

## MINISTRY OF ENVIRONMENT AND FORESTS

### NOTIFICATION

New Delhi, the 23rd October, 2006.

S.O. 1818 (E). - Whereas certain draft rules to amend the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 were published, as required by sub-sections(1), (1A) and (2) of section 17 of the Prevention of Cruelty to Animals Act, 1960 (59 of 1960), under the notification of the Government of India in the Ministry of Environment and Forests number S.O.42(E) dated 10<sup>th</sup> January, 2006 inviting suggestions from all the persons likely to be affected thereby, before the expiry of the period of thirty days from the date on which copies of the Gazette containing the said notification are made available to the public;

And whereas the said Gazette was made available to the public on 10<sup>th</sup> January, 2006;

And whereas the objections/suggestion received in respect of the said draft rules, have been duly considered;

Now, therefore, in exercise of the powers conferred by sub-section (1), (1A) and (2) of Section 17 of the Prevention of Cruelty to Animals Act, 1960 (59 of 1960), the Committee for the purpose of control and supervision of experiments on animals hereby makes the following rules to amend the Breeding of and Experiments on Animals (Control & Supervision) Rules, 1998, namely:-

1. (1) These rules may be called the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006.  
(2) They shall come into force on the date of their final publication in the Official Gazette.
  
2. In the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 (hereinafter referred to as the said rules), in rule 2, for clause (e), the following clause shall be substituted, namely:-

**'(e) "Experiment" 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 animal(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 well being for people of the country or for combating any disease whether of human beings or animals;'**

3. In rule 9 of the said rules, -

(1) after clause (b), the following clause shall be inserted, namely:-

**"(bb) 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 using minimum number of animals to give statistically valid results at 95% degree of confidence:**

**Provided that 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;" ;**

(2) after clause (c), the following clause shall be inserted, namely:

**"(cc) (i) personnel using experimental animal(s) shall be responsible for the welfare of animal(s) during their use in experiments;**

**(ii) investigators shall be responsible for the aftercare and rehabilitation of animal(s) after experimentation, and shall not euthanise animal(s) except in situations as defined in clause (ff);**

**(iii) costs of aftercare and rehabilitation of animal(s) 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 animal(s);**

**(iv) rehabilitation treatment of an animal after experimentation shall extend till the point the animal 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**

**(v) the establishment undertaking experiments or duly licensed and authorised animal welfare organization under the control of the Committee may, on payment of lump-sum amount, undertake rehabilitation of animals;" ;**

(3) after clause (f), the following clause shall be inserted, namely:-

**"(ff) the following parameters shall be adopted for application of euthanasia, namely:-**

**(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 with 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. In rule 10 of the said rules, -

(1) for clause (b), the following clause shall be substituted, namely:-

**“(b) (i) an establishment shall acquire animal(s) for experiments from registered breeders only;**

**(ii) in case of non-availability of animal(s) from registered breeders, the animal(s) may be procured from alternate legal sources;**

**(iii) in case the animal is procured from the alternate 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**

**(iv) the establishment procuring such animal shall maintain a record in this regard and shall produce the same before the Committee, whenever required;” ;**

(2) for clause (e), the following clause shall be substituted, namely:-

**“(e) In case an animal is not available from a registered breeder or from alternate legal sources within the country, genetically defined animals may be imported with permission of Directorate General of Foreign Trade:**

**Provided that the condition of non-availability within the country shall not apply for laboratory bred rats and mice of genetically defined strains;”.**

5. For rule 12 of the said rules, the following rule shall be substituted, namely:-

**“12. Contract animal experiments. - Registered establishments may undertake contract research on behalf of any other agency in accordance with the Prevention of Cruelty to Animals Act, 1960 (59 of 1960) and the rules made thereunder.”.**

6. In rule 14 of the said rules, for clause (a), the following clause shall be substituted, namely:-

**“(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 rules 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 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 any 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 purposes 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."**

(F.No.25/04/2005-AWD)

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Note:- The principal rules were published in the Gazette of India, Extraordinary, vide number S.O. 1074 dated 15<sup>th</sup> December, 1998 and subsequently amended vide number S.O.134(E) dated 15<sup>th</sup> February, 2001.