

ANIMAL EXPERIMENTATION LAWS IN INDIA

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ABSTRACT

Animals play a major role in human existence. Animals are used for pharmaceutical research to acknowledge diverse forms of human and animal diseases and moreover for anticipation and treatment of it. Since there are no other methods, animals are still being used for enhancing health conditions of humans and animals. The laws for experimentation on animals are laid down under the provisions of Prevention of Cruelty to Animals Act (PCA), 1960 and the Breeding of and Experimentation on Animals (Control and Supervision) Rules, 1998. The laws are executed by "The Committee for the Purpose and Supervision of Experiments on Animals"(CPCSEA), it is a legal body established in the year 1964 under Chapter IV, Section 15(1) of PCA Act. The main aim of the committee is to make sure the animals are used in research judiciously. Unfortunately, even after all these provisions the issue related to the behaviour of animals and lack of adequate facilities to animals still persists. This article discusses the provisions, ethics and regulations related to Animal Experimentation in India. It also provides information about the functions played by the various committee in protecting the animals from severe pain and suffering and further discusses the relevant changes made in the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998.

Keywords: Animal Experimentation; Animal Testing; Laws in India; PCA Act; CPCSEA; IAEC

INTRODUCTION

Animals have been used over and over again by the researchers all-round the history for medical research. In British period, Colesworthy Grant initiated the first Indian Society for the Prevention of Cruelty to Animals (SPCA) in 1861 in Calcutta but it didn't last long in India. After Independence, a centre was evoked for the first time in Mumbai in the year 1957 solely for laboratory animal science with the funding support of UNESCO before the Prevention of Cruelty to Animals (PCA) came into being. The centre was known as LAISC.

The aim of the centre was to provide better quality of animals for research work.

Later in 1960, the Prevention of Cruelty to Animals Act (PCA) was established. The Breeding of and Experimentation on Animals (Control and Supervision) Rules, 1988 under PCA Act lays down the obligations for using the animals for research work. The Committee for the Purpose and Supervision of Experiments on Animals (CPCSEA) initiated in 1964 executes the laws. Many establishments have come up with the stern decision, guidelines and recommendations to be followed for experimentation on animals. India now has numerous institutions, provisions and laws that protect the rights of animals and ensures them adequate facilities.

Animal experimentation is reasonable from the scientific point of view. Till today, there are no other methods to replace the system and thus animals are still being used for understanding biological system of humans and animals.

Prevention of Cruelty to Animals Act 1960 (PCA)

The laws related to Animal Experimentation come under Chapter IV, Sections 14 to Section 20 of the PCA Act. Also, the act provides punishment for causing unreasonable pain harm and suffering to animals.

THE COMMITTEE FOR THE PURPOSE AND SUPERVISION EXPERIMENT ON ANIMALS

It is a legal body established by the Government of India in 1964 under Chapter IV, Section 15(1) of the PCA Act. Its main is to protect the animals from unnecessary pain and provide

them with adequate facilities. It promotes the 4R principles *Replacement* of animal testing with any other method, *Reduction* of the number of animals used for experiments, *Refinement* of pain and suffering during experiments, *Rehabilitation* after experimentation of animals in accordance with the norms laid down under the act. To fulfill the purpose of CPCSEA The Breeding of and Experiments on Animals (Control and Supervision) Rules was instituted.

ROLE OF CPCSEA

All the institutions that are occupied for education and research involving animals have to stick by the guidelines, rules and regulations laid down by the CPCSEA.

The main roles performed by CPCSEA are:

1. to register the institutions that are involved with animal experimentation and breeding.
2. to select and appoint applicants in the IAEC of registered institution.
3. to approve Animal House Facilities in accordance with the inspection reports carried out by CPCSEA.
4. to take action against institutions if any of the rule is violated.
5. to grant permission for performing experiments involving animals.
6. To approve the import of animals for experimental use.

ETHICAL PRINCIPLES TO BE FOLLOWED BY CPCSEA

Principle 1- The experiments on animals to be carried out only for the following reasons

1. To make discoveries in physiological knowledge
2. To acquire knowledge that would be useful in improving, saving, prolonging human life
3. To find cure for a disease (the disease might be of plant animal or humans)

Principle 2- The animals that are capable of dealing with major pains should be used for experimentation. Animal testing is to be avoided if an alternative technique exists. But if even after the availability of alternate method, the animal is used for the experiment, the decision should have a strong justification.

Principle 3- Minimum pain to be caused to the animal during an experiment should be the priority. The appropriate sedation or anesthesia is to be used if the pain is to last for more than a moment or a short span. Animals must be treated equal to humans when it comes to deciding on suffering pain.

Principle 4- The examiners shall be responsible for the aftercare and rehabilitation of animals after experimentation and the cost for aftercare and rehabilitation shall be a part of research costs. Animals may be allowed to euthanize if

1. the animal is physically or mentally disabled and is unable to perceive the environment in accessible manner.
2. the animal has suffered severe pain during the process of experiment and there is chance of the pain to last long.
3. In situations where non-termination of the animal experimented upon would be life threatening to human beings or other animals.

Principle 5- The living condition should be acceptable for the species and contribute to their wellbeing. The animals must be handled by the trained scientist or veterinarian for biomedical purposes.

PRIME RULES OF BREEDING OF AND EXPERIMENTS ON ANIMALS (CONTROL AND SUPERVISION) RULES, 1998 HAVE BEEN DISCUSSED BENEATH

Rule 2(e) defines the word 'Experiments' as a scientific test carried out on animals for the accession of knowledge of biological, anatomical, ethological, physical and chemical nature. Moreover animals can be used for

1. Producing chemicals, allergens and immunizers
2. routine diagnostics
3. trial activity
4. establishment of transgenic stocks
5. for the purpose of saving or prolonging life of humans
6. for fighting any disease, whether of human beings, animals or plants.

Rule 4 states that Institutions shall perform any experiment on animals only after its registration with CPCSEA. If the registration is refused by CPCSEA, the institutions shall stop performing experiments on animals or breeding of animals for experiments.

Rule 9 (cc) states that the examiners shall be responsible for the aftercare and rehabilitation of animals after experimentation and the cost for aftercare and rehabilitation shall be a part of research costs.

Rule 10 states that:

- (i) a breeder shall not transfer or acquire any animal by sale or otherwise except from a registered breeder/establishment
- (ii) the animals can be acquired by the alternate legal sources if the animal is not available with the registered breeders
- (iii) the acquiring of animals from alternative legal sources is possible only after taking written permission from the appropriate authority. Any other method that enables non-usage of an animal must be given the priority but even after the availability of alternate method, the animal is used for the experiment, the decision should have a strong justification.

Rule 14 specifies when can CPCSEA revoke a registration The registration of the establishment will be revoked if the Member Secretary's or the authorized officer's report proves that the rules are not been followed by the breeder or the establishment and the directions given to avoid such violation haven't been implemented.

Provided that the establishment or breeder gets the opportunity of being heard in the manner. Provided further that no order of revocation of registration or ceasing of animal house facility shall be issued for minor violation. Minor violation is an act which does not affect the health of animals adversely or cause them severe pain or death.

INSTITUTIONAL ANIMAL ETHICS COMMITTEE (IAEC)

IAEC is a body that consists of group of people admitted and registered by the committee (CPCSEA) for managing the experiments on animals performed in an institution which is carried out in accordance with the rules and guidelines laid down by the committee for the purpose. IAEC will analyze and approve all types of research work which involves small animal experiments before the study starts whereas for large animal experiments, the case will be redirected to CPCSEA.

IAEC is required to keep a check on the entire process of study and after completion of the study. Also it has to visit the place where the experiments are done. The IAE Committee has to strictly stick to the guidelines, rules and laws.

MAIN FUNCTIONS OF IAEC

1. IAEC grants standard and uniformity in evaluation of research proposals and to protect the animals from severe pain and ache prior, in course of and after experiments on animals, to follow the guidelines of CPCSEA.
2. IAEC evaluates and then permits all the proposals of research that includes experiments on animals, up to phylogenetic level of Coney and leverets only, with a aim of maintaining standard and well being of animals used in pre-medical research.
3. IAEC makes sure that the experiment is performed by or under the supervision of a well educated person in the medical field and under the control of chief inquisitor. The minimum qualification required for performing the experiment by the person is Bachelor of Veterinary Science/Human Medicine or Post grad in life

sciences/Pharmaceutical sciences/Lab animal science. The person performing the experiment must be a well trained in animal testing.

4. IAEC ensures that the animal housing is as per the standards mentioned in the guidelines.
5. Ensures that the experiments on animals are avoided wherever it is possible to do so. It also promotes the 3Rs Principles i.e. Replacement, Reduction, Refinement.
6. Ensures that if the required result can be achieved by performing the experiment on small animal than experiment of large animal is avoided.

ORGANIZATIONS THAT HAVE COME WITH UP STRICT GUIDELINES

Under Rule 17(d) of the PCA Act which states the animal testing should be avoided where it is possible to do so for example in medical colleges, hospitals etc, many establishments have come up with stern guidelines which is binding on all the institutions involving animals.

University Grants Commission (UGC): It ordered all the institutions, colleges registered establishments under UGC to avoid animal testing in th anatomical, physiological, zoological study & to ban the animal autopsy and experimentation in the study of pharmacy and life sciences at undergrad and post grad level.

Medical Council of India (MCI): MCI in its gazette said that an animal house can be maintained by the pharmacological department and this central animal facility is not required is not needed. The guidelines of MCI were confusing and contradicting with regard the UG teaching of pharmacology and thus all the colleges instituted animal houses with CPCSEA license. They try to keep them active at least on inspection days. The guidelines of MCI should be re-examined and necessary changes should to be made.

Pharmacy Council of India: It has also ordered the institutions under PCI to get registered with CPCSEA and to strictly abide by the rules and guidelines of CPCSEA on experimentation on animals. Animal autopsy has been banned at the graduation level.

ADDENDUM

The Consultative Group recommended applicable changes in the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended. The changes were debated and discussed and aptly included after the Consultative group report was taken in by CPCSEA. The changes are briefly discussed below.

1. Rule 2(e) changes- The definition of the term experiment was broadened to insert the term 'remarkable profits for the well being of the people of the country' as additional norm that justifies the experimental use of animals.
2. Addition of Rule 9(bb)- This insertion issues that the preference should be in accordance with least number of animals, minimal in phylogenetic scale, that gives valid results statistically. If there is an alternative method than the animal testing is to be avoided, but if even after the availability of alternate method, the animal is used for the experiment, the decision should have a strong justification.
3. Rule 10(e) amendment- This grants permission to the institutions to acquire animals from any lawful source in case the animals are not available with the registered breeder with proper documentation process to make the procurement legal.
4. Rule 10(e) amendment- This grants permission to the institutions to import animals that are genetically determined with the consent of DGFT, in case of non availability of such animals with the registered breeders or other lawful sources in the country. This order of non availability is not applicable to genetically defined rats and mice.
5. Rule 12 amendment- This rule has been adopted to allow the institutions to take up the contract research as per the guidelines of the PCA Act 1960 and the rules and regulations made hereby.
6. Rule 14 amendment- This rule has been adopted to permit CPCSEA to take necessary action against an institution or breeder in case any rule or norm is violated according to the Member Secretary or authorized officers report. If there's any major violation then in that case CPCSEA may write orders to suspend or remove the registration of the institution and/or order to close the Animal House Facility, after hearing from the

7. other side.

CONCLUSION

India became the first country to ban the use of animals for cosmetics experimentation and the import of products that are animal tested. It has also banned the use of live animals in medical field. It's unfortunate to note that even after these many provisions are there to protect the animal rights, officials have been using various ways to escape the law to continue with illegal testing and use of animals in an abusive manner. It is high time that a lot of serious de jure binding steps should roll out in the society and market. Also there's a demand to develop the proper facilities to provide better quality animals for research work. The needs of health research are increasing and growth of medical field will continue to depend on animals in future also. The establishments in India are not even able to meet 20% of the requirement. There is need for everyone to feel the responsibility towards animals and to come up with more and more admissible terms and alter the policies of institutions to build up the requirements for existing 4R's Replacement, Reduction, Refinement, Rehabilitation.

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