

*Government Notice No. 18 of 2017*

## **THE ANIMAL WELFARE ACT**

### **Regulations made by the Minister under sections 8, 10 and 45 of the Animal Welfare Act**

1. These regulations may be cited as the Animal Welfare (Experiment on Animals) Regulations 2017.
2. In these regulations –
  - “Act” means the Animal Welfare Act;
  - “animal” means an animal specified in the First Schedule;
  - “breeder” means a person authorised by the supervising officer to breed an animal with a view to its use in an experiment, whether for profit or not;
  - “establishment” means premises where an animal is kept;
  - “international guidelines” includes the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Directives of the European Parliament and of the Council on the protection of animals used for scientific purposes, guidelines used by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) for accreditation purposes, the Institutional Animal Care and Use Committee Guidebook, the chapter on Use of Animals in Research and Education under the Terrestrial Animal Health Code 2016 of the World Organisation for Animal Health and the Organisation for Economic Cooperation and Development (OECD) Guidelines for the Testing of Chemicals;

“licensee” means a person issued with a licence under section 8 of the Act;

“supplier” means a person, other than a breeder, registered with the Livestock and Veterinary Division of the Ministry, who supplies an animal for use in an experiment, whether for profit or not.

3. These regulations shall not apply to –
  - (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 purpose of recognised animal husbandry;
  - (e) the ringing, tagging or marking of an animal or the application of any other humane procedure for the sole purpose of enabling an animal to be identified which causes only momentary pain, suffering or distress and no lasting harm to the animal.
  
4. Subject to Part III of the Act, no person shall –
  - (a) perform an experiment on an animal other than on an animal specified in the First Schedule;
  - (b) kill an animal for the sole purpose of an experiment;
  - (c) euthanise an animal solely for the use of its organs in an experiment;
  - (d) perform an experiment for the testing of cosmetics or for the marketing of cosmetic products;

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- (e) broadcast an experiment as an exhibition to the general public;
  - (f) publish any information about an experiment, including a notice or an advertisement announcing the conduct of an experiment.
5. (1) For the purpose of section 8(2) of the Act, an application for a licence to perform an experiment shall be made to the Minister in the form set out in the Second Schedule.
- (2) Every application made under paragraph (1) shall be accompanied by –
- (a) such additional information as the Minister considers appropriate; and
  - (b) the non-refundable application fee specified in the Third Schedule.
- (3) The Minister may consult any relevant experts or institutions prior to granting an application for a licence.
- (4) In considering an application for a licence, the Minister shall weigh the likely adverse effect on the animal concerned against the benefit likely to accrue as a result of the experiment.
- (5) The Minister shall not grant an application for a licence unless he is satisfied that –
- (a) the purpose of the experiment cannot be achieved satisfactorily by any other reasonably practical method not entailing the use of the animal; and
  - (b) the experiment shall –
    - (i) use the minimum number of animals;

- (ii) involve animals with lowest degree of neurophysiological sensitivity to pain; and
- (iii) cause the least pain, suffering, distress or lasting harm to the animals and is most likely to produce satisfactory results.

(6) No licence shall be granted to a person under the age of 18.

**6.** (1) For the purpose of section 8(5) of the Act, where the Minister grants an application, he shall, on payment of the licence fee specified in the Third Schedule, issue a licence to the applicant in the form set out in the Fourth Schedule, subject to such conditions as he may determine.

(2) Every licensee shall comply with the general conditions set out in the Fifth Schedule and any other conditions specified in his licence.

(3) A licence shall be valid for a period of 3 years unless earlier suspended or revoked by the Minister under regulation 12.

(4) A licence shall not be transferable.

(5) A licensee shall, 3 months prior to the expiry of his licence, apply to the Minister for the renewal of the licence in the form and in the manner specified in regulation 5.

(6) The Minister may renew the licence subject to such terms and conditions as he may determine.

**7.** Where the Minister rejects an application for the issue or renewal of a licence, he shall inform the applicant in writing, giving reasons for his decision.

**8.** (1) Any experiment shall be classified as –

- (a) non recovery;

- (b) mild;
- (c) moderate; or
- (d) severe,

on a case by case basis using the assignment criteria specified in the Sixth Schedule.

(2) Subject to section 9 of the Act, no person shall perform an experiment where it involves severe pain, suffering or distress that is likely to be long-lasting and which cannot be alleviated.

**9.** Every licensee shall, in relation to an experiment to be performed by him, observe the following principles of replacement, reduction and refinement –

- (a) wherever possible, a scientifically satisfactory method or testing strategy not entailing the use of live animals shall be used instead of an experiment using live animals;
- (b) the number of animals used in an experiment shall be reduced to a minimum without compromising the objectives of the experiment;
- (c) refinement of breeding, accommodation and care, and of methods used in an experiment which aim at eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animal shall be ensured, in line with international best practice.

**10.** (1) Every licensee shall, in respect of an establishment where an experiment is to be performed, set up an Animal Care and Use Committee which shall comprise –

- (a) a veterinarian or veterinary surgeon registered with the Veterinary Council of Mauritius and having

experience in the use of animals for experiment purposes;

- (b) a representative of the Livestock and Veterinary Division of the Ministry;
- (c) a scientist specialised in the use of animals for experiment purposes.

(2) The Animal Care and Use Committee shall –

- (a) advise the staff of the licensee dealing with animals on matters relating to their welfare and use;
- (b) advise the staff of the licensee on the application of the principles of replacement, reduction and refinement and shall keep the staff informed of technical and scientific developments concerning the application of those principles;
- (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 the experiment, taking into account the effect on the animals used; and
- (e) identify and advise the licensee on elements that further contribute to replacement, reduction and refinement.

**11.** (1) For the purpose of section 10(a) of the Act, every licensee shall, in relation to every experiment performed by him, keep a record of all animals used in that experiment, including –

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- (a) the identity, the place and date of birth of the animal, where available, the number and the species of animals acquired and used;
  - (b) the source or origin of the animals, including information as to whether they were bred for use in experiments;
  - (c) the dates on which the animals were acquired;
  - (d) the name and address of the breeder and supplier;
  - (e) the number and species of animals which died or were euthanised and the number remaining after the experiment;
  - (f) the cause of death of any animal;
  - (g) for the purpose of traceability, in the case of a macaque, whether it is the offspring of a macaque which has been caught in the wild in Mauritius or is bred in captivity in Mauritius; and
  - (h) details of the generation of each individual animal used.

(2) An individual history file of an animal used in an experiment shall be kept by the licensee and be readily available to the Ministry on demand.

(3) The individual history file referred to in paragraph (2) shall be established at birth or, as soon as possible, thereafter and shall cover any relevant reproductive, veterinary and social information on the animal and the experiments in which it has been used.

(4) Every licensee shall keep the records and individual history file referred to in paragraphs (1) and (2) for a minimum period of 5 years after the death or rehoming of the animal and shall make

them available on request to the Minister or any person authorised in writing by the Minister.

(5) For the purpose of section 10(d) of the Act, every licensee shall, within one year of the start of an experiment performed by him or within 28 days of the licence having expired, suspended or been revoked, submit to the Minister a return of that experiment specifying –

- (a) the number of animals used and their species;
- (b) the sources of the animals used;
- (c) the purpose and protocol used for each experiment performed;
- (d) the types of tests carried out;
- (e) the preliminary result or the final result of the experiment carried out, as the case may be; and
- (f) the state in which the animal is after the experiment.

**12.** (1) The Minister may suspend or revoke a licence where –

- (a) he has reasonable grounds to believe that the welfare of any animal used in relation to such licence is at risk;
- (b) a licensee fails to comply with any term or condition of his licence.

(2) Where a licence is suspended or revoked under paragraph (1), the licensee shall forthwith stop any ongoing experiment and surrender the licence to the Ministry.

(3) Any licensee who fails to comply with paragraph (2) shall commit an offence.



**13.** Any fees collected under these regulations shall be paid into the National Parks and Conservation Fund set up under the Native Terrestrial Biodiversity and National Parks Act 2015.

**14.** Any person who contravenes these regulations shall commit an offence and shall, on conviction, be liable to a fine not exceeding 10,000 rupees.

**15.** These regulations shall come into operation on 1 February 2017.

Made by the Minister on 30 January 2017.

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**FIRST SCHEDULE**

[Regulations 2 and 4(a)]

**ANIMALS TO BE USED IN EXPERIMENTS**

Macaque (*Macaca fascicularis*) bred in Mauritius

Mouse (*Mus musculus*) bred for use in experiments

Rabbit (*Oryctolagus cuniculus*) bred for use in experiments

Rat (*Rattus norvegicus*) bred for use in experiments

**SECOND SCHEDULE**

[Regulation 5(1)]

**APPLICATION FORM FOR LICENCE TO PERFORM  
EXPERIMENT ON ANIMALS****PART I – APPLICATION TO USE ANIMALS IN EXPERIMENT****1. Title of experiment**

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**2. Applicant information**

Name .....

Organisation/establishment .....

Work address .....

Work phone no. .... Fax no. ....

Emergency phone (after hours) .....

Mobile no. .... Email address .....

Please indicate how you prefer to be contacted

Fax

Email

**3. Contact person other than applicant**

Name .....

Organisation/establishment .....

Work address .....



\*\* For each individual, including the applicant who is listed above, fill a Qualifications of Personnel Form and submit it with this application. The Ministry of Agro-Industry and Food Security reserves the right not to grant approval if the Qualifications of Personnel Form is not submitted. The Qualifications of Personnel Form is annexed.

**6. Location of establishment**

(1) Please indicate the name and location of the establishment where this experiment will be conducted.

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(2) Has the establishment been approved by the Ministry of Agro-Industry and Food Security?

Yes  No

If the answer to the above is “yes”, please provide the approval number .....

**7. Description of experiment**

Provide a brief description of the experiment and of its overall objectives and intended benefits to humans, animals and/or the advancement of scientific knowledge, the use of the animals, the expected adverse effects on them, the likely/expected level of severity and the fate of the animals.

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### 8. Animals to be used for the experiment

List the total number of live vertebrate animals for the whole duration of the experiment (a maximum of 3 years) in the table below.

Number of animals to be used for the whole duration of the experiment	Specific and common name	Identification	Date of birth	Sex	Age or weight	Source/origin **	Has the animal been used in a previous experiment?

\*\* Provide certificate from competent authority in country of origin.



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(3) Explain the general measures to be taken to minimise welfare costs (harms) to the animals.

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**10. Appropriateness of number of animals**

(1) Describe in detail the basis on which the total number of animals was determined and how the number is appropriate having regard to the goals of the experiment.

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(3) Where the number of animals required is dictated by other than statistical considerations, such as the amount of tissue needed, etc., justify the number of animals requested on this basis. Provide this information for the duration of the experiment or a maximum period of 3 years, whichever is the lesser.

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**Note** – All animals involved in the experiment shall be included. This includes not only experimental animals, but also donor animals, breeding pairs, pregnant mothers, and offspring that cannot be utilised because of genotype/phenotype, sex, etc.

**11. Animal husbandry and care**

(1) Will the applicant or other staff be responsible for animal husbandry?

Yes  No

If “yes”, provide information on feeding (frequency and type of food), cage type and size, cleaning schedule, veterinary care and emergency procedures. Provide confirmation that a daily log will be maintained in order to comply with requirements that animals shall be observed on a daily basis, including weekends and holidays and in relation to the Standard Operating Procedures (“SOP”) of the establishment.

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(2) Does the experiment call for non-standard caging (i.e wire bottom) to be used?

Yes  No

If “yes”, please indicate the length of time the animals will be housed in these non-standard cages and provide justification as to why this type of caging is necessary.

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(3) How long will animals be kept out of the animal facility?

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(4) Justify why animals need to be kept outside the animal facility.

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(5) Identify the site where animals will be kept (building/room).

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(6) How often will the animals be monitored and what care will they receive?

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(7) Will the animals be housed in cages?  
If “yes”, please give details.

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(8) If the animals will be kept in a laboratory for 12 hours or longer, provide SOP on feeding (frequency and type of food), cage type and size, cleaning schedule, veterinary care and emergency procedures. Provide confirmation that a daily log will be maintained to comply with the requirements that animals shall be observed on a daily basis, including weekends and holidays.

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(9) Has the use of the laboratory been approved by the Ministry of Agro-Industry and Food Security?

Yes  No

If “Yes”, please provide the approval number .....



**13. Disposition of animals at end of experiment**

Will euthanasia be performed on any animal involved in this experiment according to an approved SOP?

Yes  No

If “yes”, please provide a copy of the SOP indicating the method to be used.

**Note** – expired drugs shall not be used in live vertebrate animals. Only approved drugs shall be used unless they are unavailable or scientific justification is provided for use of non-medical grade drugs. Controlled drugs shall be secured and logged appropriately.

**14. Hazardous agents**

Hazardous agents include radioactive substances and radiation devices such as irradiators or X-ray producing equipment, lasers, hazardous biological agents, including tissue of human origin and all biosafety level 2 and above agents, biological toxins, toxic chemicals (lethal dose ( $LD_{50}$ ) < 50 mg/kg), mutagens, carcinogens, reproductive toxins.

Will hazardous agents be used as part of the experiment?

Yes  No

If “yes”, please provide details.

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I undertake to comply with the Animal Welfare Act and the Animal Welfare (Experiment on Animals) Regulations 2017.

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Name of applicant

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Signature of applicant

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Date  
  
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**2.** What species will this individual be handling?

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(1) If macaques, provide the date the relevant working safety training was taken.

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(2) If other animals, provide the date the handlers course was taken.

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**3.** Please identify any of the species listed in question 2 above that this individual has not worked with within the last 3 years.

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**4.** Describe this individual's experience and/or training in the proper handling, care and basic needs of each species listed in question 2 above.

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**5.** Please list the procedures this individual will perform during the experiment.

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**6.** Describe the individual's experience with and/or training in relation to each procedure listed in question 5.

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**7.** Indicate any of the procedures listed above in question 5 that this individual has not performed within the last 3 years.

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**8.** Provide a recent medical fitness certificate duly certified by a medical practitioner registered with the Medical Council of Mauritius under the Medical Council Act.

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**THIRD SCHEDULE**

[Regulations 5(2) and 6(1)]

**FEES**

	<b>(Rs)</b>
Application fee	15,000
Licence fee	150,000

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**FOURTH SCHEDULE**

[Regulation 6(1)]

**MINISTRY OF AGRO-INDUSTRY AND FOOD SECURITY**

**LICENCE TO PERFORM EXPERIMENT ON ANIMAL/S  
ISSUED UNDER SECTION 8(1) OF THE  
ANIMAL WELFARE ACT**

On the application of .....

*(name of applicant)*

applicant is hereby issued with a licence to carry out an experiment  
on .....

*(title of experiment)*

at .....

*(location of establishment where experiment is to be performed)*

This licence is valid for a period of 3 years as from the date indicated  
below.

Licence no. ....

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Minister of Agro-Industry  
and Food Security

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Date

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**FIFTH SCHEDULE**

[Regulation 6(2)]

**GENERAL CONDITIONS OF LICENCE**

1. In exercising his responsibilities, the licensee shall act, at all times, in a manner that is consistent with the principles of replacement, reduction and refinement.
2. The licensee shall be entrusted with primary responsibility for the welfare of the animal on which he has performed the experiment.
3. The licensee shall ensure that an animal is properly monitored and cared for.
4. Subject to section 9 of the Animal Welfare Act, the licensee shall not perform an experiment on an animal where the experiment may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be alleviated.
5. The licensee shall not perform an experiment on an animal unless he has taken precautions to prevent or reduce to the minimum, consistent with the purposes of the experiment, any pain, suffering or distress that may be caused to the animal.
6. Where the licensee is performing an experiment on an animal, he shall ensure that any unnecessary pain, suffering, distress or lasting harm that is being caused to the animal is stopped.
7. Where the licensee is performing or has performed an experiment which is causing the animal severe pain, suffering or distress, he shall take steps to alleviate that pain, suffering or distress.
8. The licensee shall, whilst performing an experiment, ensure that death as the end point of the procedure is avoided as far as possible and is replaced by an early and humane endpoint.

**9.** The licensee shall, in all circumstances where an animal which is being or has been subjected to an experiment is in severe pain, suffering or distress which is likely to be long-lasting and which cannot be alleviated, ensure that the animal is immediately euthanised.

**10.** The licensee shall ensure that suitable arrangements exist for the care and welfare of an animal during any period when he is not in attendance.

**11.** The licensee shall ensure that, whenever necessary, veterinary advice and treatment are obtained for the animal in his care.

**12.** (1) The licensee shall ensure that all cages, pens or other enclosures are clearly labelled.

(2) The labelling shall be such as to enable an authorised officer to identify the licence authorising the experiment, the experiment in which the animal is being used, the date the protocol was started and the person in charge of the experiment.

**13.** The licensee shall maintain a record of an animal on which an experiment has been carried out, and this record shall be retained for at least 5 years and shall, on request, be submitted to the Minister or made available to the officers mentioned above.

**14.** The licensee shall give any necessary assistance to any authorised officer mentioned above carrying out visits.

**15.** No amendment to the experiment shall be allowed unless prior approval of the Minister is sought.

**16.** The licence shall remain the property of the Ministry and shall be surrendered to it on expiry.

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**17.** The licensee shall be responsible for the overall implementation of the experiment specified in this licence and for ensuring that the experiment is carried out in compliance with the conditions of the licence and for ensuring that the appropriate level of supervision is provided.

**18.** The licensee shall ensure that the experiment does not involve the application of any procedure to which there is a scientifically satisfactory alternative method or testing strategy not entailing the use of a protected animal.

**19.** The licensee shall ensure that the procedures applied as part of the experiment specified in this licence are those which, to the greatest extent, use the minimum number of animals, involve animals with the lowest capacity, cause the least pain, suffering, distress or lasting harm, and are most likely to provide satisfactory results.

**20.** The licensee shall ensure that the procedures applied as part of the experiment specified in this licence are designed to reduce to the minimum possible the duration and intensity of suffering caused to the animals that die and, as far as possible, ensure a painless death.

**21.** The licensee shall ensure that a procedure is not applied to an animal as part of the experiment specified in this licence if it may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be alleviated.

**22.** The licensee shall ensure that where a procedure has been applied to an animal as part of the experiment specified in the licence, a suitably qualified person classifies the severity of the experiment using the criteria set out in the Sixth Schedule.

**23.** (1) At the end of an experiment, a decision to keep an animal alive shall be taken by a veterinary surgeon or by another competent person.

(2) An animal shall be killed when it is likely to remain in moderate or severe pain, suffering, distress or lasting harm.

**24.** Procedures shall not be carried out on any stray animal of a domestic species as part of the experiment specified in the licence.

**25.** Where the licensee becomes aware of a failure to comply with any conditions of the licence, he shall take appropriate steps to rectify the failure and keep a record of the steps taken.

**26.** (1) The licensee shall ensure adherence to the severity limits as specified in the Sixth Schedule and observance of any other controls described in the licence.

(2) Where these constraints have been or are likely to be breached, the licensee shall ensure that the Minister is notified as soon as possible.

**27.** (1) The licensee shall maintain a record of all animals on which procedures have been carried out under the experiment specified in the licence.

(2) The record shall contain all relevant information specified in regulation 11(1) of the Animal Welfare (Experiment on Animals) Regulations 2017.

(3) The record shall, on request, be submitted to the Minister or made available to any person authorised in writing by the Minister.

**28.** The licensee shall send to the Minister, within one year of the start of an experiment performed by him or within 28 days of the licence having expired, suspended or been revoked, a return containing all relevant information specified in regulation 11(5) of the Animal Welfare (Experiment on Animals) Regulations 2017.

**29.** The licensee shall maintain a list of publications resulting from the experiment and a copy of any such publication shall be made available to the Minister on request.

**30.** The licensee shall ensure that details of the experiment specified in the licence, and any additional conditions imposed are known to –

- (a) all persons performing the experiment;
  - (b) the person responsible for compliance;
  - (c) the animal care and animal welfare officers responsible for the day to day care of the animals;
  - (d) the veterinarian or veterinary surgeon.
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**SIXTH SCHEDULE**

[Regulation 8(1)]

**SEVERITY CLASSIFICATIONS OF EXPERIMENT**

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

**1. Severity categories shall be as follows –****(a) non-recovery**

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

**(b) mild**

Experiments on an animal as a result of which the animal is likely to experience short-term mild pain, suffering or distress, as well as experiments with no significant impairment of the well-being or general condition of the animal shall be classified as mild.

**(c) moderate**

Experiments on an animal as a result of which the animal is likely to experience short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as experiments that are likely to cause moderate impairment of the well-being or general condition of the animal shall be classified as moderate.

(d) severe

Experiments on an animal as a result of which the animal is likely to experience severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress as well as experiments, that are likely to cause severe impairment of the well-being or general condition of the animal shall be classified as severe.

## 2. Assignment criteria

(1) The assignment of the severity category shall take into account any intervention or manipulation of an animal during an experiment and shall be based on the most severe effects likely to be experienced by an individual animal after applying all appropriate refinement techniques.

(2) When assigning an experiment to a particular category, the type of experiment and a number of other factors shall be taken into account. All these factors shall be considered on a case by case basis.

(3) The factors related to the experiment shall include –

- (a) the type of manipulation, handling and immobilising the animal;
- (b) the nature of pain, suffering, distress or lasting harm caused by the experiment and its intensity, including the duration, frequency and multiplicity of techniques employed;
- (c) the cumulative suffering within an experiment;
- (d) the prevention from expressing natural behaviour, including restrictions on the housing, husbandry and care standards.

(4) For the purpose of the final severity classification of the experiment, the following additional factors, assessed on a case by case basis, shall also be taken into account –

- (a) the type of species and genotype;
- (b) the maturity, age and gender of the animal;
- (c) the training experience of the animal with respect to the experiment;
- (d) if the animal is to be reused, the actual severity of the previous experiments;
- (e) the methods used to reduce or eliminate pain, suffering and distress, including refinement of housing, husbandry and care conditions;
- (f) the humane end-points.

**3.** Examples of different types of experiments assigned to each of the severity categories on the basis of factors related to the type of experiment are set out as follows –

- (a) “mild” includes –
  - (i) administration of anaesthesia except for the sole purpose of euthanising;
  - (ii) pharmacokinetic study where a single dose is administered and a limited number of blood samples are taken (totalling less than 10 per cent of circulating volume) and the substance is not expected to cause any detectable adverse effect;
  - (iii) non-invasive imaging of the animal with appropriate sedation or anaesthesia;



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- (iv) superficial experiments (for example, ear and tail biopsies), non-surgical subcutaneous implantation of mini pumps and transponders;
  - (v) application of external telemetry devices that cause only minor impairment to the animals or minor interference with normal activity and behaviour;
  - (vi) administration of substances by subcutaneous, intramuscular, intraperitoneal routes, 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;
  - (vii) induction of tumours, or spontaneous tumours, that cause no detectable clinical adverse effects (for example, small, subcutaneous, non-invasive nodules);
  - (viii) breeding of genetically altered animals which is expected to result in a phenotype with mild effects;
  - (ix) feeding of modified diets that do not meet all of the nutritional needs of the animal and are expected to cause mild clinical abnormality within the timescale of the study;
  - (x) short-term (less than 24 hours) restraint in metabolic cages;
  - (xi) studies involving short-term deprivation of social partners, short-term solitary caging of adult rats or mice of sociable strains;
  - (xii) models which expose the animal to noxious stimuli which are briefly associated with mild pain,

suffering or distress, and which the animal can successfully avoid;

(xiii) a combination or accumulation of the following examples which may result in classification as mild –

- (A) assessing body composition by non-invasive measures and with minimal restraint;
- (B) monitoring electrocardiography results with non-invasive techniques with minimal or no restraint of habituated animals;
- (C) 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;
- (D) breeding genetically altered animals which are expected to have no clinically detectable adverse phenotype;
- (E) adding inert markers in the diet to follow passage of digestion;
- (F) withdrawal of food for less than 24 hours in adult rats;
- (G) open field testing;

(b) “moderate” –

- (i) frequent application of test substances which produce moderate clinical effects, and withdrawal of blood samples (more than 10 per cent of circulating volume) in a conscious animal within a few days without volume replacement;

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- (ii) acute dose range finding studies, chronic toxicity/ carcinogenicity tests, with non-lethal end-points;
  - (iii) 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 (for example, telemetry transmitters, minipumps, etc.);
  - (iv) models of induction of tumours, or spontaneous tumours, that are expected to cause moderate pain or distress or moderate interference with normal behaviour;
  - (v) irradiation or chemotherapy with a sub-lethal 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 shall not exceed 24 hours;
  - (vi) breeding of genetically altered animals which are expected to result in a phenotype with moderate effects;
  - (vii) creation of genetically altered animals through surgical experiments;
  - (viii) use of metabolic cages involving moderate restriction of movement over a prolonged period (up to 5 days);

- (ix) studies with modified diets that do not meet all of the nutritional needs of the animal and are expected to cause moderate clinical abnormality within the timescale of the study;
  - (x) withdrawal of food for 48 hours in adult rats;
  - (xi) evoking escape and avoidance reactions where the animal is unable to escape or avoid the stimulus, and are expected to result in moderate distress;
- (c) “severe” –
- (i) 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 under the OECD Guidelines for the Testing of Chemicals;
  - (ii) testing of devices where failure may cause severe pain, distress or death of the animal, for example, cardiac assist devices;
  - (iii) vaccine potency testing characterised, for example, by persistent impairment of the animal’s condition, progressive disease leading to death, associated with long-lasting moderate pain, distress or suffering;
  - (iv) irradiation or chemotherapy with a lethal dose without reconstitution of the immune system, or reconstitution with production of graft versus host disease;
  - (v) models with induction of tumours, or with spontaneous tumours, that are expected to cause progressive lethal disease associated with long

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lasting moderate pain, distress or suffering. Examples include tumours causing cachexia, invasive bone tumours, tumours resulting in metastatic spread and tumours that are allowed to ulcerate;

- (vi) surgical and other interventions in an animal under general anaesthesia which are expected to result in severe or persistent moderate post-operative pain, suffering or distress or severe and persistent impairment of the general condition of the animal. Production of unstable fractures, thoracotomy without adequate analgesia, or trauma to produce multiple organ failure;
- (vii) organ transplantation where organ rejection is likely to lead to severe distress or impairment of the general condition of the animals, for example, xenotransplantation;
- (viii) 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;
- (ix) use of metabolic cages involving severe restriction of movement over a prolonged period;
- (x) inescapable electric shock, for example, to produce learned helplessness;
- (xi) complete isolation for prolonged periods of social species;

- (xii) immobilisation stress to induce gastric ulcers or cardiac failure in rats;
  - (xiii) forced swim or exercise tests with exhaustion as the end-point.
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