governing the conduction of animals experiments

Based on Act XXVIII of 1998 of the protection and sparing of animals (hereinafter: animals protection law) the Government orders as hereunder:

Article 1
The scope of this decree shall cover all individuals that are qualified to carry out animal experiments, all institutions (establishments) in which animal experiments are being carried out and all interventions that are performed on an animal used or intended to be used in experiments that may cause it pain, suffering, distress or lasting harm.

Definitions

Article 2
For the purposes of this decree

1. Animal means any live non-human vertebrate, (Vertebrata) including free-living and/or reproducing larval forms, but excluding other fetal or embryonic forms;
2. Experimental animal means animals used or to be used in experiments;
3. Laboratory animal means animals specifically bred for use in experiments in facilities approved by or registered with the authority;
4. Establishment means any installation, building, group of buildings or other premises that may include a place that is not wholly enclosed or covered and mobile facilities;
5. Breeding establishment means any establishment where animals are bred and raised with a view to their use in experiments;
6. Supplying establishment means any establishment, other than a breeding establishment, from which animals are supplied with a view to their use in experiments;
7. User establishment means any establishment where animals are used in experiments;
8. Holding facility means any building, premises or equipment in which experimental animals are housed.

Article 3

Official supervision

Article 4
(1) Breeding, supplying and user establishments shall be approved by, registered with and supervised by the competent county, (municipal) veterinary and food control station (hereinafter: Station).
(2) During control the Station shall respect the hygienic and operational regulation in place at approved and registered units.
Care and accommodation of experimental animals

Article 5
(1) Any animal used or intended for use in an experiment shall be provided with accommodation, an environment, at least a minimum degree of freedom of movement, food, water and care, appropriate to its health and well-being. Any restriction on the extent to which an animal can satisfy its physiological and ethological needs shall be limited as far as practicable.

(2) During the accommodation and care of experimental animals arrangements shall be made to ensure that
   a) each animal is provided with accommodation and environment, sufficient degree of movement, food, water and care appropriate to its health and well being,
   b) any restriction on the extent to which an animal can satisfy its physiological and ethological needs shall be limited as far as practicable,
   c) the environmental conditions in which animals are bred, kept or used shall be checked daily,
   d) the well-being and the state of health of animals shall be observed by a competent person to prevent pain or avoidable suffering, distress or lasting harm,
   e) arrangements shall be made to ensure that any defect or suffering discovered is corrected as quickly as possible.

(3) The detailed rules governing care and accommodation of experimental animals are set out in Appendix No.1.

Authorization of animal experiments

Article 6
(1) No animal experiment shall be carried out unless authorized by the competent Station. Application for an animal experiment as approved by the workplace veterinary committee (hereinafter: WVC) shall be lodged in accordance with Appendix no.2. When an application for the conduction of an animal experiment is assessed the Station shall seek the opinion of the Veterinary Advisory Body Scientific and Ethical Council for Animal Experiments (hereinafter: Ethical Council). The authorization shall be valid – with the exceptions determined in this decree – for a maximum period of five years.

(2) Experiments may, where authorized by the Station, be conducted outside user establishments.

(3) The Station shall have the right to regularly but at least once a year or randomly check the conduction of animal experiments authorized as per Subsection (1), and the holding rooms. During which it may inspect the files and observe the conduction of an experiment.

(4) In case of violation of the legislation concerning the conduction of an animal experiment or the keeping circumstances of experimental animals or the breach of conditions included in the application and approved by the authority the Station may suspend the experiment until after the deficiencies are corrected or withdraw the permit issued for the experiment, or for the breeding, supplying or user establishment.

(5) In case of violation of the legislation concerning the conduction of an animal experiment or the keeping circumstances of experimental animals or the breach of conditions
included in the application and approved by the authority the Station may, at the same
time with withdrawing the permit issued for experiment, breeding, supplying or user
establishment, debar the person performing animal experiments or the user
establishment – with a view to the gravity of the breach committed – from further
conduction of animals experiments for a fixed term but for a minimum of six months
and a maximum of three years.

**Article 7**

(1) Additionally to laboratory animals
   a) animals bred for economic purposes or individuals of co-species coming from a
      stock or establishment under continuous control by a veterinarian may also be used
      for the purposes of animal experiments, and
   b) …

(2) The authorization to conduct an animal experiment shall not extend to stray animals of
domesticated species including stray dogs and cats.

(3) Anthropoid primates (gorillas, chimpanzees and gibbons) shall not be used in
experiments.

(4) Experiments on species under nature conservancy protection or falling in the scope of
international nature conservancy convention may not be carried out unless the
experiment serves nature conservancy interests. Such experiments may be authorized
for essential medical research in which at least second generation bred animals are
used and no other animals would suffice for the aims of the experiment.

(5) Experiments on animals taken from the wild may not be carried out unless
experiments on other animals are not likely to provide satisfactory results.

**Article 8**

(1) A supplying establishment shall obtain animals only from a breeding or other
supplying establishment except if a general or special exemption from this is granted
by the veterinary authority and the supplier establishment complies with the conditions
therein.

(2) In user establishments, only animals supplied from registered breeding or supplying
establishments shall be used, unless a general or special exemption has been obtained
from the Station.

*Approval of animal experiments*

**Article 9**

(1) An experiment shall be notified to and have it approved by WVC in advance. Approval
shall apply to the experimental methods to be used in an experiment or in a series of
experiments.

(2) The application for the approval shall include
   a) the aim of the experiment, information that supports it scientifically,
   b) species, genetic and microbiological status, number of animals,
   c) accommodation conditions of the animals and the fate of the animals at the end
      of the experiment,
   d) start and expected duration of the experiment,
e) measures to prevent or avoid pain, suffering and lasting harm caused to the animal,
f) name and qualification of the head and the supervisor of the experiment.

(3) The Station – based on the opinion of the Ethical Council – may exceptionally authorize an experiment that entails very severe pain. The application for such an experiment shall include a detailed explanation. Judgment on the severity of pain – based on suggestion by the head of the experiment – shall be made by WVC.

(4) WVC shall keep record of experiments approved by it and of the veterinary training carried out in the institute (training thematic, list of participants).

(5) The head of the experiment shall notify the chairman of WVC in writing of experiments authorized.

Statistical information

Article 10

(1) Statistical information shall be collected on animals used in experiments. The statistical information shall be retained for five years from the end of an animal experiment.

(2) Detailed rules governing collection of statistical data shall be set out in Appendix no.3.

(3) The head of an experiment shall send statistical data referenced in Subsection (1) to the chairman of WVC by the 15th of January of the year following the subject year.

(4) The chairman of WVC shall send annual summary data on approved experimental sites and animal experiments, as referred to in Appendix no.3., to the competent Station in writing by January 31, each year. The Stations shall forward the summary data to the Ministry of Agriculture and Rural Development (hereinafter: Ministry) by February 15, each year. The Ministry shall publish the summary data in its official journal and on its internet homepage each year.

(5) The Minister of Agriculture and Rural Development shall comply with its data supply obligation to the European Commission in respect of legislation and experience relating to animal experiments and under this obligation it shall, at an interval of three years, inform the European Commission of summarized results of data supply referenced in Subsection (3).

Article 11

(1) This decree shall enter into force on April 1, 1999.

(2)-(3)

(4) This decree, in conformity with Article 3 of Act I of 1994 proclaiming the European Agreement about the establishment of an association between the Republic of Hungary and the European Communities and their member countries signed in Brussels on 16th December 1991, contains regulation comparable to Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes.
Appendix no.1 to government decree 243/1998 (XII.31)

Accommodation and care of animals used for experimental and other scientific purposes

The facility

1. Any facility and their units (premises) should be so constructed as to
   a) ensure the well-being of the animals kept there and limit the chance of their being infected from the environment or by the staff,
   b) ensure satisfactory level and safe working of people working there including prevention of infection by animal diseases transmitted by the animals,
   c) ensure a hygienically clear link between the holding facility and the environment, exclude but at least limit damage to the holding facility from the environment and to the environment from the operation of the facility (contaminating substances, smell, noise, waste, etc).

Environmental factors of holding rooms

Ventilation

2. Air changes in holding rooms should be so regulated as to keep down the level of noxious gases (carbon dioxide, hydrogen sulphide, ammonia) that are typical of premises where there are animals, to a concentration that is not harmful for the experimental animals.

3. Smoking in rooms where there are animals should be forbidden.

Temperature

4. In holding rooms
   a) the temperature should satisfy the requirement of the species housed there.
   b) the temperature should not exceed the limit values in the table below.

<table>
<thead>
<tr>
<th>Species or groups of species</th>
<th>Optimal range in °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>16-26</td>
</tr>
<tr>
<td>Rat</td>
<td>16-26</td>
</tr>
<tr>
<td>Hamsters</td>
<td>16-26</td>
</tr>
<tr>
<td>Guinea pig</td>
<td>16-28</td>
</tr>
<tr>
<td>Rabbit</td>
<td>12-24</td>
</tr>
<tr>
<td>Cat</td>
<td>16-26</td>
</tr>
<tr>
<td>Dog</td>
<td>16-26</td>
</tr>
</tbody>
</table>

The figures in the table apply to adult and healthy animals.
In breeding and user establishments a precise temperature control in the holding rooms shall be required.
**Humidity**

5. In holding premises the relative humidity should satisfy the requirement of the species housed there.

**Lighting**

6. Permanent light or permanent darkness for a long duration is harmful for animals. Therefore it is necessary to alternate light-dark periods. For animals requiring medium intensity light the holding rooms should be intensively illuminated for the duration of the work only. The intensity of light should be reduced when the work is over.

**Noise**

7. Holding rooms should be insulated against external noise sources and efforts should be made to avoid artificial and sudden noises.

**Vibration and resonance**

8. Vibration and resonance may agitate animals. No experimental laboratory is to be established in the immediate vicinity of many or high performance fans unless special vibration and noise reducers are installed.

**Housing**

9. Animals should be provided with housing which is appropriate to their well-being. Animals should be allowed adequate space to express certain behavioral needs (climbing, hiding). Cleaning and effective disinfection should be made possible.

**Feeding**

10. Rules relating to the feeding of animals are set out in specific other legislation on the production and sale of fodders.

**Watering**

11. Uncontaminated drinking water should always be available to all animals. During transport of a few hours, it is acceptable to provide water as part of a moist diet.

**Bedding**

12. Animals should be provided with litter which is appropriate to the needs of species housed and which contains non-harmful materials. Litter should be changed as frequently as necessary to allow the animal adequate rest and to absorb urine and faeces and moisture.
Appendix no. 2 to government decree 243/1998 (XII.31)

Application for authorization for the conduction of animal experiment

1. Name of institution (user establishment): ........................................
   Address: ......................................................................................

2. Name of the head of institution: ..............................................
   Position: ......................................................................................
   Mailing address: ..........................................................................

3. User establishment’s registration number: ................................
   Name of registering veterinary authority: ......................................

4. Designation of experimental activity (research theme): .................

5. Which of the following objectives does the experimental activity answers:
   (more than one objective may be given, mark the primary objective with 1 and the rest with 2.)
   - diseases, ill health, prevention, diagnosis and treatment of disorders including production, qualification, efficacy and safety testing of drugs, chemical substances and other products.
   - detection, assessment, regulation or modification of physiological conditions in man, vertebrate and invertebrate animals or plants
   - protection of the environment
   - scientific research
   - education and training
   - forensic inquiries

6. How many years is the authorization required for? (maximum five years)

7. Do you have current authorization for this experimental activity?
   yes   no
   authorization number  when expires

8. Do you have or did you have authorization for another research activity that could be considered a forerunner to the present research activity?
   yes   no
   authorization number  when expires

9. Brief description, scientific explanation of the experimental activity:

(Write down the aim of, justification, scientific grounds (possibly with literature references) for the experiment and the result anticipated. If it is a routine testing refer to documents (regulation) justifying the need. If the intervention is for the purpose of education outline its use for the training participants. This part should not be longer than one page. Indicate the justification and scientific grounds for the modern method used. In the following part please, by all means, touch upon the aspects below:)

1. Do the animals feel pain in the experiment? If they do indicate the analgesic methods used.
2. Is it an acute or chronic (longer than one day) experiment?
3. Will surgery be performed during the experiment?
4. How will the animals be killed?
10. Listing of species intended for use in the experiment, with the indication of the number of animals planned for use:

11. This part is to be filled by the Workplace Veterinary Committee (WVC):

I hereby declare that the experimental activity will involve experimental methods that WVC had assessed and approved in advance.

The experimental activity shall not involve experiment exceptionally authorized.

The experimental activity shall involve experiment exceptionally authorized for which the applicant has filed a special application.

All persons participating in the animal experiment have received adequate education and training with regard to the protection of animals.

WVC backs the application filed.

Date: ……………………………

Name legibly and signature of the chairman of WVC

12. In the experimental activity applied the user establishment shall employ colleagues with the following education and qualification:

13. Has the user establishment other qualification? (e.g. GLP, ISO, etc.)

I hereby declare that care by a veterinarian is provided for the experimental animals as required.

I hereby declare that the information provided here is true. During the experimental activity I shall respect and have others respect legislation governing the protection and sparing of animals.

Date:

corporate signature
Appendix no. 3 to government decree 243/1998 (XII.31)

Statistical data management

General principles

WVC shall annually (by January 31 each year) summarize and report to the competent Station in writing the quantity of animals used in animal experiments, according to the tables 1 to 5. Counting starts when the animals are first prepared to be used in a proceeding (experiment). Every animal shall be counted once in the same very table. Animals that are not subject to an experiment are not to be counted in the total.

Table 1

Quantity and species of animals used in experiments (annually)

<table>
<thead>
<tr>
<th>Bred for experiments</th>
<th>Bred for other purposes</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse (Mus musculus)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rat (Rattus norvegicus)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guinea pig (Cavia porcellus)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other rodents (Rodentia)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rabbit (Oryctolagus cuniculus f. domestica)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other monkeys (Cercopithecidae, Cebidate, Callithricidae)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Semi monkeys (Prosimia)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dog (Canis familiaris)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cat (Felis catus)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other carnivores (Carnivora)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Horse, donkey and hybrids (Equidae)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pig (Sus scroga domestica)</td>
<td></td>
<td></td>
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<tr>
<td>Goat and sheep (Capra hircus, Ovis aries)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other mammals (mammalian)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birds (Avesd)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reptiles (Reptilia)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amphibia (Amphibia)</td>
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<td></td>
</tr>
<tr>
<td>Fish (Pisces)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 2

**Quantity of animals used in experiment in a breakdown according to the purpose of use**

<table>
<thead>
<tr>
<th>Purpose of Use</th>
<th>All species</th>
<th>Rodents and rabbit</th>
<th>Dog, cat</th>
<th>Primate</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological basic research including medical and veterinary researches</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research, development, control of drugs for human and veterinary use</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>(excluding toxicological and safety testing)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis of diseases</td>
<td></td>
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<tr>
<td>Toxicological and other safety testing performed for the protection of man,</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>animals and the environment</td>
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</tr>
<tr>
<td>Education and training</td>
<td></td>
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<tr>
<td>Other</td>
<td></td>
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<tr>
<td>Total:</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Table 3

**Quantity of animals used in toxicological and safety experiments performed for the protection of man, animals and the environment**

<table>
<thead>
<tr>
<th>Substance</th>
<th>All species</th>
<th>Rodents and rabbit</th>
<th>Dog, cat</th>
<th>Primate</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substances used or intended for use in agriculture</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substances used in industry or intended mainly for industrial uses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substances used in household or intended mainly for household uses</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Food additives used for human consumption or intended for such use</td>
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<tr>
<td>Substances found in the general environment that are potential sources of</td>
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</tr>
<tr>
<td>infection, including harmful radiations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety testing of human and veterinary products and equipment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
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<tr>
<td>Total</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
### Table 4
Quantity of animals used in experiments performed in relation to diseases and disorders

<table>
<thead>
<tr>
<th>All species</th>
<th>Rodents and rabbit</th>
<th>Dog, cat</th>
<th>Primate</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human infectious diseases</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human immunobiological diseases</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Cancer (with the exception of carcinogenicity test)</td>
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</tr>
<tr>
<td>Cardiovascular diseases</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Nervous system and mental disorders</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Other human diseases</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Animal diseases</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table 5
Quantity of animals used in experiments required by legislation and authority

<table>
<thead>
<tr>
<th>All species</th>
<th>Rodents and rabbit</th>
<th>Dog, cat</th>
<th>Primate</th>
<th>Other</th>
</tr>
</thead>
</table>
Appendix no.4 to government decree 243/1998 (XII.31)

Reporting of animal experiments started before April 1, 1999 to the veterinary authority

1. Name of institution (user establishment):
   Address:

2. Name of the head of institution: …
   Position:
   Mailing address:

3. Designation of experimental activity (research theme): ………………………..

4. Which of the following objectives does the experimental activity answers:
   (more than one objective may be given, mark the primary objective with 1 and the rest with 2.)
   diseases, ill health, prevention, diagnosis and treatment of disorders including production, qualification, efficacy and safety testing of drugs, chemical substances and other products,
   detection, assessment, regulation or modification of physiological conditions in man, vertebrate and invertebrate animals or plants
   protection of the environment
   scientific research
   education and training
   forensic inquiries
   breeding of special experimental animals

5. Year of start of experimental activity:

6. Brief description of, scientific explanation of the experimental activity:

7. Listing of species used in the experiment:

8. In the experimental activity applied the user establishment employs colleagues with the following qualification:

I hereby declare that care by a veterinarian is provided for the experimental animals as required.

I hereby declare that the information provided here is true.

Date:

    corporate signature