



# Ahimsa and Alternatives – the Concept of the 4<sup>th</sup> R. The CPCSEA in India

Shiranee Pereira<sup>1</sup> and Massimo Tettamanti<sup>2</sup>

<sup>1</sup>Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), IN-Chennai

<sup>2</sup>International Centre for Alternatives in Research and Education (I-CARE), IN-Chennai

## Summary

*The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) in India is one of a kind in the world. It is a statutory body of the government of India formed by an act of the Indian parliament. This body consists of nominated members and representatives from national regulatory agencies, Ministry of Health and Family Welfare, Ministry of Environment and Forests, national academic and research councils, premier research institutes, eminent scientists and animal welfare organisations. The CPCSEA draws its powers from the Prevention of Cruelty to Animals (PCA) Act of 1960 which states that the duty of the committee is “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”.*

*With the power to promulgate its own laws to ensure the humane and ethical use of animals in research and education, the CPCSEA in 1998 notified in the gazette of India the “Breeding of and Experiments on Animals (Control and Supervision) Rules 1998”.*

*The CPCSEA is unique in that the law in itself has enabled the creation of a common platform of discussion for scientists and animal activists for humane and progressive solutions for the use of animals in experimentation. In a country that is caught in a paradox of violence and rich cultural and religious traditions, India still draws a lot of its power from the concept of “Ahimsa” (the philosophy of non-violence). This concept is also pertinent to the use of animals in laboratories. Unethical, inhumane and unscientific practices, and ignorance of the use of alternatives were the way of science until 1999 when CPCSEA became functional. For four years CPCSEA has waged a battle, rescued thousands of animals from laboratories, fought legal battles to victory, enforced for the first time in the country good laboratory practice, designed guidelines for the use of animals in the production of immunobiologicals, introduced the credo of 3R principles, trained and taught scientific personnel the credibility of humane science and most importantly brought forward the concept of the fourth R, “rehabilitation” of used laboratory animals. Today CPCSEA has made it a national policy that personnel using experimental animals have a moral responsibility towards these animals*

**Zusammenfassung:** Ahimsa und Alternativen – das Konzept des vierten R. Das CPCSEA in Indien

*Das Komitee zur Kontrolle und Aufsicht über Tierversuche (CPCSEA) in Indien ist weltweit einzigartig. Es ist eine Einrichtung der indischen Regierung, geschaffen durch einen Beschluss des indischen Parlaments. Das Gremium besteht aus ernannten Mitgliedern und Vertretern von nationalen Aufsichtsbehörden, des Ministeriums für Gesundheit und Familie und des Ministeriums für Umwelt und Wälder. Im Weiteren gehören ihm nationale Berater aus Akademie- und Forschungskreisen, bekannte Wissenschaftler sowie Vertreter von führenden Forschungseinrichtungen und Tierschutzorganisationen an. Das CPCSEA leitet seine Befugnisse aus dem Gesetz zur Vermeidung von Grausamkeit gegen Tiere von 1960 ab, in dem festgelegt ist, dass das Komitee „alle nötigen Massnahmen ergreifen muss, um sicherzustellen, dass Tiere vor, während und nach Versuchen keinen unnötigen Schmerzen oder Leiden ausgesetzt werden“.*

*Mit der Befugnis eigene Gesetze zu erlassen, um die humane und ethische Nutzung von Tieren in Forschung und Lehre sicherzustellen, hat das CPCSEA 1998 in der Gazette of India „Richtlinien zur Zucht und Nutzung von Tieren für Experimente (Kontrolle und Aufsicht) 1998“ publiziert.*

*Das CPCSEA ist einzigartig, weil hier ein Gesetz unmittelbar eine Plattform geschaffen hat, auf der Wissenschaftler und Tierschützer Diskussionen im Sinne humaner und fortschrittlicher Lösungen bei Tierversuchen führen. In einem Land, das sich in einem Paradoxon von Gewalt und reicher kultureller und religiöser Traditionen verfangen hat, schöpft Indien immer noch viel seiner Kraft aus dem Konzept der „Ahimsa“, der Philosophie der Gewaltlosigkeit. Dieses Prinzip findet nun auch in Tierversuchsanlagen Anwendung. Unethische, inhumane und unwissenschaftliche Praktiken und Unkenntnis gegenüber dem Einsatz von Alternativmethoden waren vor 1999, als das CPCSEA seine Arbeit aufnahm, gängige Methoden in der Wissenschaft. Vier Jahre führte das Komitee einen regelrechten Feldzug, rettete tausende Tiere aus Laboratorien, führte siegreiche Prozesse, setzte erstmals im Land die „gute Laborpraxis“ in Kraft sowie Richtlinien für die Verwendung von Tieren bei der Herstellung von Immunbiologika, führte das Credo der 3R ein, brachte wissenschaftlichem Personal die*



after their use. Costs of after-care/rehabilitation of animals post experimentation are to be a part of research costs and should be scaled in positive correlation with the level of sentience of the animals.

This paper is about the Indian law on animal experimentation and the success story of the CPCSEA in India in inculcating the credo of 4Rs – Replacement, Reduction, Refinement, and Rehabilitation of animals used in experimentation.

Grundsätze humaner Wissenschaft näher und, am allerwichtigsten, es verhalf dem Konzept des vierten Rs, der Rehabilitation verwendeter Labortiere, zur Geltung. Das Komitee hat dieses Konzept zu einem nationalen Grundsatz erhoben, nach dem Personen, die Tiere verwenden, auch nach dem Experiment eine moralische Verpflichtung gegenüber diesen Tieren haben. Die Kosten der Nachsorge und Rehabilitation der Tiere nach den Experimenten bilden Teil der Forschungskosten; sie sind positiv korreliert mit der Empfindungsfähigkeit der Tiere.

In diesem Beitrag geht es um die indische Rechtsprechung zu Tierversuchen und die Erfolgsgeschichte des CPCSEA bei der Festlegung des Bekenntnisses zu den 4Rs – Replacement, Reduction, Refinement und Rehabilitation von Versuchstieren.

**Keywords:** animal experimentation, rehabilitation, ahimsa, animal welfare in India, control and supervision

## 1 Introduction

*Ahimsa* is a Sanskrit word meaning “not to kill”. In a broader sense it refers to the concept of “non-violence”. It is derived from the word “*himsa*” which means “to kill”. *Ahimsa* is an enduring Indian tradition signifying the sacredness of life. Hindus, Buddhists and Jains view all living things as incarnations of a single life force. When a creature dies it could be re-incarnated into another form and hence be vitalised by a soul of an ancestor or friend. In a country that is caught in a paradox of violence and rich cultural and religious traditions, India still draws a lot of its power from the concept of *Ahimsa*. Like India’s struggle to freedom from British occupation, the progress towards laws that govern the care and use of animals in experimentation has been guided and propelled by *Ahimsa*.

## 2 Indian law and animal experimentation

The law that governs the use and care of animals in experimentation is the Prevention of Cruelty to Animals Act (PCA) of 1960. Sections 15 to 20 of the Act regulate the power, position and duties of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA). The CPCSEA is thus a statutory body of the government of India, constituted on the advice of the

Animal Welfare Board of India, by an act of parliament, with the sole purpose of controlling and supervising experiments on animals. The PCA 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”.

With the power to promulgate its own laws to ensure the humane and ethical use of animals in research and education, the CPCSEA in 1998 notified the “Breeding of and Experiments on Animals (Control & Supervision) Rules 1998” (Anon, 1998) which was amended in 2001. The CPCSEA is unique in that the law itself 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 experimentation.

From 1964 to 1998 little was done to alleviate the suffering of laboratory animals in India. The CPCSEA committees failed to impose the laws and lacked effective methods for implementation and a dismal scenario continued in laboratories across the country (Pereira et al., 2003). A pro-active secretariat was only created in 1999 under the committed chairpersonship of Maneka Gandhi. From 1999 the CPCSEA enforced the law of the land tirelessly, and for the first time in the history of independent India

the following changes were brought about:

- Over 850 laboratories registered with the CPCSEA
- IAEC’s (Institutional Animal Ethics Committees) were founded in all registered institutes
- Over 300 CPCSEA nominees were appointed in these institutes
- An expert committee was appointed to scrutinise and approve large animal use
- Good Laboratory Practice was introduced
- A protocol for the care and use of equines in the production of immunobiologicals was introduced
- The 3R credo was introduced
- Alternatives validated by ECVAM (European Commission for the Validation of Alternative Methods) and ICCVAM (Interagency Coordination Committee for the Validation of Alternative Methods) were recommended to regulatory authorities
- A national ban on the Sempole vaccine was urged
- Two year phase-out of the ascites method of monoclonal antibody production
- Hundreds of laboratory animals were rescued and rehabilitated

The animals rehabilitated were approximately 300 beagles, 50 mixed-breed dogs, 220 primates, 170 equines, 30 sheep, 250 birds, 110 rabbits and others, which included frogs, mice and cobras.

With this was born the concept of the 4<sup>th</sup> R, "Rehabilitation" of laboratory animals, borne out of an urgent need to provide relief and succour to the ailing animals in laboratories. Rehabilitation was undertaken when the need arose with the sole intention of alleviating any form of suffering or pain and/or to save the life of the animal. The concept of 4<sup>th</sup> R "Rehabilitation" is defined as "the after-care rendered to animal/s that has/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 purpose of alleviating any/all pain or suffering due to the physical/physiological/psychological trauma that the animal/s has/have been exposed to and to prolong the life of the animal/s until the point of natural death." During the period of rehabilitation the animal/s should not be subjected or exposed to any kind of activity/work that is unnatural/alien to their natural behaviour or needs (Tettamanti et al., 2004).

### 3 The year 2004

The proactive work of CPCSEA over the last 5 years has helped to create a great degree of awareness among research/educational establishments and has inculcated sensitivity towards understanding the pain and suffering experienced by animals during experiments. It has gradually helped to raise awareness about the need for observance of norms of humane treatment of animals.

In March 2004, in response to a complaint received from the scientific community that CPCSEA regulations were posing unnecessary hurdles to the smooth conduct of medical research, a consultative group was constituted under the chairpersonship of the Secretary of the Ministry of Environment and Forest, the ministry to which the CPCSEA belongs. Members of the group included representatives from the ICAR (Indian Council of Agricultural Research), CSIR (Council for Scientific and Industrial Research), ICMR (Indian Council for Medical Research), CDRI (Central Drug Research Institute), DBT (Department of Biotech-

nology), IVRI (Indian Veterinary Research Institute), NII (National Institute of Immunology), Ministry of Health, philosophers and animal activists.

The consultative group held six brainstorming sessions to elucidate the underlying principles for animal experimentation and their philosophical foundations, to provide the conceptual framework to review prevailing norms and promulgate new ones. Five major guiding principles for the utilisation and care of animals used in testing, research, training and education were elucidated in a consensus (Anon, 2004).

## 4 The Principles

### 4.1 Principle No. 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 will be useful for saving or for prolonging life or alleviating suffering or for significant gains in well-being for the people of the country or for combating any disease, whether of human beings, animals or plants.

### 4.2 Principle No. 2

Animals lowest on the phylogenetic scale and 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 alternatives, when available, are not used.

### 4.3 Principle No. 3

Proper use of animals in experiments and avoidance and/or minimisation of distress and pain 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 distress in human beings will also cause similar pain or distress in animals. All

scientific procedures adopted with animals that may cause more than momentary or slight pain and/or distress should be performed with appropriate sedation, analgesia or anaesthesia.

### 4.4 Principle No. 4

Personnel using experimental animals have a moral responsibility for the animals after their use. Investigators are responsible for the after-care and/or rehabilitation of animals, post-experimentation, and may be permitted to euthanise animals only in the following situations:

- When the animal is paralysed 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.
- During the course of the experimental procedure the animal has been left with a severe recurring pain wherein the animal exhibits obvious signs of long-term extreme pain and distress.
- In situations where non-termination of the animal experimented upon would be life-threatening to human beings or other animals.

Investigators are responsible for animals even after termination of the experiment and they have a moral obligation to ensure that experimental animals should be rehabilitated at the end of the experiment, or only where that is not possible, in situations as referred to above, should be humanely euthanised.

Costs of after-care 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.

### 4.5 Principle No. 5

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



## 5 Implementation

With this, the concept of the 4<sup>th</sup> R has been officially recognised and adopted as a policy decision of the government of India. Given this official status it will be imposed as a legal and mandatory requirement by the amendment of the "Breeding of and Experiments on Animals (Control & Supervision) Rules 1998".

Principle No.4 relating to the period of rehabilitation of animals after experiments, rehabilitation costs and agencies to undertake rehabilitation of such animals, is to be incorporated by amendment of the "Breeding of and Experiments on Animals (Control and Supervision) Rules 1998" by inserting a new provision which will read as follows:

*"Personnel using experimental animals have a moral responsibility for the animals after their use. Investigators are responsible for the after-care and rehabilitation of animals post-experimentation, and may be permitted to euthanise animals only in situations as defined at Rule 9 (ff).*

*Costs of after-care and rehabilitation of animals post-experimentation are to be part of research costs and should be scaled in positive correlation with the level of sentience of the animals.*

*A lump-sum amount needs to be provided for, as rehabilitation costs for each animal's entire statistically expected life span. Either the establishment undertaking experiments or a duly licensed and authorised animal welfare organisation (AWO) under the regulatory control of the CPCSEA on payment of a lump-sum, may undertake rehabilitation of animals."*

For adoption of norms for euthanasia, Rule 9 of the "Breeding of and Experiments on Animals (Control and Supervision) Rules 1998" is to be amended by inserting a new provision which will incorporate the permissible situations in which euthanasia can be performed as elaborated in Principle No.4.

## 6 Conclusion

The recognition of the concept of the 4<sup>th</sup> R and the official status rendered to it as a national policy is indeed a celebration of the Indian philosophy of *Ahimsa* and our belief in the sacredness of life. We believe the 4<sup>th</sup> R – "Rehabilitation" of laboratory animals – is a befitting moral continuum of the 3R credo of Russell and Burch (1959). So far rehabilitation has been performed by India's largest animal welfare organisation, People for Animals (PFA). Animal refuges and shelters run by the PFA and other animal welfare organisations across the country have come forward to rehabilitate the laboratory animals. In the case of dogs, most have been rehabilitated in individual homes. The shelters received a small degree of financial support from the CPCSEA. However, now with CPCSEA having officially recognised this as a moral and legal need, the funds received from scientific institutes will go a long way to establish independent laboratory animal rehabilitation centres in association with animal welfare organisations and help organise and implement the concept of the 4<sup>th</sup> R with more vigour and ease.

In a real world where we are faced with the reality, where millions of animals are and will continue to be used in experimentation, the concept of rehabilitation should become a reality and be recognised as a moral and ethical consequence of the use of animals in experimentation. Hopefully, the initiative of the Indian government will become a precedence for other nations to emulate.

The concept and act of rehabilitation is beautiful, but we must understand that it is not a romantic vision of an animal released from a stable/cage in a laboratory running onto a lawn, free and happy. An idyllic situation like this does not always correspond to the rehabilitated laboratory animal's demands and our

experience has taught us that immediate and dramatic changes could even kill the animal (Tettamanti et al., 2004). In our experience of rehabilitating laboratory animals like rats, mice, rabbits, horses, mules, dogs, cats and primates we have observed that the rehabilitation does at times present problems which, however, are resolvable with patience and care and the animals' survival is a reminder that in every form of life the strongest and deepest psychological need is to live.

## References

- Anon. (2004). Report of the consultative group on review of the norms and practices for regulation of animal experimentation. Ministry of Environment and Forests, Animal Welfare Division, Government of India.
- Anon. (1998). Breeding of and Experiments on Animals (Control and Supervision) Rules 1998. *Gazette of India No.809*, 15<sup>th</sup> December 1998.
- Pereira, S., Veeraraghavan, P., Ghosh, S. and Gandhi, M. (2004). Animal Experimentation and Ethics in India: The CPCSEA Makes a Difference. *ATLA 32, Supplement 1*, 411-415.
- Russell, W. M. S. and Burch, R. L. (1959). *The Principles of Humane Experimental Technique*. London: Methuen.
- Tettamanti, M., Pereira, S. and Veeraraghavan, P. (2004). The 4<sup>th</sup> R – "Rehabilitation" of laboratory animals. The ethos of I-CARE. *Journal of Animal Welfare* (communicated).

## Correspondence to

Dr. Shiranee Pereira  
CIBA, 75  
Santhome Hg. Road  
R. A. Puram  
IN-Chennai-600 0028  
India  
e-mail: shiraneep@hotmail.com