Law by Decree of January 27, 1992
on the protection of all animals used for experiments or other scientific purposes

Art. 1

The present decree regulates the protection of all animals used for experiments or other scientific purposes.

Art. 2

Referring to the present decree, it is intended that:

a) "animal", not otherwise specified: any alive vertebrate non human, including all forms of self-governing larvae able or non able to reproduce excluding other fetal or embryonic forms;

b) "animals for experiments": every animal used or to be used for experiments;

c) "breeding animals": bred animals to be only used for experiments in facilities with the approval, or registered, of the competent Authority.

d) "experiment": the use of an animal for experiments or other scientific matters which can cause, pain, distress, anguish or temporary lasting damages, including any action which intends or determines the birth of an animal in these conditions, but excluding all methods less painful of killing or of marking of an animal commonly accepted as humanitarians; an experiment starts when an animal is prepared, for the first time, for the experiment and ends when further observations are not needed for the experiment going on; the elimination of pain, suffering, anguish or lasting damages through the correct application of an anaesthetic, analgesic or other methods, does not include the utiliser of an animal outside this definition. Agricultural or veterinary clinic practices, non experimental, are excluded;

e) "Authority responsible for the control of experiments": Ministry of Health.

f) "Competent person": anyone, provided he/she has the right requisitions to carry out the functions foreseen in the present decree;
g) "Facility": any plant, building, group of buildings or other local; it can also include places which are not completely closed or covered and mobile structures;

h) "Breeding facility": any facility in which the animals are bred exclusively to be later on used for experiments;

i) "Supplying facility": any facility different from the breeding one, which supplies the animals that are going to the used for experiments;

j) "Utilize facility": any facility in which the animals are used for experiments;

k) "Adequately anaesthetized": bereft of sensibility through methods of local or general anaesthesia, according to the veterinary practice;

l) "Killing with humanitarians methods": killing of an animal with methods, depending on the species, of less physical and psychological suffering.

Art.3

1) The use of animals in experiments other than the ones foreseen in article 1, comma 1, of the Law of June 12, 1931, n.924, modified with Law of May 1, 1941, n.615, is allowed only for one or more of the following purposes:

a) The development, production and tests for quality, efficiency and innocuity of all pharmaceutical preparations, of food and all other substances or products needed:
   1) for the prophylaxis, diagnosis or the cure of illness, bad physical conditions or other anomalies or their effect on humans, animals or on plants;
   2) for the evaluation, the survey, the control or modifications of the physiological conditions in humans, animals or plants.

b) The protection of the environment in the interest of the well being of humans and animals.

2) The experiments can be carried out only with bred animals belonging to the species listed in annex 1, excluding dogs, cats and non human primates, and can only take place in authorized "utilize facilities".

3) The experiments are forbidden on animals belonging to species in extinction, as per Law 19 of December 1975, n.874, which confirm
the Washington Convention, and also for animals belonging to threatened species, as per annex C1 of the CEE regulations 3626/82.

4) The use of animals is allowed also in basic research experiments propaedeutic aiming at experiment as per comma 1.

5) The violation to commi 1, 2, 3 and 4, are punished with a sanction varying from ITL 5 millions to 60 millions.

Art. 4.

1) The experiments as per art. 3 can be carried out only when, to reach the wanted results, it is not possible to use other scientific valid method, which does not imply the use of animals.

2) When it is not possible, as per comma 1, to avoid an experiment, the competent health authority has to be provided with all documentation regarding the type of experiment; among all experiments, the preferable ones are:

   1) the ones which required a minor number of animals;
   2) the ones which imply the use of animals with the lowest neurologic development;
   3) the ones which cause less pain, agony, suffering or lasting damages;
   4) the ones which have the most probabilities of satisfactory results.

3) All experiments have to be carried out under general of local anaesthesia.

4) An animal cannot be utilized twice in experiments which cause strong pain, anguish or equivalent suffering.

5) The experiments have to be carried out, directly or under the direct responsibility of a graduate in medicine and surgery, veterinary medicine, biology, natural sciences or by other people with an equivalent other title recognised by the Ministry of Health, in agreement with the Ministry of University and of Scientific and Technologic Research.

6) All persons carrying out experiments or persons who are directly in charge or are responsible for the control of animals used in experiments have to be adequately instructed.
7) The person who carries out the experiment or supervise it, has to have a scientific knowledge pertaining the experimental activities for which he is responsible, and has to be able to handle and look after the laboratory animals, moreover he has to demonstrate to the competent authority a sufficient high level on the subject.

Art. 5.

1) Anyone who breeds, supplies or uses animals for experiments has to assure, as per annex II, that:

   a) the animals are kept in a place which allows freedom of movement and are provided with food, water and care for their well being;

   b) any possible limitation for the animals' physiological and behavioural satisfaction has to be reduced;

   c) daily check to verify the physical conditions in which the animals are bred, kept or utilized, have to be effected;

   d) a veterinary doctor checks the well being and the health conditions of the animals to avoid lasting damages, pain, useless anguish or suffering;

   e) the right measures have to be adopted, to correct any fault or suffering which have been noticed.

Art. 6

1) The experiments have to be carried out in a way to avoid useless anguish and pain or suffering to the animal.

2) If in line with the results of the experiment, the animal which suffers a lot after the effect of the anaesthesia is over, have to be treated with analgesics or, if this is not possible, has to be immediately killed with humanitarians methods.

3) The animal which is kept alive, after an experiment, can be kept in the utilize facility or other facility as long as the conditions as per art. 5 are assured.

4) A good veterinary doctor checks on the good execution of the experiment procedures, at the end he decides wether the animal can be kept alive or killed; he proceed to its killing when the animal
suffers or when it is not possible to keep the animal in well being conditions, as per art. 5.

5) It is forbidden to carry out on animals any operation which causes aphonia and it is forbidden the use, for experiments, of aphonic animals.

Art. 7

1) Anyone who intends to effect experiments has to communicate it to the Ministry of Health, indicating the address of the utilize facility and producing the complete documentation valid to demonstrate that the experiment is necessary to realize a research project aimed at one of the purposes as per art. 3, comma 1, inevitable as per art. 4 and assured conditions foreseen in art. 5, and sends a copy also to the region, to the prefecture, to the town council and the competent health local unit.

2) Research projects as per comma 1, which are not relative to ordinary tests or quality, efficiency and innocuity, have a maximum duration of three years; if it is foreseen that said time is not sufficient, the interested party, has to ask the Ministry of Health the authorization for the prosecution of the experiment. This has to be done a year before the end of the three years.

3) In derogation of comma 1, diagnostic, medical and veterinary medical tests, which foresee the use of animals, have to be carried out accordingly with the procedures of the present decree, prior communication to the competent local health unity.

Derogatory dispositions

Art. 8

1. The Ministry of Health, on request, can authorize:

   a) experiments on animals as per art. 3, comma 3, as long as the experiments are in agreement with the CEE 3626/82 regulations and are aimed to the research on conservation of the considered species or essential medical-biological verifications, as long as the considered specie reveals to be the only one suitable for the scope;
b) experiments on non human primates, dogs or cats, only when aiming at medical-biological verifications and when experiments on other animals do not respond at the scopes of the experiment.

2. The Ministry of Health decides, with the authorization decree, eventual prescriptions to be followed while carrying out the experiment.

3. In derogation to art. 3, comma 1, the Ministry of Health authorizes the experiments as simple method of teaching only in case of intransgressible necessity and impossibility to resort to other demonstrative methods.

Art. 9

1. In derogation to art. 4, comma 3, an experiment can be carried out without anaesthesia, only on authorization of the Ministry of Health and only if anaesthesia is more traumatic for the animal than the experiment itself or if it is exceptionally incompatible with the purpose of the experiment.

2. In the hypothesis as of comma 1, analgesics or other adequate methods have to be used, to ensure that pain, suffering and anguish are reduced and that residual pain, suffering, and anguish are not strong.

3. Each experiment, which implicates or may implicate serious lesions or strong pain which could protract, has to be specifically declared to the Ministry of Health, which authorizes it at the conditions in comma 1 and only in case of exceptional importance to the experiment.

Facilities

Art. 10

1. The Council authorizes the opening of breeding and supplying facilities, keeps an updated list of all authorized facilities and transmits a copy to the Ministry of Health, as well as the Region and the Prefecture.
2. Facilities as per comma 1 have to satisfy the conditions as of art. 4, commi 6 and 7, and art. 5.

3. The person responsible of a supplying facility can receive animals only from a breeding facility or from other supplying facilities or animal legally imported, as long as they are not wild or stray animals.

4. The authorization as per comma 1, has to specify the competent person in the facility who is in charge of assuring directly or able to organize assistance to the bred animals or the animals kept in the facility in respect to the procedures of the present decree.

Art. 11

1. The person responsible of breeding and supplying facilities, has to register the number and species of animals sold or supplied, the date in which they have been sold or supplied, the name and address of the addressee, as well as the number and specie of the animals which have died in the same facility.

2. The council authority submits to signature the registers which have to be kept in authorized facilities for a minimum of three years starting from the date of the last registration and kept at disposal of the authority which effects the inspection.

Art. 12

1. Whoever wants to open a utilizing facility has to obtain the authorization of the Ministry of Health.

2. Authorization is given if:

1) the utilizing facilities are supplied with adequate equipment for the species of animals used and the type of experiments carried out;

2) the conception, construction and functionality can guarantee that the experiments are carried out in the most appropriate way, as to obtain the best results with the minor number of animals possible and the least pain, suffering, anguish or lasting damages;
3) the persons responsible for the animals assistance and the functioning of the equipment are individualized;

4) a medical doctor can assure veterinary assistance as well as advices on the well being of the animals.

3) The person responsible for utilizing facilities has to keep a register in which all animals used are noted; in particularly, the registers have to indicate the number and the specie of all animals bought, their origin and the date of their arrival, of their birth and death.

4) The registers as per comma 3, previously signed by the Ministry of Health, have to be kept for at least three years and have to be presented upon request to the authority.

Art. 13

1. Every dog, cat or non human primates which lives in a breeding, supplying or utilizing facility, has to have, before weaning, an individual identification mark in the least painful way.

2. Dog, cats or non human primates, not marked and brought to a facility for the first time after weaning, have to be marked as soon as possible.

3. For dogs, cats or non human primates not yet weaned, which are transferred to a facility as per comma 2 or in other facility and have not been marked, the facility of destination has to keep a detailed documentation, in particularly on the of the mother, until the marking of the animal.

4. The facilities have to keep registers in which all details regarding the identity of all dogs, cats or non human primates present are shown.

Sanctions

Art. 14

1. Whoever outlaws the rules as per art. 5 and 6, is punished with the administrative sanction ranging from ITL 5 millions to 30 millions; in case of continuous or habitual violation, the sanction is extended up to ITL 150 millions.
2. The veterinary doctor who omits to the advises and assistance for the well keeping of the animals, and omits to the well execution of the experiments or carries them out with negligence or inexperience will be deferred from the veterinary doctors' Order.

3. Whoever carries out authorized experiments without observing the rules of the authorization is punished with the administrative sanction ranging from ITL 5 millions to 20 millions.

4. All violations to the other rules of the present decree are punished with the administrative sanction ranging from ITL 1 million to 6 millions.

Final and temporary rules

Art. 15

1. The Ministry of Health collects statistic data on the utilization of animals for experimental purposes on the basis of all elements contained in the authorization requests, in the communications received as well as from the reports presented and publishes them at least every three years in the Gazzetta Ufficiale of the Italian Republic.

2. Statistic data refer to:
   a) the number and species of animal used for experiments;
   b) the number of animals of which in letter a), divided per categories; utilized in experiments, as per art. 3;
   c) the number of animals of which in letter a) divided in categories, utilized in experiments requested from the laws in force.

3. Information reached in application of the present decree must not be published when they aim to a particular commercial interest.

Art. 16
1. To avoid useless repetitions of experiments in compliance with the legislative dispositions and the community dispositions relative to health and safety, the Ministry of Health, through the Superior Institute of Health with reference to the procedures foreseen to art. 9 of the law n. 833, dated December 23 1978:

a) considers valid, when possible, all data resulting from experiments carried out in other member Country unless additional verification is needed to protect public health and safety;

b) adopts, as official methods, those which require a lesser number of animals, as species and categories.

c) adopts, supporting the respective competence of the Superior Institute of Health and the General Direction of veterinary services, alternative methods for the optimization of the utilization of animals.

2. The Ministry of Health communicates to the Commission of the European Community informations on the legislation and the administrative reports regarding experiments on animals, including all obligations to follow before the commercialisation of products as well as informations on all the experiments carried out, all the authorizations and any other administrative element concerning the experiments.

Art. 17

1. In the program and planning of scientific research applied to human and animal health and to the healthiness of the environment, the preferite ones will be:

a) those which do not need experiments on animals;

b) those which use alternative methods;

c) those which use a minor number of animals and use less painful procedures;

d) research which use a minor usage of species and number of animals;

e) research intended for the study of alternative methods.
2. The Ministry of Health, with its own decree which will be issued within a year from the date of coming into force of the present decree, decides the necessary requisitions for purposes as per art. 4, commi 6 and 7.

Art. 18

1. The Ministry of Health with its own decree, heard the superior institute of Health, can limitate the number of species, as per annex I or categories within each specie.

2. The Ministry of Health, with its own decree can modify the lines of purposes as per annex, to analyse the technological progress.

3. The Ministry of Health adopts, with its own decree, serious measures in the utilization of animals in experiments.

Art. 19

1. Expenses relative to inspections and controls, necessary for the authorizations foreseen from the present decree, are charged to the requestor.

Art. 20

1. The dispositions as per law dated June 12, 1931 n. 924, modified with law dated May 1 1941, n. 615, are abrogated, with exception to art. 1, commi I and III.

The present decree, provided with the State seal, will be included in the Official Collection of the normative acts of the Italian Republic. It is a must for anyone to observe it.

Dated Rome, January 27, 1992