



## Regulatory Landscape Governing Animal Experimentation In India: An In-Depth Analysis

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### Overview

A contentious and complicated component of scientific study, animal experimentation raises ethical questions and calls for a careful balancing act between the advancement of science and the wellbeing of the animals. Several rules and regulations that guarantee moral behaviour control the use of animals in experiments in India. The advantages of scientific study are balanced against the moral concerns of animal rights in this article's critical analysis of India's current laws and regulations pertaining to animal experimentation.

"Animal testing is justified for the growth and study of science." This is a phrase that many of us have heard whenever someone tries to start a conversation about animal mistreatment and testing. Insofar as specific moral and humanitarian steps are made to guarantee the security of the animals that are handled like lab rats, then the answer is definitely justified. Regarding the section that defends using animals in research to advance science in the fields of health and technology, did you know that, out of 100 trials, 92 fail on people? This is because, as it should be evident, investigations that prove successful on animals will not necessarily be successful on humans. However, medical professionals and scientists contend that it is necessary to conduct these risky and, for the most part, pointless tests because, fact check, no People for the Ethical Treatment of Animals (PETA) has created awareness among the public to unite and vehemently reject the "mandatory need" for such painful experiments to be conducted on animals in order to resist the injustice and agony of the situation. However, have the objectives of these petitions, legal actions, and awareness campaigns improved the lives of the animals, and what is the most effective substitute for animal testing?

### Views on the use of animals in experiments

It may surprise you to learn that each year, approximately 100 million animals are slaughtered, maimed, burned, or crippled in labs for research, biology lessons, and medical experimentation. Most of them have to spend their entire lives breathing in toxic fumes to survive. Additionally, they receive strong chemical injections that result in aberrant patterns in their vital signs and are confined to equipment that restrict their range of motion. Because of the unnatural conditions in which they are kept, these should be disregarded. They are kept isolated from other animals in small, claustrophobic cages with no chance for socialization. This has a devastating and psychologically disturbing effect on the animal's mental state. Many of these animals die of mental anguish at the end of an experiment, not from pointless, never-ending investigations. To understand this, try visualizing yourself in a post-apocalyptic future where, instead of being afraid of zombies, the absence of human contact and social connection will probably drive you insane and force you to die. It is well known that when animals are isolated from their groups, their agitation levels increase.

### Some horrifying truths regarding animal testing

1. One of the reasons human experimentation is still done is because it is not only more costly but also more distressing for researchers—after all, what reasonable person would want to watch another human suffer as a result of their actions? However, animals are used as scapegoats since they are unable to communicate their anguish and misery. It is also a reasonably priced substitute.
2. Animals like dogs and cats are taken from the streets, including domesticated animals that may have strayed from their owners' homes, in order to continue the research project regardless of the quantity of animals that become "unfit," also known as sick or dying. This is to avoid unnecessary scandals and accountability.
3. When applied to people for ultimate use, 94% of effective animal experiments conducted for human benefit are unsuccessful.
4. In case you don't understand, let me explain. In many nations that still permit animal testing, torture, and the taking of human lives by cruel means, these practices are seen as morally and legally acceptable. The largest example of this is China, despite the fact that insiders have claimed otherwise despite the country not having any official records for the same.
5. Because monkeys are the closest animals to humans, they are frequently used in research to find cures for deadly illnesses like cancer and AIDS/HIV. However, the fact that monkeys have immune systems far stronger than human immune systems, which can counteract the effects of disease, is rarely considered, and it is instead assumed that the medication used to treat the illness has been effective. It is discovered years later, after the treatments have been

used on human patients, that the drugs were ineffective for the patients and had instead accelerated the disease's spread, leading to deaths.

It is a well-known truth that cosmetic and detergent goods undergo testing on mice and rats before to being finalized. It is unknown, nonetheless, that they are applied to their bare, hairless skin without the use of any analgesics to relieve burns or irritation.

Animal testing is not only unethical, but it has also shown to be quite ineffective in the disciplines of science and medicine, which intended to better prepare society to address the issues in their respective domains by abusing helpless, stupid animals for experimentation.

### **The real story of India's laws, rights, and animal testing**

Animal research is beneficial to many other disciplines of study as well; in fact, it is the primary cause of every significant advancement in the medical and scientific domains. The animal products industry makes a lot of money, yet their methods aren't always morally or legally acceptable. One such incident occurred in 1999 when PETA revealed the cruel nature of the Indian leather and meat trade. Smuggled cattle were almost pulled to the underworld and illegal slaughterhouses, where they were sold over state boundaries. On the endless trek, the cattle were not given enough food or rest breaks. If they stopped due to exhaustion or weakness, their tailbones were crushed, their tails were twisted, and chili powder was flung and rubbed into their eyes to prevent them from stopping. Furthermore, a number of government figures were implicated in offenses ranging from animal abuse to corruption. Since then, the Indian legislature has had to enact stricter laws to prevent future instances of this widespread abuse of authority and living things. Sadly, though, it is evident that despite the legal actions taken to ensure the security and well-being of the government and failed to hold the international medical associations accountable for their numerous tests on animals. However, as India does not yet have an artificial human simulator available as a substitute, it has been acknowledged that using animals in research is necessary. The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) established specific guidelines.

### **The Committee for the Regulation and Oversight of Animal Experiments (CPCSEA)**

The Central Government of India established the CPCSEA as a statutory body in accordance with Section 15(1) of Chapter IV, the Prevention of Cruelty to Animals Act, 1960. The committee's goal is to prevent unnecessary suffering or torture of animals. The regulations pertaining to breeding and experimenting were further implemented in 1998 to further fulfill this goal, and they have since been revised to maintain the laws current with the times and address any loopholes. The committee can carry out its responsibilities according to its protocol.

The Committee would be financially supported by periodic payments from the government. The Committee's funds are also open to gifts, donations, contributions, bequests, and the like from anybody.

The Ministry of Environment and Forests published rules in June 2007 for the regulation of scientific research on animals. The guidelines outline a number of ethical principles that the CPCSEA is expected to adhere to. These tenets are:

#### **Principle 1: Reason for doing the experiments**

Animal experiments may only be conducted for the following purposes:

- To aid in the advancement of physiology discoveries;
- To gather information that could be used to enhance, preserve, or extend human life;
- To considerably improve public health; and
- To discover a cure for a disease.

The illness may affect humans, animals, or plants.

#### **Principle 2: If there is a substitute, do not use animals in experiments.**

Animals utilized for experiments should be the least sentient, meaning they are not capable of feeling emotions other than pain. If an option was available but the experiment was nonetheless carried out on an animal, then the rationale behind the choice to include the animals in the experiments must be properly explained.

#### **Principle 3: Suitable anesthesia and sedation**

In an experiment, the goal of inflicting the least amount of discomfort on the animal must take precedence. When it comes to determining whether to cause pain, the animal must be regarded equally to humans. Researchers must act humanely, and if an experiment causes pain that will last longer than a few seconds, the animal must be given anesthesia or other suitable sedative. Animals must always be handled with the deepest respect and compassion.

#### **Principle 4: When is euthanasia permissible?**

Following the experiment on the animal, the animal must also get after-experiment procedures and welfare. The animal's care and restoration are the investigator's responsibility.

Only the following situations allow the investigator to decide whether to administer euthanasia:

- When the animal is suffering from severe, prolonged pain following an experimental procedure;

- When the animal is rendered physically or mentally incapable of functioning, perceiving the environment, or loses its sentience;
- When human lives are in danger because animals used in experiments are not put to death.

Rule 9(cc) of the Breeding of and Experimentation on Animals (Control and Supervision) Rules, 1998 incorporates this idea.

#### **Principle 5: Adequate living circumstances**

The animals' dwelling quarters ought to be appropriate for their kind. The animals must be handled by a qualified scientist or veterinarian in order to be used for biomedical purposes.

#### **CPCSEA's functions**

- Organizations that grow animals or carry out animal studies ought to register with CPCSEA.
- The selection of nominees for the registered institutions' Institutional Animal Ethics Committee.
- Authorizing animal facilities deemed suitable for housing animals based on CPCSEA inspection findings.
- Giving approval for studies involving animals.
- Endorsing the import of animals for use in research;
- CPCSEA has the right to take enforcement action against enterprises that violate this policy.

The 1998 Breeding and Animal Experiments (Control and Supervision) Rules were implemented in 1982.

The rules embody the principles and make registration with CPCSEA a necessity amongst other essentials. The important rules have been discussed below:

#### **What constitutes an experiment, defined**

- According to the definition of "experiment" in Rule 2(e) of the Rules, an experiment is any effort or program that uses animals. This kind of use is done to learn about subjects like biology, physiology, ethology, or anything chemical or physical.
- The animals can also be used for the following purposes:
  - producing reagents, which are substances or mixtures used in other reactions; producing antibodies or antigens;
  - conducting diagnostic and testing procedures; creating transgenic stock; saving and improving lives;
  - engaging in an activity that will significantly improve the nation's population's well-being; and
  - In an activity that will help come up with a cure for a disease related to human beings, plants or animals.

Any activity taken up for the fulfilment of any of the aforementioned objects would qualify as an 'experiment'.

#### **Rule 10: Purchasing Animals**

It specifies that:

- If registered breeders are not available, alternative legal sources must be found; and
- Animals for experimentation may be obtained from "registered" breeders.
- If purchasing from authorized sources, formal authorization from the relevant body ought to have been requested.

The replacement approach should take precedence if it permits the non-use of animals. In situations where an alternative approach is available but an animal is nonetheless employed for an experiment, the use of the animal must be strongly justified.

- Rule 14: CPCSEA Cancel an Establishment's Registration
- According to the Rules, CPCSEA may suspend or cancel an establishment's registration at any time:
- The Committee decides to suspend or revoke the establishment's registration if it is demonstrated in the report of the Member Secretary or the authorized officer that the establishment or a breeder is not abiding by the rules and that the directions provided by the Committee to address such a violation have not been followed.
- It is important to give the breeder or the establishment a voice.
- Revocation or suspension shouldn't happen for any little infraction. A minor infraction is any conduct that does not directly affect the animal's health or well-being or cause it to suffer, suffer, or endure any other unfavorable health condition or die.

#### **Committee on Institutional Animal Ethics (IAEC)**

In accordance with Rule 13 of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, this committee was established. The committee is made up of individuals whose primary responsibility is to monitor how the facility operates during an experiment. The case is sent to CPCSEA for large animal experimentation. The committee has a three-year term in office. The registration is meant to be recreated at the time of renewal. Six people make up the quorum.

In addition to including experts from diverse domains, the IAEC should include a member who is socially conscious and a nomination from CPCSEA. Meetings must always include a CPCSEA nominee in attendance. The meetings are handled by the chairperson, and in some circumstances, an alternate chairperson is appointed.

The minutes of the meeting must be prepared by the committee member secretary and forwarded to the member secretary of CPCSEA within 15 days of the meeting's completion in order for it to be deemed legitimate.

### **A few regulations issued by different authorities**

Many educational regulatory authorities introduced stronger regulations in response to the issue of animal mistreatment for study in educational institutions, as per Section 17(d) of the PCA Act.

### **Commission on University Grants**

In accordance with the Wild Life (Protection) Act, 1972 and the PCA Act, 1960, the UGC outlawed the usage, dissection, and experimentation on animals in colleges that teach undergraduate and graduate students courses on zoology, physiology, anatomy, etc.

### **Medical Council of India**

The guidelines issued by the MCI were confusing and contradictory regarding their stand on the matter. They had stated in their circular that they would continue with clinical aspects of teaching and at the same time, would have central or departmental animal houses. Due to this confusion, all colleges under the MCI have obtained a CPCSEA license to maintain the animal houses.

### **Council for Indian Pharmacy**

The notifications from the UGC and the PCI were similar. It had declared that the use of animals for dissection in educational institutions must end at the graduation level and that the use of animals for any purpose whatsoever is prohibited. Furthermore, clarification reinforced the notion that research with animals can only begin after a thorough inquiry and Institutional Animals Ethics Committee permission.

It's ironic that despite all of their efforts, India still ignores fields like research, technology, agriculture, and medicine where animal torture and mistreatment are commonplace. Animal experimentation in the cosmetic sector was outlawed by the Bureau of Indian Standards in 2013, and computer simulations and artificial intelligence were to take its place.

In 2016, the detergent and soap sectors were also subject to the prohibition. In the case of *Narayan Dutt Bhatt v. Union of India*, the Uttarakhand High Court rendered a historic decision in 2018 that "extended the rights of a living person to the animal kingdom" and declared animals to be legal entities. Does this not imply that animals should not be treated inhumanely, just as humans cannot and should not be exposed to such treatment? This ruling has, in some little way, contributed to the reduction of violations concerning the security and protection of animals.

### **To what extent are animal testing rules in India enforced?**

Positively, India has demonstrated progress in actively defending animal rights while upholding the interests of those involved in the process. Can they, however, be sustained long enough to reduce the number of abuse cases? The answer is "no," as demonstrated by the judges' discussion of "animal rights" in the 2018 Uttarakhand High Court ruling, but those rights were limited to those that "non-citizens" are granted, depriving animals of some extremely important rights that are reserved for citizens alone. Similarly, while some animal rights are protected, the means by which the humane rights can be upheld have been completely eliminated.

### **• A few legal protections and rights for animals**

- Compassion for all living things is a fundamental civic duty, as stated in Article 51A(g).
- Cosmetics tested on animals are prohibited from being imported under Rules 135B and 148C of the Drugs and Cosmetics Rules, 1945; killing or maiming any animal, including strays, is illegal under Sections 428 and 429 of the Indian Penal Code.
- Long-term chained or confined confinement of an animal without proper food, water, shelter, or exercise is illegal under Section 11(1)(h) of the PCA Act. The punishment for this offense is either a fine, up to three months in jail, or both.
- According to Section 9 of the Wild Life (Protection) Act, 1972, any animal that is caught, trapped, baited, or poisoned faces a fine of Rs. 25,000, a maximum of seven years in jail, or both.

All of these laws and regulations were put in place a long time ago, but they weren't implemented until recently, and even then, only after PETA's 1999 controversy revealed the existence of serious penalties. It is regrettable that India still conducts business with nations and provides funding to corporations who engage in such flagrant abuses despite the existence of such regulations. Even though there have been fewer instances of these violations since 2015, there is still a lack of transparency in the system as evidenced by a study that showed 90% of the animals in the labs' records for gathering information on animal subjects were left out because they were brought into the labs illegally. There are still loopholes in the system which allows for these figures to come up.

### **Critical Analysis:**

#### **1. Ethical monitoring:**

Although the creation of IAECs and CPCSEA is a good start, questions exist regarding the efficacy of ethical monitoring. There may be differences in the makeup and operation of IAECs, which causes irregularities in ethical assessments. Standardized procedures and greater transparency in these panels' decision-making processes are recommended by a critical review.

## 2. Regulations' Ambit:

The primary goal of the current legislative framework is to stop animal abuse during experiments. More thorough laws are nevertheless required to address the scientific validity of research, the reduction of animal exploitation through substitute techniques, and the open publishing of study findings. More laws are needed to ensure a balance between animal welfare and scientific advancement.

## 3. Encouragement of Alternatives:

The three R's (Replacement, Reduction, and Refinement) are internationally acknowledged as the best practices for morally sound animal testing. Although the 3Rs are included in the CPCSEA recommendations, more attention and incentives are required to encourage researchers to use alternative techniques, which will lessen the total reliance on animal testing.

## 4. Public Awareness and Participation:

These two factors are essential in determining how laws pertaining to animal testing are shaped. There are no tools in the current legal framework to promote public knowledge and engagement. A more comprehensive strategy incorporating the general public, animal welfare groups, and the scientific community may help to produce more thoughtful and impartial decisions.

## In summary

Unfortunately, despite the fact that laws have been passed to safeguard the rights and interests of animals, authorities have continued to abuse and test animals without permission by taking advantage of significant gaps in the system. Even though animal testing on cosmetics and soaps has been outlawed in India, imports of cruelty-free goods are not always carefully adhered to. India continues to purchase from China, where animals are being used in scientific, medicinal, and cosmetic experiments—many of which end in the animals' deaths. Additionally, foreign businesses that conduct business in India still use animals in their experiments, and certain universities that offer science and medical degrees agree. Additionally, there are still instances of animal maltreatment in the towns, villages, and smaller cities.

Legislators now need to concentrate on both Indian businesses and foreign corporations doing business in India, as well as on those who allowed the abusers to escape punishment. Not only should the person who commits the crime be punished, but also those who knew about it but chose not to report or complain. It is past time to implement numerous significant and all-encompassing legally-binding measures in the marketplace and society.

Although there is need for improvement, India's laws and regulations pertaining to animal research demonstrate a commitment to moral behavior. A critical examination emphasizes the need for a more thorough and open regulatory framework that takes ethical issues and scientific breakthroughs into account. Finding the ideal balance will benefit scientific research in India by enhancing its legitimacy and integrity while also ensuring the wellbeing of the animals used in experiments. Stakeholder collaboration is essential to addressing these issues and promoting a responsible and ethical culture surrounding animal testing.

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