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*Avinash Kumar has completed his Ph.D. in International Investment Law from the Dept. of Law & Governance, Central University of South Bihar. His research work is on "International Investment Agreement and State's right to regulate Foreign Investment." He qualified UGC-NET and has been selected for the prestigious ICSSR Doctoral Fellowship. He is an alumnus of the Faculty of Law, University of Delhi. Formerly he has been elected as Students Union President of Law Centre-1, University of Delhi. Moreover, he completed his LL.M. from the University of Delhi (2014-16), dissertation on "Cross-border Merger & Acquisition"; LL.B. from the University of Delhi (2011-14), and B.A. (Hons.) from Maharaja Agrasen College, University of Delhi. He has also obtained P.G. Diploma in IPR from the Indian Society of International Law, New Delhi. He has qualified UGC - NET examination and has been awarded ICSSR - Doctoral Fellowship. He has published six-plus articles and presented 9 plus papers in national and international seminars/conferences. He participated in several workshops on research methodology and teaching and learning.*

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# **ANIMAL TESTING REGULATION:** **LEGAL AND ETHICAL ISSUE**

AUTHORED BY - RAKSHA GIRISH

School of law, Christ Deemed to be university

## **ABSTRACT**

The contentious practice of animal testing in scientific research has emerged as a topic of profound ethical, legal, and scientific debate. This paper delves into the intricate intersection of law and ethics within the domain of animal testing, exploring the inherent conflicts and alignment between these principles. While legal frameworks exist to regulate the use of animals in experiments, including the Prevention of Cruelty to Animals Act of 1960 and the New drugs and clinical trial (Amendment) rules 2023 in India, they present substantial shortcomings, such as minimal penalties and an institutionalized acceptance of animal testing.

The ethical dimension of animal testing takes centre stage, emphasizing the moral significance of animal suffering, the rational basis for safeguarding their welfare, and the need to address the differential treatment of animals and humans within a legal framework. This ethical discourse highlights the potential application of the *parens patriae* doctrine to protect the rights and well-being of animals, recognizing their inherent value as sentient beings.

In response to these ethical concerns, scientists have undertaken efforts to replace, reduce, and refine animal testing through innovative methods, collectively known as the 3Rs—Replacing, Reducing, and Refining. These approaches, including *in vitro* testing, computational models, and stem cell research, hold the promise of minimizing animal suffering while promoting ethical research practices.

The paper further explores a paradigm shift by proposing the utilization of prisoners serving life sentences as test subjects in lieu of innocent animals. This proposition seeks to redirect scientific experimentation away from animals and toward individuals held accountable within the criminal justice system, maintaining ethical standards while addressing concerns regarding animal testing. In conclusion, the paper advocates for a thorough reevaluation of the ethical and legal frameworks

surrounding animal testing. It underscores the significance of integrating advanced research methods that prioritize the welfare of all sentient beings and implementing more stringent legal regulations to foster a more compassionate and responsible approach to scientific research. This comprehensive endeavor strives to balance and protect the interests of both humans and animals in the pursuit of scientific progress.

**KEYWORDS:** Animal testing, India, Ethics, Law, The prevent of cruelty to animals Act 1960, Regulations, New drugs and clinical trial (Amendment) rules 2023

## WHAT IS ANIMAL TESTING?

Animal testing is the practice of performing studies on captive animals, frequently involving invasive and painful treatments. The animals used in these tests frequently go through pain, stress, and are eventually put to death, all in the hopes that the findings would have implications for people.

Test subjects include a broad variety of animals, such as rats, mice, rabbits, cats, dogs, fish, and primates. It's important to note that it can be challenging to pinpoint the precise number of animals utilized because some, like mice and rats, are not covered effectively and efficiently by the legal framework.

Using animals for research is needless, harsh, and unethical. It is unlikely that the findings of these tests can be consistently applied to people due to the conditions of captivity. Because they are confined during studies and subjected to psychological stress and social isolation, many animals, especially monkeys, display deviant behavior patterns. Self-mutilation and other indications of extreme distress are examples of these behaviors.

Animal testing is permitted by the government. Painkillers are frequently not necessary for the painful and hazardous procedures that animals may undergo. Even in cases where there are good substitutes for animal experimentation, the law does not mandate their use.

## HISTORICAL PERSPECTIVE

In colonial India, the Pasteur Institutes and bacteriological research centres expanded, leading to an anti-vivisection issue becoming largely irrelevant. Despite protests from the British Union for

the Abolition of Vivisection, Pasteur Institutes were established, as the colonial state and scientific community viewed them as a crucial aspect of medical progress.

British colonialists in India held complex attitudes towards animals, combining care, empathy, and romanticism with utilitarian purposes. This duality manifested in their roles as both experimenters and caregivers for animals, imbuing their relationship with animals with a moral and paternalistic dimension.

Animal experimentation in colonial India extended beyond bacteriology, encompassing experiments related to chloroform as an anesthetic. The second Hyderabad Chloroform Commission involved extensive animal testing and clinical studies on humans, underscoring the significant scale of these experiments.

The colonial context in India contributed to the clearing of forests, the promotion of animal sports, and the emergence of new moral values related to animal welfare. Animals became valuable resources in the colonial expansion and the development of capitalist agriculture.

The clash between scientific progress and ethical concerns is central to the discussion, shedding light on the historical and ethical complexities of animal experimentation, particularly in the unique context of colonial India during a pivotal period in history.

In colonial India, British residents exhibited a coexistence of empathy and cruelty towards animals. Compassion for Indian animals, particularly street and draught animals, led to the establishment of the first Indian Society for the Prevention of Cruelty to Animals (SPCA) in 1861, predating similar developments in the United States.

The British adoption of the term 'pariah' for Indian mongrel dogs reflected a unique attitude towards Indian animals. Pariah dogs, associated with a low-caste community in South India, were considered outcasts similar to the 'pariahs' in society, embodying the realities of Indian life. British attitudes toward these dogs blended compassion and fear, symbolizing both objects of pity and symbols of class and elitism.

Indian SPCAs played a significant role in introducing legislation for the prevention of cruelty to

animals. The Cruelty Acts were distinct from contemporary British legislation and aimed to establish a legal and rational framework for the human-animal relationship within Indian society. They were influenced by British perceptions of Indian character and society, particularly in the post-1857 context, when the British viewed Indians as both childlike and cruel.

Colonial legislation on animal cruelty was marked by a combination of romanticism and authoritarianism. It reflected the British desire to save Indian animals from perceived cruelty while introducing legal and rational paradigms into the human-animal relationship within Indian society. This approach was consistent with the British attitude toward Indian character and society during the colonial era.

The moral horizon of modern politics extended care and empathy to animals, playing a significant role in shaping British attitudes. This moral universe also extended to Indian Hindu politics, further influencing the Indian engagement with scientific experimentation and the role of animals in the colonial era.

the resurgence of the Cow Protection movement and its significance in political and social movements in India arose. The movement adopted the cow as a symbol of Hindu compassion and unity while expressing opposition to colonial rule and beef consumption. This movement led to heightened Hindu-Muslim conflicts over cow slaughter in North India and sparked riots in various regions.

The Cow Protection movement also increased the activities of traditional animal sanctuaries, known as pinjrapoles, primarily maintained by Hindus. These groups established moral and institutional links with the animal protection movement supported by the Indian Societies for the Prevention of Cruelty to Animals (SPCAs), contributing to the expansion of animal shelters. Both movements displayed empathy towards animals, with Isabel Burton, an animal lover and antivivisectionist from London, expressing admiration for a pinjrapole in India.

The opposition to the establishment of Pasteur institutes and bacteriological laboratories in India for the treatment of diseases, such as rabies, was influenced by British antivivisectionists. They sought to leverage contemporary Hindu sentiments for animals to oppose these initiatives, aligning British antivivisectionist sentiments with Hindu beliefs about animals.

However, the convergence of British and Hindu sentiments had limitations due to their distinct religious motivations. The antivivisectionist movement was rooted in late Victorian Christian ethics, while the Cow Protection movement was an expression of Hindu nationalism. The text underscores the different attitudes toward scientific research, particularly Pasteur institutes, in Britain and colonial India. In India, the Pasteur movement had more social legitimacy, with many Indian newspapers and prominent figures supporting it, despite antivivisectionist protests from Britain.

While there was a strong rhetoric around animals in political discourse, it largely overlooked the use of animals in Indian laboratories, where animals, including pariahs and rabbits, were subjected to cruel scientific experiments. The laboratories producing vaccines and conducting experiments became symbols of scientific progress in colonial India, transcending political and moral critique. This selective absorption of late Victorian animal ethics within Indian politics led to a failure to generate a comprehensive critique of laboratory science.

In the context of animal experimentation in colonial India, colonial legislation played a pivotal role. Colonial officials, driven by the needs of the scientific community and the Pasteur movement, disregarded ethical concerns associated with animal experimentation. The conflict emerged between antivivisectionists in England, who called for legislation against animal experimentation in India, and colonial scientists who supported Pasteurian methods and opposed such legislation for fear of hindering scientific progress. While supporters of animal experimentation argued for its necessity for scientific advancement, the focus of colonial legislation primarily addressed perceived cruelty within Indian social practices rather than laboratory experimentation. This led to strong opposition from Indian Societies for the Prevention of Cruelty to Animals (SPCAs), which believed that proposed legislation would legitimize cruelty to animals. The contrasting attitudes and priorities between Britain and India resulted in the absence of comprehensive animal experimentation legislation in India, with scientists in India advocating for their research methods with limited external oversight.<sup>1</sup>

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<sup>1</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2997667/>

## **PRESENT LEGAL FRAMEWORK.**

The primary cruelty law in India is the Prevention of Cruelty to Animals Act, 1960. It aims to prevent unnecessary pain or suffering to animals and defines various acts of cruelty towards animals. The Act established the Animal Welfare Board of India (AWBI) to advise the government on animal welfare issues.

The Act outlines various actions that constitute cruelty to animals, such as beating, injuring, and using animals for work when they are unfit. Penalties for cruelty range from fines to imprisonment. The law does not consider certain activities as cruelty, like dehorning/castration of cattle in prescribed manners or extermination of animals as authorized by law.

The Act permits experimentation on animals for scientific and medical purposes. A committee is established for the control and supervision of experiments on animals. It also allows for the killing of animals as required by religious practices.

## **SHORTCOMINGS OF THE ACT**

Chapter 4 deals with the experimentation on animals.

Section 14 of this Act states that “Experiments on animals. —Nothing contained in this Act shall render unlawful the performance of experiments (including experiments involving operations) on animals for the purpose of advancement by new discovery of physiological knowledge or of knowledge which will be useful for saving or for prolonging life or alleviating suffering or for combating any disease, whether of human beings, animals or plants.”

The commencement of this chapter inherently legitimizes animal experimentation, explicitly stating that no provisions within this act can be construed as prohibiting or rendering unlawful any aspects related to the practice of experimenting on animals. This substantial legal hurdle significantly impedes the progress of animal rights advocacy.

Section 15 of the aforementioned Act establishes a committee tasked with overseeing and enforcing regulations related to animal experimentation. While this provision may appear welfare-focused at first glance, the practical exercise of this committee's powers holds limited significance in the prevailing circumstances.

Sections 17, 18 and 19 focus upon the functions of the committee.

Section 17 says “It shall be the duty of the Committee 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 statement itself carries an inherent contradiction. While the section explicitly states that animals should not endure unnecessary pain or suffering during experimentation, the very act of experimentation inherently inflicts such pain and suffering upon the animals. Even seemingly minor or "safe" experiments can lead to adverse health effects, psychological distress, and various issues for animals.

Section 17(e) states “that experiments on larger animals are avoided when it is possible to achieve the same results by experiments upon small laboratory animals like guinea-pigs, rabbits, frogs and rats;”

This subsection introduces a distinction based on the size of animals, suggesting that experimentation should be minimized on larger animals. However, it raises a fundamental ethical concern: the presumption of humans assigning varying levels of worthiness to different animals. In reality, animals, regardless of their size, possess emotional and moral significance. Such differentiation undermines the value of smaller animals, such as rats, and implies that their lives are somehow less valuable than others.

Section 20 of the Act prescribes penalties for violations of its regulations, with a maximum fine of 200 Indian Rupees. This relatively meager penalty for inflicting pain on innocent animals reflects the minimal value attributed to animals in India. In the context of the country's economy, 200 INR is an insubstantial amount. Such a lenient penalty provides little deterrence, encouraging continued violations of these laws. Despite India's cultural reverence for certain animals, such as cows, these religious beliefs lose their significance when animals, regardless of their species, are subjected to cruelty, and the punishment for such actions remains economically inconsequential for the perpetrators. Consequently, there is a pressing need for more stringent regulations and substantially higher fines to discourage such practices effectively.

## ETHICAL CONCERNS OF ANIMAL TESTING

The ethical dimensions of animal testing extend beyond the legal framework and give rise to significant concerns. Animals, akin to humans, possess emotions and the capacity to experience fear or distress when exposed to external factors. To draw a parallel with the human context, human beings benefit from a robust legal framework that safeguards their liberty and ensures they are not held captive against their will, with the exception of lawful incarceration within the criminal justice system. Conversely, animals lack equivalent safeguards that would entirely prohibit their captivity, relying instead on regulatory measures for their protection.

Under the Prevention of Cruelty to Animals Act of 1960, the practice of keeping animals in captivity is not outright abolished but subject to regulation. However, if we were to transpose this situation to the realm of human rights, where captivity is regulated rather than abolished, it would be considered wholly unacceptable. Such a scenario would contravene fundamental human rights, casting doubt upon the preservation of essential liberties. This marked differentiation in the treatment of humans and animals underscores a critical ethical question, as it implies that humans are granted a privileged status, while animals are not afforded comparable consideration.

It is crucial to emphasize that the superiority of humans over animals is not a tenable standpoint within contemporary ethical discourse. Instead, humans bear the responsibility of being stewards of the animal kingdom due to their advanced cognitive faculties. As given in the case of **Animal Welfare Board Of India vs A. Nagaraja & Ors**<sup>2</sup>, the doctrine of *parens patriae*, (rooted in the principle of the state as the "parent of the nation," extends its protective embrace to safeguard the rights and interests of those individuals who are unable to independently protect themselves. This legal doctrine predominantly pertains to humans. However, in light of the intrinsic vulnerability of animals when contrasted with humans, there is a compelling argument to invoke this doctrine for the welfare of animals.

Given the incapacity of animals to advocate for their own rights or interests within a human-centric legal framework, it becomes increasingly pertinent for the court to assume the role of protector. This approach recognizes that animals, as non-human entities, lack the inherent capacity to assert their rights or seek remedies when subjected to mistreatment or cruelty. In such

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<sup>2</sup> ANIMAL WELFARE BOARD OF INDIA VS. A NAGARAJA & ORS. (2014)7 SCC 547

circumstances, the court, as the embodiment of *parens patriae*, acts as a custodian, ensuring that the rights and well-being of animals are duly safeguarded. This underscores the court's vital role in preserving the interests of these sentient beings who, by virtue of their inherent limitations, rely on the protective mandate of the state.

This elevated intellectual capacity should ideally be harnessed to alleviate the suffering of animals rather than perpetuate it. Consequently, it is imperative to reevaluate the ethical underpinnings of animal testing in light of these considerations, with the ultimate aim of ensuring greater ethical integrity and compassion towards all sentient beings.

The ethical debate surrounding animal testing comprises several key aspects. First, it centers on the moral significance of animal suffering. This argument asserts that animals, like humans, are capable of experiencing pain and distress, emphasizing the moral importance of considering their welfare.

Furthermore, this ethical standpoint is not rooted solely in emotions; it is underpinned by rational considerations. Animals lack the capacity to provide consent, represent their interests, understand the harm inflicted upon them, and they are morally innocent and vulnerable. These rational factors underscore the need to protect animals from unnecessary harm.

Another dimension of this debate revolves around the balance between the benefits and ethical considerations of animal testing. While proponents argue that it has contributed to scientific and medical progress, a careful cost-benefit analysis suggests that the utility of many experiments is questionable. Additionally, the emergence of alternative testing methods challenges the necessity of animal testing.

Within the ethical spectrum, there are differing standpoints. Some animal protectionists, such as Peter Singer, acknowledge that specific experiments may be morally justified if they save a substantial number of human lives. However, critics question this utilitarian approach, which could potentially prioritize the interests of more developed beings over morally relevant factors like moral innocence and defenselessness.

Furthermore, the ethical debate extends to whether the same utilitarian logic that justifies animal testing could apply to human subjects. Ethical objections argue against inflicting suffering on innocents, whether they are animals or children, even when potential gains are at stake.

Lastly, the institutionalization of animal testing is a noteworthy concern. This institutionalization perpetuates itself, resulting in routine scientific procedures where animals are treated as mere means to human ends. This practice is criticized for prioritizing convenience and tradition over ethical considerations.

In summary, the ethical quandary surrounding animal testing revolves around finding a balance between scientific progress and the moral responsibility to prevent the unnecessary suffering of animals.<sup>3</sup>

## AN ALTERNATIVE TO ANIMAL TESTING

In the realm of scientific research and toxicology testing, a significant effort is made to minimize the use of animals, whenever feasible. Scientists aim to replace, reduce, or refine animal testing through various approaches.

The first approach, known as "Replacing," involves substituting traditional animal models with non-animal systems. This may include using computer models, biochemical systems, or cell-based methods in place of animals. For example, in vitro methods have been developed to identify eye irritants and potential allergens, reducing reliance on animal testing. However, replacing animal testing for identifying complex hazards like cancer or birth defects remains a challenge due to the intricacies of the biological processes involved.

The second approach, "Reducing," focuses on minimizing the number of animals used in testing while still achieving research objectives. This approach emphasizes efficiency, ensuring that the fewest animals are involved in experiments. This reduction in animal use contributes to ethical and practical considerations.

The third approach, "Refining," aims to improve the welfare and minimize suffering of animals

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<sup>3</sup> Andrew Linzey, THE ETHICS OF TESTING, in The Global Guide to Animal Protection (Andrew Linzey ed., University of Illinois Press),

used in testing. This involves providing better housing conditions, enrichment, and eliminating pain or distress in animals during experiments.

Collectively, these three approaches are known as the 3Rs—Replacing, Reducing, and Refining. They represent a fundamental framework for advancing ethical and responsible practices in research and testing. By incorporating the 3Rs, scientists can develop and implement new alternative methods that align with these principles, ultimately reducing the reliance on animal testing in various scientific fields.<sup>4</sup>

Some alternative methods are as follows:

Testing cells and tissues in test tubes or cell cultures

- 3D tissue culture, also referred to as organs on a chip
- Computational and mathematical models
- Stem cell research
- Non-invasive diagnostic imaging
- Clinical research involving people<sup>5</sup>

## SUGGESTION

Animals are inherently innocent beings, devoid of any moral culpability, and therefore, subjecting them to the horrors of testing raises profound ethical concerns. On the contrary, humans who have been found guilty of crimes by a court of law bear the burden of accountability for their actions. Among these individuals, those serving sentences within the criminal justice system can potentially serve as test subjects under specific conditions in exchange for compensation. These tests must be meticulously designed to ensure the absolute safety of the individuals involved, with no risk of fatality or harm.

In the context of testing, it is crucial to distinguish between prisoners who are incarcerated for heinous crimes such as rape, premeditated murder, or serial offenses, and those sentenced to life imprisonment. Instead of sacrificing the life and well-being of animals that have inflicted no harm, consider utilizing the latter category—individuals serving life sentences—as test subjects.

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<sup>4</sup> <https://www.niehs.nih.gov/health/topics/science/sya-iccvam/index.cfm>

<sup>5</sup> <https://grants.nih.gov/grants/policy/air/alternatives>

This proposition aligns with the principles of justice and ethical consideration. By offering testing opportunities to prisoners convicted of the most inhumane and grievous offenses, we can redirect scientific experimentation away from innocent animals towards individuals who, due to their actions, are held accountable within the criminal justice system. This paradigm shift would enable us to address ethical concerns surrounding animal testing while maintaining strict ethical standards in the use of human subjects.

## **A STEP FORWARD?**

The "New drugs and clinical trial (Amendment) rules 2023" recognize the necessity of animal testing in various scenarios. However, the 2023 amendment introduces a list of alternative methodologies most of which exclude animal testing, offering more ethical and effective approaches to drug development and clinical trials.

The amendment rules state:

“The non-clinical testing methods to assess the safety and efficacy of a new drug or investigational new drug include the following, namely: -

- (i) Cell-based assay;
- (ii) Organ chips and micro physiological systems;
- (iii) Sophisticated computer modeling;
- (iv) Other human biology-based test methods;
- (v) Animal Studies.”<sup>6</sup>

While the legislation aims to promote alternative methods to animal testing, the concept remains prevalent due to the presence of the provision (v) mentioned above. The term "animal studies" still authorizes companies to use animals as study subjects. Despite the availability of alternatives, these alternatives are expensive and complex technologies requiring expertise and specialized equipment, due to this only a few companies would be willing to transition. Many would prefer to continue with their current methods rather than assuming the financial burden and risk associated with adopting these alternatives.

While the legislation may gradually reduce the use of animal testing over time, it is unlikely to

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<sup>6</sup> New drugs and clinical trial (Amendment) rules 2023

eliminate it or reduce the number of animals used to a minimal level.

## CONCLUSION

In conclusion, the practice of animal testing raises significant ethical, legal, and scientific concerns. While legal frameworks exist to regulate the use of animals in experiments, there are inherent shortcomings in these regulations, including inadequate penalties and an institutionalized acceptance of animal testing. Ethically, the differential treatment of humans and animals in this context is a subject of profound moral debate.

The ethical debate surrounding animal testing revolves around finding a balance between scientific progress and the moral responsibility to prevent the suffering of animals. Animals, like humans, are sentient beings capable of experiencing pain and distress. Consequently, the principles of *parens patriae*, often applied to protect vulnerable individuals, should extend to safeguard the rights and well-being of animals. Such a paradigm shift would align with contemporary ethical discourse that recognizes the intrinsic value of all sentient beings.

Efforts to replace, reduce, and refine animal testing through innovative methods such as *in vitro* testing, computational models, and stem cell research provide a promising path toward ethical scientific research. These 3Rs—Replacing, Reducing, and Refining—promote ethical research practices while minimizing animal suffering.

The paper also explores the concept of utilizing prisoners serving life sentences as test subjects in place of innocent animals. This proposition reflects a paradigm shift, one that channels scientific experimentation away from animals and towards individuals accountable within the criminal justice system. This approach maintains ethical standards while addressing concerns regarding animal testing.

In light of these considerations, the ethical and legal frameworks surrounding animal testing demand a thorough reevaluation. The integration of advanced research methods that prioritize the welfare of all sentient beings, along with more stringent legal regulations, is essential to foster a more compassionate and responsible approach to scientific research. Ultimately, this endeavour will ensure that both human and animal interests are carefully balanced and protected in the pursuit of scientific progress.