B 1652

L.N. 124 of 2013

ANIMAL WELFARE ACT
(CAP. 439)

Protection of Animals for Scientific Purposes Regulations, 2013

IN exercise of the powers conferred by Part XI of the Animal Welfare Act, the Minister for Sustainable Development, the Environment and Climate Change has made the following regulations:-

Citation and scope.

1. (1) The title of these regulations is the Protection of Animals for Scientific Purposes Regulations, 2013.

(2) The scope of these regulations is to transpose Directive 2010/63/EU on the protection of animals used for scientific purposes which establishes measures for the protection of animals used for scientific or educational purposes. For this purpose, these regulations provide the following rules:

(a) the replacement and reduction of the use of animals in procedures and the refinement of the breeding, accommodation, care and use of animals in procedures;

(b) the origin, breeding, marking, care and accommodation and killing of animals;

(c) the operations of breeders, suppliers and users;

(d) the evaluation and authorisation of projects involving the use of animals in procedures.

(3) These regulations are being made for the safeguarding of the public interest and public safety. Any requirements and safeguard measures contained therein including those relating to authorisations are made for overriding reasons relating to public interest.

Interpretation.

2. (1) Unless otherwise stated in these regulations, the definitions in the Act shall apply.

(2) For the purpose of these regulations and unless the context otherwise requires, the following definitions shall apply:

Cap. 439.

"the Act" means the Animal Welfare Act;

"animal experiment" has the same meaning as that provided in the Act;

"animal-welfare body" means a body set up by breeders, suppliers and users in terms of regulation 27 with the aim to carry out tasks as provided in terms of regulation 28;

"Animal Welfare Council" means the national committee as established by articles 4, 5 and 6 of the Act for the protection of animals used for scientific purposes in terms of these regulations;

"authorisation" means any authorisation which:

(a) in relation to competent persons and their activities, may be granted in terms of the Act, to such persons to carry out a procedure or animal experiments, which may only be performed by such competent persons, or under the direct responsibility of such person and may include any licence, warrant, permit, appointment, concession or any decision concerning access to the activity in question, or the exercise thereof; and

(b) in relation to breeders, suppliers, users and their services means a permit, licence, appointment, concession or any decision concerning access to the service activity in question or the exercise thereof, issued to such persons in terms of the Act and for the term stipulated in these regulations;

"breeder" means any natural or legal person breeding animals referred to in Schedule I with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, or breeding other animals primarily for those purposes, whether for economic remuneration or not;

"the Commission" means the European Commission;

"expert competent person" means the veterinarians or veterinary surgeons responsible for procedures or any person or officer in charge duly authorised to act on their behalf having adequate knowledge and professional experience in terms of article 43 of the Veterinary Services Act or as recognised by the Veterinary Surgeons' Council to exercise his duties and act on behalf of the veterinarian; Cap. 437.

Provided that competent personnel mentioned in regulation 24 shall, for the purpose of carrying out procedures, be at all times supervised in terms of regulation 24(3) and conform with the requirement set out in regulation 25(1)(c);

"debilitating clinical condition" means a reduction in an animal's normal physical and psychological ability to function;

"the Department" means the Department for Veterinary Services in Malta as established by article 2 of the Act;

"the Director" has the same meaning as that provided under the Act;

"endangered species" means those species listed in Annex A to Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein;

"establishment" means any installation, building, group of buildings or other premises and may include a place that is not wholly enclosed or covered and mobile facilities;

"final consumer" means any natural or legal person purchasing animals and animal products subject to trade for his own use and not for resale or retail purposes;

"genetically modified animal" means all animals having their genes artificially added or removed from their DNA;

"intra-Community trade" means trade in animals and their products between Member States including commercial activities with the intention to make profit or gain;

"live cephalopods" means live animals of the cephalopoda class including *inter alia* octopuses, squids, cuttlefish and nautiloids;

"Member State" means a state which is a member of the European Union;

"non-human primates" means all species of the primates order excluding *homo sapiens*;

"non-human vertebrate animals" means all animals with a backbone structure excluding *homo sapiens*;

"overriding reasons relating to public interest" means reasons recognised as such in case law of the Court of Justice of the European Union and which reasons present a justification for the issue of an authorisation and, or the issue of a condition thereto and, or to any other policy decision taken in terms of such authorisation, when such authorisation, and, or condition and, or policy decision thereto could not have been issued or taken under normal circumstances but for such overriding reasons relating to public interest which include the emergency circumstances referred to in regulation 7(4);

"procedure" means any use, invasive or non-invasive, of an

animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice. This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition, but excludes the killing of animals solely for the use of their organs or tissues; the severity classification of such procedures is set out in Schedule IX;

"project" means a programme of work having a defined scientific objective and involving one or more procedures;

"self-sustaining colony" means a colony in which animals 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;

"specimen" has the same meaning as that provided under Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein;

"supplier" means any natural or legal person, other than a breeder, supplying animals with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, whether for economic remuneration or not;

"TFEU" means the Treaty on the Functioning of the European Union as amended by the Lisbon Treaty, 2009 as may be subject to subsequent amendments;

"user" means any natural or legal person using animals in procedures, whether for economic remuneration or not.

Applicability.

3. (1) These regulations shall apply where animals are used or intended to be used in procedures, or bred specifically so that their organs or tissues may be used for scientific purposes, and shall apply until the animals referred to in this sub-regulation have been killed, rehomed or returned to a suitable habitat or husbandry system. The elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia, analgesia or other methods shall not exclude the animal used in procedures from the scope of these regulations.

(2) These regulations shall also apply to the following animals:

(a) live non-human vertebrate animals, including:

(i) independently feeding larval forms; and

(ii) foetal forms of mammals as from the last third of their normal development;

(b) live cephalopods.

(3) Furthermore, these regulations shall apply to animals used in procedures, which are at an earlier stage of development than that referred to in sub-regulation (2)(a), if the animal is to be allowed to live beyond that stage of development and, as a result of the procedures performed, is likely to experience pain, suffering, distress or lasting harm after it has reached that stage of development.

(4) Without prejudice to sub-regulation (1), these regulations shall not apply to the following:

(a) non-experimental agricultural practices;

(b) non-experimental clinical veterinary practices;

(c) veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product;

(d) practices undertaken for the purposes of recognised animal husbandry;

(e) practices undertaken for the primary purpose of identification of an animal;

(f) practices not likely to cause pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

(5) These regulations shall apply without prejudice to the Cosmetics Products Regulations. S.L. 427.58

National measures.

4. (1) When the Department opts to maintain national laws and regulations aimed at ensuring more extensive protection of animals falling within the scope these regulations, it shall not prohibit or impede the supply or use of animals bred or kept in another Member State in accordance with these regulations, nor shall it prohibit or impede the placing on the market of products developed with the use of such animals in accordance with these regulations, provided that such supply, use or breeding of animals do not breach

any other national laws regarding any prohibitions to intra-Community trade, or any other Community laws or regulations intended for the safeguarding and protection of human and animal health.

(2) The Department shall apply all such necessary administrative measures according to the requirements of these regulations to ensure that there is no breach thereto, and also to reduce the risk for final consumers and any additional risk to animals and to the environment. Such measures shall be in conformity with the requirements of the food chain and animal health.

(3) These measures shall include the direct confiscation of the product, the suspension of the activities carried out by the breeder, supplier or user of animals, being primarily responsible for animal welfare, and the withdrawal, forfeiture or suspension of the authorisation, licence or permit with regard to such activities when these are creating a risk to final consumers and to the environment. The application of administrative fines and effective and dissuasive penalties in terms of articles 45 and 47 of the Act shall also apply in this regard.

Principle of replacement, reduction and refinement.

5. (1) The Department shall establish and maintain a monitoring system for the enforcement of:

(a) a scientifically satisfactory method or testing strategy, not entailing the use of live animals, to be used instead of a procedure, wherever this is technically feasible and possible;

(b) the reduction in the number of animals to be used in procedures to a minimum without compromising the objectives of the project; and

(c) breeding, accommodation and care, as well as refinement of methods used in procedures, by eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals.

(2) This regulation shall, as regards the choice of methods, be implemented in accordance with regulation 14.

Purposes of procedures.

6. Procedures may only be carried out for the following purposes:

(a) basic research;

(b) applied research with any of the following aims:

(i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants;

(ii) the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants; or

(iii) the welfare of animals and the improvement of the production conditions for animals reared for agricultural purposes;

(c) for any of the aims in paragraph (b) in the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products;

(d) protection of the natural environment in the interests of the health or welfare of human beings or animals;

(e) research aimed at preservation of the species;

(f) higher education, or training for the acquisition, maintenance or improvement of professional skills;

(g) forensic inquiries.

Methods of killing.

7. (1) The Department shall establish and maintain a monitoring system for the enforcement of killing of animals with minimum pain, suffering and distress, and such system shall include that such animals are killed in the establishment of a breeder, supplier or user, by a competent person, provided that in the case of a field study an animal may be killed by a competent person outside an establishment.

(2) In relation to animals listed in Schedule IV, the appropriate method of killing as set out in that Schedule shall be used.

(3) The Department may grant exemptions from the requirement in sub-regulation (2):

(a) to allow the use of another method provided that, on the basis of scientific evidence, the method is considered to be at least as humane; or

(b) when, on the basis of scientific justification, the purpose of the procedure may not be achieved by the use of a method of killing set out in Schedule IV.

(4) Sub-regulations (1) and (2) shall not apply where an animal has to be killed in emergency circumstances for animal-welfare, public-health, public-security, animal-health or environmental reasons.

Endangered species.

8. (1) Specimens of endangered species listed in Annex A to Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein, which do not fall within the scope of Article 7(1) of such Regulation, shall not be used in procedures, except for those procedures meeting the following conditions:

(a) the procedure has one of the purposes referred to in regulation 6(b)(i), (c) or (e); and

(b) there is scientific justification to the effect that the purpose of the procedure may not be achieved by the use of species other than those listed in such Annex.

(2) Sub-regulation (1) shall not apply to any species of non-human primates.

Non-human primates.

9. (1) Subject to sub-regulation (2), specimens of non-human primates shall not be used in procedures, except for those procedures meeting the following conditions:

(a) the procedure has one of the purposes referred to in:

(i) regulation 6(b)(i) or (c) and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings; or

(ii) regulation 6(a) or (e); and

(b) there is scientific justification to the effect that the purpose of the procedure may not be achieved by the use of species other than non-human primates.

(2) Specimens of non-human primates listed in Annex A to Council Regulation (EC) No 338/97, which do not fall within the scope of Article 7(1) of such Regulation, shall not be used in procedures, except for those procedures meeting the following conditions:

(a) the procedure has one of the purposes referred to in:

(i) regulation 6(b)(i) or (c) and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings; or

(ii) regulation 6(e); and

(b) there is scientific justification to the effect that the purpose of the procedure may not be achieved by the use of species other than non-human primates and by the use of species not listed in such Annex.

Animals taken from the wild.

10. (1) Animals taken from the wild shall not be used in procedures.

(2) The Department may grant exemptions from sub-regulation (1) on the basis of scientific justification to the effect that the purpose of the procedure may not be achieved by the use of an animal which has been bred for use in procedures.

(3) 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 veterinarian or another competent person and action shall be taken to minimise the suffering of the animal.

(4) The Department may grant exemptions from the requirement in sub-regulation (3) of taking action to minimise the suffering of the animal, if there is scientific justification.

Animals bred for use in procedures.

11. (1) The Department shall establish and maintain a monitoring and enforcement system to ensure that animals belonging to the species listed in Schedule I may only be used in procedures where such animals have been bred for use in procedures.

(2) Notwithstanding what is mentioned in sub-regulation (1), as from the dates set out in Schedule II, the Department shall further establish and maintain a monitoring and enforcement system to ensure that non-human primates listed in Schedule I may be used in procedures only where they are the offspring of non-human primates which have been bred in captivity or where they are sourced from self-sustaining colonies.

(3) The Department may grant exemptions from the requirement in sub-regulation (1) on the basis of scientific justification.

Stray and feral animals of domestic species.

12. (1) Stray and feral animals of domestic species shall not be used in procedures.

(2) The Department may only grant exemptions from sub-regulation (1) provided that:

(a) there is an essential need for studies concerning the health and welfare of the animals or serious threats to the environment or to human or animal health; and

(b) there is scientific justification to the effect that the purpose of the procedure may be achieved only by the use of a stray or a feral animal.

Procedures.

13. (1) The Department shall take all necessary administrative measures to monitor and enforce procedures which shall be carried out in a user's establishment.

(2) The Department may grant an exemption from sub-regulation (1) on the basis of scientific justification. Procedures may be carried out only within the framework of a project.

Choice of methods.

14. (1) The Department shall establish and maintain a monitoring and control system for the enforcement of a procedure not to be carried out if another method or alternative testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under other applicable EU legislation.

(2) When choosing between procedures, the selection criteria shall be based taking into account the following requirements:

(a) the minimum number of animals to be used;

(b) the use of animals with the lowest capacity to experience pain, suffering, distress or lasting harm;

(c) the least pain, suffering, distress or lasting harm to be caused; and

(d) the most satisfactory results provided or likely to be provided.

(3) Death as the end-point of a procedure shall be avoided as far as possible and replaced by early and humane end-points. Where death as the end-point is unavoidable, the procedure shall be designed so as to:

(a) result in the least deaths of animals as possible; and

(b) reduce the duration and intensity of suffering to the animal to the possible minimum and guarantee a painless death, in so far as this is technically and physically feasible and possible.

Anaesthesia.

15. (1) The Department shall establish and maintain a monitoring and control system for the enforcement of procedures which shall be carried out under general or local anaesthesia, unless it is inappropriate, and that analgesia or another appropriate method shall be used to ensure that pain, suffering and distress are kept to a minimum. Procedures involving serious injuries which may cause severe pain shall not be carried out without anaesthesia.

(2) When deciding on the appropriateness of using anaesthesia, the following shall be taken into account:

(a) whether anaesthesia is more traumatic to the animal than the procedure itself; and

(b) whether anaesthesia is incompatible with the purpose of the procedure.

(3) The Department shall further establish and maintain a monitoring and enforcement system to ensure that animals are not given any drug to stop or restrict their showing pain without an adequate level of anaesthesia or analgesia. In such cases, a scientific justification shall be provided, accompanied by the details of the anaesthetic or analgesic regimen.

(4) An animal, which may suffer pain once anaesthesia has worn off, shall be treated with pre-emptive and post-operative analgesics or other appropriate pain-relieving methods provided that it is compatible with the purpose of the procedure.

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

Classification of severity of procedures.

16. The Department shall establish and maintain a monitoring and control system for the purpose of enforcing that all procedures shall be classified as "non-recovery", "mild", "moderate", or "severe" on a case-by-case basis using the assignment criteria set out in Schedule IX.

(2) The Department shall establish and maintain a monitoring and control system for the purpose of enforcing that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and may not be subject to improvement.

Reuse of animals in procedures.

17. (1) The Department shall also establish and maintain a monitoring and enforcement system to ensure that an animal already used in one or more procedures shall not be reused, provided there is a different animal on which a previous procedure has not been carried out.

(2) Notwithstanding what is mentioned in sub-regulation (1), and as a derogation thereof, an animal already used in one or more procedures may be re-used provided the following conditions are met:

(a) the actual severity of the previous procedures was "mild" or "moderate";

(b) it is shown that the animal's general state of health and well-being has been fully restored;

(c) the further procedure is classified as "mild", "moderate" or "non-recovery"; and

(d) it is in accordance with veterinary advice taking into account the lifetime experience of the animal.

(3) In exceptional circumstances and by way of derogation from sub-regulation (2)(a), the Department, following a veterinary examination of the animal, may allow the reuse of an animal, provided the animal has not been used more than once in a procedure entailing severe pain, distress or equivalent suffering.

Termination of procedure.

18. (1) A procedure shall be deemed to end when no further observations need be made for that procedure or, as regards new genetically modified animal lines, when the offsprings are no longer observed or expected to experience pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle.

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

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

Sharing organs and tissues.

19. The Department shall facilitate, where appropriate, the establishment of programmes for the sharing of organs and tissues of animals killed.

Setting free of animals and rehoming.

20. The Department shall allow animals used or intended to be used in procedures to be rehomed, or returned to a suitable habitat or husbandry system appropriate to the species, provided that the following conditions are met:

(a) the state of health of the animal permits so;

(b) there is no danger to public health, animal health or the environment; and

(c) appropriate measures have been taken to safeguard the well-being of the animal.

Authorisation of breeders, suppliers and users.

21. (1) The Department shall establish and maintain a monitoring and enforcement system to ensure that all breeders, suppliers and users of animals to be used for experimentation are authorised and registered in terms of article 42 of the Act. Such authorisation may only be granted for a limited period. Authorisation shall be granted only if the breeder, supplier or user and its establishment is in compliance with the requirements of these regulations.

(2) The authorisation shall specify the person responsible for ensuring compliance with the provisions of these regulations and the person or persons referred to in regulations 25(1) and 26.

(3) Renewal of the authorisation shall be required for any significant change to the structure or the function of an establishment of a breeder, supplier or user that could negatively affect animal welfare.

(4) The Department shall at all times be notified of any changes of the person or persons referred to in sub-regulation (2).

Suspension, withdrawal, or cancellation of an authorisation.

22. (1) Where a breeder, supplier or user no longer complies with the requirements set out in these regulations, the Department shall take appropriate remedial action, or require such action to be taken, or suspend or withdraw its authorisation.

(2) The Department shall, where the authorisation is suspended or withdrawn, take all necessary measures to maintain the welfare of the animals housed in the establishment to the extent that such welfare is not adversely affected.

Requirements for installations and equipment.

23. (1) The Department shall establish and maintain a monitoring and control system to enforce that all establishments of a breeder, supplier or user have installations and equipment suited to the species of animals housed and, where procedures are carried out,

according to the performance of the procedures.

(2) The design, construction and method of functioning of the installations and equipment referred to in sub-regulation (1) shall guarantee that the procedures are carried out as effectively as possible, and aim at obtaining reliable results using the minimum number of animals and causing the minimum degree of pain, suffering, distress or lasting harm.

(3) For the purposes of implementation of sub-regulations (1) and (2), the Department shall also establish and maintain a monitoring and control system to enforce compliance with the relevant requirements set out in Schedule III.

(4) The design, construction and method of functioning of the establishment shall ensure the maximum bio security to guarantee that there will be no dispersion of biological or chemical material or other residues into the surrounding environment.

Competence of personnel.

24. (1) The Department shall establish and maintain a monitoring and enforcement system to ensure that each breeder, supplier and user has sufficient staff on site.

(2) The staff shall be adequately educated and well-trained before they perform any of the following functions:

(a) carrying out procedures on animals;

(b) designing procedures and projects;

(c) taking care of animals; or

(d) killing animals:

Provided that for the purpose of paragraphs (a) and (d), the staff shall be recognised as a competent person.

(3) Persons carrying out the functions referred to in sub-regulation (2)(b) shall have received instruction in a scientific order and authority relevant to the work being undertaken and shall have specific knowledge on species. Staff carrying out functions referred to in sub-regulation (2)(a), (c) or (d) shall be supervised in the performance of their tasks until they have demonstrated the requisite competence.

(4) The Department shall take all necessary administrative measure by means of authorisation or otherwise, to ensure that the requirements laid down in sub-regulation (3) are fulfilled.

(5) The Department shall publish, on the basis of the elements set out in Schedule V, the minimum requirements with regard to education and training and the requirements for obtaining, maintaining and demonstrating requisite competence for the functions set out in sub-regulation (2).

Specific requirements for personnel.

25. (1) The Department shall establish and maintain a monitoring and enforcement system to ensure that each breeder, supplier and user has one or several persons on site who shall:

(a) be responsible for overseeing the welfare and care of the animals in the establishment;

(b) ensure that the staff dealing with animals have access to specific information relating to the species kept in the establishment;

(c) be responsible for ensuring that the staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence.

(2) The Department shall at all times guarantee that persons mentioned in regulation 41(2)(b) shall:

(a) eliminate any unnecessary pain, suffering, distress or lasting harm that is being inflicted on an animal in the course of a procedure;

(b) ensure that the projects are carried out in accordance with the project authorisation in terms of regulation 37, or in the cases referred to in regulation 43, in accordance with the application sent to the Department in terms of regulation 38, or any decision taken by the Department; and

(c) in the event of non-compliance, ensure that all appropriate measures are taken to rectify such position or mal-practice as the case may be. Such measures taken for such rectification shall be recorded.

Designated veterinarian.

26. The Department shall at all times maintain a monitoring and control system to enforce that each breeder, supplier and user has a designated veterinarian with expertise in laboratory animal medicine, or where it is more appropriate, an expert competent person charged with advisory duties in relation to the well-being, treatment and welfare of the animals.

Animal-welfare body.

27. (1) The Department shall establish and maintain a

monitoring and enforcement system to ensure that each breeder, supplier and user sets up an animal-welfare body.

(2) The animal-welfare body shall include at least the person or persons responsible for the welfare and care of the animals and, in the case of a user, a scientific member. The animal-welfare body shall also receive input from the designated veterinarian or the expert competent person referred to in regulation 26.

(3) Such body shall also:

(a) as a primary task, focus on giving advice on animal-welfare issues; the advice given by the animal-welfare body shall be properly documented and open to scrutiny during inspections;

(b) follow the development and outcome of projects at establishment level; and

(c) foster a climate of care and provide tools for the practical application and timely implementation of recent technical and scientific developments in relation to the principles of replacement, reduction and refinement, in order to enhance the life-time experience of the animals.

Tasks of the animal-welfare body.

28. (1) Without prejudice to the provisions of regulation 27(3), the animal-welfare body shall, as a minimum, carry out the following tasks:

(a) advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;

(b) advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement;

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

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

(e) advise on rehoming schemes, including the

appropriate socialization of the animals to be rehomed.

(2) The Department shall establish a monitoring and enforcement system to ensure that the records of any advice given by the animal-welfare body and decisions taken regarding that advice are kept for at least three years. The records shall be made available to the Department upon its request.

Breeding strategy for non-human primates.

29. The Department shall also establish and maintain a monitoring system for the purpose of ensuring that breeders of non-human primates 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.

Scheme for rehoming or setting free of animals.

30. Where the Department allows rehoming, the breeders, suppliers and users from which animals are intended to be rehomed shall have a rehoming scheme in place that ensures socialization of the animals that are rehomed. In the case of wild animals, where appropriate, a programme of rehabilitation shall be in place before they are returned to their natural habitat.

Animal records.

31. (1) The Department shall establish a monitoring and enforcement system to ensure all breeders, suppliers and users keep records of at least the following:

(a) the number and the species of animals bred, acquired, supplied, used in procedures, set-free or rehomed;

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

(c) the dates on which the animals are acquired, supplied, released or rehomed;

(d) from whom the animals are acquired;

(e) the name and address of the recipient of animals;

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

(g) in the case of users, the projects in which animals are used.

(2) The records referred to in sub-regulation (1) shall be kept for a minimum of five years and made available to the Department upon its request.

Information on dogs, cats and non-human primates.

32. (1) The Department shall establish a monitoring and enforcement system to ensure that all breeders, suppliers and users keep the following information on each dog, cat and non-human primate:

(a) identification of each animal;

(b) place and date of birth, when available;

(c) whether it is bred for use in procedures; and

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

(2) 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 of these regulations. The file shall be set up at birth, or in the case of dogs, prior to the eruption of the lower pair of permanent canine teeth, or prior to six months of age, whichever comes first, and shall cover any relevant reproductive, veterinary and social information on the individual animal and the projects in which it has been used.

(3) The information referred to in 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 Department upon request. In the case of rehoming, relevant veterinary care and social information from the individual history file referred to in sub-regulation (2) shall accompany the animal.

Marking and identification of dogs, cats and non-human primates.

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

(2) 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 microchip shall be applied and a record shall be maintained by the receiver.

(3) No unmarked dogs, cats or non-human primates, which are weaned, shall be transferred, and the breeder, supplier or user shall permanently mark any animal as soon as possible, in the least painful manner possible and prior to its transfer.

(4) The breeder, supplier and user shall provide, at the request of the Department, reasons for which an animal is unmarked.

S.L. 437.101

(5) The provisions of this regulation shall apply without prejudice to the Electronic Identification of Dogs Regulations.

Care and accommodation.

34. (1) The Department shall, in so far as the care and accommodation of animals is concerned, establish and maintain a monitoring and enforcement system to ensure that:

(a) all animals are provided with accommodation, an environment, food, water and care which are appropriate to their health and well-being;

(b) any restrictions on the extent to which an animal may satisfy its physiological and ethological needs are kept to a minimum;

(c) the environmental conditions in which animals are bred, kept or used are checked daily;

(d) arrangements are made to ensure that any defect or avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible; and

(e) animals are transported under appropriate conditions.

(2) For the purposes of sub-regulation (1), the Department shall further establish a monitoring and enforcement system to ensure that the care and accommodation standards set out in Schedule III are applied from the dates provided for therein.

(3) The Department may allow exemptions from the requirements of sub-regulations (1)(c) and (2) on the basis of scientific and animal-welfare justifications or animal-health reasons.

Inspections by the Department.

35. (1) The Department shall carry out regular inspections of all breeders, suppliers and users, including their establishments, to verify compliance with the requirements of these regulations.

(2) The Department shall adapt the frequency of inspections on the basis of a risk analysis for each establishment, taking account of:

(a) the number and species of animals housed;

(b) the record of the breeder, supplier or user in complying with the requirements of these regulations;

(c) the number and types of projects carried out by the user in question; and

(d) any information that might indicate non-compliance.

(3) Inspections shall be carried out on at least one third of the users each year in accordance with the risk analysis referred to in sub-regulation (2). Nonetheless, breeders, suppliers and users of non-human primates shall be inspected at least once a year.

(4) Records of all inspections shall be kept for at least five years. An appropriate proportion of the inspections shall be carried out without prior warning.

Controls inspections by experts of the Commission.

36. (1) The Department shall give all necessary assistance to the experts of the Commission when carrying out inspections in Malta.

(2) The Department shall take measures to take account of the results of the controls inspections referred to in sub-regulation (1).

Requirements for projects authorisation.

37. (1) Without prejudice to regulation 43, projects shall not be carried out without prior authorisation from the Department, and they shall be carried out in accordance with the authorisation or, in the cases referred to in regulation 43, in accordance with the application sent to the Department or any decision taken by the Department.

(2) No project shall be carried out unless a favourable project evaluation by the Department has been concluded in accordance with regulation 39.

Application for project authorisation.

38. The Department shall establish a monitoring and enforcement system to ensure that an application for a project authorisation is submitted by the user or the person responsible for the project. The application shall include at least the following:

(a) the project proposal;

(b) a non-technical project summary; and

(c) information on the elements set out in Schedule VI.

Project evaluation.

39. (1) The project evaluation shall be performed with a degree of detail appropriate for the type of project and shall verify that the project meets the following criteria:

(a) the project is justified from a scientific or educational point of view or required by law;

(b) the purposes of the project justify the use of

animals; and

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

(2) The project evaluation shall consist in particular of the following:

(a) an evaluation of the objectives of the project, the predicted scientific benefits or educational value;

(b) an assessment of the compliance of the project with the requirement of replacement, reduction and refinement in procedures in terms of regulation 5;

(c) an assessment and assignment of the classification of the severity of procedures;

(d) a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and which may ultimately benefit human beings, animals or the environment;

(e) an assessment of any justification referred to in regulations 7 to 13, 15, 17 and 34(3); and

(f) a determination as to whether and when the project should be assessed retrospectively.

(3) The Department carrying out the project evaluation shall consider expertise in particular in the following areas:

(a) the areas of scientific use for which animals shall be used including replacement, reduction and refinement in the respective areas in procedures in accordance with regulation 5;

(b) experimental design, including statistics where appropriate;

(c) veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;

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

(4) The project evaluation process shall be transparent,

objective and non-discriminatory. Without prejudice to intellectual property rights, protection of data and the safeguarding of confidential information, the project evaluation shall be performed in an impartial manner and may integrate and include the opinion of independent parties.

Retrospective assessment.

40. (1) The Department shall determine, in accordance with regulation 39(2)(f), the retrospective assessment which shall be carried out by the same Department, which shall, on the basis of the necessary documentation submitted by the user, evaluate the following:

(a) whether the objectives of the project were achieved;

(b) the harm inflicted on animals, including the numbers and species of animals used, and the severity of the procedures; and

(c) any elements which may contribute to the further implementation of the requirement of replacement, reduction and refinement.

(2) All projects using non-human primates and projects involving procedures classified as "severe", including those referred to in regulation 16(2), shall undergo a retrospective assessment.

(3) Without prejudice to sub-regulation (2) and by way of derogation from regulation 39(2)(f), the Department shall exempt projects involving only procedures classified as "mild" or "non-recovery" from the requirement for a retrospective assessment.

Granting of project authorisation.

41. (1) The project authorisation shall be limited to procedures which have been subject to:

(a) a project evaluation; and

(b) the severity classifications assigned to those procedures.

(2) The project authorisation shall specify the following:

(a) the user who undertakes the project;

(b) the persons responsible for the overall implementation of the project and compliance of such implementation with the project authorisation;

(c) the establishments in which the project will be undertaken, where applicable;

(d) any specific conditions following the project evaluation, including whether and when the project shall be assessed retrospectively; and

(e) the designated veterinarian responsible for the overall implementation of procedures and an expert competent person where necessary.

(3) Project authorisations shall be granted for a period not exceeding five years.

Authorisation decisions.

42. (1) The Department shall take a decision regarding the authorisation which shall be communicated to the applicant forty working days at the latest from the receipt of the complete and correct application. This period shall include the project evaluation.

(2) When duly justified by the complexity or the multi-disciplinary nature of the project, the Department may extend the period referred to in sub-regulation (1) once, by an additional period not exceeding fifteen working days. The extension and its duration shall be duly motivated and shall be notified to the applicant before the expiry of the period referred to in sub-regulation (1).

(3) The Department shall acknowledge to the applicant all applications for authorisations immediately as possible, and shall indicate the period referred to in sub-regulation (1) within which the decision is to be taken.

(4) In the case of an incomplete or incorrect application, the Department shall immediately inform the applicant of the need to supply any additional documentation and of any possible effects on the running of the applicable time period.

Simplified administrative procedure.

43. (1) When introducing a simplified administrative procedure, the Department shall establish and maintain a monitoring and control system to ensure that the following provisions are met:

(a) the application specifies elements referred to in regulation 41(2)(a), (b), (c) and (e);

(b) a project evaluation is performed in accordance with regulation 39; and

(c) the period referred to in regulation 42(1) is not exceeded.

(2) If a project is changed in a way which may have a negative impact on animal welfare, the Department shall require an additional project evaluation with a favourable outcome.

(3) Regulations 41(3), 42(3), and 45(3) and (4) shall apply *mutatis mutandis* to projects which are allowed to be carried out in accordance with this regulation.

Non-technical project summaries.

44. (1) Without prejudice to intellectual property rights, data protection and confidentiality of information, non-technical project summaries shall provide and include the following:

(a) information on the objectives of the project, including the predicted harm and benefits and the number and types of animals to be used;

(b) a demonstration of compliance with the requirement of replacement, reduction and refinement in procedures in terms of regulation 5. The non-technical project summary shall be anonymous and shall not contain the names and addresses of the user and its personnel.

(2) In case of a project undergoing a retrospective assessment, the Department shall establish a monitoring and enforcement system to ensure that the non-technical project summary is updated with the results of any retrospective assessment.

(3) The Department shall publish the non-technical project summaries of authorised projects and any updates thereto.

Amendment, renewal and withdrawal of a project authorisation.

45. (1) An amendment or renewal of the project authorisation shall be required for any change of the project that may have a negative impact on animal welfare as established and enforced by the Department.

(2) Any amendment or renewal of a project authorisation shall be subject to a further favourable outcome of the project evaluation.

(3) The Department shall withdraw the project authorisation where the project is not carried out in accordance with the project authorisation, provided that the welfare of the animals used or intended to be used in the project is not be adversely affected.

(4) The Department shall establish and publish conditions for amendments and renewal of project authorisations.

Documentation.

46. (1) The Department shall establish a monitoring and enforcement system to ensure that all relevant documentation,

including project authorisations and the result of the project evaluation, is kept for at least three years from the expiry date of the authorisation of the project or from the expiry of the period referred to in regulation 42(1). Such documentation shall be made available to the Department.

(2) Without prejudice to sub-regulation (1), the documentation for projects which shall undergo retrospective assessment shall be kept until the retrospective assessment has been completed.

Duplication of procedures.

47. The Department shall accept data from other competent authorities which is generated by procedures recognised by European Union legislation, unless further procedures need to be carried out regarding such data for the protection of public health, safety or the environment.

National Reference Laboratory and alternative approaches.

48. (1) The Department shall contribute with other competent authorities in other Member States to the development and validation of alternative approaches which may provide the same or higher levels of information as those obtained in procedures using animals:

Provided that such approaches do not involve the use of animals, or the use of fewer animals, or which entail less painful procedures on animals, and the Department shall take such other steps as it considers appropriate to encourage and promote research in this field.

(2) The Department shall, at national level, encourage and promote the development and validation of alternative approaches and the dissemination of information thereon.

(3) Such validation studies shall be carried out by the National Reference Laboratory referred to in Part A of Schedule VIII. The tasks of such Laboratory are established under Part B of the Schedule VIII.

Union Reference Laboratory.

49. The Union Reference Laboratory and its duties and tasks shall be those referred to in Schedule VII.

Animal Welfare Council for the protection of animals used for scientific purposes.

50. (1) The Animal Welfare Council established for the protection of animals used for scientific purposes shall advise the animal-welfare body on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice.

(2) The Animal Welfare Council shall further exchange information on the operation of the animal-welfare body and project

evaluation and share best practice within the Union.

Reporting.

51. (1) The Department shall by 10 November 2018, and every five years thereafter, send to the Commission the information on the implementation of these regulations and in particular regulations 11(1), 27, 29, 35, 39, 40, 44 and 47.

(2) The Department shall collect and publish, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures.

(3) The Department shall submit such statistical information to the Commission by 10 November 2015 and every year thereafter.

(4) The Department shall submit to the Commission, on annual basis, detailed information on exemptions granted under regulation 7(3)(a).

Offences and penalties.

52. (1) Any person who fails to abide by these regulations shall be guilty of an offence, and shall be liable to the provisions and measures referred to in regulation 4(2) and (3).

(2) Any right given to the Department under these regulations to apply all such necessary measures prescribed in regulation 4(2) and (3), shall be given without prejudice to other criminal procedures which may be taken under the Act or any other law when a person commits an offence by failing to abide by these regulations.

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Schedule I

LIST OF ANIMALS REFERRED TO IN REGULATION 11

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*), Rana (*temporaria*, *pipiens*))
12. Zebra fish (*Danio rerio*)

Schedule II

LIST OF NON-HUMAN PRIMATES AND DATES REFERRED TO IN REGULATION 11(1)

Species	Dates
Marmoset (*Callithrix jacchus*)	1 January 2013
Cynomolgus monkey (*Macaca fascicularis*)	5 years after the publication of the feasibility study referred to in regulation 11(1), provided the study does not recommend an extended period
Rhesus monkey (*Macaca mulatta*)	5 years after the publication of the feasibility study referred to in regulation 11(1), provided the study does not recommend an extended period
Other species of non-human primates	5 years after the publication of the feasibility study referred to in regulation 11(1), provided the study does not recommend an extended period

Schedule III

REQUIREMENTS FOR ESTABLISHMENTS AND FOR THE CARE AND ACCOMMODATION OF ANIMALS

Section A: General section

1. The physical facilities

1.1. Functions and general design

(a) All facilities shall be constructed so as to provide an 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.

(b) Establishments shall have an active maintenance programme to prevent and remedy any defect in buildings or equipment.

1.2. Holding rooms

(a) Establishments shall have a regular and efficient cleaning schedule for the rooms and shall maintain satisfactory hygienic standards.

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

(c) Species that are incompatible, for example predator and prey, or 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.

1.3. General and special purpose procedure rooms

(a) Establishments shall, where appropriate, have available laboratory facilities for the carrying out of simple diagnostic tests, post-mortem examinations, and/or 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.

(b) 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.

(c) There shall be accommodation for the separate housing of sick or injured animals.

1.4. Service rooms

(a) 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 animals or staff, shall be stored separately.

(b) 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.

(c) Establishments shall provide for the hygienic storage and safe disposal of carcasses and animal waste.

(d) 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.

2. The environment and control thereof

2.1. Ventilation and temperature

(a) 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 animals housed.

(b) 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.

(c) Animals shall not be restricted to outdoor areas under climatic conditions which may cause them distress.

2.2. Lighting

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

(b) Illumination shall satisfy the needs for the performance of

husbandry procedures and inspection of the animals.

(c) Regular photoperiods and intensity of light adapted to the species shall be provided.

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

2.3. Noise

(a) Noise levels including ultrasound, shall not adversely affect animal welfare.

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

(c) Holding rooms shall where appropriate be provided with noise insulation and absorption materials.

2.4. Alarm systems

(a) 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.

(b) Heating and ventilation systems shall be equipped with monitoring devices and alarms.

(c) Clear instructions on emergency procedures shall be prominently displayed.

3. Care of animals

3.1. Health

(a) Establishments shall have a strategy in place to ensure that a health status of the animals is maintained that safeguards animal welfare and meets scientific requirements. This strategy shall include regular health monitoring, a microbiological surveillance programme and plans for dealing with health breakdowns and shall define health parameters and procedures for the introduction of new animals.

(b) 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 with immediate effect.

3.2. Animals taken from the wild

(a) 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.

(b) 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.

3.3. Housing and enrichment

(a) Housing

Animals, except those which are naturally solitary, shall be socially housed in stable groups of compatible individuals. In cases where single housing is allowed in accordance with regulation 34(3) the duration shall be limited to the minimum period necessary and visual, auditory, olfactory and/or tactile contact shall be maintained. The introduction or re-introduction of animals to established groups shall be carefully monitored to avoid problems of incompatibility and disrupted social relationships.

(b) Enrichment

All 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. Establishments shall have appropriate enrichment techniques in place, to extend the range of activities available to the animals and increase their coping activities including physical exercise, foraging, manipulative and cognitive activities, as appropriate to the species. Environmental enrichment in 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.

(c) Animal enclosures

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 animals is caused. Unless they are disposable, they shall be made from impermeable materials that will withstand cleaning and decontamination techniques. The design of animal enclosure floors shall be adapted to the species and age of the animals and be designed to facilitate the removal of excreta.

3.4. Feeding

(a) The form, content and presentation of the diet shall meet the nutritional and behavioural needs of the animal.

(b) The animals' diet shall be palatable and non-contaminated. In the selection of raw materials, production, preparation and presentation of feed, establishments shall take measures to minimise chemical, physical and microbiological contamination.

(c) 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.

(d) Each animal shall be able to access the food, with sufficient feeding space provided to limit competition.

3.5. Watering

(a) Uncontaminated drinking water shall always be available to all animals.

(b) When automatic watering systems are used, they shall be regularly checked, serviced and flushed to avoid accidents. If solid-bottomed cages are used, care shall be taken to minimise the risk of flooding.

(c) 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.

3.6. Resting and sleeping areas

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

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

3.7. Handling

Establishments shall set up habituation and training programmes suitable for the animals, the procedures and length of the project.

3.8. Cleaning

Cleaning schedules shall be established for each species to ensure that the holdings and environments do not remain soiled and are not a source of ill health

to the animal.

Section B: Species-specific section

1. Mice, rats, gerbils, hamsters and guinea pigs

In this and subsequent tables 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 (as detailed in Tables 1.1 to 1.5) for the duration of the study.

Table 1.1.

Mice

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in regulation 34(2)
In stock and during procedures	up to 20	330	60	12	1 January 2017
	over 20 to 25	330	70	12	
	over 25 to 30	330	80	12	
	over 30	330	100	12	
Breeding		330 For a monogamous pair (outbred/ inbred) or a trio (inbred). For each additional female plus litter 180 cm^2 shall be added.		12	
Stock at breeders (*) Enclosure size 950 cm^2	less than 20	950	40	12	
Enclosure size 1500 cm^2	less than 20	1 500	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.

Table 1.2

Rats

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in regulation 34(2)
In stock and during procedures (*)	up to 200	800	200	18	1 January 2017
	over 200 to 300	800	250	18	
	over 300 to 400	800	350	18	
	over 400 to 600	800	450	18	
	over 600	1 500	600	18	
Breeding		800 Mother and litter. For each additional adult animal permanently added to the enclosure add 400 cm^2		18	
Stock at breeders (**) Enclosure size 1 500 cm^2	up to 50	1 500	100	18	
	over 50 to 100	1 500	125	18	
	over 100 to 150	1 500	150	18	
	over 150 to 200	1 500	175	18	
Stock at breeders (**) Enclosure size 2 500 cm^2	up to 100	2 500	100	18	
	over 100 to 150	2 500	125	18	
	over 150 to 200	2 500	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.

(**) 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.

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Table 1.3

Gerbils

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in regulation 34(2)
In stock and during procedures	up to 40 over 40	1 200 1 200	150 250	18 18	1 January 2017
Breeding		1 200 Monogamous pair or trio with offspring		18	

Table 1.4

Hamsters

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in regulation 34(2)
In stock and during procedures	up to 60 over 60 to 100 over 100	800 800 800	150 200 250	14 14 14	1 January 2017
Breeding		800 Mother or monogamous pair with litter		14	
Stock at breeders (*)	less than 60	1 500	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.

Table 1.5

Guinea pigs

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in regulation 34(2)
In stock and during procedures	up to 200	1 800	200	23	1 January 2017
	over 200 to 300	1 800	350	23	
	over 300 to 450	1 800	500	23	
	over 450 to 700	2 500	700	23	
	over 700	2 500	900	23	
Breeding		2 500 Pair with litter. For each additional breeding female add 1 000 cm^2		23	

2. Rabbits

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 Directive 98/58/EC*.

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

Table 2.1.

Rabbits over 10 weeks of age

Table 2.1 is to be used for both cages and pens. The additional floor area is as a minimum 3 000 cm^2 per rabbit for the third, the fourth, the fifth and the sixth rabbit, while 2 500cm^2 as a minimum shall be added for each additional rabbit

*Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes.

above a number of six.

Final body weight (kg)	Minimum floor area for one or two socially harmonious animals (cm^2)	Minimum height (cm)	Date referred to in regulation 34(2)
less than 3	3 500	45	1 January 2017
from 3 to 5	4 200	45	
over 5	5 400	60	

Table 2.2.

Doe plus litter

Doe weight (kg)	Minimum enclosure size (cm^2)	Addition for nest boxes (cm^2)	Minimum height (cm)	Date referred to in regulation 34(2)
less than 3	3 500	1 000	45	1 January 2017
from 3 to 5	4 200	1 2000	45	
over 5	5 400	1 400	60	

Table 2.3

Rabbits less than 10 weeks of age

Table 2.3 is to be used for both cages and pens.

Age	Minimum enclosure size (cm^2)	Minimum floor area per animal (cm^2)	Minimum height (cm)	Date referred to in regulation 34(2)
Weaning to 7 weeks	4 000	800	40	1 January 2017
From 7 to 10 weeks	4 000	1 200	40	

Table 2.4

Rabbits: Optimal dimensions for raised areas for enclosures having the dimensions indicated in Table 2.1.

Age in weeks	Final body weight (kg)	Optimum size (cm x cm)	Optimum height from the enclosure floor (cm)	Date referred to in regulation 34(2)
over 10	less than 3	55 x 25	25	1 January 2017
	from 3 to 5	55 x 30	25	
	over 5	60 x 35	30	

3. Cats

Cats shall not be single-housed for more than 24 hours at a time. Cats that are repeatedly aggressive towards other cats shall be housed singly only if a compatible companion cannot be found. 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.

Table 3

Cats

The minimum space in which a queen and litter may be held is the space for a single cat, which shall be gradually increased so that by 4 months of age litters have been rehomed following 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.

	Floor (*) (m^2)	Shelves (m^2)	Height (m^2)	Date referred to in regulation 34(2)
Minimum for one adult animal	1.5	0.5	2	1 January 2017
For each additional animal add	0.75	0.25	-	
(*) Floor area excluding shelves.				

4. Dogs

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 Table 4.1.

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 Table 4.1. For breeds other than the laboratory beagle, space allowances shall be determined in consultation with veterinary staff.

Table 4.1.

Dogs

Dogs that are pair or group housed may each be constrained to half the total space provided ($2m^2$ for a dog under 20 kg, $4m^2$ for a dog over 20 kg) while they are undergoing procedures as defined in these regulations, 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.

Weight (Kg)	Minimum enclosure Size (m^2)	Minimum floor area animal add for one or two animals (m^2)	For each additional animal add a Minimum of (m^2)	Minimum height (m)	Date referred to in regulation 34(2)
Up to 20	4	4	2	2	1 January 2017
Over 20	8	8	4	2	

Table 4.2

Dogs-post weaned stock

Weight of Dog (Kg)	Minimum enclosure size (m^2)	Minimum floor area/ animal (m^2)	Minimum height (cm)	Date referred to in regulation 34(2)
Up to 5	4	0.5	2	1 January 2017
Over 5 to 10	4	1.0	2	
Over 10 to 15	4	1.5	2	
Over 15 to 20	4	2	2	
Over 20	8	4	2	

Table 5

Ferrets

	Minimum enclosure size (cm^2)	Minimum floor area/ animal (cm^2)	Minimum enclosure height (cm)	Date referred to in regulation 34(2)
Animals up to 600g	4 500	1 500	50	1 January 2017
Animals over 600g	4 500	3 000	50	
Adult males	6 000	6 000	50	
Jill and Litter	5 400	5 400	50	

6. Non-human primates

Young non-human primates shall not be separated from their mothers until they are, depending on the species, 6 to 12 months old.

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

Table 6.1

Marmosets and tamarins

	Minimum floor area of enclosures for 1(*) or 2 animals plus offspring up to 5 months (m^2)	Minimum volume per additional animal over 5 months old (m^3)	Minimum enclosure height (m) (**)	Date referred to in regulation 34(2)
Marmosets	0.5	0.2	1.5	1 January 2017
Tamarins	1.5	0.2	1.5	

(*) Animals shall be kept single only in exceptional circumstances.

(**) The top of the enclosure shall be kept at least 1.8 m from the floor.

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

Table 6.2

Squirrel monkeys

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)	Date referred to in regulation 34(2)
2.0	0.5	1.8	1 January 2017

(*) Animals should be kept singly only in exceptional circumstances.

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

Table 6.3

Macaques and vervets (*)

	Minimum enclosure size (m^2)	Minimum enclosure volume (m^3)	Minimum volume per animal (m^3)	Minimum enclosure height (m)	Date referred in regulation 34(2)
Animals less than 3 years of age (**)	2.0	3.6	1.0	1.8	1 January 2017
Animals from 3 years of age (***)	2.0	3.6	1.8	1.0	
Animals held for breeding purposes (****)			3.5	2.0	

(*) Animals should be kept singly only in exceptional circumstances.

(**) An enclosure of minimum dimensions may hold up to three animals.

(***) An enclosure of minimum dimensions may hold up to two animals.

(****) In breeding colonies no additional space/volume allowance is required for young animals up to 2 years of age housed with their mother.

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

Table 6.4

Baboons

	Minimum enclosure size (m^2)	Minimum enclosure volume (m^3)	Minimum volume per animal (m^3)	Minimum enclosure height (m)	Date referred in regulation 34(2)
Animals less than 4 years of age	4.0	7.2	3.0	1.8	1 January 2017
Animals from 4 years of age (**)	7.0	12.6	6.0	1.8	
Animals held for breeding purposes (***)			12.0	2.0	

(*) Animals shall be kept singly only in exceptional circumstances.

(*) An enclosure of minimum dimensions may hold up to 2 animals.

(***) In breeding colonies no additional space/volume allowance is required for young animals up to 2 years of age housed with their mothers.

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

7. Farm animals

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 comply at least with the standards laid down in Directives 98/58/EC, 91/629/EEC* and 91/630/EEC**.

*Council Directive 91/629/EEC of 19 November 1991 laying down minimum standards for the protection of calves

**Council Directive 91/630/EEC of 19 November 1991 laying down minimum standards for the protection of pigs

Table 7.1

Cattle

Body weight (Kg)	Minimum enclosure size (m^2)	Minimum floor area/animal (m^2/animal)	Trough space for ad-libitium feeding of polled cattle (m/animal)	Trough space for restricted feeding polled cattle (m/animal)	Date referred in regulation (34)2
Up to 100	2.50	2.30	0.10	0.30	1 January 2017
Over 100 to 200	4.25	3.40	0.15	0.50	
Over 200 to 400	6.00	4.80	0.18	0.60	
Over 400 to 600	9.00	7.50	0.21	0.70	
Over 600 to 800	11.00	8.75	0.24	0.80	
Over 800	16.00	10.00	0.30	1.00	

Table 7.2

Sheep and goats

Body Weight (Kg)	Minimum Enclosure (m^2)	Minimum Floor area/ animal (m^2/animal)	Minimum partition height (m)	Tough space for ad-libitum feeding (m/animal)	Tough Space for restricted feeding (m/animal)	Date referred in regulation 34(2)
Less than 20	1.0	0.7	1.0	0.10	0.25	1 January 2017
Over 20 to 35	1.5	1.0	1.2	0.10	0.30	
Over 35 to 60	2.0	1.5	1.2	0.12	0.40	
Over 60	3.0	1.8	1.5	0.12	0.50	

Table 7.3

Pigs and Minipigs

Live Weight (Kg)	Minimum Enclosure (*) (m^2)	Minimum floor area per animal (m^2/animal)	Minimum laying space per animal (in thermo neutral conditions (m^2/animal)	Date referred in regulation 34(2)
Up to 5	2.0	0.20	0.10	1 January 2017
Over 5 to 10	2.0	0.25	0.11	
Over 10 to 20	2.0	0.35	0.18	
Over 20 to 30	2.0	0.50	0.24	
Over 30 to 50	2.0	0.70	0.33	
Over 50 to 70	3.0	0.80	0.41	
Over 70 to 100	3.0	1.00	0.53	
Over 100 to 150	4.0	1.35	0.70	
Over 150	5.0	2.50	0.95	
Adult (conventional) boars	7.5		1.30	

(*) 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 is required .

Table 7.4

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.

Wither height (m)	Minimum Floor area/ animal (m^2/animal)			Minimum Enclosure height (m)	Date referred in regulation 34(2)
	For each animal held singly or in groups of up to 3 animals	For each animal held in groups of 4 or more animals	Foaling box / mare with foal		1 January 2017
1.00 to 1.40	9.0	6.0	16	3.00	
Over 1.40 to 1.60	12.0	9.0	20	3.00	
Over 1.60	16.0	$(2 \times WH)^2$ (*)	20	3.00	

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

8. Birds

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 comply at least with the standards laid down in Directives 98/58/EC, 1999/74/EC* and 2007/43/EC**.

Table 8.1

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

*Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens

**Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production

Body Mass (g)	Minimum Enclosure size (m^2)	Minimum area per bird (m^2)	Minimum height (cm)	Minimum length of feed through per bird (cm)	Date referred in regulation 34(2)
Up to 200	1.00	0.025	30	3	1 January 2017
Over 200 to 300	1.00	0.03	30	3	
Over 300 to 600	1.00	0.05	40	7	
Over 600 to 1200	2.00	0.09	50	15	
Over 1200 to 1800	2.00	0.11	75	15	
Over 1800 to 2400	2.00	0.13	75	15	
Over 2400	2.00	0.21	75	15	

Table 8.2

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 veterinary staff. In such circumstances, birds can be housed in smaller enclosures containing appropriate enrichment and with a minimum floor area of $0.75m^2$ and a minimum height of 50cm for birds below 0.6kg, 75cm for birds below 4kg, and 100cm for birds over 4kg. These can be used to house small groups of birds in accordance with the space allowances given in table 8.2.

Body Mass (kg)	Minimum enclosure size (m^2)	Minimum area per bird (m^2)	Minimum height (cm)	Minimum length of feed through per bird (cm)	Date referred in regulation 34(2)
Up to 0.3	2.00	0.13	50	3	1 January 2017
Over 0.3 to 0.6	2.00	0.17	50	7	
Over 0.6 to 1	2.00	0.30	100	15	
Over 1 to 4	2.00	0.35	100	15	
Over 4 to 8	2.00	0.40	100	15	
Over 8 to 12	2.00	0.50	150	20	
Over 12 to 16	2.00	0.55	150	20	
Over 16 to 20	2.00	0.60	150	20	
Over 20	3.00	1.00	150	20	

Table 8.3

Quails

Body Mass (g)	Minimum enclosure size (m^2)	Area per bird pair-housed (m^2)	Area per additional bird group-housed (m^2)	Minimum height (cm)	Minimum length of trough per bird (cm)	Data referred in regulation 34(2)
Up to 150	1.00	0.5	0.10	20	4	1 January 2017
Over 150	1.00	0.6	0.15	30	4	

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Table 8.4

Ducks and geese

Where these minimum enclosures sizes cannot be provided for scientific reasons, the duration of the confinement shall be justified by the experimenter in consultation with veterinary staff. In such circumstances, birds can be housed in smaller enclosures containing appropriate enrichment and with a minimum floor area of 0.75m^2 . These can be used to house small groups of birds in accordance with the space allowances given in table 8.4.

Body Mass (g)	Minimum Enclosure Size (m^2)	Area per bird (m^2) (*)	Minimum height (cm)	Minimum length of feed trough per bird (cm)	Data referred in regulation 34(2)
Ducks					
Up to 300	2.00	0.10	50	10	1 January 2017
Over 300 to 1200 (*)(**)	2.00	0.20	200	10	
Over 1200 to 3500	2.00	0.25	200	15	
Over 3500	2.00	0.50	200	15	
Geese					
Up to 500	2.00	0.20	200	10	
Over 500 to 2000	2.00	0.33	200	15	
Over 2000	2.00	0.50	200	15	

(*) This shall include a pond of minimum area 0.5m^2 per 2m^2 enclosure with a minimum depth of 30cm.The pond may contribute up to 50% of the minimum enclosure size.

(**) Pre-fledged birds may be held in enclosures with a minimum height of 75cm.

Table 8.5

Ducks and geese: Minimum pond sizes (*)

	Area (m^2)	Depth (cm)
Ducks	0.5	30
Geese	0.5	From 10 to 30

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

Table 8.6

Pigeons

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

Group size	Minimum enclosure size (m^2)	Minimum height (cm)	Minimum length of food trough per bird (cm)	Minimum length of perch per bird (cm)	Date referred in regulation 34(2)
Up to 6	2	200	5	30	1 January 2017
From 7 to 12	3	200	5	30	
For each additional bird above 12	0.15	200	5	30	

Table 8.7

Zebra finches

Enclosures shall be long and narrow (for example 2m by 1m) to enable birds to perform short flights. For breeding studies, pairs may be housed in smaller enclosures containing appropriate enrichment with a minimum floor area of $0.5m^2$ and a minimum height of 40 cm. The duration of the confinement shall be justified by the experimenter in consultation with veterinary staff.

Group size	Minimum enclosure size (m^2)	Minimum height (cm)	Minimum number of feeders	Date referred in regulation 34(2)
Up to 6	1.0	100	2	1 January 2017
7 to 12	1.5	200	2	
13 to 20	2.0	200	3	
For each additional bird above 20	0.05		1 per 6 birds	

Table 9.1

Aquatic urodeles

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)	Date referred in regulation 34(2)
Up to 10	262.5	50	13	1 January 2017
Over 10 to 15	525	110	13	
Over 15 to 20	875	200	15	
Over 20 to 30	1 837.5	440	15	
Over 30	3150	800	20	

(*) Measured from snout to vent.

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Table 9.2

Aquatic anurans (*)

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)	Date referred in 34(2)
Less than 6	160	40	6	1 January 2017
From 6 to 8	300	75	8	
Over 9 to 12	600	150	10	
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.

(**) Measured from snout to vent.

Table 9.3

Semi-aquatic anurans

Body length (**) (cm)	Minimum water surface area (cm^2)	Minimum water surface area for each additional animal in group holding (cm^2)	Minimum enclosure height (***) (cm)	Minimum water depth (cm)	Date referred in regulation 34(2)
Up to 5.0	1500	200	20	10	1 January 2017
Over 5.0 to 7.5	3500	500	30	10	
Over 7.5	4000	700	30	15	

(*) Measured from snout to vent.

(**) One third land division, two thirds water division sufficient for animals to submerge.

(***) 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.

Table 9.4

Semi-terrestrial anurans

Body length (**) (cm)	Minimum water surface area (cm^2)	Minimum water surface area for each additional animal in group holding (cm^2)	Minimum enclosure height (***) (cm)	Minimum water depth (cm)	Date referred in regulation 34(2)
Up to 5.0	1 500	200	20	10	1 January 2017
Over 5.0 to 7.5	3 500	500	30	10	
Over 7.5	4 000	700	30	15	

(*) Measured from snout to vent.

(**) One third land division, two thirds water division sufficient for animals to submerge.

(***) 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.

Table 9.5

Arboreal anurans

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)	Date referred in regulation 34(2)
Up to 3.0	900	100	30	1 January 2017
Over 3.0	1 500	200	30	

(*) Measured from snout to vent.

(**) One third land division, two thirds water division sufficient for animals to submerge.

(***) 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.

10. Reptiles

Table 10.1

Aquatic chelonians

Body length (**) (cm)	Minimum floor area (cm^2)	Minimum water surface area for each additional animal in group holding (cm^2)	Minimum water depth (cm)	Date referred in regulation 34(2)
Up to 5	600	100	10	1 January 2017
Over 5 to 10	1 600	300	15	
Over 10 to 15	3 500	600	20	
Over 15 to 20	6 000	1 200	30	
Over 20 to 30	10 000	2 000	35	
Over 35	20 000	5 000	40	

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

Table 10.2

Terrestrial snakes

Body length (**) (cm)	Minimum floor are (cm^2)	Minimum area for each additional animal in group holding (cm^2)	Minimum enclosure height (**) (cm)	Date referred to in regulation 34(2)
Up to 30	300	150	10	1 January 2017
Over 30 to 40	400	200	12	
Over 40 to 50	600	300	15	
Over 50 to 75	1 200	600	20	
Over 75	2 500	1 200	28	

(*) Measured from snout to vent.

(**) Measured from the surface o 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.

11. Fish

11.1. 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.

11.2. 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.

11.3. 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.

11.4. 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.

11.5. 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.

Schedule IV

METHODS OF KILLING 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:

(a) on unconscious animals, providing the animal does not regain consciousness before death;

(b) on animals used in agricultural research, when the aim of the project requires that the animals are kept under similar conditions to those under which commercial farm animals are kept; these animals may be killed in accordance with the requirements laid down in Annex I to Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing.

2. The killing of animals shall be completed by one of the following methods:

(a) confirmation of permanent cessation of the circulation;

(b) destruction of the brain;

(c) dislocation of the neck;

(d) exsanguination; or

(e) confirmation of the onset of *rigor mortis*.

3. Table

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

Requirements:

1. Shall, where appropriate, be used with prior sedation.

2. Only to be used on large reptiles.

3. Only to be used in gradual fill. Not to be 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.

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.

Schedule V

LIST OF ELEMENTS REFERRED TO IN REGULATION 24(3)

1. National legislation in force relevant to the acquisition, husbandry, care and use of animals for scientific purposes.

2. Ethics in relation to human-animal relationship, intrinsic value of life and arguments for and against the use of animals for scientific purposes.

3. Basic and appropriate species-specific biology in relation to anatomy, physiological features, breeding, genetics and genetic alteration.

4. Animal behaviour, husbandry and enrichment.

5. Species-specific methods of handling and procedures, where appropriate.

6. Animal health management and hygiene.

7. Recognition of species-specific distress, pain and suffering of most common laboratory species.

8. Anaesthesia, pain relieving methods and killing.

9. Use of humane end-points.

10. Requirement of replacement, reduction and refinement.

11. Design of procedures and projects, where appropriate.

Schedule VI

LIST OF ELEMENTS REFERRED TO IN REGULATION 38(1)(c)

1. Relevance and justification of the following:

(a) use of animals including their origin, estimated numbers, species and life stages;

(b) procedures.

2. Application of methods to replace, reduce and refine the use of animals in procedures.

3. The planned use of anaesthesia, analgesia and other pain relieving methods.

4. Reduction, avoidance and alleviation of any form of animal suffering, from birth to death where appropriate.

5. Use of humane end-points.

6. Experimental or observational strategy and statistical design to minimise animal numbers, pain, suffering, distress and environmental impact where appropriate.

7. Reuse of animals and the accumulative effect thereof on the animals.

8. The proposed severity classification of procedures.

9. Avoidance of unjustified duplication of procedures where appropriate.

10. Housing, husbandry and care conditions for the animals.

11. Methods of killing.

12. Competence of persons involved in the project.

Schedule VII

Part A - The Union Reference Laboratory

The Union Reference Laboratory referred to in regulation 49 is the Commission's Joint Research Centre.

Part B - Duties and tasks of the Union Reference Laboratory

1. The Union Reference Laboratory shall be responsible, in particular, for:

(a) coordinating and promoting the development and use of alternatives to procedures including in the areas of basic and applied research and regulatory testing;

(b) coordinating the validation of alternative approaches at Union level;

(c) acting as a focal point for the exchange of information on the development of alternative approaches;

(d) setting up, maintaining and managing public databases and information systems on alternative approaches and their state of development;

(e) promoting dialogue between legislators, regulators, and all relevant stakeholders, in particular, industry, biomedical scientists, consumer organisations and animal-welfare groups, with a view to the development, validation, regulatory acceptance, international recognition, and application of alternative approaches.

2. The Union Reference Laboratory shall participate in the validation of alternative approaches.

Schedule VIII

Part A - The National Reference Laboratory

The National Reference Laboratory in Malta referred to in regulation 48 is the National Veterinary Laboratory situated in Abattoir Street, Albertown, Marsa.

Part B - Tasks of the National Reference Laboratory

The National Reference Laboratory shall be responsible interalia and in particular for the following:

(a) carrying out of validation studies and coordinating the validation of alternative approaches at national level;

(b) ensuring the promotion of alternative approaches and the dissemination of information thereon;

(c) providing advice on the regulatory relevance and suitability and development of alternative approaches proposed for validation as a point of single contact for the purpose of exchange of information;

(d) contributing with other competent authorities in other Member States to the development and validation of alternative approaches which could provide the same or higher levels of information as those obtained in procedures using animals in terms of regulation 48(1);

(e) setting up, maintaining and managing public databases and information systems on alternative approaches and their state of development;

(f) promoting dialogue between legislators, regulators, and all relevant stakeholders, consumer organisations and animal-welfare groups in particular, with a view to the development, validation, regulatory acceptance, international recognition, and application of alternative approaches.

Schedule IX

SEVERITY CLASSIFICATION OF PROCEDURES

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.

Section I: Severity categories

Non-recovery:

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

Mild:

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

Moderate:

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

Severe:

Procedures on animals as a result of which the animals are likely to experience severe pain, suffering or distress, or long- lasting moderate pain, suffering or distress as well as procedures, that are likely to cause severe

impairment of the well- being or general condition of the animals shall be classified as ‘severe’.

Section II: Assignment criteria

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

When assigning a procedure to a particular category, the type of procedure and a number of other factors shall be taken into account. All these factors shall be considered on a case-by-case basis.

The factors related to the procedure shall include:

(a) type of manipulation, handling,

(b) 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,

(c) cumulative suffering within a procedure,

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

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

However, for the purposes of the final severity classification of the procedure, the following additional factors, assessed on a case-by-case basis, shall also be taken into account:

(a) type of species and genotype,

(b) maturity, age and gender of the animal,

(c) training experience of the animal with respect to the procedure,

(d) if the animal is to be reused, the actual severity of the previous procedures,

(e) the methods used to reduce or eliminate pain, suffering and distress, including refinement of housing, husbandry and care conditions,

(f) humane end-points.

Section III:

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

1. Mild:

(a) administration of anaesthesia except for the sole purpose of killing;

(b) pharmacokinetic study where a single dose is administered and a limited number of blood samples are taken (totalling < 10 % of circulating volume) and the substance is not expected to cause any detectable adverse effect;

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

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

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

(f) administration of substances by subcutaneous, intramuscular, intraperitoneal routes, gavage and intravenously via superficial blood vessels, where the substance has no more than mild impact on the animal, and the volumes are within appropriate limits for the size and species of the animal;

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

(h) breeding of genetically altered animals, which is expected to result in a phenotype with mild effects;

(i) feeding of modified diets, that do not meet all of the animals' nutritional needs and are expected to cause mild clinical abnormality within the time-scale of the study;

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

(k) studies involving short-term deprivation of social partners, short-term solitary caging of adult rats or mice of sociable strains;

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

(m) a combination or accumulation of the following examples may result in classification as 'mild':

(i) assessing body composition by non-invasive measures and with minimal restraint;

(ii) monitoring ECG with non-invasive techniques with minimal or no restraint of habituated animals;

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

(iv) breeding genetically altered animals which are expected to have no clinically detectable adverse phenotype;

(v) adding inert markers in the diet to follow passage of digesta;

(vi) withdrawal of food for < 24h in adult rats;

(vii) open field testing.

2. Moderate:

(a) frequent application of test substances which produce moderate clinical effects, and withdrawal of blood samples (> 10% of circulating volume) in a conscious animal within a few days without volume replacement;

(b) acute dose-range finding studies, chronic toxicity/ carcinogenicity tests, with non-lethal end-points;

(c) surgery under general anaesthesia and appropriate analgesia, associated with post surgical pain, suffering or impairment of general condition. Examples include: thoracotomy, craniotomy, laparotomy, orchidectomy, lymphadenectomy, thyroidectomy, orthopaedic surgery with effective stabilisation and wound management, organ transplantation with effective management of rejection, surgical implantation of catheters, or biomedical devices (e.g. telemetry transmitters, minipumps etc.);

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

(e) irradiation or chemotherapy with a sublethal dose, or with an otherwise lethal dose but with reconstitution of the immune system. Adverse effects would be expected to be mild or moderate and would be short-lived (< 5 days);

(f) breeding of genetically altered animals which are expected to result in a phenotype with moderate effects;

(g) creation of genetically altered animals through surgical procedures;

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

(i) studies with modified diets that do not meet all of the animals' nutritional needs and are expected to cause moderate clinical abnormality within the time-scale of the study;

(j) withdrawal of food for 48 hours in adult rats;

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

3. Severe:

(a) toxicity testing where death is the end-point, or fatalities are to be expected and severe pathophysiological states are induced. For example, single dose acute toxicity testing;

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

(c) vaccine potency testing characterised by persistent impairment of the animal's condition, progressive disease leading to death, associated with long-lasting moderate pain, distress or suffering;

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

(e) models with induction of tumours, or with spontaneous tumours, that are expected to cause progressive lethal disease associated with long-lasting moderate pain, distress or suffering. For example tumours causing cachexia, invasive bone tumours, tumours resulting in metastatic spread, and tumours that are allowed to ulcerate;

(f) surgical and other interventions in animals under general

anaesthesia which are expected to result in severe or persistent moderate postoperative pain, suffering or distress or severe and persistent impairment of the general condition of the animals. Production of unstable fractures, thoracotomy without adequate analgesia, or trauma to produce multiple organ failure;

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

(h) breeding animals with genetic disorders that are expected to experience severe and persistent impairment of general condition, for example Huntington's disease, Muscular dystrophy, chronic relapsing neuritis models;

(i) use of metabolic cages involving severe restriction of movement over a prolonged period;

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

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

(l) immobilisation stress to induce gastric ulcers or cardiac failure in rats;

(m) forced swim or exercise tests with exhaustion as the end-point.

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