GUIDELINES
ON THE REGULATION OF SCIENTIFIC EXPERIMENTS ON ANIMALS

Ministry of Environment & Forests

(Animal Welfare Division)

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INTRODUCTION

1.1 Background

The use of animals in scientific research has been an area of concern in India, given the sharp polarization of views between animal welfare activists and the scientific community of the country regarding use of animals. This led to proliferation of litigation, which impeded the pace of research.

In order to eliminate the potential for conflict, it was considered necessary to examine the international norms regarding the use of animals in scientific experiments, update regulations, streamline and simplify procedures, while ensuring ethical use of animals and reducing infliction of pain and stress on animals, during experimentation.

1.2 Process of Evolution of the Guidelines

Against this backdrop, in 2004, the Ministry of Environment and Forests set out to create a sound and cohesive regulatory framework for the use of animals in experimentation. A consultative Group was set up, to facilitate interaction with a wide spectrum of stakeholders, both within and outside the government, including the scientific community, as also animal welfare activists. To clarify the underlying ethical principles, a professor of Philosophy was also associated in the exercise.

Recognizing the intrinsic worth of animals as sentient beings, the consultative Group enunciated the underlying ethical principles and identified objectives of s scientific experiments which would justify the use of animals in the cause of scientific advancement and promoting human welfare while ensuring humane treatment of such animals.

Deliberations of the Group led to a consensus between hitherto divergent viewpoints. Six brainstorming sessions were held, wherein the principles and practices of utilization and care of animals in testing, research and training were finalized.

The report of the consultative Group was communicated to the Committee for the Purpose of Control and Supervision of Experimentation on Animals (CPCSEA) in terms of Section 17 (3) of the Prevention of Cruelty to Animals Act, 1960. The report was accepted by CPCSEA in to, in its meeting held on 20 December 2004, and formed the basis of the Breeding of and Experiments on Animals (control and supervision) Amendment rules, 2006.

The report has been well received and its impact may be noted from the fact of speedy settlement of pending court cases and absence of any new court case.

However, in order to clarify various aspects regarding the use of experimental animals, there was a perceived need for a comprehensive set of Guidelines that could be used as reference material by the Scientific establishment. Regarding ethical use of animals in scientific experiments. The present Guidelines respond to that need.

1.3 Aim

The aim of these Guidelines is to ensure humane and ethical treatment of animals, while facilitating legitimate scientific research involving experiments on animals.

2. Statutory provisions regarding scientific experiments on animals

Persons engaged in conducting scientific experiments on animals must act in conformity with the provisions of the prevention of Cruelty to Animals Act, 1960, and the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended.

These provisions are enforced by the independent Committee for the Purpose of Control and supervision of Experimentation on animals (CPCSEA), a statutory body under the Prevention of Cruelty to Animals Act, 1960, in the Ministry of Environment and Forests.

2.1 Other legal provisions regarding animal experimentation

Compliance is also required with CPCSEA Guidelines for Laboratory animal facility.

3. Principles for scientific experiments on animals, relevant changes in Rules and guidelines for specific situations evolved by the Consultative Group accepted by CPCSEA

3.1 Ethical principles adopted by CPCSEA for use of animals in scientific experiments

Principle 1

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

Principle 2

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

Principle 3

Proper use of animals in experiments and avoidance or minimization (when avoidance is not possible) of pain and suffering inflicted on experimental animals should be an issue of priority for research personnel, and unless the contrary is scientifically established, investigators should process 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 4

Persons engaged in animal experimentation have a moral responsibility for the welfare of the animals after their use in experiments. Investigators are responsible for the aftercare and/or rehabilitation of animals after experimentation, and may be permitted to euthanize

Animals only in the following situations:

a. When the animal is paralyzed and is not able to perform its natural functions; it becomes incapable of independent locomotion; and/or can no longer perceive the environment in an intelligible manner.

b. During the course of experimental procedure the animal has been left with a severe recurring pain and the animal exhibits obvious signs of long term extreme pain and suffering.

c. In situations where non-termination of the animal experimented upon would be life threatening to human beings or other animals. Costs of aftercare and/or rehabilitation of animals post-experimentation are to be part of research costs and should be scaled per animal in positive correlation with the level of sentience of the animals.

Principle 5

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

3.2.1 CPCSEA Guidelines on specific aspects regarding the use of animals in scientific experiments

3.2.1 Need to avoid/minimize pain and suffering inflicted on experimental animals

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.

3.2.2 Proper care, handling and use of experimental animals

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.

3.2.3 Agricultural production research

The conventional regulatory framework may not be applied regarding use of experimental animals in agricultural production research. The practitioners would be responsible for self-regulation, based on operational guidelines to be framed by CPCSEA.

3.2.4 Powers of the Institutional Animals Ethics Committee (IAEC)

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

3.2.5 Inspection of animal house facilities

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 house facility, or suspension of registration of the animal facility, or impose any other penalty, but must report their finding to the CPCSEA for further action.

4. Procedures for approval of scientific experiments on animals

4.1 Definition of experiment In terms of Rule 2 (e) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, "Experiments" means any programme or project involving use of animal(s) for the acquisition of knowledge of a biological, physiological, ethological, physical or chemical nature; and includes the use of animals(s) in the production of reagents and products such as antigens and antibodies, routine diagnostics, testing activity and establishment of transgenic stocks, for the purpose of saving or prolonging life or alleviating suffering, or significant gains in the well-being for people of the country or for combating any disease, whether of human beings, animals or plants.

4.2 Experimental animals which are subject to regulation The relative sentience of different species of animals are as follows:

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

Anything higher than invertebrates in terms of level of sentience requires regulation. Thus rats, mice, birds, and farm animals are also subject to regulation.

4.3 Function of CPCSEA

All establishments engaged in research and education involving animals, are required to comply with the various guidelines, norms and stipulations set out by CPCSEA.

The main functions of CPCSEA are:

- Registration of establishments conducting animal experimentation or breeding of animals for this purpose.
- Selection and appointment of nominees in the Institutional Animal Ethics Committees of registered establishments.
- Approval of Animal House Facilities on the basis of reports of inspections conducted by CPCSEA.
- Permission for conducting experiments involving use of animals.
- Recommendation for import of animals for use in experiments.
- Action against establishments in case of violation of any legal norm/stipulation.

4.4 Functions of the Institutional Animals Ethics Committee (IAEC) Every establishment constituted and operated in accordance with the

procedures specified by CPCSEA is required to constitute an Institutional Animals Ethics Committee (IAEC).

In terms of Rule 13 of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, as amended, every IAEC shall include a biological scientist, two scientists from different biological disciplines, a veterinarian involved in the care of animals, the scientist in charge of the animal facility of the establishment concerned, a scientist from outside the institute, a non-scientific socially aware member and a representative or nominee of the CPCSEA. A specialist may be co-opted while reviewing special projects using hazardous agents such as radioactive substances and deadly micro organisms.

IAEC may approve experiments on animals, up to the phylogenetic level of rodents (e.g. mice, rats and rabbits). However, IAEC is not empowered to clear research project proposals that involve experimentation on animals higher on the phylogenetic scale than rodents. In such cases, IAEC may consider proposals for scientific experiments involving animals above the sentience level of rodents, and forward its recommendations for consideration by CPCSEA.

4.5 Registration of establishments

In terms of Rule 3 of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, no establishment shall carry on the business of breeding of animals or trade of animals for the purpose of experiments unless it is registered, In terms of Rule 4 of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, no establishment shall perform any experiment on animals unless it is registered with CPCSEA. Every such establishment shall stop performing experiments on animals or breeding of animals for use in experiments, if registration is refused to it by CPCSEA.

4.6 Approval of animal house facilities

In terms of Rule 5 of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, as amended, approval of animal house facilities by CPCSEA is required to be obtained, for premises where experiments are to be conducted.

4.7 Use of animals in experiments

In terms of Rule 9 (bb) of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, as amended, animals lowest on the phylogenetic scale which may give scientifically valid results should be first considered for any experimental procedure, and the experiment should be designed with the

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

Replacement alternatives, not involving experiments on animals, should be given due and full consideration and sound justification must be provided, in case alternatives, though available, are not used.

4.8 Procurement of animals

In terms of Rule 10 of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, as amended,

i. an establishment shall acquire animals for experiments from registered breeders only;

ii. in case of non-availability of animals from registered breeders, the animals may be procured from alternative legal sources;

iii. in case the animal is procured from alternative legal sources, the same shall be procured after taking written permission from the authority competent under the law for the time being in force, to give such permission; and Replacement alternatives, not involving experiments on animals, should be given due and full consideration, and sound justification must be provided, in case alternatives, though available, are not used.

4.9 Welfare of animals during use in experiments

In terms of Rule 9 (cc) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, personnel using the experimental animals shall be responsible for the welfare of the animals during their use in experiments. The CPCSEA Guidelines for Laboratory Animal Facility also spell out the baseline procedures to be followed when using animals in the course of scientific experimentation, including quarantine and animal care.

4.10. Aftercare and rehabilitation of animals after use in scientific experiments

In terms of Rule 9 (cc) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, Investigators shall be responsible for the aftercare and rehabilitation of the animals after experimentation.

Costs of aftercare and rehabilitation of the animals after experimentation shall be made part of research costs and shall be scaled in positive correlation with the level of costs involved in such aftercare and rehabilitation of the animals.

Rehabilitation treatment of an animal after experimentation shall extend till the point the animals is able to resume a normal existence by providing a lump-sum amount as costs for rehabilitation and care of such animal to cover its entire statistical expected life span; and

The establishment undertaking experiments or duly licensed and authorized animal welfare organizations under the control of the Committee may, on payment of lump-sum amount, undertake rehabilitation of animals.

4.11. Situations Where euthanisation of animals is permissible

In terms of Rule 9 (cc) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, Investigators shall not euthanize animals except in situations as defined below:

i. When the animal is paralyzed and is not able to perform its natural functions or it becomes incapable of independent locomotion or it can no longer perceive the environment in an intelligible manner; or
ii. If during the course of experimental procedure the animal has been left wiyth a recurring pain wherein the animal exhibits obvious signs of pain and suffering; or
iii. Where the non-termination of the life of the experimental animal will be life threatening to human beings or other animals.

4.11 Suspension/revocation of registration of an establishment by CPCSEA

Rule 14 of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, provides as follows:

a. The Committee, if it is satisfied with the report of the Member- Secretary or the authorized officer of the Committee (made to it as a result of any inspection or information received or otherwise) that-

i. the rule made by it are not being complied with by an establishment or breeder; or
ii. a violation of the directions of the Committee has been committed by any establishment or breeder and the Committee's directions to rectify such violation have not been complied within the period so specified,

The Committee may, by order in writing, suspend or revoke the registration of the establishment or breeder and / or direct the closure of the animal house facility for such a period as may be specified in the order:

Provided that no order under this clause shall be made without giving the establishment or breeder nay opportunity of being heard in the matter.

Provided further that no order for suspension or revocation of registration, or closure of animal house facility shall be issued in a case of minor violation.

Explanation :

For the purpose of this clause, "minor violation" means an act of commission or omission which does not have direct bearing on the health of an animal; which may not lead to adverse health effect or pain or suffering or death of an animal.

Note :

All relevant Rules, Guidelines and minutes of the meetings of CPCSEA are available on the website of the Ministry of Environment and Forests: www.envfor.nic.in

APPENDIX

Relevant changes in Rules based on recommendations of the Consultative Group Based on the ethical principals so enunciated, the Consultative Group recommended changes in the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended. These were further deliberated upon, and duly incorporated after the Report of the Consultative Group was accepted in toto by CPCSEA. The changes in the relevant Rules are summarized as follows:

1. Change in Rule 2 (e) in the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, as amended

The definition of experiments has been widened to include the term "significant gains in the well-being of the people of the country", as additional criteria justifying the use of animals in experiment.

2. Insertion of Rule 9 (bb) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended

This addition provides that preference be according to the use of the minimum number of animals, lowest in the phylogenetic scale, which provide for statistically valid results at 95% degree of confidence. Use of replacement/alternatives is encouraged and sound justification is required in case alternatives to use of animals are not used, when available.

3. Insertion of Rule 9 (cc) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended

This provision makes the personnel using animals in experiments responsible for their welfare after use in experimentation, including aftercare and rehabilitation and also makes it mandatory for the costs of aftercare and rehabilitation to be made part of the research costs, as a lump sum provision based on the statistically expected life span of the animals. Rehabilitation may be undertake n by the establishment or by a duly licensed and authorized animal welfare organization.

4. Insertion of Rule 9 (ff) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended

This provides for the specific parameters, which are to be adopted when considering euthanisation of any animal used in scientific experiments. These include impairment of the natural functions of the animal including independent locomotion, when the animal faces recurring pan and suffering, and when the non termination of the life of the experimental animal would be life threatening of humans or other animals.

5. Amendment of Rule 10 (b) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended

This amendment allows the establishment to procure animals from any other legal source in case of non-availability with registered breeders, with suitable documentation to establish legality of the procurement process.

6. Amendment of Rule 10 (e) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended.

This provision allows the establishment to import genetically defined animals with the permission of DGFT, in case such animals are not available with registered breeders or other legal sources within the country. The condition of non-availability will not apply to genetically defined or laboratory bred rats and mice.

7. Amendment of Rule 12 in the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended

This Rule has been amended to allow establishments to undertake contract research as per the provisions of the PCA Act 1960 and the rules made there under.

8. Amendment of Rule 14 in the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended

The Rule has been amended to allow CPCSEA to take action against an establishment or breeder, based on the report of the Member Secretary or authorized officer, regarding any violations of the rules, or of directions of the Committee. In case of a major violation, CPCSEA may by written orders, suspend or revoke the registration of the establishment and / or order closure of the animal house facility, after giving the establishment or breeder an opportunity of being heard in the matter.