

Animal Welfare

The greatness of a nation and its moral progress can be judged by the way its animals are treated

- Mahatma Gandhi (Mohandas Karamchand Gandhi, 1869-1948)

1. DEFINITION

Animal welfare is defined as the well-being of animals. The well-being of animals is again defined by many people, organizations and societies in different ways. The indicators of animal welfare are the longevity, health, behaviour, physiology, immunity, reproduction, expressions etc. The concerns of animal welfare are that non-human animals are sentient like human beings and care should be given for their need, health and well-being.

1.1 Principles of Animal Welfare

The principles of animal welfare may be best understood by the five freedoms of animals. The World Health Organization for Animal Health (OIE) recognises the following five internationally recognized freedoms for animals:

- i. Freedom from thirst and hunger – by ready access to fresh water and a diet to maintain full health and vigour
- ii. Freedom from discomfort – by providing an appropriate environment including shelter and a comfortable resting area
- iii. Freedom from pain, injury, and disease – by prevention or rapid diagnosis and treatment
- iv. Freedom to express most normal behaviour – by providing sufficient space, proper facilities, and company of the animal's own kind
- v. Freedom from fear and distress – by ensuring conditions and treatment which avoid mental suffering

An animal's primary welfare needs can be met by safeguarding the above mentioned five freedoms. The animals can live a natural life, fit and healthy by advocating these five freedoms.

1.2 Animal Welfare Vs. Animal Rights

The animal welfare philosophy endorses the responsible use of animals to satisfy certain human needs. Animal welfare means ensuring that all animals used by humans have their basic needs fulfilled in terms of food, shelter and health, and that animals experience no unnecessary suffering in providing for human needs. Whereas, animal rights advocates do not distinguish between lives of human beings and animals. As per them, all lives are equal. When the needs of humans and animal lives come into conflict, animal rights advocates put the animals first.

1.3 Balancing the welfare and the rights

The governments put their efforts to balance the animal welfare and animal rights through various regulatory bodies, associations and societies. In India, the Animal Welfare Board of India (AWBI) and Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) under the Ministry of Environment, Forest and Climate Change (MoEF&CC) oversee the animal welfare issues through the Acts of Parliament.

2. ANIMAL WELFARE IN INDIA

The Animal Welfare in our country is monitored by India's first national animal welfare law, the Prevention of Cruelty to Animals Act (PCA Act), 1960, which makes cruelty to animals a punishable offence, though exceptions are made for the treatment of animals used for food and scientific experiments. The PCA Act, 1960, is administered by Animal Welfare Division presently under the Ministry of Environment, Forest and Climate Change (MoEF&CC). Subsequent laws have placed regulations and restrictions on the use of draught animals, use of performing animals, animal transport, animal slaughter, and animal experimentation. The PCA Act, 1960 has also established the Animal Welfare Board of India and the Committee for the purpose of Control and Supervision of Experiments on Animals to ensure the anti-cruelty provisions are enforced and promote the cause of animal welfare.

2.1 Animal Welfare Board of India (AWBI)

The Animal Welfare Board of India is a statutory advisory body advising the Government of India on animal welfare laws, and promotes animal welfare in the country. It is located at Thiruvananthapuram in Chennai. It works to ensure that animal welfare laws in the country are followed and provides grants to Animal Welfare Organisations (AWOs). The Animal Welfare Board of India was established in 1960 under Section 4 of the PCA Act, 1960. Some of the functions of the board are recognition of AWOs, financial assistance to AWOs, laws and rules related to animal welfare and raising awareness of various animal welfare issues.

2.2 Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)

The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) was established under Section 15(1) of the Prevention of Cruelty to Animals Act 1960. CPCSEA is a statutory Committee, which is duty bound to take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pains or suffering *before, during or after* performance of experiments on them. For this purpose, the Committee formulated the "Breeding of and Experiments on Animals (Control & Supervision) Rules, 1998" (*amended in 2001 & 2006*) to regulate the experimentation on animals.

Under the provisions of the above rules, establishments who are engaged in Bio-medical research are required to get themselves registered with CPCSEA, constitute Institutional Animal Ethics Committee (IAEC), get their Animal House Facilities inspected, and also get specific projects for research cleared by IAEC (in case of small laboratory animals) or CPCSEA (in case of large animals) before commencing them. Further, breeding and trade of animals for such experimentation are also regulated under these Rules.

The present CPCSEA at Animal Welfare Division, Ministry of Environment, Forest and Climate Change, New Delhi consists of the Special Secretary (MoEF&CC) as Chairman, Joint Secretary (Animal Welfare) as Vice Chairman and Deputy Secretary (Animal Welfare) as Member Secretary. The other members include Director, National Institute of Animal Welfare (NIAW), Drug Controller General of India, experts/ officials from Medical Council of India (MCI), Veterinary Council of India (VCI), Pharmacy Council of India (PCI), University Grant Commission (UGC), Wildlife Institute of India, Institutes under Department of Biotechnology (DBT), experts from Medical and Pharmacy Colleges, experts from Universities (Biotech, Zoology, Life sciences etc.).

Mandates of CPCSEA:

- Registration of establishments conducting experiments on animals.
- Registration of establishments engaged in Breeding of Laboratory animals.
- Constitution of Institutional Animals Ethics Committees (IAECs) in the establishments registered.
- Approval of Animal House Facilities for Small and Large animals.
- Permission for conducting experiments on large animals.
- Recommendation for import of animals for experimentations and breeding.

3. ANIMAL EXPERIMENTATION IN INDIA

3.1 Rules and Regulations

The Prevention of Cruelty to Animals Act, 1960 regulates the power and duties of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA). The CPCSEA is thus a statutory body constituted by the Government of India, with the sole purpose of controlling and supervising experiments on animals. The PCA Act, 1960 lays down the duty of the CPCSEA as "to take all such measures as may be necessary to ensure that animals are not subject to unnecessary pain or suffering before, during or after the performance of experiments on them". The Government has notified the "Breeding of and Experiments on Animals (Control & Supervision) Rules 1998 (amended in 2001 and 2006)", to ensure humane and ethical use of animals in research and education. The CPCSEA has enabled the creation of a common platform for recourse and discussion between scientists, policy makers and animal activists by way of which the CPCSEA works for humane and progressive solutions in the use of animals in research.

3.2 Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 (as amended in 2001 and 2006)

These rules published in 15th November 1998 and amended in 2001 and 2006, emphasize on the registration of establishments prior to conduct of experimentation and breeding, inspections of the animal house facilities, maintenance of registers for documenting information in the animal house facilities, housing conditions for the animal house facilities, permission for conduct of experiments from IAECs and CPCSEA, conditions for the conduct of experiments, conditions for breeding animals, conditions for undertaking contract research, composition of Institutional Animal Ethics Committee and Power of CPCSEA to suspend or revoke registration of any establishment.

3.3 CPCSEA Guidelines for laboratory Animal Facility

The CPCSEA brought the guidelines for laboratory animal facility in 2003 (aiming the implementation of Good Laboratory Practices) for animal facilities which are intended to assure quality maintenance and safety of animals used in laboratory studies while conducting biomedical and behavioural research and testing of products. The goal of these Guidelines is to promote the humane care of animals used in biomedical and behavioural research and testing with the basic objective of providing specifications that will enhance animal wellbeing, quality in the pursuit of advancement of biological knowledge that is relevant to humans and animals.

3.4 Standard Operating Procedures (SOP) for Institutional Animal Ethics Committees (IAEC)

The CPCSEA released SOP for IAECs in January 2010, which contains the Standard Operating Procedures for Institutional Animal Ethics Committees. The Rules for Breeding of and Experiments on Animals (Control & Supervision) permit Institutional Animal Ethics Committee (IAEC) of the establishments to permit the experiments on small animals. Only proposals for conducting experiments on large animals are required to be sent to CPCSEA for approval. Accordingly, it is important that all the IAEC members are fully aware of the extant rules and guidelines. The approvals given by IAEC's which are not in accordance with the extant rules are invalid. This document is a step to apprise the IAEC members about the rules and guidelines and provides a compilation of the same and would serve as an important document for all IAEC's. It also describes the objectives, role of IAEC, formation, procedure in which the meeting are to be conducted and other relevant information like decision making, reporting, record keeping etc.

3.5 Ethical Principles of CPCSEA for use of animals in scientific experiments

Principle 1: "Experiments on animals" (including experiments involving operations on animals) may be carried out for the purposes of advancement by new discovery of physiological knowledge; or of knowledge which is expected to be useful for saving or prolonging human life or alleviating suffering; or for significant gains in the wellbeing for the people of the country; or for combating any disease, whether of human being, animals or plants.

Principle 2: Animals lowest on the phylogenetic scale (i.e., with the least degree of sentience), which may give scientifically valid results, should be used for any Experimental procedure. Experiments should be designed with the minimum number of animals to give statistically valid results at 95% level of confidence. Alternatives not involving animal testing should be given due and full consideration and sound justification provided, if alternative, when available, are not used.

Principle 3: Proper use of animals in experiments and avoidance or minimization (when avoidance is not possible) of pain and suffering inflicted on experimental animals should be an issue of priority for research personnel, and unless the contrary is scientifically established, investigators should proceed on the basis that procedures that cause pain or suffering in human beings will also cause similar pain or suffering in animals. All scientific procedures adopted with animals that may cause more than momentary or slight pain and/or suffering should be performed with appropriate sedation, analgesia or anaesthesia.

Principle 4: Persons engaged in animal experimentation have a moral responsibility for the welfare of the animals after their use in experiments. Investigators are responsible for the aftercare and/or rehabilitation of animals after experimentation, and may be permitted to euthanize animals only in the following situations: (a) When the animal is paralyzed and is not able to perform its natural functions; it becomes incapable of independent locomotion; and/or can no longer perceive the environment in an intelligible manner. (b) During the course of experimental procedure the animal has been left with a severe recurring pain and the animal exhibits obvious signs of long term extreme pain and suffering. (c) In situations where non-termination of the animal experimented upon would be life threatening to human beings or other animals. Costs of aftercare and/or rehabilitation of animals post-experimentation are to be part of research costs and should be scaled per animal in positive correlation with the level of sentience of the animals.

Principle 5: The living conditions of animals should be appropriate for their species and contribute to their health and comfort. The housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist in a relevant discipline who is trained and experienced in the proper care, handling, and use of the species being maintained or studied. In all circumstances, veterinary care shall be provided as necessary.

4 CONDUCT OF ANIMAL EXPERIMENTS

4.1 Definition of 'Experiment'

As per rule 2(e) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 "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 the well-being for people of the country or for combating any disease, whether of human beings, animals or plants.

4.2 Why are animals being used in experiments and research?

The animals are used in research because very limited number of studies can be done on humans, their physiology/anatomy can be matched to humans, animals are mostly susceptible to the diseases that affect humans, the short life span allows animals to be studied throughout their entire life in a limited period, it also allows controlled experiments and environmental variables can be minimized. The dosage/route of exposures can be controlled/ varied and the experiments can be replicated. Animal experimentation is used in several areas of biomedical research and product testing, developing new treatments for diseases, or ways of preventing diseases, fundamental biological and medical research, safety testing of non-medical products used in the household, agriculture and industry, developing new methods of diagnosis.

4.3 Points to be taken care off while using animals in Research:

The drug/ substance to be tested for the first time in animals should be for specific purpose. The detailed literature review and comparison of data available on previous studies should be done. Wherever possible, computational modelling, simulations or *in silico* analysis should be carried out. The *in vitro* assays with cell lines/ tissue culture should support the desired activity/ experiment to be conducted in animals. The *ex vivo* studies with organs collected from slaughter houses or culling animals may be used, wherever feasible avoiding live animal experiment. All the animal experiments need the approval of IAEC or CPCSEA as the case may be. Required training and education on the handling care, and use of animals is mandatory. All research using animals must adhere to scientific, institutional, and governmental principles, policies, laws, regulations and guidelines. It is ethical and moral responsibility of each researcher for the lives of animals. Researchers are responsible for quality of animal care, appropriateness of animal use and minimization or relief of pain and distress.

4.4 Why to use animals in Education?

The path to quality research is via excellence in higher education. Primarily due to generous funding from the Govt. of India, last two decades have witnessed a surge in high quality research in the field of life sciences, emanating from various state and central universities. With a view to build on this foundation, India will need a strong force of talented students capable of facing the challenges in basic as well as applied biology. On the global scenario, India is rapidly emerging as a hub of intense activity in the field of (a) contract research for drug discovery, (b) preclinical screening of potential drugs for life-style and neurodegenerative diseases, (c) drug toxicology, and (d) generation of transgenic animal models for use in research. In all these studies, application of *in vivo* animal models is indispensable, and there is a pressing need for personnel trained to handle live animals and perform complicated surgical procedures. To this end, the use of laboratory bred rodents is a basic necessity that must be met with in the institutions of higher learning, as practiced in renowned universities across the world. The students need to be sensitized to the moral and ethical issues in the use of the animals, and also be trained to work in strict compliance of CPCSEA norms.

4.5 Which are the experimental animals subject to regulations?

Most of the animals that are being used for experimentation are under the purview of CPCSEA. Anything higher than invertebrates in terms of level of sentience requires regulation. Thus rats, mice, birds, fishes and farm animals are all subjected to regulation. The relative sentience of different species of animals is as follows:

Invertebrates (e.g. cockroaches) < Birds < Rodents < Canines/Felines < Bovine/Equines < Primates (e.g. Rhesus Macaque) < More evolved Primates (e.g. Chimpanzee)

The 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 with the minimum number of animals to give statistically valid results at 95% degree of confidence. 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.

4.6 The 3Rs (Replacement, Reduction and Refinement)

The Three Rs (3Rs) in relation to science are guiding principles for more ethical use of animals in testing. They were first described by W. M. S. Russell and R. L. Burch in 1959. The 3Rs are (1) Replacement: methods which avoid or replace the use of animals in research, (2) Reduction: use of methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals. (3) Refinement: use of methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals used.

The concept of the 3Rs - Reduction, Refinement and Replacement has paved way to the concept of "Science of Alternatives" which brings finest discoveries in *in vitro* technologies.

4.7. The 4th R (Reuse and Rehabilitation)

The concept of Rehabilitation has been recognised in India as the 4th R and evolved as an official policy of the CPCSEA in 2004. It is defined as "the aftercare rendered to animals that have been (i) bred for the purpose of experimentation (ii) subject to any form of experimentation (iii) retained in laboratory animal houses or breeding houses for the purpose of experimentation, both for education and research, with the sole intention of alleviating the pain/distress or suffering due to the physical, physiological and psychological trauma that the animals have been exposed to and to provide the animal a life distinctly different from laboratory housing and care, until the point of natural death".

"Reuse" of laboratory animals is a term used where in, after completion of an experiment (experiment as defined in Breeding of and Experiments on Animals (Control and Supervision) Rules 1998 and as amended in 2004) an animal is used again in the same or a different protocol, where an unused animal would have equally sufficed to meet the objectives of the second/or subsequent use.

5. EDUCATION AND TRAINING ON ANIMAL WELFARE IN INDIA.

5.1 National Institute of Animal Welfare (NIAW), Ballabgarh

National Institute of Animal Welfare (NIAW) is a premier training institute of the Government of India under the Animal Welfare Division in the Ministry of Environment, Forest & Climate Change functioning with the mandate of organizing and imparting training on diversified subjects in animal welfare. The main objective is to create a pool of qualified and technical personnel at each level to ensure proper implementation of the welfare of animal scheme and for fulfilment of the requirements and rules framed under the "Prevention of Cruelty to Animals Act, 1960. The trainings enable strict enforcement of the PCA Act at every level, be it in animal welfare or in animal experimentation in bio-medical field.

Different training programmes are generally conducted for CPCSEA nominees/ socially aware nominees/ IAEC members, pool of scientists, CPCSEA nominee's refresher courses, Honorary Animal Welfare Officers, B. Pharmacy and Veterinary students/interns, Gaushala workers, farmers, NGO workers etc. Besides these, trainings are also conducted for zoo keepers across the country and volunteers of Wild Life Crime Control Bureau.

Apart from NIAW the various courses on laboratory animal welfare are being run at different institutes at different levels of expertise like Tamil Nadu Veterinary & Animal Sciences University (TANUVAS), National Centre for Laboratory Animal Science, Hyderabad, CSIR- Mysore.