

Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998

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Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998

Ministry of Social Justice and Employment, Noti. No. S.O. 1074(E), dated December 15, 1998, published in the Gazette of India, Extra., Part II, Section 3(ii), dated 15th December, 1998, pp. 5-9, No. 809 [F. No. 7-5/98-AW] In exercise of the powers conferred by sub-section (1)(1-A) and (2) of Section 17 of the Prevention of Cruelty to Animals Act, 1960 (59 of 1960), the Committee for control and supervision of experiments on animals hereby makes the following rules, namely :-

1. Short title and commencement :-

(1) These rules may be called the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions :-

In these rules, unless the context otherwise requires,-

(a) "Act" means the Prevention of Cruelty to Animals Act, 1960 (59.of 1960);

(b) "breeder" means a person including an institution, which breeds animals for the purpose of transfer to other authorised institution for performing experiments;

(c) "Committee" means the Committee constituted under Section 15 of the Act for control and supervision of experiments on animals;

(d) "establishment" means any individual, company, firm, corporation, institution other than schools up to higher secondary level, which performs experiments on animals;

1 (e) "experiment" means any programme/project involving use of animal(s) for acquisition of knowledge of a biological, psychological, 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, testings 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 the combating any disease whether of human beings or animals ;

(f) "Institutional Animals Ethics Committee" means a body comprising of a group of persons recognised and registered by the Committee for the purpose of control and supervision of experiments on animals performed in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the Committee;

(g) "contract research" means any research undertaken by an individual, company, firm, corporation or institution on behalf of a foreign individual, company, firm, corporation or institution for any consideration;

(h) "collaborative research" means any research undertaken between two or more research institutions on an equal footing which does not involve any financial or monetary considerations and is undertaken solely for the purpose of advancement of scientific research and human welfare;

(i) "specified format" means the form specified for the purpose by the Committee from time to time.

In the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, In Rule 2, clause (e) substituted in place of :- "(e) "experiment" means any programme/project involving experiments on an animal/animals for the purpose of advancement by new discovery of physiological knowledge which will be useful for saving or prolonging life or alleviating suffering or for combating any disease whether on human beings or animals;" by the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006 on Notification N.F.No.25/04/2005;AWD,dt.23rd October, 2006-Gazette of India, Ext.,Pt.II- S.3(ii), No. 1279, dt.25th Oct., 2006,p.5]= 2006 CCS/P.1387/H. 510.

3. Breeding of animals :-

(a) No establishment shall carry on the business of breeding of animals or trade of animals for the purpose of experiments unless it is registered.

(b) Every breeder/establishment carrying on the business of breeding animals or trade of animals for the purpose of experiments, shall, apply for registration within sixty days from the date of commencement of these rules and, stop breeding of animals if registration is subsequently refused to it by the Committee.

4. Registration of establishments :-

(a) No establishment shall perform any experiment on animals unless it is registered.

(b) Every establishment performing experiments on animals, shall, apply for registration within sixty days from the date of commencement of these rules and, stop performing experiments on animals if registration is subsequently refused to it by the Committee.

5. Application for registration :-

(a) The application for registration by a breeder under sub-rule (b) of Rule 3 and an establishment under sub-rule (b) of Rule 4 shall be made in the specified format to the Member-Secretary or any other officer authorised in this regard by the Committee.

(b) The Member-Secretary or the authorised officer of the Committee, may for deciding the issue of registration, ask for information relating to premises where the experiments are to be conducted, animal housing facilities, details of breeding of animals

and its trade, other infrastructure including availability of manpower trained in handling animals and for verification of facts mentioned in the application for registration, and if satisfied, shall register such establishment or the breeder.

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(c) A breeder or the establishment on registration for the purpose of performing experiments on animals shall comply with the conditions as may be specified at the time of registration by the Committee.

(d) The Committee or any other officer authorised in this regard by the Committee shall take decision on the registration within three months of making the application.

(e) If any modification of facilities are required before registration, the details needed shall be communicated by the Committee.

".]

1. Substituted for "(c) A breeder or the establishment on registration for the purpose of performing experiments on animals shall comply with the conditions as may be specified, at the time of registration, by the Member-Secretary of the Committee or any officer authorised in this regard by the Committee.", by the "Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2001".

6. Details of the experiments conducted :-

". .

(a) Every registered establishment shall maintain a register of particulars about the animals used from day to day for conducting experiments, with the number of animals, the species, the age, gender and other relevant particulars."

(b) "The Committee or any other officer authorised by the Committee may examine the register so maintained and if the Committee is not satisfied even after opportunities given for improvement, it may take such action as may be appropriate under these rules."

7. Stocking of animals :-

The animals shall be stocked by the breeder and the establishment in the following manner :-

(a) animal houses shall be located in a quiet atmosphere undisturbed by traffic, and the premises kept tidy, hygienic and the

animals protected from drought and extremes of weather;

(b) animal cages for small animals and stables for large animals shall be such that animals can live in comfort and overcrowding is avoided;

(c) where standards have been laid down by the Indian Standards Institution, the cages, the stable, as the case may be, shall conform to those standards;

(d) animals' attendants must be suitably trained and experienced in the duties allotted to them;

(e) animals shall be looked after, before and after the experiments by a trained and experienced attendant;

(f) there shall be satisfactory arrangement for looking after the animals during off hours and on holidays.

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"(g) detailed specifications for housing, feeding and maintenance of various species to be used in animal experimentation as notified by the Committee, shall be adhered to by the registered establishment.

(h) In the interim period till such details specifications are notified, the breeders and establishments shall comply with the standards specified by the Indian National Science Academy guidelines."

1. "Sub-rule (g) and (h)" inserted after sub-rule (f) of Rule 7, by the "Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2001".

8. Permission of the Committee required for conducting experiments :-

(a) Every registered establishment before acquiring an animal or conducting any experiment on an animal/animals shall apply for permission of the Committee or the Institutional Animals Ethics Committee recognised for the purpose by the Committee along with the details contained in the specified format to the Member-Secretary of the Committee or the Institutional Animals Ethics Committee, as the case may be.

(b) The Member-Secretary of the Committee or the Institutional Animals Ethics Committee, shall cause the application for permission to be brought before the Committee/ Institutional Animals Ethics

Committee as the case may be, and the Committee/Institutional Animals Ethics Committee after scrutiny of the application, if satisfied, may grant permission to the establishment stating the name of the species and the number of animals that can be acquired for carrying out the experiments.

(c) The Committee or Institutional Animals Ethics Committee, as the case may be, may, while granting permission for conducting experiments on animals, put conditions as it may deem fit to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them.

(d) The Committee may require the establishments and Institutional Animals Ethics Committees and persons carrying on experiments on animals to forward to the Committee such information as it may require, on completion of experiments for which the permission has been granted.

9. Performance of experiments :-

In conducting experiments on animals, regard shall be had to the following conditions, namely :- ⁵

["(a) experiments shall be performed in every case by or under the supervision of a person duly qualified in that behalf, that is, Degree holders in Medicine or Veterinary Science, Post Graduate and above in Life Sciences/Pharmaceutical Sciences or any other Natural Sciences, Degree or Diploma holders in Pharmacy, Diploma or Certificate in Laboratory Animal Techniques Sciences from a recognized institution as identified by Committee for the Purpose of Control and Supervision of Experiments on Animals for the purpose and under the responsibility of the person performing the experiment;";]

(b) experiments shall be performed with due care and humanity;

⁶"(bb) animals lowest on the phylogeneratic scale which may give scientifically valid result shold be first considered for any experimental produce and the experiment shold be designed using minimum number of animals to give statistically valid result at 95% degree of confidence:

provided that replacement alternatives not involving experimentals on animals should be given due and full consideration and should justification must be provided in case alternatives, though available

are not used;"

(c) animals intended for the performance of experiments are properly looked both before and after experiments;

7(cc)

(i) personal 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) cost of aftercare and rehabilitation of animal(s) after experimentation shall be made part oof research costs and shall be scaled in positive correlation with the level of costs involved in such aftercare and rehabilitation of animal(s).

(iv)rehabilitation treatment of an animal after experimentation shall extend till the point the animal is able to resume a normal existance 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.

(d) experiments involving operative procedure more severe than simple inoculation or superficial venesection shall be performed under the influence of anaesthetic to prevent the animal feeling pain and it shall remain so throughout the experiment. Anaesthesia shall be administered by a Veterinary Surgeon trained in methods of anaesthesia or a Scientist/technician so trained for this purpose and who shall remain present near the animals till the completion of the experiment;

(e) animals which in the course of experiments under the influence of anaesthetic are so injured that their recovery would involve pain or suffering shall be destroyed humanely while still under the influence of anaesthesia;

(f) when there is reason to believe that an animal is suffering abnormal or severe pain at any stage of a continuing experiment, it

shall be painlessly destroyed at that stage without proceeding with the experiment;

8(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."

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["(g) the experiments shall not be performed for the sole purpose of attaining or retaining manual skill except in schools, colleges and programmes duly scrutinized and permitted in registered establishments by the Committee;"]

(h) experiments shall not be performed by way of an illustration;

(i) experiments shall not be performed as a public demonstration;

(j) **10** ["no paralyzing agent, including but not limited to curare, shall be used"] or administered for the purpose of any experiment except in conjunction with anaesthetic of sufficient depth to produce loss of consciousness;

(k) no experiment, the result of which is already conclusively known, shall be repeated without previous justification;

(l) there shall not be applied to the eye of an animal by way of experiment any chemical substance for the purpose of absorption through the conjunctival membrane or through the cornea calculated to only give pain;

(m) dogs held for experimental purposes shall not be debarked;

(n) where experiments are performed in any institution, the responsibility therefor is placed on the person in charge of the institution and in cases where experiments are performed outside

an institution by an individual qualified in that behalf, the experiments are performed on his responsibility,

Substituted for "(a) experiments shall be performed in every case by or under the supervision of a person duly qualified in that behalf, that is Degree or Diploma holders in Veterinary Science or Medicine or Laboratory Animal Science of a University or an Institution recognised by the Government for the purpose and under the responsibility of the person performing the experiment;" by the "Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2001".

In the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, In Rule 9, clause (bb) inserted as follows:- "(bb) animals lowest on the phylogenetic scale which may give scientifically valid result should be first considered for any experimental purpose and the experiment should be designed using minimum number of animals to give statistically valid result at 95% degree of confidence: provided that replacement alternatives not involving experiments on animals should be given due and full consideration and should justification must be provided in case alternatives, though available are not used;" by the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006 on Notification N.F.No.25/04/2005;AWD,dt.23rd October, 2006-Gazette of India, Ext.,Pt.II- S.3(ii), No. 1279, dt.25th Oct., 2006,p.5]= 2006 CCS/P.1387/H. 510.

In the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, In Rule 9, clause (cc) inserted as follows:- "(cc)(i) person 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) cost 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 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. by the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006 on Notification N.F.No.25/04/2005;AWD,dt.23rd October, 2006-Gazette of India, Ext.,Pt.II- S.3(ii), No. 1279, dt.25th Oct., 2006,p.5]= 2006 CCS/P.1387/H. 510.

In the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, In Rule 9, clause (ff) inserted as follows:-

"(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." by the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006 on Notification N.F.No.25/04/2005;AWD,dt.23rd October, 2006-Gazette of India, Ext.,Pt.II- S.3(ii), No. 1279, dt.25th Oct., 2006,p.5]= 2006 CCS/P.1387/H. 510.

Substituted for "(g) the experiment shall not be performed for the purpose of attaining or retaining manual skill except in schools, colleges and recognised training institutions;", by the "Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2001".

Substituted for "the substance known as Urari or Curare or any such Paralyisan shall not be used", by the "Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2001".

10. Transfer and acquisition of animals for experiment :-

(a) A breeder shall not transfer any animal by sale or otherwise to an establishment which is not registered under these rules.

11(b)

(i) an establishment shall acquire animal(s) for experimental from registered breeders only;

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

(iii) in case the animal is produced from the alternate legal sources, the same shall be produced taking written permission from the authority competent under the law for the time being in force, to give such permission; and

(iv) the establishment producing such animal shall maintain a record in this regard and shall produce the same before the committee, whenever required;

(bb) For the acquisition of laboratory bred experimental rats and mice species of genetically defined strains not available within the

country, the registered breeders or establishments shall apply for permission to the Institutional Animal Ethics Committee recognized by the Committee for the Purpose of Control and Supervision of Experiments on Animals."

(c) Every establishment after acquisition of an animal or animals shall not transfer such animal or animals by sale or otherwise to any other establishment or person except to a registered breeder/establishment.

(d) The animals used for experimentation in a production/breed improvement programme may be given out by the breeder institution for domestic use.

12 (e) In case of 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 the laboratory bred rats and mice of genetically defined strains;

(f) A breeder or an establishment shall comply with the directions given by the Committee for the purpose of controlling and supervising experiments on animals.

In the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, In Rule 10, clause (b) shall be substituted in place of:- "(b) A breeder or establishment shall not acquire any animal by sale or otherwise except from a registered breeder or establishment." by the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006 on Notification N.F.No.25/04/2005;AWD,dt.23rd October, 2006-Gazette of India, Ext.,Pt.II- S.3(ii), No. 1279, dt.25th Oct., 2006,p.5]= 2006 CCS/P.1387/H. 510.

In the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, In Rule 10, clause (e) shall be substituted in place of:- "(e) No animal shall be imported by a registered breeder or establishment, except genetically defined or laboratory bred experimental rats and mice of genetically defined strains, which is available in the country." by the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006 on Notification N.F.No.25/04/2005;AWD,dt.23rd October, 2006-Gazette of India, Ext.,Pt.II- S.3(ii), No. 1279, dt.25th Oct., 2006,p.5]= 2006 CCS/P.1387/H. 510.

11. Records :-

(a) Every establishment/institutional Animals Ethics Committee shall maintain a record of the animals under its control and custody in the specified format.

(b) Every establishment/institutional Animals Ethics Committee shall furnish such information, as the Committee may, from time to time require in the specified format.

(c) All laboratories shall inform the exact number/species of animals to the Member Secretary or any officer authorised in this regard by the Committee as per the specified format.

12. Contract animal experiments :-

13 Registered establishment 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.

In the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, In Rule 12 shall be substituted in place of:- "12. Contract animal experiments.- No establishment shall contract or undertake to perform contract research or experiments on contract basis on behalf of any other establishment or research or educational institution, except with prior permission of the Committee: Provided that no such restriction shall apply to collaborative research between academic institutions." by the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006 on Notification N.F.No.25/04/2005;AWD,dt.23rd October, 2006-Gazette of India, Ext.,Pt.II- S.3(ii), No. 1279, dt.25th Oct., 2006,p.5]= 2006 CCS/P.1387/H. 510.

13. Composition of Institutional Animals Ethics Committee

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Every Institutional Animals Ethics Committee shall include: a biological scientist, two scientists from different biological disciplines, a veterinarian involved in the care of animals, the scientist in charge of animals facility of the establishment concerned, a scientist from outside the institute, a non- scientific socially aware member and a representative or nominee of the Committee, A specialist may be co-opted while reviewing special projects using hazardous agents such as radioactive substance and deadly microorganisms.

14. Power to suspend or revoke registration :-

14 (a) the Committee, if it is satisfied with the report of the

Member-Secretary or the authorised officer of the Committee (made to it as a result of any inspection of information or otherwise) that-

(i) the rules made by it are not being complied with by an establishment or breeder;

(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 with 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 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 suffering or death of an animal."

(b) The Committee may, pending the final determination, if, it is of the opinion that an establishment or breeder has prima facie failed to comply with the provisions of these rules, suspend the registration of such establishment or the breeder.

(c) The Committee may in the event of revocation or suspension of registration of an establishment or breeder, issue such directions as it deems fit for the care and protection of the animals which are under the custody or control of such establishment or the breeder.

(d) That in the event of suspension or revocation of a license, such establishment or breeder shall forthwith on the communication of the order cease to perform any experiment on any animal or acquire or transfer any animal.

In the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, In Rule 14, clause (a) shall be substituted in place of:- "(a) If the Committee is satisfied, on the report of the Member-Secretary or the authorised officer of the Committee made to it as a result of any inspection or information received otherwise that the rules made by it are not being complied with by any establishment or breeder or an Institutional Animals Ethics Committee, the Committee may, after giving a reasonable opportunity to the establishment or breeder or Institutional Animals

Ethics Committee of being heard in the matter, revoke the registration of such establishment or breeder or Institutional Animals Ethics Committee either for a specified period or indefinitely, or may allow the establishment or breeder or Institutional Animals Ethics Committee to carry on subject to such special conditions as the Committee may impose." by the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006 on Notification N.F.No.25/04/2005;AWD,dt.23rd October, 2006-Gazette of India, Ext.,Pt.II- S.3(ii), No. 1279, dt.25th Oct., 2006,p.5]= 2006 CCS/P.1387/H. 510.