

Breeding and Experimentation (Control and Supervision of Rules)

- **Rule 2 - Definitions:**

Note: In any legislation, terms defined by a definition clause will assume the meaning provided in such definition throughout the statute. The following definitions will therefore aid you throughout your interpretation of these rules.

In these rules, unless the context otherwise requires -

(a) "Act" means the Prevention of Cruelty to Animals Act, 1960 (59 of 1960);

(b) "breeder" means a person including an institution, which breeds animals for the purpose of transfer to other authorised institution for performing experiments;

(c) "Committee" means the Committee under section 15 of the Act for control and supervision of experiments on animals;

(d) "establishment" means any individual, company, firm, corporation, institution other than schools up to higher secondary level, which performs experiments on animals;

(e) "experiment" means any programme or project involving use of animal(s) for the acquisition of knowledge of a biological, physiological, ethological, physical or chemical nature; and includes the use of animal(s) in the production of reagents and products such as antigens and antibodies, routine diagnostics, testing activity and establishment of transgenic stocks, for the purpose of saving or prolonging life or alleviating suffering or significant gains in well being for people of the country or for combating any disease whether of human beings or animals;

Note: This definition of experiment, though amended several times over the past decade, remains wide in nature and includes within its purview any programme or project which helps increase one's knowledge in terms of science, and claims to help save or prolong the lives of either humans or animals, or minimise their suffering.

This definition unfortunately allows animals to be tested for all such medicine based scientific endeavours.

(f) "Institutional Animals Ethics Committee" means a body comprising of a group of persons recognised and registered by the Committee for the purpose of control and supervision of

experiments on animal performed in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the Committee;

(i) "specified format" means the form specified for the purpose by the Committee from time to time.

- **Rule 3 - Breeding of animals:**

Note: This rule makes it illegal to be involved in activities where animals are bred and traded for experiments, unless the breeder or establishment is registered.

Sub-rule (b) states that is mandatory for every breeder or establishment carrying on such business to apply for registration within sixty days from the commencement of these rules. Further, if the Committee refuses to register them, they are not permitted to carry on these activities.

(a) No establishment shall carry on the business of breeding of animals or trade of animals for the purpose of experiments unless it is registered.

(b) Every breeder/establishment carrying on the business of breeding animals or trade of animals for the purpose of experiments, shall, apply for registration within sixty days from the date of commencement of these rules and, stop breeding of animals if registration is subsequently refused to it by the Committee.

- **Rule 4 - Registration of establishments:**

Note: This rule expressly prohibits all establishments from experimenting on animals unless they are registered. Sub-rule (b) states that it is compulsory for every establishment that conducts experiments on animals to apply for registration within sixty days from the commencement of these rules. Further, if the Committee refuses to register them, they are not permitted to carry on these activities.

(a) No establishment shall perform any experiment on animals unless it is registered.

(b) Every establishment performing experiments on animals, shall, apply for registration within sixty days from the date of commencement of these rules and, stop performing experiments on animals if registration is subsequently refused to it by the Committee.

- **Rule 6 - Details of the experiments conducted:**

Note: This rule makes it mandatory for every registered establishment to keep a daily record which notes the details of animals being experimented on.

(a) Every registered establishment shall maintain a register of particulars about the animals used from day to day for conducting experiments, with the number of animals, the species, the age, gender and other relevant particulars

- **Rule 7 - Stocking of animals:**

Note: This rule is extremely significant as it mandates that the breeder or establishment follows certain standards by which the animals must be kept. Sub-rule (a) states the requirement of a quiet atmosphere which is undisturbed by traffic noises. It also directs institutions to maintain a hygienic premises where the animals will be safe from all weather conditions.

Sub-rule (b) states that whatever cages or stables are being provided must be allotted such that the animals occupying them are comfortable. It expressly states that overcrowding must be avoided.

Sub-rule (c) states that if standards for cages have been set down by the Indian Standards Institution, then these must be followed.

Sub-rule (d) makes it mandatory to have trained animal attendants who are well-versed in their duties.

Sub-rule (e) requires that animals should be looked after both before and after the experiments are conducted by a trained and experienced attendant.

Sub-rule (f) states that animals must be looked after even on holidays and off-hours, and the establishment must make arrangements for the same.

Sub-rules (g) and (h) state that breeders and establishments must follow the Committee's species-specific directions regarding the food, housing and maintenance. Until specifications are notified, the Indian National Science Academy Guidelines must be followed.

The animals shall be stocked by the breeder and the establishment in the following manner:-

(a) animal houses shall be located in a quiet atmosphere undisturbed by traffic, and the premises kept tidy, hygienic and the animals protected from drought and extremes of weather;

(b) animal cages for small animals and stables for large animals shall be such that animals can live in comfort and overcrowding is avoided;

(c) where standards have been laid down by the Indian Standards Institution, the cages, the stable, as the case may be, shall conform to those standards;

(d) animals attendants must be suitably trained and experienced in the duties allotted to them,

(e) animals shall be looked after, before and after the experiments by a trained and experienced attendant;

(f) there shall be satisfactory arrangement for looking after the animals during off hours and on holidays

(g) detailed specifications for housing, feeding and maintenance of various species to be used in animal experimentation as notified by the Committee, shall be adhered to by the registered establishment.

(h) In the Interim period till such detailed specifications are notified, the breeders and establishments shall comply with the Indian National Science Academy Guidelines.

- **Rule 8 - Permission of the Committee required for conducting experiments:**

Note: Sub-rule (a) states that every registered establishment must apply for permission of the Committee before experimenting on any animal. Even before an establishment gets an animal for experimentation, it must first be given permission by the Committee.

(a) Every registered establishment before acquiring an animal or conducting any experiment on an animal/animals shall apply for permission of the Committee or the Institutional Animals Ethics Committee recognised for the purpose by the Committee along with the details contained in the specified format to the Member Secretary of the Committee or the Institutional Animals Ethics Committee, as the case may be.

- **Rule 9 - Performance of experiments:**

Note: This rule governs the actual experiment being conducted on each animal. A failure to implement any of the following violates these rules under the PCA.

Sub-rule (a) states that all experiments can only be performed by or under the supervision of a qualified person.

Sub-rule (b) directs the conduct of all experiments with reasonable care, caution and compassion expected from a normal human being towards the animal.

Sub-rule (bb) is extremely significant as it states that only the animals who are lowest on the phylogenetic scale must first be considered for experimentation before larger, more evolved creatures are taken for experimentation. This sub-rule also mandates that the number of animals being tested on must be kept to a minimum. The proviso to this sub-rule also states that while it is permitted to experiment on animals, it is mandatory to consider alternative methods which do not involve the use of animals first. If such alternatives do exist, then the establishment has to adequately justify why it still requires experimentation on animals.

Sub-rule (c) mandates that animals are sufficiently looked after both before and after the experiments.

Sub-rule (cc) holds the personnel of the establishment responsible for the welfare of the animals during the experiment. An animal must not be euthanised unless the conditions in sub-rule (ff) are met. The animal must be rehabilitated and provided sufficient aftercare following the experiment and these costs shall form part of the research costs of the establishment. This sub-rule also mandates that the establishment is responsible for the rehabilitation of animals after experiments such that the animal is once again able to lead a normal life expected of its species' life span, and the establishment shall provide the necessary monetary amounts to ensure the same.

Sub-rule (d) expressly mandates the use of anaesthesia for all operative procedures except vaccinations (inoculation) or superficial withdrawing of blood or introducing fluid (venesection). Anything more complex, including a more invasive version of venesection must be performed with sufficient anaesthesia, else they cannot be performed.

Further, only a trained veterinary surgeon or a scientist or technician who is specially trained can administer the anaesthesia and they must remain present throughout the experiment to ensure that the animal does not feel pain.

Sub-rule (e) directs that animals who are anaesthetised and then get irrecoverably injured during the experiment must be killed in a merciful way. They can only be killed while they are still under the influence of anaesthesia.

Further, all animals which will have to endure a painful recovery from the experiment must also be spared such pain and destroyed in a humane manner.

Sub-rule (f) mandates that in all cases where there is reason to believe that the animal is suffering abnormal pain while an experiment is being conducted, the animal must be mercifully killed while under the influence of anaesthesia so that it cannot feel any pain. This sub-rule prohibits the experiment from being further conducted on the animal.

Sub-rule (ff) provides the only situations wherein euthanasia is permissible, namely, where an animal is paralysed, unable to perform its natural functions, unable to move by itself, or mentally incapable of perceiving the environment around it in a normal manner.

Further, where the experiment conducted causes the animal recurring pain or where the animal is clearly seen to be suffering in pain, then this sub-rule states that it is mandatory to euthanise such animal to end its pain and suffering. Additionally, in a situation where the animal becomes violent or threatens humans or animals around it, it must be euthanized.

Sub-rule (g) prohibits experiments being performed for practice to enhance skill. Only schools, colleges and programmes which are permitted by the Committee in recognised establishments.

Sub-rules (h) and (i) prohibit experiments being performed for displays as examples, illustrations or public demonstrations.

Sub-rule (j) prohibits the use of paralysing agents. It can only be used with a proper amount of anaesthesia which is sufficient for the animal to lose consciousness and feel no pain.

Sub-rule (k) expressly prohibits experiments on animals where the results of the experiment are already known. Such experiment can only be repeated if it is justified prior to the conduct of the experiment.

Sub-rule (l) prohibits any experiment involving application of any chemicals to an animal's eye to test the absorption of pain through the eye.

Sub-rule (m) expressly prevents all experimental dogs from being debarked.

In conducting experiments on animals, regard shall be had to the following conditions, namely:

(a) experiments shall be performed in every case by or under the supervision of a person duly qualified in that behalf, that is, Degree holders in Medicine or Veterinary Science, Post Graduate and above in life Sciences/Pharmaceutical Sciences or any other natural sciences, Degree or Diploma holders in Pharmacy, Diploma or Certificate In Laboratory Animal Techniques Sciences from a recognized Institution as Identified by Committee for the Purpose of Control and Supervision of Experiments on Animals for the purpose and under the responsibility of the person performing the experiment;

(b) experiments shall be performed with due care and humanity;

(bb) animals lowest on the phylogenetic scale which may give scientifically valid results should be first considered for any experimental procedure and the experiment should be designed using minimum number of animals to give statistically valid results at 95% degree of confidence:

Provided that replacement alternatives not involving experiments on animals should be given due and full consideration and sound justification must be provided in case alternatives, though available, are not used;

(c) animals intended for the performance of experiments are properly looked both before and after experiments;

(cc) (i) personnel using experimental animals shall be responsible for the welfare of animal during their use in experiments;

(ii) investigators shall be responsible for the aftercare and rehabilitation of animal after experimentation, and shall not euthanise animals except in situations as defined in clause (ff);

(iii) costs of aftercare and rehabilitation of animal after experimentation shall be made part of research costs and shall be scaled in positive correlation with the level of costs involved in such aftercare and rehabilitation of the animals;

(iv) rehabilitation treatment of animals after experimentation shall extend till the point the animal is able to resume a normal existence by providing a lump-sum amount as costs for rehabilitation and care of such animal to cover its entire statistical expected life span; and

(v) the establishment undertaking experiments or duly licensed and authorised animal welfare organization under the control of the Committee may, on payment of lump-sum amount, undertake rehabilitation of animals;

(d) experiments involving operative procedure more severe than simple inoculation or superficial venesection shall be performed under the influence of anaesthetic to prevent the animal feeling pain and it shall remain so throughout the experiment. Anesthesia shall be administered by a Veterinary Surgeon trained in methods of anesthesia or a Scientist/technician so trained for this purpose and who shall remain present near the animal till the completion of the experiment;

(e) animals which in the course of experiments under the influence of anaesthetic are so injured that their recovery would involve pain or suffering shall be destroyed humanely while still under the influence of anesthesia;

(f) when there is reason to believe that an animal is suffering abnormal or severe pain at any stage of a continuing experiment, it shall be painlessly destroyed at that stage without proceeding with the experiment;

(ff) the following parameters shall be adopted for application of euthanasia, namely:-

(i) when the animal is paralyzed and is not able to perform its natural functions or it becomes incapable of independent locomotion or it can no longer perceive the environment in an intelligible manner; or

(ii) if during the course of experimental procedure the animal has been left with a recurring pain wherein the animal exhibits obvious signs of pain and suffering; or

(iii) where the non-termination of the life of the experimental animal will be life threatening to human beings or other animals;

(g) experiments shall not be performed for the sole purpose of attaining or retaining manual skill except in schools, colleges and programmes duly scrutinized and permitted in registered establishments by the Committee;

(h) experiments shall not be performed by way of an illustration;

(i) experiments shall not be performed as a public demonstration;

(j) no paralyzing agent, including but not limited to curare, shall be used or administered for the purpose of any experiment except in conjunction with anaesthetic of sufficient depth to produce loss of consciousness;

(k) no experiment the result of which is already conclusively known, shall be repeated without previous justification;

(l) there shall not be applied to the eye of an animal by way of experiment any chemical substance for the purpose of absorption through the conjunctival membrane or through the cornea calculated to only give pain;

(m) dogs held for experimental purposes shall not be debarked.

- **Rule 10 - Transfer and acquisition of animals for experiment:**

Note: Sub-rule (a) restricts the sale or similar transfer of animals by breeders only to establishments registered under these rules. Similarly sub-rule (b) restricts establishments to acquiring animals from registered breeders or alternate legal sources after acquiring the

permission of the concerned authority. Following such purchase or acquisition of animal, sub-rule (c) restricts the further sale or transfer by the acquiring establishment to registered establishments only.

Sub-rule (d) states that all animals which are experimented on in a production/breed improvement programme are permitted to be distributed to the public for the animals to be kept as pets domestically.

Sub-rule (e) permits the import of genetically defined animals only after acquiring permission of the Director General of a Foreign Trade where animals are not available within India. However, this does not apply to laboratory bred experimental rats and mice.

Sub-rule (f) makes it mandatory for breeders and establishments to follow all directions given by the Committee to control and supervise experimentation on animals.

(a) A breeder shall not transfer any animal by sale or otherwise to an establishment which is not registered under these rules.

(b) (i) an establishment shall acquire animal for experiments from registered breeders only;
(ii) in case of non-availability of animal from registered breeders, the animal may be procured from alternate legal sources;
(iii) in case the animal is procured from the alternate legal sources, the same shall be procured after taking written permission from the authority competent under the law for the time being in force, to give such permission; and
(iv) the establishment procuring such animal shall maintain a record in this regard and shall produce the same before the Committee, whenever required;

(c) Every establishment after acquisition of a animal or animals shall not transfer such animal or animals by sale or otherwise to any other establishment or person except to a registered breeder/establishment.

(d) The animals used for experimentation in a production/ breed improvement programme may be given out by the breeder institution for domestic use.

(e) In case an animal is not available from a registered breeder or from alternate legal sources within the country, genetically defined animals may be imported with permission of Directorate General of Foreign Trade:

Provided that the condition of non-availability within the country shall not apply for laboratory bred rats and mice of genetically defined strains;

(f) A breeder or establishment shall comply, with the directions given by the Committee for the purpose of controlling and supervising experiments on animals.

- **Rule 11 - Records:**

Note: This rule mandates the maintenance of records by establishments of its Institutional Animal Ethics Committee.

(a) Every, establishment/Institutional Animals Ethics Committee shall maintain a record of the animals under its control and custody in the specified format..

(b) Every establishment/Institutional Animals Ethics Committee shall furnish such information, as the Committee may from time to time require in the specified format.

(c) All laboratories shall inform the exact number/ species of animals to the Member Secretary or any officer authorised in this regard by the Committee as per the specified format.