proportion of animals that are the offspring of non-human primates that have been bred in captivity.

17. Procedures shall only be allowed in the establishment of a breeder of experimental animals.

18. Procedures shall only by allowed in relation to the experimental project.

19. The Service shall develop and maintain a list of breeders, suppliers and users of experimental animals (hereinafter – list) in the supervisory objects database.

20. The list shall include the information indicated in the application referred to in Sub-paragraph 21.1 of this Regulation, and the Service shall ensure access thereto in accordance with the requirements laid down in the Personal Data Protection Law.

## II. Procedures for the Registration of a Breeder, Supplier and User of Experimental Animals and Cancellation Thereof

21. Before a breeder, supplier or user of experimental animals starts breeding, supplying and using experimental animals, the following documents shall be submitted to the Service:

21.1. a registration application of the breeder, supplier or user of experimental animals (Annex 3);

21.2. a copy of the lease agreement for the premises or area allocated for the breeder, supplier or user of experimental animals, and a written authorisation of the manager for activities with experimental animals if the premises or area is not owned by the breeder, supplier or user of experimental animals.

22. The Service shall, within 10 working days after receipt of the application referred to in Paragraph 21 of this Regulation and documents attached thereto, verify the conformity of the breeder, supplier or user of experimental animals with the requirements laid down in Chapter III of this Regulation, and take one of the following decisions:

22.1. to register the breeder, supplier or user of experimental animals; or

22.2. to refuse to register the breeder, supplier or user of experimental animals.

23. The Service shall send a written notification regarding the decision to the breeder, supplier or user of experimental animals within three working days after verification.

24. If the Service decides to register the breeder, supplier or user of experimental animals, it shall ensure inclusion thereof in the list within three working days after taking of the decision.

25. If experimental animals to be used in procedures are bred in the premises of a user of experimental animals, the user shall also ensure conformity with the requirements for breeders of experimental animals laid down in Chapter III of this Regulation, but the Service shall only register it as a user of experimental animals.

26. In case of any changes in activities of a breeder, supplier or user of experimental animals, it shall lodge a written submission to the Service within 10 days after occurrence of such changes, indicating the following information therein:

26.1. changes in the information indicated in Paragraph 1, 2, 3, 4, or 5 of the application referred to in Sub-paragraph 21.1 of this Regulation;

26.2. essential changes in the establishment or activities which could cause any unfavourable effects on welfare of experimental animals;

26.3. termination of activities, reorganisation or re-registration of the breeder, supplier or user of experimental animals.

27. The Sevice shall examine the submission referred to in Paragraph 26 of this Regulation within 10 working days, verify whether the breeder, supplier and user of experimental animals conforms to the requirement of Chapter III of this Regulation, and:

27.1. take one of the following decisions:

27.1.2. to include the necessary changes in the list;

27.1.3. to cancel the registration of the breeder, supplier or user of experimental animals;

27.2. notify the breeder, supplier or user of experimental animals regarding the decision within three working days in writing and make the respective changes in the list.

28. If the Service establishes that the breeder, supplier or user of experimental animals does not conform to the requirements of Chapter III of this Regulation, it shall determine a time period for elimination of non-conformities in accordance with the procedures laid down in Chapter XII of the Veterinary Medicine Law.

29. The Service shall take a decision to cancel the registration of the breeder, supplier or user of experimental animals if the breeder, supplier or user of experimental animals has not eliminated non-conformities within the time period defined by the Service.

 

30. The Service shall, within three working days, provide a written notification to the breeder, supplier or user of experimental animals regarding the decision to cancel the registration and exclude the breeder, supplier or user of experimental animals from the list.

31. If registration of a breeder, supplier or user of experimental animals is cancelled, it shall not result in worse welfare of the experimental animals placed in the establishment. The breeder, supplier or user of experimental animals shall act with experimental animals according to the instructions of the Service.

## III. Requirements for the Breeder, Supplier and User of Experimental Animals, Requirements for Premises, Welfare Requirements for Experimental Animals, as well as Requirements for Staff Members

32. The breeder, supplier and user of experimental animals have a duty to provide:

32.1. accommodation, environment, food, water and care which are appropriate to health and well-being of experimental animals;

32.2. that any restrictions on the extent to which an animal can satisfy its physiological and ethological needs are kept to a minimum by preventing uncontrolled reproduction of animals unless provided for in the experimental project.

33. The responsible employee of the breeder, supplier and user of experimental animals shall perform a daily check of the environmental conditions in which animals are bred, kept or used in accordance with the requirements of Chapter II of Annex 4 to this Regulation, and record the data acquired.

34. The data referred to in Paragraph 33 of this Regulation shall be kept for at least five years and presented to the Service upon request.

35. The responsible employee of the breeder, supplier and user of experimental animals shall ensure that any defect or avoidable pain, suffering, distress or lasting harm discovered in animal is eliminated as quickly as possible.

36. Experimental animals shall be transported in accordance with the requirements laid down in Council Regulation No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97.

37. The breeder, supplier and user of experimental animals have a duty to ensure premises, facilities, equipment and welfare requirements for keeping, breeding and care of experimental animals in accordance with the requirements referred to in Annex 4 to this Regulation.

38. Facilities and equipment of the breeder, supplier and user of experimental animals shall be appropriate for the species of experimental animals and procedure. Their design, construction and functioning shall be such as to ensure that the procedures are performed as effectively as possible, with the objective of obtaining consistent results with the minimum number of animals and causing the minimum degree of pain, suffering, distress or lasting harm.

39. The breeder, supplier and user of experimental animals shall ensure that their staff members are trained for the following activities:

39.1. procedures with experimental animals;

39.2. design of procedures and experimental projects;

39.3. care of experimental animals;

39.4. killing of experimental animals.

40. The breeder, supplier and user of experimental animals shall designate a responsible person who:

40.1. supervises welfare and care of experimental animals bred, kept or used;

40.2. provides information regarding the animal species accommodated to those staff members who deal with experimental animals;

40.3. ensures that staff members are appropriately educated, competent and continuously trained and that they are supervised until they prove their own competence.

41. The person responsible for an experimental project is entitled to fulfil the duties referred to in Paragraph 40 of this Regulation if the person has received an authorisation in accordance with the procedures laid down in Chapter IX of this Regulation.

42. The staff members referred to in Paragraph 39 of this Regulation shall possess knowledge of the minimum welfare requirements for experimental animals in the following areas:

42.1. laws and regulations regarding the protection of animals used for scientific purposes, including their acquisition, breeding, care and use for scientific purposes;

42.2. ethics in human-animal relationships, the value of life and arguments in favour of or against the use of animals for scientific purposes;

42.3. primary knowledge of biology and characteristic biological features of individual species in relation to their anatomy, physiological traits, breed, genetics and gene conversion;

42.4. animal behaviour, breeding and enrichment;

42.5. methods of behaviour and procedures adapted to the individual species, when applicable;

42.6. animal health management and hygiene;

42.7. awareness of distress, pain and suffering characteristic for individual laboratory animal species;

42.8. anaesthesia, pain-relieving methods and killing of experimental animals;

42.9. use of human end-points;

42.10. requirements of replacement, reduction and refinement;

42.11. design of procedures and experimental projects, when applicable.

43. The staff members referred to in Paragraph 39 of this Regulation shall by their signatures confirm their knowledge of the minimum welfare requirements for experimental animals in the respective areas as referred to in Paragraph 42 of this Regulation.

44. The person responsible for the overall implementation of an experimental project shall ensure in accordance with the experimental project authorisation issued by the Service for the use of an animal in a procedure that:

44.1. unnecessary pain, suffering, distress or lasting harm incurred to the experimental animal during any procedure is prevented;

44.2. experimental project is conducted in strict compliance with the experimental project authorisation for the use of an animal in a procedure, and in case of any non-compliance with the respective conditions undertakes and records the respective measures aimed at ensuring such compliance.

45. The breeder, supplier and user of experimental animals shall employ a practicing veterinarian who possesses professional work experience with laboratory animals.

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

 

Any animal found, at or after capture, to be injured or in poor health shall be examined by a practicing veterinarian or another competent person and action shall be taken to minimise the suffering of the animal.

## IV. Procedures and Classification of Their Severity

47. The person responsible for an experimental project or another person under his or her supervision shall perform procedures:

47.1. at the premises of the establishment of the user of experimental animals;

47.2. outside the premises of the establishment of the user of experimental animals if there is some scientific justification.

48. Procedures may only be performed in relation to the experimental project, and they shall be classified by severity in the following groups:

48.1. non-recovery;

48.2. mild;

48.3. moderate; or

48.4. severe.

49. Procedures shall be classified by their severity according to the criteria referred to in Annex 5 to this Regulation.

50. If procedures with experimental animals involve serious injuries that may cause severe pain, the experimental animal shall be put under anaesthesia..

51. Procedures with experimental animals shall be carried out under general or local anaesthesia, using analgesia or another appropriate method and ensuring that pain, suffering and distress of the experimental animal are kept to a minimum if:

51.1. anaesthesia is judged to be not more traumatic to the experimental animal than the procedure itself;

51.2. anaesthesia is not incompatible with the purpose of the procedure.

52. Experimental animals shall not be given any drug to stop or restrict their showing pain without an adequate level of anaesthesia or analgesia. A scientific justification shall be provided by the user to the Service, accompanied by the details of the anaesthetic or analgesic regimen.

53. 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.

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

55. Death as the end-point of a procedure shall be avoided as far as possible. It shall be replaced by early and humane end-points but where death as the end-point is unavoidable, the procedure shall be designed so as to:

55.1. result in the deaths of as few animals as possible; and

55.2. reduce the duration and intensity of suffering to the animal to the minimum possible and, as far as possible, ensure a painless death.

 

## V. Requirements for Reusing Experimental Animals in a Procedure

56. Only an experimental animal on which no procedure has previously been carried out may be used in a procedure.

57. An experimental animal already used in procedures may only be reused in a new procedure provided that the following conditions are met:

57.1. the actual severity of the previous procedures was mild or moderate;

57.2. it is demonstrated that the animal's general state of health and well-being has been fully restored;

57.3. the further procedure is classified as mild, moderate or non-recovery;

57.4. it is in accordance with a decision of a practicing veterinarian with special medical knowledge about laboratory animals (hereinafter – veterinarian), taking into account the previous experience of procedures of every individual experimental animal.

58. By way of derogation from the criteria referred to in Sub-paragraph 57.1 of this Regulation and after a veterinary examination of the experimental animal, the Service may allow reuse of an animal, provided that the animal has not been used more than once in a procedure entailing severe pain, distress or equivalent suffering.

59. 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.

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

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

## VI. Methods of Killing Experimental Animals

62. Experimental animals shall be killed in the establishment of a breeder, supplier or user of experimental animals by a practicing veterinarian or staff member trained for the activity referred to in Sub-paragraph 39.4 of this Regulation.

63. In the case of a field study an experimental animal may be killed by a practicing veterinarian or appropriately trained staff member outside of an establishment.

64. In relation to the experimental animals referred to in Annex 6 to this Regulation, the appropriate method of killing as laid down in that Annex shall be used, except in the following cases:

64.1. if, on the basis of scientific justification, the use of the method of killing selected by the user of an experimental animal is considered to be at least as humane as the method of killing indicated for the individual experimental animal;

64.2. if, on the basis of scientific justification, the purpose of the procedure cannot be achieved by the use of the method of killing indicated for the individual experimental animal.

 

65. Paragraphs 62, 63 and 64 of this Regulation shall not apply where an experimental animal has to be killed in emergency circumstances for animal-welfare, public-health, public-security, animal-health or environmental reasons.

66. The killed experimental animals shall be disposed in accordance with the laws and regulations regarding circulation of animal by-products and derived products not intended for human consumption.

67. Experimental animals used in a procedure or intended to be used but not actually used in a procedure may be:

67.1. rehomed;

67.2. in case of a wild animal – returned to a suitable habitat as close to the place where the animal was captured as possible;

67.3. returned to a suitable husbandry system appropriate to the species.

68. The conditions referred to in Paragraph 67 of this Regulation shall apply if:

68.1. the state of health of the experimental animal allows it;

68.2. there is no danger caused by the experimental animal to public health or animal health, as well as the environment;

68.3. appropriate measures have been taken to safeguard the well-being of the animal.

69. If the requirements referred to in Sub-paragraph 67.1 of this Regulation are fulfilled, the breeder, supplier and user of experimental animals shall act in accordance with a rehoming scheme drawn up, which ensures socialisation of the animal that is rehomed.

70. If it is intended to return a wild animal to its habitat, where appropriate, the breeder, supplier and user of experimental animals shall conduct a programme of rehabilitation before the animals are returned to their habitat.

71. It is prohibited to use the experimental animal used in an experiment for food, except the case referred to in Article 3(2) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.

## VII. Requirements for the Animal Welfare Body and Tasks of such Body

72. Every breeder, supplier and user of experimental animals shall have an animal-welfare body in place.

73. The animal-welfare body shall include a person made responsible for the care and welfare of experimental animals. In the case of a user of experimental animals such person shall be a scientific member. The animal-welfare body shall also include a practicing veterinarian who possesses work experience with laboratory animals.

74. In case of a small-scale operation of a breeder, supplier and user of experimental animals the tasks of the animal-welfare body shall be fulfilled by using an animal-welfare body established by other breeders, suppliers and users of experimental animals.

75. The animal-welfare body shall carry out the following tasks:

75.1. advise the staff dealing with experimental animals on matters related to their acquisition, accommodation, care and use;

75.2. advise the staff on the replacement, reduction and refinement of the use of experimental animals, and keep it continuously informed regarding technical and scientific developments concerning the application of the referred-to requirements;

75.3. advise on the rehoming schemes, also the appropriate socialisation of the experimental animals to be rehomed, and to ensure exchange of information with other users and breeders of experimental animals in this area;

75.4. establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of experimental animals housed or used in the establishment;

75.5. follow the development and outcome of experimental projects, taking into account the effect on the experimental animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement of the use of experimental animals;

75.6. consult with the Animal Protection Ethics Council as regards welfare and protection of experimental animals;

75.7. keep the records of any advice given by the animal-welfare body and decisions taken regarding that advice for at least three years.

76. The records referred to Sub-paragraph 75.7 of this Regulation shall be made available to the Service upon request.

## VIII. Procedures for the Registering and Collecting Information, Reporting and Storing of Documents

77. All breeders, suppliers and users shall keep records of the following:

77.1. the number and the species of experimental animals bred, acquired, supplied, used and reused in procedures, set-free or rehomed;

77.2. the origin of the animals (including whether they are bred for use in procedures);

77.3. the dates on which the animals are acquired, supplied, released or rehomed;

77.4. the place where the animals are acquired;

77.5. the given name, surname or the name and address of the recipient of animals;

77.6. the number and species of experimental animals which died or were killed in each establishment. For experimental animals that have died, the cause of death shall, when known, be noted;

77.7. in the case of users of experimental animals, the projects in which experimental animals are used.

78. The records referred to in Paragraph 77 of this Regulation shall be kept for a minimum of five years and made available to the Service upon request.

79. All breeders, suppliers and users of experimental animals shall keep the following information on each dog, cat and non-human primate:

79.1. identity;

79.2. place and date of birth (when available);

79.3. whether it is bred for use in procedures;

79.4. in the case of a non-human primate, whether it is the offspring of non-human primates that have been bred in captivity.

80. Each dog, cat and non-human primate shall have an individual history file, which follows the animal as long as it is kept for the purposes laid down in Section 25 of the Animal Protection Law.

81. The file shall be established at birth or as soon as possible thereafter and shall cover any relevant reproductive, veterinary and social information on the individual animal, as well as the projects in which it has been used.

82. The information referred to in Paragraphs 79 and 81 of this Regulation shall be kept for a minimum of three years after the death or rehoming of the animal and shall be made available to the Service upon request.

83. In the case of rehoming, the relevant veterinary care and social information from the individual history file and the pet passport or vaccination record shall accompany the animal.

84. Each dog, cat or non-human primate shall be provided with a permanent individual identification mark in the least painful manner possible. The identification shall be provided at the latest at the time of weaning.

85. Where a dog, cat or non-human primate is transferred from one breeder, supplier or user to another before it is weaned, and it is not practicable to mark it beforehand, a record, specifying in particular its mother, must be maintained by the receiver until it is marked.

86. Where an unmarked dog, cat or non-human primate, which is weaned, is received by a breeder, supplier or user of experimental animals, it shall be permanently marked as soon as possible and in the least painful manner possible.

87. The breeder, supplier and user of experimental animals shall provide, upon request of the competent authority, reasons for which the animal is unmarked.

88. All relevant documentation, including experimental project authorisations for the use of an animal in a procedure and the result of the project evaluation, shall be kept for at least three years from the expiry date of the experimental project authorisation for the use of an animal in a procedure or from the expiry of the period referred to in Paragraph 105 or 106 of this Regulation and shall be available to the Service upon request.

89. In addition to the requirements referred to in Paragraph 88 of this Regulation, the documentation regarding experimental projects which have to undergo retrospective assessment shall be kept by the Service until the retrospective assessment has been completed

## IX. Procedures for the Granting and Cancellation of an Experimental Project Authorisation of a Person Responsible for the Experimental Project

90. In order to receive an experimental project authorisation the person responsible for the experimental project shall submit to the Service:

90.1. an application including the given name, surname, personal identity number, address of the place of residence, phone number of the natural person;

90.2. a copy of the education document on at least an academic degree in the area related to experimental projects;

90.3. a copy of a document issued by the Federation of European Laboratory Animal Science Associations, which certifies training under Category C course on welfare requirements of experimental animals.

91. The Service shall take one of the following decisions within five working days after receipt of the application referred to in Paragraph 90 of this Regulation and its accompanying documents:

91.1. to issue an experimental project authorisation;
91.2. to refuse to issue an experimental project authorisation.

92. The Service shall, within three working days, notify the person responsible for the experimental project in writing regarding the decision taken.

93. If a decision to issue an experimental project authorisation has been taken, the Service shall, within three working days after taking of the decision, issue the referred-to authorisation to the person responsible for the experimental project.

94. The Service shall cancel an experimental project authorisation issued to the person responsible for the experimental project if it is detected during a control procedure that implementation of the experimental project does not conform to the experimental project authorisation issued.

95. The Service shall, within three working days, notify the person responsible for the experimental project in writing regarding the decision to cancel the experimental project authorisation.

## X. Procedures for the Issuance, Renewal and Cancellation of an Experimental Project Authorisation for the Use of an Animal in a Procedure

96. In order to implement an experimental project, a user of an experimental animal shall receive from the Service an experimental project authorisation for the use of the animal in a procedure.

97. In order to receive an experimental project authorisation for the use of an animal in a procedure, the person responsible for an experimental project or the person responsible for the overall implementation of the experimental project (hereinafter – applicant) shall submit to the Service an application indicating:
97.1. the user of experimental animals;
97.2. the location of the procedure (or information regarding a location of the procedure outside the establishment of the user of experimental animals);
97.3. the given name, surname of the person responsible for the experimental project and the number of the authorisation issued;
97.4. the given names and surnames of those persons who will perform the activities indicated in the procedure;
97.5. the person responsible for the overall implementation of the experimental project;
97.6. the start date and end date of the procedure.

98. The following shall be appended to the application referred to in Paragraph 97 of this Regulation:
98.1. experimental project indicating:
98.1.1. title of the experimental project;
98.1.2. title of the procedures in the experimental project;
98.1.3. aims of the experimental project and procedure;
98.1.4. justification and topicality of the experimental project and procedure;
98.1.5. expected scientific results and educational value of the experimental project;
98.1.6. number, species, life stage, origin and place of birth of experimental animals;

98.1.7. housing, husbandry and care conditions for experimental animals;

98.1.8. relevance and justification for the use of experimental animals, and the number of animals reused in procedures;

98.1.9. list and description of those procedures to which experimental animals will be exposed;

98.1.10. degree of severity of the proposed procedure;

98.1.11. a demonstration of evaluation and rejection of such alternative methods which aim to replace, reduce and refine the use of animals in procedures;

98.1.12. description of the measures taken in order to avoid duplication of procedures;

98.1.13. justification of reduction, avoidance and alleviation of any form of suffering of experimental animals, from birth to death;

98.1.14. the planned use of anaesthesia, analgesia and other pain relieving methods;

98.1.15. justification for not using anaesthesia, analgesia and other pain relieving methods if the procedure can cause suffering or lasting (significant) pain for experimental animals;

98.1.16. justification if it is planned to kill the experimental animal, and the planned methods of killing;

98.1.17. justification for reusing experimental animals in procedures and evaluation of the accumulative effect thereof;

98.1.18. (experimental or observational) strategy and statistical design to minimise the number, pain, suffering, distress of animals and environmental impact of the experimental project where appropriate;

98.2. non-technical summary of the experimental project;

98.3. if it is planned to use animals not referred to in Sub-paragraphs 13.2 and 13.3 of this Regulation in the experimental project, scientific justification why it is impossible to use the animals referred to in Sub-paragraphs 13.2 and 13.3 of this Regulation.

99. A user of experimental animals shall indicate the following in the non-technical project summary, in conformity with safeguarding restricted access information:

99.1. information regarding the title and objectives of the experimental project, including the predicted harm and benefits of experimental animals, as well as the number and species of animals to be used;

99.2. a demonstration of evaluation and rejection of such alternative methods which aim to replace, reduce and refine the use of animals in procedures;

99.3. description of the measures taken in order to avoid duplication of procedures.

100. The non-technical experimental project summary shall be anonymous and shall not contain the names and addresses of the user of experimental animals or its personnel.

101. The Service shall within three working days check whether the application includes all the information referred to in Paragraph 97 of this Regulation and whether all the documents referred to in Paragraph 98 of this Regulation have been submitted, and inform the applicant:

101.1. that all the necessary documents have been received and the application will be examined within the term laid down in the Animal Protection Law;

101.2. that the necessary additional documents should be lodged within five working days.

102. If the applicant fails to lodge the necessary additional documents within the time period laid down in Sub-paragraph 101.2 of this Regulation, the Service shall take a decision not to

issue an experimental project authorisation for the use of an animal in a procedure and shall notify the applicant regarding the referred-to decision in writing within three working days.

103. The Service shall issue an experimental project authorisation for such procedures only for which:

103.1. an evaluation of the experimental project has been carried out in accordance with Chapter XI of this Regulation and a favourable evaluation has been received;

103.2. severity classification of procedures has been determined in accordance with Chapter IV of this Regulation.

104. The Service shall not issue an experimental project authorisation for the use of an animal in a procedure if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated, except the case referred to in Paragraph 12 of this Regulation.

105. The Service shall examine the application lodged in accordance with Paragraph 97 of this Regulation and the documents referred to in Paragraph 98 of this Regulation within the time period laid down in the Animal Protection Law and shall take one of the following decisions:

105.1. to issue an experimental project authorisation for the use of an animal in a procedure;

105.2. to refuse to issue an experimental project authorisation for the use of an animal in a procedure.

106. If the Service takes a decision to extend the time period for examination of an application referred to in the Animal Protection Law up to 15 working days, it shall notify the applicant thereof in writing before the expiry of the primary time period.

107. The Service shall, within three working days, notify the applicant in writing regarding the decision taken.

108. If a decision to issue an experimental project authorisation for the use of an animal in a procedure has been taken, the Service shall, within three working days after taking of the decision, issue it to the applicant indicating:

108.1. the user of experimental animals;

108.2. the person responsible for the overall implementation of the experimental project and conformity of the experimental project with the experimental project authorisation issued;

108.3. the establishment in which the experimental project will be implemented, where applicable;

108.4. any specific conditions if such arise from the experimental project evaluation, including whether the project is assessed retrospectively;

108.5. term of validity of the authorisation which does not exceed five years.

109. If an experimental project is changed in a way that may have a negative impact on welfare of experimental animals or in case of changes in the information provided to the Service in accordance with Paragraphs 97 and 98 of this Regulation, the person responsible for the experimental project or for the overall implementation of the experimental project shall lodge an application to the Service, indicating the respective changes.

110. The Service shall examine the application referred to in Paragraph 109 of this Regulation within 10 working days and take one of the following decisions:

110.1. to amend the experimental project authorisation for the use of an animal in a procedure if the changes indicated in the application are directly related to the experimental project (for instance, changed name of the person responsible for the overall implementation of the experimental project);

110.2. to renew the experimental project authorisation for the use of an animal in a procedure if the changes indicated in the application are directly related to the experimental project, as well as may cause unfavourable effects on the welfare of experimental animals, and if the outcome of an evaluation of changes carried out in accordance with the procedures laid down in Chapter XI of this Regulation is favourable;

110.3. to refuse to amend or renew the experimental project authorisation for the use of an animal in a procedure.

111. The Service shall, within three working days, notify the user of experimental animals in writing regarding the decision taken and if the decision referred to in Sub-paragraph 110.1 or 110.2 of this Regulation has been taken, shall amend or renew the experimental project authorisation for the use of an animal in a procedure.

112. If the implementation of an experimental project does not conform to the experimental project authorisation, the Service shall take a decision to withdraw the experimental project authorisation for the use of an animal in a procedure and shall, within three working days, notify the user of experimental animals in writing regarding the decision taken.

113. If the Service takes a decision to cancel the experimental project authorisation for the use of an animal in a procedure, it shall not result in worse welfare of the experimental animals used or intended to be used in the experimental project.

## XI. Experimental Project Evaluation

114. In order to issue an experimental project authorisation for the use of an animal in a procedure, the Service shall evaluate the experimental project, ensuring transparency of the evaluation process.

115. The experimental project evaluation shall be performed with a degree of detail appropriate for the type of experimental project and shall verify that the experimental project meets the following criteria:

115.1. the project is justified from a scientific or educational point of view or implementation thereof is required by the laws and regulations on scientific activities;

115.2. the purposes of the experimental project justify the use of animals;

115.3. the experimental project is designed so as to enable procedures to be carried out in the most humane and environmentally sensitive manner possible.

116. In order to avoid duplication of procedures, the Service shall recognise the validity of data of other Member States produced by using test methods recognised as referred to in directly applicable legal acts of the European Union, except cases when additional procedures need to be carried out regarding such data for the protection of public health, safety or the environment.

117. The experimental project evaluation shall consist of the following:

117.1. an evaluation of the objectives of the experimental project, the predicted scientific benefits and environmental impact or educational value;

117.2. an evaluation of the conformity of the experimental project with the requirement of replacement, reduction and refinement of animals;

117.3. an evaluation and assignment of the classification of the severity of procedures;

117.4. a harm-benefit analysis of the experimental project in order to assess whether the harm to the animals is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment;

117.5. an evaluation of any justification referred to in Paragraph 52 and Sub-paragraphs 47.2, 57.2, 64.2 and 98.3 of this Regulation;

117.6. a determination as to whether and when the experimental project should be assessed retrospectively.

118. In carrying out the experimental project evaluation the Service shall consider expertise in particular in the following areas:

118.1. introduction of alternative methods in order to replace, reduce and refine the existing methods;

118.2. experimental design, including statistics where appropriate;

118.3. veterinary practice in experimental (laboratory) animal science or wildlife veterinary practice where appropriate;

118.4. animal husbandry and care, in relation to the species that are intended to be used.

119. Project evaluation shall be subject to safeguarding intellectual property and commercial secret.

120. In accordance with Sub-paragraph 117.6 of this Regulation, the Service shall carry out a retrospective assessment of all experimental projects which:

120.1. involve use of non-human primates;

120.2. include procedures which are classified as severe, involve severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

121. The person responsible for the experimental project shall submit to the Service within 30 days after the end of the respective procedure of the experimental projects referred to in Paragraph 120 of this Regulation:

121.1. information explaining the objective of the experimental project and whether the objective was achieved;

121.2. analytical description of the harm inflicted on experimental animals if it differs from that indicated in the application, as well as the number and species of experimental animals used, and the severity of the procedures;

121.3. information regarding any measures implemented, which may contribute to further replacement, reduction and refinement of animals.

122. The Service shall evaluate the following on the basis of the documentation referred to in Paragraph 121 of this Regulation:

122.1. whether the objectives of the experimental project were achieved;

122.2. the harm inflicted on animals, including the number and species of experimental animals used, and the severity of the procedures;

122.3. measures that may contribute to further replacement, reduction and refinement of animals.

123. The Service shall not perform retrospective assessment of experimental projects using onlu such procedures which are classified as mild or non-recovery.

## XII. Monitoring and Control

124. The Service shall carry out regular inspections of breeders, suppliers and users of experimental animals to verify conformity with the requirements of Chapters II, III, IV, V, VI and VII of this Regulation.

125. The Service shall adjust the frequency of inspections on the basis of a risk analysis for each breeder, supplier and user of experimental animals, taking into account:

125.1. the number and species of animals housed;

125.2. the record of the breeder, supplier or user of experimental animals regarding conformity thereof with the requirements of laws and regulations for the protection of animals used for scientific purposes;

125.3. the number and types of experimental projects implemented by the respective user of experimental animals;

125.4. any information that might indicate non-conformity.

126. Inspections shall be carried out on at least one third of users of experimental animals each year in accordance with the risk analysis referred to in Paragraph 125 of this Regulation. Breeders, suppliers and users of of experimental animals carrying out activities involving non-human primates shall be inspected at least once a year.

127. A proportion of the inspections shall be carried out without prior warning

128. Records of all inspections shall be kept for at least five years.

129. Once a year the Service shall publish statistics on its website regarding:

129.1. the species and number of experimental animals used in procedures;

129.2. the actual severity of procedures;

129.3. the origin and species of non-human primates used in procedures.

130. The Service shall publish on its website a non-technical summary of the authorised experimental project and its updates.

## XIII. Closing Provisions

131. The requirements for animal enclosures referred to in Annex 4 to this Regulation shall come into force on 1 January 2017.

132. A breeder, supplier and user of experimental animals registered with the Service before the coming into force of this Regulation shall keep the previous status if by 1 July 2013 it lodges an application to the Service in accordance with Annex 3 to this Regulation.

133. Such experimental projects for which an authorisation for the use of animals in a procedure has been issued before coming into force of this Regulation shall be subject to the laws and regulations on registration of breeders, suppliers and users of experimental animals, on the procedures for dealing with experimental animals and on welfare requirements to be ensured for experimental animals.

**Informative Reference to the European Union Directive**

This Regulation contains legal norms arising from 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.

Prime Minister V. Dombrovskis

Minister for Agriculture L. Straujuma

**Annex 1**
Cabinet Regulation No. 52
22 January 2013

# Animals to be Used in Procedures which may Only be Taken from Establishments for Breeding Experimental Animals

| No. | Animal species | Latin name |
|---|---|---|
| 1. | Mouse | *Mus musculus* |
| 2. | Rat | *Rattus norvegicus* |
| 3. | Guinea pig | *Cavia porcellus* |
| 4. | Syrian (golden) hamster | *Mesocricetus auratus* |
| 5. | Chinese hamster | *Cricetulus griseus* |
| 6. | Mongolian gerbil | *Meriones unguiculatus* |
| 7. | Rabbit | *Oryctolagus cuniculus* |
| 8. | Dog | *Canis familiaris* |
| 9. | Cat | *Felis catus* |
| 10. | All species of non-human primates | |
| 11. | Frog | *Xenopus (laevis, tropicalis)*<br>*Rana (temporaria, pipiens)* |
| 12. | Zebra fish | *Danio rerio* |

Minister for Agriculture L. Straujuma

 

**Annex 2**
Cabinet Regulation No. 52
22 January 2013

# Non-human Primates to be Used in Procedures

| No. | Species | Date |
|---|---|---|
| 1. | Marmoset *(Callithrix jacchus)* | 1 January 2013 |
| 2. | Cynomolgus monkey *(Macaca fascicularis)* | 10 November 2022 |
| 3. | Rhesus monkey *(Macaca mulata)* | 10 November 2022 |
| 4. | Other species of non-human primates | 10 November 2022 |

Minister for Agriculture L. Straujuma

 

**Annex 3**
Cabinet Regulation No. 52
22 January 2013

# Registration Application of a Breeder, Supplier or User of Experimental Animals

**1. Breeder, supplier or user of experimental animals**

(the name of the legal person/the given name and surname of the natural person)

(registration No.) in the Enterprise Register)

– (for a natural person – personal identity number)

(registered office/ for a natural person – declared place of residence)

(address of the actual location)

(telephone number) (fax number) (e-mail address)

**2. Representative of the breeder, supplier or user of experimental animals**

– (personal identity number)

(given name and surname)

(telephone number)

**3. The person responsible for experimental animals and staff members**

– (personal identity number)

(given name and surname)

(specialisation)

(telephone number)

**4. Practising veterinarian**

| | | | | | | – | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | |

(personal identity number)

| |
|---|
| |

(given name and surname)

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | |

(telephone number)

**5. Type of activity**

| No. | Type of activity | Animal | |
|---|---|---|---|
| | | species | number |
| 5.1. | Breeding of experimental animals | | |
| 5.2. | Supply of experimental animals | | |
| 5.3. | Use of experimental animals | | |

**6. I would like to receive a registration certificate:**

| Yes | | No | |
|---|---|---|---|

| | | . | | | . | | | | | . | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | |

(date) (given name and surname) (signature)

**7. Registration of the application** (to be filled in by a staff member of the Food and Veterinary Service)

| | | |
|---|---|---|
| | | |

(date) (position/given name and surname) (signature)

Notes.
The details “signature”, “date” and Paragraph 7 “Registration of the application” of the document shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up, storage and circulation of electronic documents.

Minister for Agriculture L. Straujuma

 

**Annex 4**
Cabinet Regulation No. 52
22 January 2013

# Requirements for Breeders, Suppliers and Users of Experimental Animals

## I. The physical facilities

1. All facilities shall be constructed so as to provide an environment which takes into account the physiological and ethological needs of the species kept in them. Facilities shall also be designed and managed to prevent access by unauthorised persons and the ingress or escape of animals.

2. Breeders, suppliers and users of experimental animals shall have a maintenance programme to prevent and remedy any defect in buildings or equipment.

3. Holding rooms

3.1. Breeders, suppliers and users of experimental animals shall have a regular and efficient cleaning schedule for the rooms and shall maintain satisfactory hygienic standards therein.

3.2. Walls and floors shall be surfaced with a material resistant to the heavy wear and tear caused by the experimental animals and the cleaning process. The material shall not be detrimental to the health of the experimental animals and shall be such that the experimental animals cannot hurt themselves. Additional protection shall be given to any equipment or fixtures so that they are not damaged by the experimental animals nor do they cause injury to the animals themselves.

3.3. Species that are incompatible, for example predator and prey, or experimental animals requiring different environmental conditions, shall not be housed in the same room nor, in the case of predator and prey, within sight, smell or sound of each other.

4. General and special purpose procedure rooms

4.1. Breeders, suppliers and users of experimental animals shall, where appropriate, have available laboratory facilities for the carrying out of simple diagnostic tests, post-mortem examinations, and the collection of samples that are to be subjected to more extensive laboratory investigations elsewhere. General and special purpose procedure rooms shall be available for situations where it is undesirable to carry out the procedures or observations in the holding rooms.

4.2. Facilities shall be provided to enable newly-acquired animals to be isolated until their health status can be determined and the potential health risk to established animals assessed and minimised.

4.3. There shall be accommodation for the separate housing of sick or injured animals.

5. Service rooms

5.1. Store-rooms shall be designed, used and maintained to safeguard the quality of food and bedding. These rooms shall be vermin and insect-proof, as far as possible. Other materials, which may be contaminated or present a hazard to experimental animals or staff, shall be stored separately.

5.2. The cleaning and washing areas shall be large enough to accommodate the installations necessary to decontaminate and clean used equipment. The cleaning process shall

 

be arranged so as to separate the flow of clean and dirty equipment to prevent the contamination of newly-cleaned equipment.

5.3. Breeders, suppliers and users of experimental animals shall provide for the hygienic storage and safe disposal of carcasses of experimental animals and animal waste. If disposal cannot be performed or is not necessary at the respective establishment, it shall be ensured in accordance with the laws and regulations regarding the requirements for the circulation of animal by-products and derived products not intended for human consumption.

5.4. Where surgical procedures under aseptic conditions are required there shall be provision for one or more than one suitably equipped room, and facilities provided for postoperative recovery.

## II. The environment and control thereof

6. Ventilation and temperature

6.1. Insulation, heating and ventilation of the holding room shall ensure that the air circulation, dust levels, and gas concentrations are kept within limits that are not harmful to the experimental animals housed.

6.2. Temperature and relative humidity in the holding rooms shall be adapted to the species and age groups housed. The temperature shall be measured and logged on a daily basis.

6.3. Experimental animals shall not be restricted to outdoor areas under climatic conditions which may cause them distress.

7. Lighting

7.1. Where natural light does not provide an appropriate light/dark cycle, controlled lighting shall be provided to satisfy the biological requirements of the experimental animals and to provide a satisfactory working environment.

7.2. Illumination shall satisfy the needs for the performance of husbandry procedures and inspection of the experimental animals.

7.3. Regular photoperiods and intensity of light adapted to the species shall be provided.

7.4. When keeping albino animals, the lighting shall be adjusted to take into account their sensitivity to light.

8. Noise

8.1. Noise levels including ultrasound, shall not adversely affect experimental animal welfare.

8.2. Establishments shall have alarm systems that sound outside the sensitive hearing range of the animals, where this does not conflict with their audibility to human beings.

8.3. Holding rooms shall where appropriate be provided with noise insulation and absorption materials.

9. Alarm systems

9.1. Establishments relying on electrical or mechanical equipment for environmental control and protection, shall have a stand-by system to maintain essential services and emergency lighting systems as well as to ensure that alarm systems themselves do not fail to operate.

9.2. Heating and ventilation systems shall be equipped with monitoring devices and alarms.

9.3. Instructions on emergency procedures shall be prominently displayed.

 

## III. Care of animals

10. Health

10.1. Breeders, suppliers and users of experimental animals shall have a strategy in place to ensure that a health status of the experimental animals is maintained that safeguards experimental animal welfare and meets scientific requirements. This strategy shall include:

10.1.1. regular health monitoring;

10.1.2. a microbiological surveillance programme;

10.1.3. plans for dealing with health breakdowns; and

10.1.4. health parameters and procedures for the introduction of new animals.

10.2. Experimental animals shall be checked at least daily by a competent person. These checks shall ensure that all sick or injured animals are identified and appropriate action is taken.

11. Animals taken from the wild

11.1. Transport containers and means of transport adapted to the species concerned shall be available at capture sites, in case animals need to be moved for examination or treatment.

11.2. Special consideration shall be given and appropriate measures taken for the acclimatisation, quarantine, housing, husbandry, care of animals taken from the wild and, as appropriate, provisions for setting them free at the end of procedures.

12. Housing and enrichment

12.1. Experimental animals, except those which are naturally solitary, shall be socially housed in stable groups of compatible individuals. The introduction or re-introduction of animals to established groups shall be carefully monitored to avoid problems of incompatibility and disrupted social relationships.

12.2. All experimental animals shall be provided with space of sufficient complexity to allow expression of a wide range of normal behaviour. They shall be given a degree of control and choice over their environment to reduce stress-induced behaviour.

12.3. Establishments shall have appropriate enrichment techniques in place, to extend the range of activities available to the experimental animals and increase their coping activities including physical exercise, foraging, manipulative and cognitive activities, as appropriate to the species. Environmental enrichment in experimental animal enclosures shall be adapted to the species and individual needs of the animals concerned. The enrichment strategies in establishments shall be regularly reviewed and updated.

13. Animal enclosures

13.1. Experimental animal enclosures shall not be made out of materials detrimental to the health of the animals. Their design and construction shall be such that no injury to the experimental animals is caused. Unless they are disposable, they shall be made from materials that will withstand cleaning and decontamination techniques.

13.2. The design of experimental animal enclosure floors shall be adapted to the species and age of the animals and be designed to facilitate the removal of excreta.

14. Feeding

14.1. The form, content and presentation of the diet shall meet the nutritional and behavioural needs of the experimental animal.

14.2. The experimental animals' diet shall be palatable and non-contaminated. In the selection of raw materials, production, preparation and presentation of feed, breeders, suppliers and users of experimental animals shall take measures to minimise chemical, physical and microbiological contamination.

 

14.3. Packing, transport and storage shall be such as to avoid contamination, deterioration or destruction. All feed hoppers, troughs or other utensils used for feeding shall be regularly cleaned and, if necessary, sterilised.

14.4. Each experimental animal shall be able to access the food, with sufficient feeding space provided to limit competition.

15. Watering

15.1. Uncontaminated drinking water shall always be available to all experimental animals.

15.2. When automatic watering systems are used, they shall be regularly checked, serviced and flushed. If solid-bottomed cages are used, care shall be taken to prevent the risk of flooding.

15.3. Provision shall be made to adapt the water supply for aquaria and tanks to the needs and tolerance limits of the individual fish, amphibian and reptile species.

16. Resting and sleeping areas

16.1. Bedding materials or sleeping structures adapted to the species shall always be provided, including nesting materials or structures for breeding experimental animals.

16.2. Within the animal enclosure, as appropriate to the species, a solid, comfortable resting area for all experimental animals shall be provided. All sleeping areas shall be kept clean and dry.

17. Breeders, suppliers and users of experimental animals shall set up habituation and training programmes for experimental animals suitable for the procedures and length of the Project.

## IV. Enclosures

18. For mice, rats, gerbils, hamsters and guinea pigs, 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. 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.

18.1. Mice

| No. | Mice | Body weight (g) | Minimum enclosure size ($cm^2$) | Floor area per animal ($cm^2$) | Minimum enclosure height (cm) |
|---|---|---|---|---|---|
| 18.1.1. | In stock and during procedures | up to 20 | 330 | 60 | 12 |
| | | from 20 up to 25 | 330 | 70 | 12 |
| | | over 25 to 30 | 330 | 80 | 12 |
| | | over 30 | 330 | 100 | 12 |
| 18.1.2. | Breeding | | 330<br>For a monogamous pair (outbred/inbred) or a trio (inbred). For each additional female plus litter 180 $cm^2$ shall be added | | 12 |
| 18.1.3. | Stock at | up to 20 | 950 | 40 | 12 |

| | | | | | |
|---|---|---|---|---|---|
| | breeders(*) when enclosure size is 950 $cm^2$ | | | | |
| 18.1.4. | Stock at breeders(*) when enclosure size is 1500 $cm^2$ | up to 20 | 1500 | 30 | 12 |
| (*) Post-weaned mice may be kept at these higher stocking densities for the short period after weaning until issue, 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 and other behavioural deficits, weight loss, or other physiological or behavioural stress responses. | | | | | |

18.2. Rats

| No. | Rats | Body weight (g) | Minimum enclosure size ($cm^2$) | Floor area per animal ($cm^2$) | Minimum enclosure height (cm) |
|---|---|---|---|---|---|
| 18.2.1. | In stock and during procedures(*) | up to 200 | 800 | 200 | 18 |
| | | over 200 to 300 | 800 | 250 | 18 |
| | | over 300 to 400 | 800 | 350 | 18 |
| | | over 400 to 600 | 800 | 450 | 18 |
| | | over 600 | 1500 | 600 | 18 |
| 18.2.2. | Breeding | | 800 Mother and litter. For each additional adult animal permanently added to the enclosure add 400 $cm^2$ | | 18 |
| 18.2.3. | Stock at breeders(**) when enclosure size is 1500 $cm^2$ | up to 50 | 1500 | 100 | 18 |
| | | over 50 to 100 | 1500 | 125 | 18 |
| | | over 100 to 150 | 1500 | 150 | 18 |
| | | over 150 to 200 | 1500 | 175 | 18 |
| 18.2.4. | Stock at breeders(**) when enclosure size is 2500 $cm^2$ | up to 100 | 2500 | 100 | 18 |
| | | over 100 to 150 | 2500 | 125 | 18 |
| | | over 150 to 200 | 2500 | 150 | 18 |
| (*) 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.<br>(**) Post-weaned rats may be kept at these higher stocking densities for the short period after weaning until issue, 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 and other behavioural deficits, weight loss, or other physiological or behavioural stress responses. | | | | | |

18.3. Gerbils

| No. | Gerbils | Body weight (g) | Minimum enclosure size ($cm^2$) | Floor area per animal ($cm^2$) | Minimum enclosure height (cm) |
|---|---|---|---|---|---|
| 18.3.1. | In stock and during procedures | up to 40 | 1200 | 150 | 18 |
| | | over 40 | 1200 | 250 | 18 |
| 18.3.2. | Breeding | | 1200 Monogamous pair or trio with offspring | | 18 |

18.4. Hamsters

| No. | Hamsters | Body weight (g) | Minimum enclosure size ($cm^2$) | Floor area per animal ($cm^2$) | Minimum enclosure height (cm) |
|---|---|---|---|---|---|
| 18.4.1. | In stock and during procedures | up to 60 | 800 | 150 | 14 |
| | | over 60 to 100 | 800 | 200 | 14 |
| | | over 100 | 800 | 250 | 14 |
| 18.4.2. | Breeding | | 800 Mother or monogamous pair with litter | | 14 |
| 18.4.3. | Stock at breeders(*) | up to 60 | 1500 | 100 | 14 |
| (*) Post-weaned hamsters may be kept at these higher stocking densities for the short period after weaning until issue, 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 and other behavioural deficits, weight loss, or other physiological or behavioural stress responses. | | | | | |

18.5. Guinea pigs

| No. | Guinea pigs | Body weight (g) | Minimum enclosure size ($cm^2$) | Floor area per animal ($cm^2$) | Minimum enclosure height (cm) |
|---|---|---|---|---|---|
| 18.5.1. | In stock and during procedures | up to 200 | 1800 | 200 | 23 |
| | | over 200 to 300 | 1800 | 350 | 23 |
| | | over 300 to 450 | 1800 | 500 | 23 |
| | | over 450 to 700 | 2500 | 700 | 23 |
| | | over 700 | 2500 | 900 | 23 |
| 18.5.2. | Breeding | | 2500 Pair with litter. For each additional breeding female | | 23 |

| | | | | | |
|---|---|---|---|---|---|
| | | | add 1000 $cm^2$ | | |

19. During agricultural research, when the aim of the project requires that the rabbits are kept under similar conditions to those under which commercial farm animals are kept, the keeping of the animals shall at least follow the standards laid down in the laws and regulations regarding general welfare requirements of animals kept for farming purposes. 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 exceptional 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.

19.1. Rabbits over 10 weeks of age

| No. | Final body weight (kg) | Minimum floor area for one or two socially harmonious animals ($cm^2$) | Minimum height (cm) | Optimal size of the raised area in enclosures | |
|---|---|---|---|---|---|
| | | | | Optimal area (cm by cm) | Optimal height from enclosure's floor (cm) |
| 19.1.1. | Up to 3 | 3500 | 45 | 55 x 25 | 25 |
| 19.1.2. | Over 3 to 5 | 4200 | 45 | 55 x 30 | 25 |
| 19.1.3. | Over 5 | 5400 | 60 | 60 x 35 | 30 |
| The table is to be used for both cages and pens. The additional floor area is as a minimum 3000 $cm^2$ per rabbit for the third, the fourth, the fifth and the sixth rabbit, while 2500 $cm^2$ as a minimum shall be added for each additional rabbit above a number of six. | | | | | |

19.2. Doe plus litter

| No. | Doe weight (kg) | Minimum enclosure size ($cm^2$) | Addition for nest boxes ($cm^2$) | Minimum height (cm) |
|---|---|---|---|---|
| 19.2.1. | Up to 3 | 3500 | 1000 | 45 |
| 19.2.2. | Over 3 to 5 | 4200 | 1200 | 45 |
| 19.2.3. | Over 5 | 5400 | 1400 | 60 |

19.3. Rabbits less than 10 weeks of age

| No. | Age | Minimum enclosure size ($cm^2$) | Minimum floor area per animal ($cm^2$) | Minimum height (cm) |
|---|---|---|---|---|
| 19.3.1. | Weaning to 7 weeks | 4000 | 800 | 40 |
| 19.3.2. | From 7 to 10 weeks | 4000 | 1200 | 40 |
| The table is to be used for both cages and pens. | | | | |

20. 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. Social stress in all pair- or group-housed individuals shall be monitored at least weekly. Females with kittens under four weeks of age or in the last two weeks of pregnancy may be housed singly. The minimum space in which a female and kittens may be held is the

space for a single cat, and it shall be gradually increased so that by 4 months of age kittens are rehoused in conformity with the space requirements for adults. Areas for feeding and for litter trays shall not be less than 0,5 metres apart and shall not be interchanged.

| No. | Cats | Floor (*) ($m^2$) | Shelves ($m^2$) | Height (m) |
|---|---|---|---|---|
| 20.1. | Minimum for one adult animal | 1,5 | 0,5 | 2 |
| 20.2. | For each additional animal add | 0,75 | 0,25 | – |
| (*) Floor area excluding shelves. | | | | |

21. Dogs shall where possible be provided with outside runs. Dogs shall not be single-housed for more than 4 hours at a time. The internal enclosure shall represent at least 50 % of the minimum space to be made available to the dogs, as detailed in Sub-paragraph 21.1. The space allowances detailed below 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 Sub-paragraph 21.1. For breeds other than the laboratory beagle, space allowances shall be determined in consultation with veterinary staff. 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 as defined in this Regulation, 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. 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.

21.1. Dogs

| No. | 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) |
|---|---|---|---|---|---|
| 21.1.1. | Up to 20 | 4 | 4 | 2 | 2 |
| 21.1.2. | Over 20 | 8 | 8 | 4 | 2 |

21.2. Dogs – post-weaned stock

| No. | Weight of dog (kg) | Minimum enclosure size ($m^2$) | Minimum floor area/animal ($m^2$) | Minimum height (m) |
|---|---|---|---|---|
| 21.2.1. | Up to 5 | 4 | 0,5 | 2 |
| 21.2.2. | Over 5 to 10 | 4 | 1,0 | 2 |
| 21.2.3. | Over 10 to 15 | 4 | 1,5 | 2 |
| 21.2.4. | Over 15 to 20 | 4 | 2 | 2 |
| 21.2.5. | Over 20 | 8 | 4 | – |

22. Ferrets

| No. | Ferrets | Minimum enclosure size ($cm^2$) | Minimum floor area/animal ($cm^2$) | Minimum height (cm) |
|---|---|---|---|---|
| 22.1. | Animals up to 600 g | 4500 | 1500 | 50 |

| | | | | |
|---|---|---|---|---|
| 22.2. | Animals over 600 g | 4500 | 3000 | 50 |
| 22.3. | Adult males | 6000 | 6000 | 50 |
| 22.4. | Jill and litter | 5400 | 5400 | 50 |

23. Young non-human primates shall not be separated from their mothers until they are, depending on the species, 6 to 12 months old. The environment shall enable non-human primates to carry out a complex daily programme of activity. The enclosure shall provide non-human primates with a sense of security, and a suitably complex environment to allow the animal as wide a behavioural repertoire as possible – to run, walk, climb and jump.

23.1. Marmosets and tamarinds. For marmosets and tamarins, separation from the mother shall not take place before 8 months of age.

| No. | Marmosets and tamarinds | Minimum floor area of enclosures for 1(*) or 2 animals plus offspring up to 5 months old ($m^2$) | Minimum volume per additional animal over 5 months of age ($m^3$) | Minimum enclosure height (m)(**) |
|---|---|---|---|---|
| 23.1.1. | Marmosets | 0,5 | 0,2 | 1,5 |
| 23.1.2. | Tamarins | 1,5 | 0,2 | |
| (*) Animals shall be kept singly only in exceptional circumstances.<br>(**) The top of the enclosure shall be at least 1.8 m from the floor. | | | | |

23.2. Squirrel monkeys. For squirrel monkeys, separation from the mother shall not take place before 6 months of age.

| Minimum floor area for 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 |
| (*) Animals shall be kept singly only in exceptional circumstances. | | |

23.3. Macaques and vervets. For macaques and vervets, separation from the mother shall not take place before 8 months of age.

| No. | Macaques and vervets | Minimum enclosure size ($cm^2$) | Minimum enclosure volume ($m^3$) | Minimum volume per animal ($m^3$) | Minimum enclosure height (m) |
|---|---|---|---|---|---|
| 23.3.1. | Animals less than 3 yrs of age(**) | 2,0 | 3,6 | 1,0 | 1,8 |
| 23.3.2. | Animals from 3 yrs of age(***) | 2,0 | 3,6 | 1,8 | 1,8 |
| 23.3.3. | Animals held for breeding purposes (****) | | | 3,5 | 2,0 |
| (*) Animals shall be kept singly only in exceptional circumstances.<br>(**) An enclosure of minimum dimensions may hold up to three animals.<br>(***) An enclosure of minimum dimensions may hold up to two animals.<br>(****) In breeding colonies no additional space/volume allowance is required for young animals up to 2 years of age housed with their mother. | | | | | |

23.4. Baboons. For baboons, separation from the mother shall not take place before 8 months of age.

| No. | Baboons(*) | Minimum enclosure size ($m^2$) | Minimum enclosure volume ($m^3$) | Minimum volume per animal ($m^3$) | Minimum enclosure height (m) |
|---|---|---|---|---|---|
| 23.4.1. | Animals less than 4 yrs of age(**) | 4,0 | 7,2 | 3,0 | 1,8 |
| 23.4.2. | Animals from 4 yrs of age(**) | 7,0 | 12,6 | 6,0 | 1,8 |
| 23.4.3. | Animals held for breeding purposes (***) | | | 12,0 | 2,0 |
| (*) Animals shall be kept singly only in exceptional circumstances.<br>(**) An enclosure of minimum dimensions may hold up to two animals.<br>(***) In breeding colonies no additional space/volume allowance is required for young animals up to 2 years of age housed with their mother. | | | | | |

24. During 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, the keeping of the animals shall at least follow the standards laid down in the laws and regulations regarding general welfare requirements of animals kept for farming purposes, welfare requirements of calves and welfare requirements of pigs.

24.1. Cattle

| No. | Body weight (kg) | Minimum enclosure size ($m^2$) | Minimum floor area per 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) |
|---|---|---|---|---|---|
| 24.1.1. | Up to 100 | 2,50 | 2,30 | 0,10 | 0,30 |
| 24.1.2. | Over 100 to 200 | 4,25 | 3,4 | 0,15 | 0,50 |
| 24.1.3. | Over 200 to 400 | 6,00 | 4,80 | 0,18 | 0,60 |
| 24.1.4. | Over 400 to 600 | 9,00 | 7,50 | 0.21 | 0,70 |
| 24.1.5. | Over 600 to 800 | 11,00 | 8,75 | 0,24 | 0,80 |
| 24.1.6. | Over 800 | 16,00 | 10,00 | 0,30 | 1,00 |

24.2. Sheep and goats

| No. | Body weight (kg) | Minimum enclosure size ($m^2$) | Minimum floor area per animal ($m^2$/animal) | Minimum partition height (m) | Trough space for ad-libitum feeding (m/animal) | Trough space for restricted feeding (m/animal) |
|---|---|---|---|---|---|---|
| 24.2.1. | Up to 20 | 1,0 | 0,7 | 1,0 | 0,10 | 0,25 |
| 24.2.2. | Over 20 to 35 | 1,5 | 1,0 | 1,2 | 0,10 | 0,30 |
| 24.2.3. | Over 35 to 60 | 2,0 | 1,5 | 1,2 | 0,12 | 0,40 |
| 24.2.4. | Over 60 | 3,0 | 1,8 | 1,5 | 0,12 | 0,50 |

24.3. Pigs and minipigs

| No. | Live weight (kg) | Minimum enclosure size(*) ($m^2$) | Minimum floor area per animal ($m^2$/animal) | Minimum lying space per animal (in thermoneutral conditions) ($m^2$/animal) |
|---|---|---|---|---|
| 24.3.1. | Up to 5 | 2,0 | 0,20 | 0,10 |
| 24.3.2. | Over 5 to 10 | 2,0 | 0,25 | 0,11 |
| 24.3.3. | Over 10 to 20 | 2,0 | 0,35 | 0,18 |
| 24.3.4. | Over 20 to 30 | 2,0 | 0,50 | 0,24 |
| 24.3.5. | Over 30 to 50 | 2,0 | 0,70 | 0,33 |
| 24.3.6. | Over 50 to 70 | 3,0 | 0,80 | 0,41 |
| 24.3.7. | Over 70 to 100 | 3,0 | 1,0 | 0,53 |
| 24.3.8. | Over 100 to 150 | 4,0 | 1,35 | 0,70 |
| 24.3.9. | Over 150 | 5,0 | 2,50 | 0,95 |
| 24.3.10. | Adult (conventional) boars | 7,5 | | 1,3 |
| (*) 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. | | | | |

24.4. Equines 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.

| No. | Wither height (m) | Minimum floor area per 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 | |
| 24.4.1. | From 1,00 to 1,40 | 9,0 | 6,0 | 16 | 3,00 |
| 24.4.2. | Over 1,40 to 1,60 | 12,0 | 9,0 | 20 | 3,00 |
| 24.4.3. | Over 1,60 | 16,0 | $(0 \times WH)^2$ (*) | 20 | 3,00 |
| (*) To ensure adequate space is provided, space allowances for each individual animal shall be based on height to withers. | | | | | |

25. During 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, the keeping of the birds shall conform at least to the standards laid down in the laws and regulations regarding general welfare requirements of animals kept for farming purposes, the laws and regulations regardng welfare requirements of laying hens and the procedures for registration of undertakings keeping laying hens, and the laws and regulations regarding welfare requirements of chickens kept for meat production:

25.1. Domestic fowl 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 a veterinarian. In such circumstances, birds can be housed in smaller enclosures containing appropriate enrichment and with a minimum floor area of 0.75 $m^2$

| No. | Body weight (g) | Minimum enclosure size ($m^2$) | Minimum area per bird ($m^2$) | Minimum height (cm) | Minimum length of feed trough per bird (cm) |
|---|---|---|---|---|---|
| 25.1.1. | Up to 200 | 1,00 | 0,025 | 30 | 3 |
| 25.1.2. | Over 200 to 300 | 1,00 | 0,03 | 30 | 3 |
| 25.1.3. | Over 300 to 600 | 1,00 | 0,05 | 40 | 7 |
| 25.1.4. | Over 600 to 1200 | 2,00 | 0,09 | 50 | 15 |
| 25.1.5. | Over 1200 to 1800 | 2,00 | 0,11 | 75 | 15 |
| 25.1.6. | Over 1800 to 2400 | 2,00 | 0,13 | 75 | 15 |
| 25.1.7. | Over 2400 | 2,00 | 0,21 | 75 | 15 |

25.2. Domestic turkeys 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 a veterinarian. In such circumstances, birds can be housed in smaller enclosures containing appropriate enrichment and with a minimum floor area of 0.75 $m^2$ 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 the table.

| No. | Body weight (kg) | Minimum enclosure size ($m^2$) | Minimum area per bird ($m^2$) | Minimum height (cm) | Minimum length of feed trough per bird (cm) |
|---|---|---|---|---|---|
| 25.2.1. | Up to 0,3 | 2,00 | 0,13 | 50 | 3 |
| 25.2.2. | Over 0,3 to 0,6 | 2,00 | 0,17 | 50 | 7 |
| 25.2.3. | Over 0,6 to 1 | 2,00 | 0,30 | 100 | 15 |
| 25.2.4. | Over 1 to 4 | 2,00 | 0,35 | 100 | 15 |
| 25.2.5. | Over 4 to 8 | 2,00 | 0,40 | 100 | 15 |
| 25.2.6. | Over 8 to 12 | 2,00 | 0,50 | 150 | 20 |
| 25.2.7. | Over 12 to 16 | 2,00 | 0,55 | 150 | 20 |
| 25.2.8. | Over 16 to 20 | 2,00 | 0,60 | 150 | 20 |
| 25.2.9. | Over 20 | 3,00 | 1,00 | 150 | 20 |

25.3. Quails

| No. | Body weight (g) | Minimum enclosure size ($m^2$) | Area per bird pair-housed ($m^2$) | Area per bird group-housed ($m^2$) | Minimum height (cm) | Minimum length of feed trough per bird (cm) |
|---|---|---|---|---|---|---|
| 25.3.1. | Up to 150 | 1,00 | 0,5 | 0,10 | 20 | 4 |
| 25.3.2. | Over 150 | 1,00 | 0,6 | 0,15 | 30 | 4 |

25.4. Ducks and geese 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 a veterinarian. 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 25.4.

| No. | Body weight (g) | Minimum enclosure size ($m^2$) | Minimum area per bird ($m^2$)(*) | Minimum height (cm) | Minimum length of feed trough per bird (cm) |
|---|---|---|---|---|---|
| 25.4.1. | Ducks | | | | |
| 25.4.1.1. | Up to 300 | 2,00 | 0,10 | 50 | 10 |
| 25.4.1.2. | Over 300 to 1200(**) | 2,00 | 0,20 | 200 | 10 |
| 25.4.1.3. | Over 1200 to 3500 | 2,00 | 0,25 | 200 | 15 |
| 25.4.1.4. | Over 3500 | 2,00 | 0,50 | 200 | 15 |
| 25.4.2. | Geese | | | | |
| 25.4.2.1. | Up to 500 | 2,00 | 0,20 | 200 | 10 |
| 25.4.2.2. | Over 500 to 2000 | 2,00 | 0,33 | 200 | 15 |
| 25.4.2.3. | Over 2000 | 2,00 | 0,50 | 200 | 15 |
| (*) 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.<br>(**) Pre-fledged birds may be held in enclosures with a minimum height of 75 cm. | | | | | |

25.5. Ducks and geese(*): minimum pond sizes

| No. | Birds | Area ($m^2$) | Depth (cm) |
|---|---|---|---|
| 25.5.1. | Ducks | 0,5 | 30 |
| 25.5.2. | 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. | | | |

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

| No. | Group size | Minimum enclosure size ($m^2$) | Minimum height (cm) | Minimum length of feed trough per bird (cm) | Minimum length of perch per bird (cm) |
|---|---|---|---|---|---|
| 25.6.1. | Up to 6 | 2 | 200 | 5 | 30 |
| 25.6.2. | Over 6 to 12 | 3 | 200 | 5 | 30 |
| 25.6.3. | For each additional bird above 12 | 0,15 | | 5 | 30 |

25.7. Zebra finches Enclosures shall be long and narrow, for example, 2 × 1 m, to allow 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 a veterinarian.

| No. | Group size | Minimum enclosure size ($m^2$) | Minimum height (cm) | Minimum number of feeders |
|---|---|---|---|---|
| 25.7.1. | Up to 6 | 1,0 | 100 | 2 |
| 25.7.2. | Over 6 to 12 | 1,5 | 200 | 2 |
| 25.7.3. | Over 12 to 20 | 2,0 | 200 | 3 |
| 25.7.4. | For each additional bird above 20 | 0,05 | | 1 per 6 birds |

26. Amphibians

26.1. Aquatic urodeles

| No. | Body length(*) (cm) | Minimum water surface area ($cm^2$) | Minimum water surface area for each additional animal in group-holding ($cm^2$) | Minimum water depth (cm) |
|---|---|---|---|---|
| 26.1.1. | Up to 10 | 262,5 | 50 | 13 |
| 26.1.2. | Over 10 to 15 | 525 | 110 | 13 |
| 26.1.3. | Over 15 to 20 | 875 | 200 | 15 |
| 26.1.4. | Over 20 to 30 | 1837,5 | 440 | 15 |
| 26.1.5. | Over 30 | 3150 | 800 | 20 |
| (*) Measured from snout to vent. | | | | |

26.2. Aquatic anurans(*)

| No. | Body length(**) (cm) | Minimum water surface area ($cm^2$) | Minimum water surface area for each additional animal in group-holding ($cm^2$) | Minimum water depth (cm) |
|---|---|---|---|---|
| 26.2.1. | Up to 6 | 160 | 40 | 6 |
| 26.2.2. | Over 6 to 9 | 300 | 75 | 8 |
| 26.2.3. | Over 9 to 12 | 600 | 150 | 10 |
| 26.2.4. | Over 12 | 920 | 230 | 12,5 |
| (*) 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.<br>(**) Measured from snout to vent. | | | | |

26.3. Semi-aquatic anuans

| No. | Body length(*) (cm) | Minimum enclosure size(**) ($cm^2$) | Minimum area for each additional animal in group-holding ($cm^2$) | Minimum enclosure height(***) (cm) | Minimum water depth (cm) |
|---|---|---|---|---|---|
| 26.3.1. | Up to 5,0 | 1500 | 200 | 20 | 10 |
| 26.3.2. | Over 5,0 to 7,5 | 3500 | 500 | 30 | 10 |
| 26.3.3. | Over 7,5 | 4000 | 700 | 30 | 15 |
| (*) Measured from snout to vent.<br>(**) One-third land division, two-thirds water division sufficient for animals to submerge.<br>(***) 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. | | | | | |

26.4. Semi-terrestrial anurans

| No. | Body length(*) (cm) | Minimum enclosure size(**) ($cm^2$) | Minimum area for each additional animal in group-holding ($cm^2$) | Minimum enclosure height(***) (cm) | Minimum water depth (cm) |
|---|---|---|---|---|---|
| 26.4.1. | Up to 5,0 | 1500 | 200 | 20 | 10 |
| 26.4.2. | Over 5,0 to 7,5 | 3500 | 500 | 30 | 10 |
| 26.4.3. | Over 7,5 | 4000 | 700 | 30 | 15 |
| (*) Measured from snout to vent.<br>(**) One-third land division, one-third water division sufficient for animals to submerge.<br>(***) 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. | | | | | |

26.5. Arboreal anurans

| No. | Body length(*) (cm) | Minimum enclosure size(**) ($cm^2$) | Minimum area for each additional animal in group-holding ($cm^2$) | Minimum enclosure height(***) (cm) |
|---|---|---|---|---|
| 26.5.1. | Up to 3,0 | 900 | 100 | 30 |
| 26.5.2. | Over 3,0 | 1500 | 200 | 30 |
| (*) Measured from snout to vent.<br>(**) Two-thirds land division, one-third water division sufficient for animals to submerge.<br>(***) 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. | | | | |

27. Reptiles

27.1. Aquatic chelonians

| No. | Body length(*) (cm) | Minimum water surface area ($cm^2$) | Minimum water surface area for each additional animal in group-holding ($cm^2$) | Minimum water depth (cm) |
|---|---|---|---|---|
| 27.1.1. | Up to 5 | 600 | 100 | 10 |

| | | | | |
|---|---|---|---|---|
| 27.1.2. | Over 5 to 10 | 1600 | 300 | 15 |
| 27.1.3. | Over 10 to 15 | 3500 | 600 | 20 |
| 27.1.4. | Over 15 to 20 | 6000 | 1200 | 30 |
| 27.1.5. | Over 20 to 30 | 10000 | 2000 | 35 |
| 27.1.6. | Over 30 | 20000 | 5000 | 40 |
| (*) Measured in a straight line from the front edge to the back edge of the shell. | | | | |

27.2. Terrestrial snakes

| No. | Body length(*) (cm) | Minimum floor area ($cm^2$) | Minimum area for each additional animal in group-holding ($cm^2$) | Minimum enclosure height(**) (cm) |
|---|---|---|---|---|
| 27.2.1. | Up to 30 | 300 | 150 | 10 |
| 27.2.2. | Over 30 to 40 | 400 | 200 | 12 |
| 27.2.3. | Over 40 to 50 | 600 | 300 | 15 |
| 27.2.4. | Over 50 to 75 | 1200 | 600 | 20 |
| 27.2.5. | Over 75 | 2500 | 1200 | 28 |
| (*) Measured from snout to tail.<br>(**) 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. | | | | |

28. Fish

28.1. Water supply and quality 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.

28.2. Oxygen, nitrogen compounds, pH, and salinity. Oxygen concentration 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 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.

28.3. Temperature, lighting, noise. 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.

28.4. Stocking density and environmental complexity. 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.

28.5. Feeding and handling. 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.

Minister for Agriculture L. Straujuma

 

**Annex 5**
Cabinet Regulation No. 52
22 January 2013

# Requirements Concerning Types of Experimental Animal Procedures and their Severity Classification

## I. Types of procedures

1. Non-recovery procedures: procedures which are performed entirely under general anaesthesia from which the experimental animal shall not recover consciousness.

2. Mild procedures: 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.

3. Moderate procedures: 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.

4. Severe procedures: 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.

## II. Criteria for assigning categories of severity of procedures

5. The severity of a procedure shall be determined by the degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of the procedure.

6. 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:

6.1. type of species and genotype;

6.2. maturity, age and gender of the animal;

6.3. training experience of the animal with respect to the procedure;

6.4. if the animal is to be reused, the actual severity of the previous procedures;

6.5. the methods used to reduce or eliminate pain, suffering and distress, including refinement of housing, husbandry and care conditions;

6.6. humane end-points.

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

 

8. 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.

9. Procedures shall include:

9.1. type of manipulation, handling;

9.2. 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;

9.3. cumulative suffering within a procedure;

9.4. prevention from expressing natural behaviour including restrictions on the housing, husbandry and care standards.

## III. Types of procedures assigned to each of the severity categories on the basis of factors related to the type of the procedure

10. Examples are given in this chapter 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.

11. Mild procedure:

11.1. administration of anaesthesia except for the sole purpose of killing;

11.2. 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;

11.3. non-invasive imaging of animals (e.g. MRI) with appropriate sedation or anaesthesia;

11.4. superficial procedures, e.g. ear and tail biopsies, non-surgical subcutaneous implantation of mini-pumps and transponders;

11.5. application of external telemetry devices that cause only minor impairment to the animals or minor interference with normal activity and behaviour;

11.6. 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;

11.7. induction of tumours, or spontaneous tumours, that cause no detectable clinical adverse effects (e.g. small, subcutaneous, non-invasive nodules);

11.8. breeding of genetically altered animals, which is expected to result in a phenotype with mild effects;

11.9. 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;

11.10. short-term (< 24 h) restraint in metabolic cages;

11.11. studies involving short-term deprivation of social partners, short-term solitary caging of adult rats or mice of sociable strains;

11.12. models which expose animals to noxious stimuli which are briefly associated with mild pain, suffering or distress, and which the animals can successfully avoid;

11.13. a combination or accumulation of the following examples may result in classification as mild:

11.13.1. assessing body composition by non-invasive measures and with minimal restraint;

11.13.2. monitoring ECG with non-invasive techniques with minimal or no restraint of habituated experimental animals;

11.13.3. application of external telemetry devices that are expected to cause no impairment to socially adapted experimental animals and do not interfere with normal activity and behaviour;

11.13.4. breeding genetically altered animals which are expected to have no clinically detectable adverse phenotype;

11.13.5. adding inert markers in the diet to follow passage of digesta;

11.13.6. withdrawal of food for < 24 h in adult rats;

11.13.7. open field testing.

12. Moderate procedure:

12.1. 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;

12.2. acute dose-range finding studies, chronic toxicity/carcinogenicity tests, with non-lethal end-points;

12.3. 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.);

12.4. models of induction of tumours, or spontaneous tumours, that are expected to cause moderate pain or distress or moderate interference with normal behaviour;

12.5. 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);

12.6. breeding of genetically altered animals which are expected to result in a phenotype with moderate effects;

12.7. creation of genetically altered animals through surgical procedures;

12.8. use of metabolic cages involving moderate restriction of movement over a prolonged period (up to 5 days);

12.9. 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;

12.10. withdrawal of food for 48 hours in adult rats;

12.11. evoking escape and avoidance reactions where the animal is unable to escape or avoid the stimulus, and are expected to result in moderate distress.

13. Severe procedure:

13.1. 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;

13.2. testing of device where failure may cause severe pain, distress or death of the animal (e.g. cardiac assist devices);

13.3. 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;

13.4. irradiation or chemotherapy with a lethal dose without reconstitution of the immune system, or reconstitution with production of graft versus host disease;

13.5. 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;

13.6. 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;

13.7. organ transplantation where organ rejection is likely to lead to severe distress or impairment of the general condition of the animals (e.g. xenotransplantation);

13.8. 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;

13.9. use of metabolic cages involving severe restriction of movement over a prolonged period;

13.10. inescapable electric shock (e.g. to produce learned helplessness);

13.11. complete isolation for prolonged periods of social species e.g. dogs and non-human primates;

13.12. immobilisation stress to induce gastric ulcers or cardiac failure in rats;

13.13. forced swim or exercise tests with exhaustion as the end-point.

Minister for Agriculture L. Straujuma

 

**Annex 6**
Cabinet Regulation No. 52
22 January 2013

# Methods of Killing Experimental Animals

1. In the process of killing animals, methods listed in the table below shall be used. Methods other than those listed in the table may be used:

1.1. on unconscious animals, providing the animal does not regain consciousness before death;

1.2. 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:

2.1. confirmation of permanent cessation of the circulation;

2.2. destruction of the brain;

2.3. dislocation of the neck;

2.4. exsanguination; or

2.5. confirmation of the onset of *rigor mortis*.

| No. | Methods | Animals | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | fish | amphibians | reptiles | birds | rodents | rabbits | dogs, cats, ferrets and foxes | large mammals | non-human primates |
| 1. | Anaesthetic overdose | (1) | (1) | (1) | (1) | (1) | (1) | (1) | (1) | (1) |
| 2. | Captive bolt | X | X | (2) | X | X | | X | | X |
| 3. | Carbon dioxide | X | X | X | | (3) | X | X | X | X |
| 4. | Cervical dislocation | X | X | X | (4) | (5) | (6) | X | X | X |
| 5. | Concussion/percussive blow to the head | | | | (7) | (8) | (9) | (10) | X | X |
| 6. | Decapitation | X | X | X | (11) | (12) | X | X | X | X |
| 7. | Electrical stunning | (13) | (13) | X | (13) | X | (13) | (13) | (13) | X |
| 8. | Inert gases (Ar, N2) | X | X | X | | | X | X | (14) | X |
| 9. | Shooting with appropriate rifles, guns and ammunition | X | X | (15) | X | X | X | (16) | (15) | X |

Notes.
(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) 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 when other methods are not possible.
(X) Not to be used.

Minister for Agriculture L. Straujuma