

**REPORT OF THE CONSULTATIVE GROUP
ON REVIEW OF THE NORMS AND PRACTICES FOR
REGULATION OF ANIMAL EXPERIMENTATION**

MINISTRY OF ENVIRONMENT & FORESTS
(ANIMAL WELFARE DIVISION)
GOVERNMENT OF INDIA

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1. INTRODUCTION:

The main objective of the Prevention of Cruelty to Animals Act (PCA), 1960 is to prevent infliction of unnecessary pain or suffering on animals. Accordingly, the Committee for Purpose of Control and Supervision of Experiments on Animals (CPCSEA) has been constituted under provisions of Section 15 of this Act. The Act provides for the duties and powers of the CPCSEA, and also penalties, in event of contravention of orders made, or conditions imposed by the Committee. The mandate of the Committee is to ensure that while conducting various types of experiments, in connection with medical research or education, animals are not subjected to avoidable pain or suffering. The CPCSEA functions within the ambit of the PCA Act, and Rules frame under it e.g. Rules for Breeding of and Experiments on Animals (Control and Supervision), 1998 as amended in February, 2001.

2. NEED TO REVIEW CPCSEA NORMS :

The functioning of the CPCSEA has helped to enhance awareness among medical research establishments that experiments on animals have to be necessarily carried out with sensitivity to, and avoiding wherever possible, and if not, in any case minimizing the pain and suffering experienced by them. However, there have been complaints of CPCSEA regulations and practices posing unnecessary hurdles in smooth conduct of medical research, without necessarily accomplishing its mandate of preventing cruelty to animals.

Existing procedures of animal experimentation were therefore proposed to be examined taking into account national and international norms, and formal ethical principles relevant to animal experimentation. Dr.S.C. Adlakha, Retd. Assistant Director General (ICAR) was assigned the task of preparing a report in this regard. To consider the issues in depth, a Consultative Group was constituted under Chairmanship of Secretary (E&F). This report was considered by the Consultative Group in six sessions in its meetings held on 19.3.2004, 12.4.2004, 7.5.2004, 27.5.2004, 17.6.2004 and 17.8.2004 under the Chairpersonship of Secretary (E&F).

The fifth meeting held on 17.6.2004 was chaired by the Addl. Secretary. These meetings were attended by representatives of CSIR, Central Drug Research Institute, ICMR, ICAR, Ministry of Health, Department of Biotechnology, IVRI, National Institute of Immunology. Besides this, animal welfare activists Ms. Norma Alvares, PFA Goa, and Ms. Geeta Seshamani, Friendicos SECA, New Delhi, also participated. Prof. Shashi Motilal, Department of Philosophy, Delhi University, an expert on ethical issues relating to humane treatment of animals, also participated, on invitation, at several of these meetings. The report submitted by Dr. Adlakha was not a formal proposal for amendments in the existing CPCSEA norms and/or promulgation of new ones. It was discussed only as one input to evolving a basis for streamlining of existing rules and regulations of CPCSEA.

In the meetings of the Consultative Group, the underlying Principles for Animal Experimentation and their philosophical foundations were discussed at length. A detailed presentation on the formal ethical basis of humane treatment of animals was made by Prof. Shashi Motilal, a summary of which is at Appendix I. This presentation was of critical importance as it provided the conceptual framework for review of prevailing norms and also for guidance in the functioning of the CPCSEA. The "Principle" as norms suggested in Dr. Adlakha's Report were also discussed in detail. The views expressed are recorded in the Minutes of the respective meetings.

3. PRINCIPLES FOR UTILIZATION AND CARE OF ANIMALS TO BE USED IN TESTING, RESEARCH AND TRAINING

After detailed discussion and taking into account the philosophical basis of humane treatment of animals, the Group agreed on the following Principles for utilization and care of animals used in testing, research, and training:

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 is expected to be useful for saving or for prolonging human 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.

Principle No.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 alternatives, when available, are not used.

Principle No.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 anesthesia.

Principle No.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 euthanise 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 wherein 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 No.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. APPROACHES TO SPECIFIC SITUATIONS IN ANIMAL EXPERIMENTATION

The following specific issues relevant to practical aspects of animal experimentation were discussed:

- (i) Whether CPCSEA should exclude rats, mice, birds, and farm animals, used in production and agricultural research, from regulation?
- (ii) Should the conventional regulatory framework apply in agricultural production research?
- (iii) Difficulties in getting animals from registered breeders.
- (iv) Should contract research involving animals be permitted?
- (v) Should IAEC be given the power to clear research project proposals that involve experimentation on animals of higher sentience than rodents?
- (vi) Process to be followed by CPCSEA before penalizing an institute for alleged legal violation.
- (vii) A broad definition of major and minor violations and how to deal with them.

The committee agreed as follows:

4.1 **Whether CPCSEA should exclude rats, mice, birds, and farm animals, used in production and agricultural research, from regulation?**

To facilitate discussions, an ordering of relative sentience of different species was formulated as follows:

“Cockroach”(Invertebrates) < Birds < Rodents < Canines/Felines < Bovine/Equines < Primates (e.g. Rhesus macaque) < More evolved Primates (e.g. chimpanzee)

It was agreed that anything higher than the “Cockroach”(invertebrates) in terms of sentience would require regulation. However, in each case, Principles 1 and 2 would apply in identifying the purposes for which experiments may be carried

out, and the species/number that may be used. Thus rats, mice, birds, and farm animals should not be excluded from regulation.

4.2 Should the conventional regulatory framework apply in agricultural production research?

It was highlighted that generally speaking these research activities did not involve causing any pain or injury to animals or injection of any toxic substance. In such cases what was required was laying down of norms to address their housing and general care of animal husbandry.

It was agreed that the conventional regulatory framework could not be made applicable in this case. A model of regulation termed as "Blinking Traffic Lights Model" is relevant. Under this model the regulatees are cautioned that if they do not follow the norms, they would be penalized. Thus for conducting these activities one is required to follow the specified Principles and Norms by way of self-regulation, but otherwise there is no need for prior clearance, so long as no procedures are carried out involving inflicting pain and/or suffering on experimental animals.

4.3 Difficulties in getting animals from registered breeders.

Several representatives from the Medical Community expressed difficulties in getting animals from registered breeders. The main reason cited was that breeding of animals was not profitable in the absence of significant demand, and hence there was no supply. It was agreed that while it is desirable to get animals for experimentation from registered breeders, if the animals are not available from registered breeders they may be obtained from any other "legal source" within India. By "legal sources" is meant a source in respect of which the fact of procurement with valid permission from the duly empowered authorities under any applicable law is documented. In the absence of proper documentation the presumption would be that the animals had been obtained from unauthorized sources, and use of such animals is not to be allowed.

It was also agreed that if after taking all feasible steps for procurement of animals in India from registered breeders or other legal sources, it was still not possible to obtain them, animals genetically defined in terms of experimental requirements may be imported from other countries (with permission from DGFT, if legally necessary).

4.4 Should contract research be permitted?

The advisability of conducting research involving experiments on animals on contract from Indian or foreign parties or from domestic was considered, and it was agreed that there was no reason to distinguish between research conducted in-house or by contract. The determining factor is that any agency, which conducts experiments on animals, should follow law, and the Principles and norms set forth in this Report.

4.5 Should IAEC be given the power to clear research project proposals that involve experimentation on animals of higher sentience than rodents?

An inference from Principle 3 is the need to have more oversight for animals of higher degree of sentience. There is a cardinal difference between IAEC and CPCSEA, in that the IAEC is not a disinterested body unlike the CPCSEA.

Accordingly, IAEC may not on its own (i.e. without reference to CPCSEA) approve research project proposals that involve experimentation of animal of greater sentience than rodents.

4.6 Process to be followed by CPCSEA before penalizing an institute for alleged legal violation.

It was agreed that:

- (a) The norms of natural justice would be followed without exception and there would be no summary proceedings for award of penalties. These norms include the right to personal hearing, submission of evidence, examination of evidence, no consideration to facts or evidence not produced, and speaking orders. However, there is no need for strict adherence to the CPC or CrPC provisions.
- (b) Both announced and unannounced inspections by duly authorized personnel (only) to inspect the animal house facilities of institutes may be carried out.
- (c) The CPCSEA is the authorized regulator of animal experimentation and personnel conducting inspections are not empowered to take independent decisions regarding the penalty to be imposed on the institutes, or temporary or permanent closure, or suspension of the facilities of the institute.
- (d) Major and minor violations would need to be dealt with differently.

4.7 How to deal with major and minor violations?

Any violations that lead to serious adverse health effects on animals would be a major violation. On the other hand, technicalities which do not have direct bearing on the health of the animal, such as irregular record keeping, etc, would constitute minor violations.

For minor violations, it was agreed that the regulatee would be given reasonable opportunities for rectification by the CPCSEA. After this, CPCSEA may order stoppage of experiments till rectification of the violation. In case of minor violations, the animal facility should not be closed down nor the registration cancelled.

In the case of major violations, CPCSEA may cancel or revoke the registration of the facility. On considering the inspection report, if considered necessary, the

Committee may stop all experiments for a specified period, and at the end of that period if the regulatee has not carried out specified rectification, the CPCSEA may order closure of the animal facility or revoke its registration.

In any event, no penalties of any kind, including suspension, may be imposed, without due process as per the norms of natural justice set forth at (a) above.

Since major violations would be concerned with animal health and care, the CPCSEA may constitute a standing sub-committee to examine such violations and take decisions (as set forth below) in case of emergencies, but always in accordance with the norms of natural justice. The CPCSEA would set up a mechanism for effectively monitoring the functioning of this sub-committee. This sub-committee may take decisions regarding stoppage of experiments in case of major violations on an emergency basis, but permanent closure of a registered facility would have to be a decision of the full Committee.

It was also agreed that the penalty as prescribed in the PCA Act, 1960 regarding the fine of Rs.250/- has to be enhanced manifold, and the Act amended accordingly.

5. IMPLEMENTATION STEPS

The following specific steps would be taken:

(a) Amendments to the PCA Act, 1960.

- (i) Section 14 of PCA Act is required to be amended in context of definition of experiments on animals with regards to Principle No.1. Accordingly, the Section 14 of PCA Act, may read as follows:

"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 significant gains in well-being for the people of the country, or for combating any disease, whether of human beings, animals or plants".

(ii) For enhancement of fine, Section 20 of the Act (last four lines) to be amended as under:

He shall be punishable with fine which may extend to Rs.X (to be determined) and, when the contravention or breach of condition has taken place in any institution the person in charge of the institution shall be deemed to be guilty of the offence and shall be punishable accordingly.

(b) Amendment to the Breeding Rules 1998, as amended in 2001.

(i) Principle No.1

For incorporation of Principle No.1, Rule 2 (e) Breeding of and Experiment on animal (Control and Supervision) Rules is required to be amended by addition of the phrase "significant gains in well being for the people of the country". The amended Rule 2 (e) of Breeding Rules 2001 will read as follows:

"Experiment" means any programme/project involving use of animal/animals for the acquisition of knowledge of a biological physiological, ethological, physical or chemical nature; and includes the use of animal 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 well being for people of the country, or for combating any disease whether on human beings or animals".

(ii) Principle No.2

To incorporate Principle No.2, amendment of the Rule (9) of 1998 is required by inserting a new provision after (b) as (bb) which will read as follows:

"Animals lowest on the phylogenetic scale which may give scientifically valid results should be first considered for any experimental procedure, and the experiment 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 provided, if alternatives, when available, are not used".

(iii) Principle No.4

Principle No.4 relating to 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 Rule (9) 1998 by inserting a new provision as (cc) after (c) which will read as follows:

"Personnel using experimental animals are responsible for the welfare of animals after their use in experiments. Investigators are responsible for the aftercare and rehabilitation of animals after experimentation, and may be permitted to euthanise animals only in situations as defined at Rule (9) (ff)."

"Costs of aftercare 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."

"Rehabilitation treatment of animals after experiments should extend till the point the subject animal is able to resume a normal existence. A lump-sum amount must

be provided costs for rehabilitation and care of the animals after experimentation to cover their entire statistical expected life span."

"Either the establishment undertaking experiments or duly licensed and authorized animal welfare organization (AWO) under the regulatory control of the CPCSEA on payment of lump-sum, may undertake rehabilitation of animals."

The following specific issues as finalized by the consultative group shall be taken into the fold of Breeding Rules by amending them as follows:

(iv) For adoption of norms for euthanasia, Rule 9 of Breeding Rules, 1998 is to be amended by inserting a new provision as 9(ff) as follows:

"The following parameters would be adopted for adoption of euthanasia:

- (i) 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; or*
- (ii) If during the course of experimental procedure the animal has been left with a recurring pain wherein the animal exhibits obvious signs of pain and suffering; or*
- (iii) In situations where the non-termination of the life of the experimental animal would be life threatening to human beings or other animals.*

(v) With regards to obtaining animals from other legal sources, the Rule 10 (b) of Breeding Rules, 1998 may be amended as under:

"An establishment shall acquire animal/animals for experiments from registered breeders. In case of non-availability of animal/animals from registered breeders, the animal/animals may be procured from alternate legal sources. With respect to every such procured animal/animals, there should be written records to establish that the animal/animals has/have been procured with permission from any authority duly empowered under a relevant Central or State Act to give such permission."

(vi) For import of animals which are not available from a registered breeder or alternate legal sources the Rule 10 (e) of Breeding rules, 1998 may be amended as under:

"In case an animal is not available from a Registered Breeder or other legal sources within the country, genetically defined animals may be imported with permission of DGFT, provided that the condition of non-availability within the country will not apply for genetically defined or laboratory bred rats and mice."

(vii) To incorporate the decision regarding approval of contract research by the Sub-Committee of CPCSEA, Section 12 of the Breeding Rules 1998 may be amended as under:

"Registered establishment may undertake contract research on behalf of any other agency, in accordance with the PCA Act, 1960 and the rules thereunder."

(viii) Regarding the process to be followed by CPCSEA before penalizing an institute for alleged legal violation and procedure to be followed to deal with major and minor violation with their definitions, the Rule 14 is to be amended by inserting Rule 14 (aa), 14 (e) and 14 (f) as under:

Rule 14 (aa)

"The norms of natural justice would be followed without exception and there would be no summary proceedings. These norms include the right to personal hearing, submission of evidence, examination of evidence, no consideration to facts or evidence not produced, and speaking orders."

Rule 14 (e)

"Definition of Minor violation – Technicalities which do not have direct bearing on the health of animal such as irregular record keeping, etc."

"Definition of Major violation - Any violation that may lead to serious adverse health effects or pain or suffering or death of an animal or animals."

Rule 14 (f)

"Process to be followed before penalizing an institute for alleged violation:

(i) Minor violation - The institutes will be given two opportunities for rectification. After this, CPCSEA may order stoppage of experiments till rectification of the violation. However, the animal house facility is not to be closed down nor the registration cancelled.

(ii) Major violation - The committee may stop all experiments for a specified period and at the end of the period if the institute still has not carried out the rectification, the CPCSEA may order closure or revocation of the registration of the animal facility."

(C) Guidelines.

(i) Principle No.3 may be issued as a guideline in the following form:

"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 anesthesia."

(ii) Principle No.5 may be issued as a guideline in following form:

"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"

(iii) On the issue of Agriculture Production Research where the conventional regulatory framework may not be applied, operational guidelines will be framed by CPCSEA to provide a model for self regulation by practitioners.

(iv) With regards to prohibiting the IAEC for clearing research project proposals that involve experimentation on animal of greater sentience than rodents, guidelines will be issued in the following form:

"IAEC is not empowered to clear research project proposals that involve experimentation on animals higher on the phylogenetic scale than rodents."

(v) On the issue of inspection of animal house facilities, a guideline will be issued in the following form:

"Both announced and unannounced visits by duly authorized personnel (only) to inspect the animal house facilities of institutes may be carried out. However, the personnel undertaking inspections may not order either temporary or permanent closure of the animal facility, or suspension of registration of the animal facility, or impose any other penalty, but must report their findings to the CPCSEA for further action."

Appendix I**SUMMARY OF PRESENTATION GIVEN BY PROF.(Ms.) SHASHI MOTILAL,
DEPARTMENT OF PHILOSOPHY, UNIVERSITY OF DELHI**

- 1) The practical role of philosophy is to help understand moral issues arising in different spheres of life. This is contrary to the popular impression that philosophy is something abstract and irrelevant to practical problems in life. The practical focus of philosophy is evident from the fact that in more and more professions, Institutional Ethics Committees have been set up to look into the moral aspects of problems arising in pursuit of these professions.
- 2) To consider any subject, it was important not only to know the moral norms, but also the rationale behind it, and this is precisely the task of philosophy. There can be two approaches in understanding the issues involved: (1) the rational, dispassionate and objective approach, (2) the emotional, passionate and subjective approach. A contemporary philosopher observed that "it sometimes appears that the quality of our thought on a topic is inversely proportional to the intensity of our emotions concerning that topic." A common misconception is that ordinary intuitions are necessarily moral. For example, a common practice in professional ethics is that decisions by majority are often considered to be morally right decisions. However, this presumption of a majority being morally right is not necessarily a correct one.
- 3) There is a clear conflict of interests between the scientific/research community engaged in animal experimentation, and animal welfare groups. The scientific/research community give foremost importance to the welfare of human beings. They advocate the norms for animals experimentation to facilitate the process of easy breeding and procurement of animals for this purpose. On the other hand, the animal welfare groups' main agenda is that animal experimentation should be totally banned and alternative methods should be used for the purpose of testing drugs and related matters. If a total ban is not

possible, at least animal experimentation should be minimized, since it is carried out in inhuman conditions causing unnecessary pain and sufferings to animals. In this context, issues about animals and the moral status of animal rights become crucial.

- 4) Legal rights are to be distinguished from moral rights. It could be established that animals do have legal rights by virtue of laws of the State. For example there are laws that prohibit hunting, fishing or trapping in designated areas. However, the issue of moral status of animal rests on the basic right to existence, to self respect, not to be treated merely as a means and not as an end in itself, the right to free movement, etc.
- 5) Can we accord moral rights to animals? A wide spectrum of philosophers have expressed divergent views on this subject. On the one hand, a great moral philosopher Immanuel Kant was of the view that animals do not have any moral status. Similarly, Michael A. Fox in his book "The Case for Animal Experimentation" set out to prove that animals are not members of the moral community and therefore humans have no moral obligation towards them. However, a diametrically opposite view that animals have rights was articulated by Tom Regan in "The Case for Animal Rights". While giving ten reasons for animal rights, Tom Regan claimed that the philosophy of animal rights is rational, scientific, socially progressive, and environmentally wise. On the other hand, ten arguments may also be cited against animal rights. The most important among them is that animals and humans cannot be equated, as they are essentially different, and it is absurd to say that they have the same rights. The issue of drawing a line somewhere as for instance between primates and amoebas, besides the overriding importance of other issues which demand attention such as world hunger, may also be cited.
- 6) Paul Taylor, in his "Respect for Nature" argues for an extended sense for animal rights for animals. His argument is that every thing which people can afford to achieve by an extension of the concept of rights can equally be accomplished by

means of ideas of respect for nature and the inherent worth of living things. The underlying thought of this belief system constitutes the biocentric outlook of nature and rejects the human centered view point that justifies an exploitative attitude towards non-human creatures.

- 7) On the use of animals in experimentation, in Prof. Motilal's view, instead of animal rights, we may speak of our relationship to them, so as to use them for the benefit of humans as well as animals. Experimentation does have a purpose, but care should be taken that animals are treated humanely for the worth they have for us. Insensible use of animals cannot be justified.

- 8) In conclusion, everything that we wish to say about a valid system of environmental ethics may be stated without using the language of "rights". The concept of the good of a living thing, of the inherent worth of a living thing, of the attitude of respect for nature, and the traditional idea of moral principles as validly binding upon all moral agents are fully adequate. To add the notion of moral rights to this conceptual structure is not to add anything ethically significantly. Confusion is likely to be engendered by the use of rights in the domain of environmental issues.
