

**ORDINANCE No. 25 OF 10 JUNE 2003 ON PROTECTION AND WELFARE OF
EXPERIMENTAL ANIMALS**

*ISSUED BY THE MINISTRY OF HEALTH, In force as of 01.01.2004
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Section I
General provisions

Article 1. This Ordinance shall lay down:

1. the conditions and procedure for using experimental animals;
2. the minimum zoo-hygiene parameters and criteria for animal welfare when keeping in stock and using experimental animals;
3. the requirements applicable to:
 - a) the persons who carry out experiments with animals;
 - b) the establishments for breeding, keeping in stock and/or supplying experimental animals;
 - c) the establishments where animals are used for experiments ;
4. the obligations of the control authorities.

Article 2. Experiments with animals shall only be carried out for one of the following reasons:

1. development, production, assessment of effectiveness and safety of application for humans and environment of drugs for the human and veterinary medicine, foodstuffs and food additives for humans and animals and other substances:
 - a) for diagnostics and prevention of diseases, testing of new schemes and methods of treatment of illnesses or ill-health conditions or other abnormalities and their effects in man, animals or plants;
 - b) for assessment, detection, regulation or modification of physiological functions in man, animals or plants;
2. study of the behavioural responses of the animals;
3. training at the secondary special, semi-high and high schools;
4. protection of the natural environment with view of preserving the health of humans and animals.

Section II
Procedure for obtaining permission to use animals for experimental and other scientific purposes

Article 3. (1) The use of animals for experimental and other scientific purposes shall be carried out only at the establishments specified in Article 69 of the Law on Veterinary Activities (LVA), after issue of permission to use animals in experiments by the Minister of Agriculture and Forestry or by a person authorized by the Minister.

(2) In performing his activity under paragraph 1 the Minister of Agriculture and Forestry is supported by an Animal Ethics Panel, hereinafter referred to as "the Panel".

(3) The Panel comprises nine members. It is composed by:

1. a veterinarian, representative of the National Veterinary Service (NVS);
2. a veterinarian, representative of the Veterinary Faculties);
3. a physician – toxicologist, representative of the Ministry of Health;
4. a scientist – biologist, representative of the Bulgarian Academy of Science (BAS);
5. an environmentalist, representative of the Ministry of Environment and Waters;
6. a zoologist, representative of the Biology Faculty at the Sofia University;
7. a physician, representative of the Medical University in Sofia;
8. a representative of the non-government organizations for protection of animals;
9. a jurist, representative of the Ministry of Agriculture and Forestry.

(4) The Panel members are nominated at the proposal of the managers of the respective institutions and organizations specified in paragraph 3 above. The representatives of the Veterinary Faculties are nominated on the basis of agreement between the Deans of the two Faculties.

(5) On its first meeting the Animal Ethics Panel adopts Rules of Operation and elects a Chairman and Deputy Chairman. The Rules of Operation are approved by the Minister of Agriculture and Forestry.

(6) The Panel convenes at least twice a year with minimum 2/3 of its members attending. It adopts its decisions with simple majority, and in case of equal number of votes the Chairman has a casting vote.

Article 4. (1) The owners or managers of the establishments where experiments are conducted, submit to the Minister of Agriculture and Forestry an application to obtain a permission to use animals in experiments.

(2) The application under paragraph 1 above must contain:

1. seat, address of headquarters and BULSTAT Code of the legal entity;
2. the objective of the experiments or other scientific studies in which animals will be used;
3. name, address, civil identification code of a person authorized by the owner or the manager of the establishment who will observe for the correct functioning of the equipment and for the hygiene at the premises for accommodation of the animals and their condition and who bears the overall responsibility with respect to the care for the experimental animals and observing by the requirements for their welfare;

4. name, address, civil identification code of a person authorized by the owner or the manager of the establishment who will conduct and/or under whose responsibility will the experiments or other scientific studies be conducted.

(3) The following shall be attached to the application under paragraph 1:

1. a certificate of registration for the vivarium at the establishments where experiments are conducted using animals, issued by the NVS;

2. list of the species and number of animals which will be used and detailed justification regarding the choice of animals, along with information describing where and in what manner will care be provided to the animals upon completion of the experiments;

3. list of persons participating in the performance of experiments or other scientific studies, and documents certifying that they have attained a level of vocational qualification sufficient for performing such experiments and studies;

4. documents evidencing an attained level of vocational qualification by the persons under items 3 and 4 of paragraph 2 above.

(4) In the cases of a designed scientific project for which it is unavoidable to use experimental animals, the following should also be attached to the application:

1. description of the procedures to be performed;

2. assessment of the possible harm to the animals;

3. forecast duration of the project;

4. where and in what manner will care be provided to the animals upon completion of the experiments.

(5) The persons under paragraph 1 shall be bound to notify the Ministry of Agriculture and Forestry within 14 days of any change in the circumstances under paragraphs 2 – 4 above.

(6) Upon finding inconsistencies in the presented documents the Ministry of Agriculture and Forestry forwards to the persons under paragraph 1 above, within 14 days as from their receipt, a notification for their elimination.

(7) The persons remedy the inconsistencies within 14 days as from the receipt of the notification under paragraph 6 above.

(8) The Minister of Agriculture and Forestry provides the application to the Panel for statement within one week as from its receipt or as from the remedy of the inconsistencies.

Article 5. (1) Within two months as from submission of the application and its accompanying documents or as from the date of remedy of the inconsistencies in the application the Minister of Agriculture and Forestry, on the grounds of a statement of the Panel, issues or denies to issue a permission for using animals in experiments.

(2) When preparing its statement for issue of permission for using animals in experiments the Panel considers whether the experiments:

1. involve the minimum possible number of animals;
2. involve animals with lower degree of neurophysiologic sensitivity;
3. cause the least pain, suffering, distress or lasting harm to the animals.

(3) When preparing its statement the Panel may consult independent experts in the field of the respective scientific study.

(4) The Minister of Agriculture and Forestry, on the grounds of the statement of the Panel issues permission for using animals in experiments for a period of 5 years.

(5) The data specified in Article 4, paragraphs 2, 3 and 4 above shall be recorded in the decision.

(6) Each issued permission shall be recorded in a Register by persons authorized by the Minister of Agriculture and Forestry. Information about an issued permission shall be forwarded to the Headquarters of the NVS.

(7) The Minister of Agriculture and Forestry issues a special permission if it is necessary to conduct experiments in which the animals will be subject to severe and lasting pain, only in the cases where such experiments are of particular importance. The special permission may include additional requirements and conditions with view of minimizing the suffering of the animals.

(8) Application for a new permission shall be submitted upon:

1. transformation of the applicant – legal person (inflow, merger, separation);
2. expiry of the term for which the permission was issued.

Article 6. (1) The Minister of Agriculture and Forestry makes a motivated rejection to issue permission and notifies the applicant in writing whenever:

1. the submitted application and the documents attached thereto don't comply with the requirements of the Ordinance;
2. the omissions in the presented documents are not remedied within the term specified in Article 4, paragraph 7 above;
3. the result of the experiment may be achieved with methods in which animals are not used;
4. the results of the experiment are already known and published in the scientific publications; in this case the person under Article 4, paragraph 1 above is advised, with view of avoiding unnecessary repetition of experiments, to use the data from similar experiments already conducted locally and abroad and published in the scientific publications.

(2) The rejection to issue permission shall be subject to appeal with the Supreme Administrative Court pursuant to the procedure of the Law on Administrative Proceedings.

Article 7. (1) The Minister of Agriculture and Forestry withdraws the issued permission:

1. whenever the data contained in the application and in its accompanying documents, on the grounds of which the permission has been issued, are found to be incorrect;
2. upon finding a breach to the requirements of this Ordinance by the control authorities under Section IX;
3. upon termination of the legal entity which has obtained the permission.

(2) The decision for withdrawal of permission and the motives for it are communicated in writing to the person concerned.

(3) The decision under paragraph 2 above may be appealed against pursuant to the procedure of the Law on Administrative Proceedings.

Section III

General conditions applicable to the use of experimental animals

Article 8. (1) Where animals belonging to the species listed in Annex No. 1 are to be used for experimental and other scientific purposes, they must be specially bred for this purpose at the establishment where experiments are conducted with animals or at the establishments under Article 21.

(2) Exceptions under paragraph 1 are admissible after obtaining permission of the Minister of Agriculture and Forestry.

Article 9. Endangered animal species included in the Red Book of the Republic of Bulgaria, in Appendix I of the Convention on International Trade in Endangered Species of Fauna and Flora (SG, No. 6 of 1992) and Annex No. 3 of the Bio Diversity Law (SG, No. 77 of 2002) shall be used for experimental and other scientific purposes only in the case of:

1. research aimed at preservation of the endangered species in question;
2. scientific research of exceptional importance in the field of medicine, for which the endangered species in question are the only one suitable for achieving the sought results.

Article 10. (1) It is prohibited to use stray dogs and cats for experimental and other scientific purposes.

(2) It is prohibited to conduct experiments for training purposes in which death is caused to the animals. At the training institutions the experiments with animals shall be replaced by other methods of visualization of the training material in all instances where the aim is not for the trainees to learn specific practical skills.

Article 11. (1) The use of wild animals in experiments is admissible where it is not practicable to achieve the objectives of the experiment by using other animals, provided that this does not violate the provisions of the Bern Convention on Preserving the Wild Flora and Fauna (SG, No. 13 of 1991) and after obtaining permission of the Minister of Agriculture and Forestry upon proposal of the Panel.

(2) For each particular case under paragraph 1 and under Article 9 the Minister of Agriculture and Forestry shall issue separate permission, provided that a detailed justification of the necessity to conduct the experiment is submitted together with the application. The Panel shall draw up its statement to the Minister of Agriculture and Forestry after consultations pursuant to the procedure of Article 5, paragraph 3.

(3) The provisions of the Law on Hunting and Preservation of Game and the provisions of Articles 133 and 134 of the Implementing Regulation on the Law on Veterinary Activities (SG, No.55 of 2000; amend. SG, No. 4 of 2001) and Section IV of Chapter Three of the Bio Diversity Act shall be observed when catching wild animals.

(4) The wild animals shall be caught in a humane manner and by people with experience who have knowledge about the habits and the natural habitat of the animals subject to catching.

(5) Where it is necessary to apply anaesthetic or sedative medical drug to catch the animals provided for in paragraph 1 above, the anaesthetic shall be applied by a veterinarian.

(6) Veterinary aid shall be immediately provided to the animals in the cases of injury at the time of catching.

(7) If the veterinarian judges that the animal will keep living in pain or suffering, regardless of the veterinary aid provided, it shall be subject to euthanasia.

Section IV

Minimum zoo-hygiene parameters and criteria for welfare of the experimental animals

Article 12. The owners and managers of the establishments for breeding, keeping in stock and/or supplying animals, and of the establishments where animals are used for experiments, are bound to:

1. provide premises for keeping the animals in stock, where these premises:
 - a) enable freedom of movement of the animals;
 - b) are suitable for their normal anatomic and physiological development;
 - c) do not obstruct the normal reproductive process of the given animal species;
2. provide an opportunity for maximum satisfaction of the physiological and ethological needs of the animals;
3. perform daily control of the conditions of feeding, watering, breeding and working with the animals;
4. enable free access of each animal to the feeding and watering troughs;
5. ensure conditions, care and attention appropriate to the inherent needs of the animals;
6. ensure daily cleaning up and removal of excrements in the premises and cages without causing stress to the animals;

7. provide regular mechanical cleaning up and disinfection of the premises, facilities and inventory and mandatory disinfection upon changing one batch of animals with another;
8. reliable system in place to control the entrance into and exit from the establishment of external persons;
9. provide appropriate facilities for protection of the animals against insects, rodents and other pests;
10. avoid accommodating in the same premises animals of species that are not compatible, animals of different age groups and sex, where this may result in aggression and hostile behaviour of the animals;
11. prohibit the smoking at the premises for accommodation of the animals;
12. check on daily basis the automatic lines and mechanical facilities (if such are available at the establishment) and immediately repair all failures that have occurred, and where this is not possible, provide for other ways of feeding, watering and maintaining the zoo-hygiene requirements;
13. provide regular veterinary services with view of preventing or eliminating as soon as possible a condition of pain, suffering, distress or lasting harm of the animals;
14. ensure daily check-up of the health status of the animals and the conditions of their surrounding environment;
15. ensure the issue and abidance by internal rules for keeping in stock and care for the animals in line with the provisions of this Ordinance.

Article 13. (1) The experimental animals shall be transported pursuant to the requirements of Ordinance No. 4 of 2000 on the veterinary requirements for the welfare of animals during transportation (SG, No. 16 of 2000).

(2) With a written declaration the sender guarantees that the animals are in good health for transportation and notifies the recipient in advance about the date and time of delivery.

(3) The sender and the shipper shall take all measures of precaution with regard to the loading and transportation in order to avoid unwanted suffering inflicted as a result of traumas, inappropriate ventilation, exposure to high temperatures, shortage of food and water, delays, etc.

(4) Transportation of sick animals and animals with ill health shall be prohibited, except for the cases where such is required because of therapeutic or diagnostic reasons.

(5) Transportation of female animals in advanced stage of pregnancy and of female animals with probability to deliver during the transportation, or which have delivered in the last 48 hours, and their litter, where the umbilical cord has not yet fallen off, shall be prohibited.

(6) The shipment with animals shall be accepted and unloaded without delay and all supplied animals shall be registered and marked in accordance with the provisions of Articles 24, 25 and 30.

(7) After check-up the animals shall be accommodated in cages or pens and provided with food and water.

(8) The boxes for transportation and the vehicles shall be cleaned up and disinfected after each use.

Article 14. (1) The animals newly arriving at the establishments under Articles 21 and 26 shall be put under quarantine for a given period of time depending on their species, where the quarantine period shall be determined by a veterinarian in accordance with Annex No. 2.

(2) During the quarantine period the animals shall not be used for experimental and other scientific purposes.

(3) The sick animals shall be isolated from the other animals in separate premises and shall be subject to continuous veterinary observation. They shall be examined by a veterinarian as soon as possible and, where necessary, treated. The animals which are not likely to recover shall be subject to euthanasia.

Article 15. (1) The animals used for experimental and other scientific purposes shall be accommodated, depending on the features of their species, in cages, pens or stalls pursuant to Annex No. 3.

(2) The cages, pens and stalls under paragraph 1 above shall be made of material which is not hazardous to the health of the animals and does not hurt them.

(3) Where the cages are intended for use more than once they have to be made of material suitable for cleaning and disinfection.

(4) The floor of the cages, pens and stalls shall be suitable for the species and age of the animals and shall be constructed so as to facilitate the removal of waste.

(5) The pens must be constructed in a manner which facilitates their cleaning and enables the animals to satisfy their basic ethological needs such as climbing, hiding or finding a shelter and protection against coming into contact with other animals.

Article 16. (1) All experimental animals shall be provided with enough quantity of food and water depending to the species, age and their physiological condition.

(2) All feeding racks must be regularly cleaned and if necessary – sterilized. Where damp feedingstuffs are used or it is likely for the feedingstuff to easily become soiled with water and urine, regularly cleaning shall be ensured.

(3) The food for the animals shall be prepared in a manner which prevents the chemical, physical and microbiological contamination.

Article 17. (1) All animals shall be provided free access at any time to fresh drinking water which meets the requirements of Ordinance No. 9 of 2001 on the quality of water intended for drinking and domestic use (SG, No. 30 of 2001) by using:

1. bottles for small rodents that are:

a) made of transparent material which enables observing their contents and equipped with wide neck which makes their cleaning efficient and easy; in the instances where plastic materials have been used it should be thermo-resistant;

b) equipped with caps, plugs and nozzles made of materials resistant to sterilization and easy to clean;

2. automatic systems for watering which shall be regularly checked up, washed out and maintained in order to avoid incidents and spreading of infections;

3. other systems for watering.

(2) All bottles and their accessories shall be regularly disassembled, cleaned up and sterilized or replaced by clean and sterile new bottles.

(3) Regular chemical and bacteriological studies of the used system for watering shall be carried out in order to monitor the quality of the water.

(4) The water for animals raised under strictly determined chemical and microbiological parameters of the environment shall be acidated or additionally chlorinated in order to limit the outgrowth of microorganisms and some potential pathogens.

(5) The aquariums and reservoirs for pecies, amphibians and reptiles whose susceptibility to acidity, chlorine and other substances in the water varies within broad ranges shall be provided with water adapted to the needs and susceptibility limits of the individual species.

(6) In the cases where the animals are accommodated in cages with solid bottom the risk of flooding must be minimized.

Article 18. (1) The animals shall be provided with bedding which is dry, absorbing, does not accommodate dust, is not toxic, does not contain infectious agents or pests and does not harm their health in any other way.

(2) It shall be prohibited to use saw dust or materials obtained from wood or other chemically processed materials.

(3) The bedding of the animals shall be changed regularly to prevent it from becoming a source of infections and outgrowth of parasites.

Article 19. The owners and managers of the establishments under Articles 21 and 26 shall be bound to organize the up-keeping of high standard of hygiene at the establishments through regular mechanical cleaning, washing, disinfection and replacement of the cages, accessories, bottles and the remaining equipment with clean ones.

Article 20. (1) Where it becomes necessary to kill the experimental animals because of medical indications, the killing shall be done by a veterinarian, or under his direct supervision, using the methods specified in Annex No. 4.

(2) The methods of killing presented in the table of Annex No. 4 shall be applied only provided that the process of killing is completed in one of the ways specified and the occurrence of death is confirmed by the veterinarian:

1. confirmation of the irreversible stopping of blood circulation;
2. destruction of the cerebrum;
3. breaking the neck;
4. complete draining of blood;
5. occurrence of *rigor mortis*;
6. destruction of the body in an apparatus (masserator).

(3) Killing experimental animals by using electricity, where the electrical current is not passing through the brain, and by using non-depolarization miorelaxants with competitive type of effect shall be admissible only after preliminary application of anaesthesia.

(4) The ascertaining of death shall be reflected in a protocol which represents an integral part of the documents of the establishment and, where necessary, shall be supplemented by a post mortem protocol and histopathological examinations.

(5) Upon occurrence of the *rigor mortis* the corpses of the killed animals shall be treated pursuant to the procedure of the Ordinance No. 29 of 2002 on the veterinary and sanitary requirements to the collection and decontamination of waste of animal origin (SG, No. 75 of 2002).

Section V

Requirements to the establishments for breeding, keeping in stock and/or supplying experimental animals

Article 21. (1) The owners of the establishments for breeding, keeping in stock and/or supplying experimental animals shall register their activity pursuant to the procedure of Article 50 of the Implementing Regulations on the Law on Veterinary Activities. The Regional Veterinary Service forwards to the Headquarters of the NVS information about each registration made.

(2) With exception of the cases specified by the Minister of Agriculture and Forestry on the grounds of a statement of the Panel, the establishments under paragraph 1 above shall supply animals:

1. obtained from establishments for breeding and keeping animals in stock;
2. obtained from other supplying establishments for animals;
3. acquired through lawful import;
4. that are not feral or stray animals.

Article 22. The owners or managers of the establishments under Article 21 shall be bound to ensure:

1. a person authorized by them or by the persons in charge of the establishment, where this authorised person:

a) has higher education in biology, medicine, veterinary medicine, zoengineering or secondary specialized education in veterinary medicine;

b) monitors for compliance with the requirements for care and accommodation of the experimental animals in line with the provisions of this Ordinance and the internal rules at the establishment and bears the overall responsibility with regard to the care for the animals and meeting the requirements for animal welfare;

c) keeps the register provided for in Article 24;

d) organizes the process of feeding and watering of the animals, the cleaning and disinfection of the premises used for accommodation of the animals, and the cleaning and disinfection of the used equipment;

e) issues internal rules for work and care for the animals in accordance with the provisions of this Ordinance, and is responsible for their fulfillment;

2. medical service to the animals by a veterinarian who:

- a) regularly visits and makes observations on the health condition of the animals and takes immediate actions for elimination of a condition of pain, suffering, distress or illness experienced by the animals;
 - b) makes decisions for putting the animals into the isolation premises and determines the period of quarantine;
 - c) where necessary, performs euthanasia;
 - d) marks the animals;
 - e) maintains an ambulatory log book for any kind of treatment and manipulation applied to the animals;
3. personnel to care for the animals.

Article 23. (1) The owners or managers of the establishments under Article 21 shall be bound to provide at the establishments:

- 1. a changing room for the staff;
- 2. a filter for disinfection of the shoes prior to entering into the premises for accommodation of the animals;
- 3. premises for accommodation of the animals;
- 4. a room for manipulations equipped with laboratory glassware, equipment and instruments for conducting diagnostic tests, examinations and treatment of the animals and taking samples;
- 5. a room for preparing the animals for transportation;
- 6. a quarantine room for newly arriving animals;
- 7. a room for isolation of sick or injured animals;
- 8. service premises:
 - a) for storing food;
 - b) for storing clean cages, instruments and other equipment;
 - c) safe place for storing detergents and disinfection substances;
- 9. washing room large enough to enable installation of devices necessary for cleaning and disinfection of the used equipment, where the process of cleaning is organized in a way which separates the flow of the clean from dirty equipment, in order to prevent the contamination of the newly cleaned equipment;
- 10. an isolated room or containers for storing corpses and waste of animal origin; the premises, the vessels and the containers for storing the waste shall be cleaned, washed up and disinfected every time after use.

(2) The premises under paragraph 1 shall meet the following requirements:

- 1. the ceilings, walls, floors and doors shall be made of smooth surface which is resistant to corrosion and damages, impermeable to water and easy to clean and disinfect;
- 2. the angles between the walls and the floor shall be rounded or supplied with a specially constructed plinth made of material suitable for cleaning and disinfection;
- 3. the doors and the windows shall be constructed and safeguarded in a manner which prevents the entrance of animals, pests and insects; an observation lid shall be installed on the doors of the premises for accommodation of animals;
- 4. the design and construction of the corridors shall meet the standards applicable to the premises used for inhabitation; the corridors shall be wide enough to enable easy moving of the mobile equipment;
- 5. the siphons on the floor, if any, shall be appropriately covered and secured with a barrier preventing access of animals;
- 6. the premises used for accommodation of farming animals shall meet the requirements of Ordinance No. 14 of 2000 on protection and welfare of animals bred in holdings by means of intensive technologies (SG, No. 62 of 2000);
- 7. the premises intended for rodents shall be used also for accommodation of bigger species;
- 8. the yards to the premises for accommodation of experimental animals shall be fenced in a way which prevents direct contact and unauthorised access of persons and other animals.

(3) The premises under paragraph 1, item 3 shall:

- 1. be equipped with appropriate ventilation system constructed in a manner which prevents occurrence of draughts in the room and recirculation of the exhaust air and provides:

- a) fresh air for the animals;
 - b) low levels of smells, harmful gases, dust and infectious agents;
 - c) removal of the excess heat and humidity;
 - d) from 15 to 20 air exchanges per hour, where the density of the animals is bigger, and from 8 to 10 air exchanges per hour, where the density of the animals is smaller;
2. guarantee appropriate air temperature pursuant to Annex No. 5, which is subject to strict control and regulation in response to the climatic changes, the physiological condition and needs of the animals and the specific objectives of the experiment; the temperature shall be monitored by means of a thermometer installed in the room and by recording the data from the measurements in a log book at least twice a day;
3. guarantee that air humidity is maintained within the range of $55\% \pm 10\%$;
4. provide lighting as follows:
- a) natural lighting, by ensuring that the windows are situated so that the light spreads smoothly throughout the entire area used for accommodation of the animals;
 - b) controlled artificial lighting at the premises without windows, which shall be such as to simultaneously secure the biological needs of the animals and a satisfactory work environment;
 - c) lighting appropriate for albino animals or fir-less animals – depending on their sensitivity to the light;
5. ensure minimizing the level of noise and avoidance of constant and sudden noise; where appropriate, a constant sound may be provided with moderate intensity such as quiet music;
6. (in force from 01.01.2006) be equipped with an alarm system which, when activated, causes the least possible disturbance to the animals, and is used to signalize in the event of:
- a) fire;
 - b) unauthorized access;
 - c) technical problems or failure of the ventilation system;
 - d) temperature increases and decreases;
 - e) failure of the systems supplying with water the reservoirs for fish and the watering troughs;
7. a generator for the systems sustaining the life of the animals and the lighting in case of emergency or power supply interruption.

Article 24. (1) The person under Article 22, item 1 above shall keep a register at the establishments for breeding, keeping in stock and/or supplying animals.

(2) Subject to entry into the register under paragraph 1 above shall be information regarding:

- 1. the species and number of the animals newly arrived at the establishment, with their identification number and data about the origin;
- 2. the species and number of the animals sold, with their identification number;
- 3. the name and address of the supplier or the recipient of the animals;
- 4. the date of delivery and sale of the animals;
- 5. the species and number of the dead animals, with their identification number.

(3) The register shall be stored for at least 3 years as from the date of the last entry and shall be provided to the control authorities under Section IX upon inspection or request.

Article 25. (1) Each dog, cat and primate bred as experimental animal shall be marked by a veterinarian or his assistant.

(2) The animals shall be marked by fixing a microchip, ear tag or tattoo bearing an individual identification number before they are weaned and definitely before they leave the establishment of origin.

(3) Where the animals under paragraph 1 above are transferred from one establishment to another before they are weaned and it is not practicable to mark them beforehand, a full documentary record about the origin of the animal and detailed data about the parents must go along with the animal.

(4) Each animal which is taken into the establishments under Articles 21 and 26 for the first time must be marked as soon as possible.

(5) The method of marking and the individual identification number of the animals under paragraph 1 above shall be entered into the register under Article 24, paragraph 1 above.

Section VI

Requirements to the establishments where animals are used for experiments

Article 26. The owners or managers of the establishments where animals are used for experiments, shall register the vivarium to be used for accommodating the animals pursuant to the procedure of Article 50 of the Implementing Regulations on the Law on Veterinary Activities.

Article 27. The owners or managers of the establishments under Article 26 shall be bound to:

1. appoint an authorised person who:
 - a) has higher education in biology, medicine, veterinary medicine, zooengineering or secondary specialized education in veterinary medicine;
 - b) monitors for compliance with the zoo-hygiene requirements for accommodation of the experimental animals in line with the provisions of this Ordinance and the internal rules at the establishment, and bears the overall responsibility with regard to the care for the animals and satisfying the requirements for animal welfare;
 - c) organizes the process of feeding and watering of the animals, the cleaning and disinfection of the premises used for accommodation of the animals, and the cleaning and disinfection of the used equipment;
 - d) keeps the register provided for in Article 30;
 - e) issues internal rules for work and care for the animals in accordance with the provisions of this Ordinance, and is responsible for their fulfillment;
2. provide medical service to the animals by a veterinarian who:
 - a) is permanently appointed and controls on daily basis the health of the animals and gives advice during each stage or at the end of the experiment with respect to the well-being of animals and avoidance of unnecessary pain, suffering, distress or lasting harm;
 - b) makes decisions for putting the animals into the isolation premises and determines the period of quarantine;
 - c) where necessary, performs euthanasia of the experimental animals;
 - d) determines if the animals are fit to be used in experiments;
 - e) assesses the need to keep the animal alive or kill it at the end of the experiment;
 - f) marks the animals;
 - g) maintains an ambulatory log book for any kind of treatment and manipulation applied to the animals;
3. provide personnel to care for the animals.

Article 28. (1) The premises and equipment provided for in Article 23 shall be available at the establishments under Article 26, where such premises and equipment shall be suitable for the specifics of the experiments to be performed.

(2) The premises shall be constructed in a manner which enables conducting the experiments in the most effective way for the purpose of obtaining specific results while using minimum number of animals and inflicting minimum pain, suffering, distress or lasting harm to the animals.

Article 29. (1) Used at the establishments under Article 26 shall be only experimental animals bred, kept in stock or supplied from the registered establishments provided for in Article 21, except for the cases where special permission has been issued by the Minister of Agriculture and Forestry.

(2) Experiments outside the approved and registered establishment under Article 26 may be carried out on the basis of permission of the Minister of Agriculture and Forestry issued upon proposal of the Panel.

(3) The person in charge of the experiment shall draw up a protocol for each conducted experiment providing details about:

1. the species, number, sex and individual identification number of the used animals;
2. the starting date of the experiment;
3. brief description of the performed manipulations/operations;
4. description of any unexpectedly occurring disturbances or death of the animal;

5. the ending date of the experiment.

(4) The protocol shall be stored for at least 3 years as from the date of the last entry and shall be provided to the control authorities under Section IX upon inspection or request.

Article 30. (1) At the establishments where animals are used for experiments the person provided for in Article 27, paragraph 1 above shall keep a register recording details about:

1. the number, species, method of marking, individual identification number and details about the origin of the received and used animals;

2. the date of receipt;

3. the details regarding the site from where the animals have been supplied.

(2) The register shall be stored for at least 3 years as from the date of the last entry and shall be provided to the control authorities under Section IX upon inspection or request.

Article 31. (1) In the cases where experimental animals are bred or kept in stock at the establishments under Article 26, such establishments must also meet the conditions applicable to the establishments provided for in Article 21.

(2) In the cases pursuant to paragraph 1 above a common registration certificate shall be issued by the NVS.

Section VII

Requirements when conducting experiments with animals

Article 32. (1) The experiments with animals shall be performed by persons who have education directly connected to the subject of the experimental work and who have the required theoretical and practical knowledge about manipulations and care for the experimental animals, gained as a result of completion of a specialized course at an accredited training establishment under a programme approved by the NVS.

(2) The experiments under paragraph 1 shall be performed under the direct responsibility and/or supervision of the person provided for in Article 27, paragraph 1 or another competent person authorized by the owner or the manager of the establishment, where this person must:

1. have higher education in biology, medicine, veterinary medicine or zoengineering;

2. have 5 years of professional experience of which 3 years practical experimental work;

3. exercise control over the conducted experiments.

(3) Prior to, during and after completion of each stage of the experiment all persons participating in its performance shall strictly follow and fulfill the recommendations of the veterinarian with regard to the well-being of the animals and prevention of unnecessary pain, suffering, distress or lasting harm.

(4) When an experiment has to be performed, the choice of animal species shall be considered in the context of the specifics of the species and purpose of the study. The methods applied shall be those which use the minimum number of animals with low degree of neurophysiological sensitivity, and procedures which do not result in any pain, suffering, distress or lasting harm or cause such pain, suffering, distress or lasting harm to a minimum extent.

(5) Experiments on animals shall be conducted provided that it is not practicable to achieve the result sought of the experiment with methods not entailing the use of animals.

Article 33. The results from experiments carried out locally and abroad published in the scientific publications shall be deemed valid with view of avoiding the unnecessary repetition.

Article 34. (1) All experiments on animals shall be performed in a way which minimizes the causing of distress, unnecessary pain, suffering and lasting harm to the animals.

(2) To achieve the objective provided for under paragraph 1 above all experiments shall be carried out with application of general or local anaesthesia to the animals, unless the veterinarian judges that:

1. application of anaesthesia will be more traumatic to the animal than the experiment itself;

2. anaesthesia is incompatible with the objective of the experiment.

(3) A special permit is required to conduct experiments under the conditions of paragraph 2, item 2, to be issued when the Minister of Agriculture and Forestry, on the grounds of a statement of the Panel, judges whether the performance of the experiment is not unnecessary or is of exceptional importance.

(4) When conducting experiments under the conditions of paragraph 2, item 2 the veterinarian shall apply pain-relieving means or other appropriate methods to minimize the distress, pain and suffering experienced by the animals.

(5) After completion of each stage of the experiment and once the effect of anaesthesia has worn off, those animals which, upon judgment of the veterinarian, experience considerable pain shall be treated with pain-relieving means, provided that such action does not contradict with the objective of the experiment. Whenever the use of pain-relieving means is not possible, the animals shall be subject to euthanasia.

Article 35. (1) At the end of the experiment the veterinarian makes a detailed examination of each used animal and if the veterinarian judges that the health of the animal will be recovered completely, he/she shall accommodate the animal into the premises provided for in Article 23, paragraph 1, item 3, where the animal will be kept in accordance with the provisions of Section IV.

(2) If, after the examination provided for under paragraph 1 above, the veterinarian judges as unlikely that the health of animals recovers completely and it is likely that they will remain in a condition of strong pain and distress or it is not appropriate to keep them under the conditions provided for in paragraph 1 above, the veterinarian applies euthanasia to these animals.

(3) Whenever after the examination provided for in paragraph 1 above the veterinarian judges that the animal is in good health and does not represent hazard for the environment and the health of the people and animals, it may, depending on its species, be:

1. placed at a zoo or shelter for animals – for wild and exotic animals;
2. placed at a shelter or sold as animal companion – in particular, dogs, cats, hamsters, guinea-pigs;
3. set free in its natural habitat, back in the same aerial from where it was taken – in particular, wild animals typical for the Republic of Bulgaria that have been taken from the wild.

Article 36. (1) Any re-use of experimental animals shall be carried out under the conditions and according to the procedure of this Ordinance.

(2) Experimental animals shall not be used more than once for experimental and other scientific purposes inflicting severe pain, suffering, distress or lasting harm.

Section VIII Statistical information

Article 37. (1) On the basis of the permissions issued pursuant to Section II persons authorized by the Minister of Agriculture and Forestry collect and publish annually statistical information regarding the use of animals for experimental and other scientific purposes, in particular with regard to:

1. the number of the permissions issued for use of experimental animals;
2. the scientific field in which the experiments have been conducted, and number and species of the used experimental animals in the respective scientific fields according to Annex No 6.

(2) The company or trade secret shall be kept upon publishing the information under paragraph 1 above.

Section IX Control authorities

Article 38. (1) The Minister of Agriculture and Forestry through the NVS exercises control for compliance with the animal welfare requirements for the animals used for experimental and other scientific purposes, and for compliance with the permission issued pursuant to Article 5, paragraph 4.

(2) The Minister of Agriculture and Forestry with an order determines the officials who have the right to make inspections and compile acts for finding breaches to the provisions of this Ordinance.

(3) The National Veterinary Service controls for the compliance of the establishments under Articles 21 and 26 with the requirements of the Ordinance.

(4) The control is exercised in the course of routine veterinary activity or through inspections on the basis of signal about breach to the requirements of the Ordinance.

(5) The owners and managers of the establishments under Articles 21 and 26 provide access to the control authorities to all locations inside the establishment and supply them with the entire documentation to be inspected.

Article 39. (1) Upon finding breaches to the requirements pursuant to this Ordinance the control authorities issue instructions for their remedy.

(2) Whenever the breaches under paragraph 1 are not remedied within the term specified in the instruction, the control authorities impose administrative penalties pursuant to the Law on Veterinary Activities.

Supplementary provisions

§ 1. For the purpose of this Ordinance:

1. "Animals" shall mean mammals, poultry, amphibians, reptiles, pisces, mollusca, crustacea, amphibious, other vertebrate and invertebrate, bred by the man for profit and non-profit purpose or inhabiting the wild nature, including the free-living larval and/or reproducing larval forms, but excluding the foetal and embryonic forms.

2. "Care for the experimental animals" shall mean all tangible and intangible resources, used by the persons conducting experiments, for maintaining the animals in normal physical and mental condition, for reducing the suffering and increasing their stamina during an experiment. The care for the animals starts from the delivery of the animals for the experiment and continues till the experiment is complete and decision is made regarding the future fate of the animals pursuant to the requirements of Article 35.

3. "Euthanasia" means the killing of the animals by inflicting minimum physical or mental suffering, depending on their species.

4. "Cage" means a steadily fixed or mobile container which is closed by means of two solid walls and the other two are with grids or made of iron mesh, where one or more animals are kept during experiments or are transported. Depending on the number of animals and the size of the container, the freedom of movement of the animals is relatively limited.

5. "Pen" means an area surrounded by wall and grids where one or more animals are kept in stock. The freedom of movement of the animals in the pen is less limited than their freedom of movement in the cage.

6. "Box" means a space limited for individual servicing of the animals, their keeping in stock, breeding, quarantine, isolation and conducting experiments with them.

7. "Establishment" means building, facilities, group of buildings or other premises and may include an area which is not wholly enclosed or covered, along with the mobile equipment/apparatuses.

8. "Establishment for breeding, keeping in stock and/or supply of experimental animals" means any establishment where animals are kept in stock and bred with a view to their use in experiments or which supplies animals for use in experiments.

9. "Establishment where experiments are conducted with animals" shall mean the establishments under Article 69 of the Law on Veterinary Activities.

10. "Experiment" means any manipulation which is applied to animals for scientific research purpose and which may cause pain, suffering, distress or lasting harm to the animals, including any genetic modifications and actions intended, or liable, to result in the birth of animals in any such condition. The experiment starts when the animals are first prepared for the manipulations and ends when no further observations are to be made. Within the scope of the term are included also those manipulations that are undertaken with application of anaesthesia and analgesia on the animals. The

zoo-technical and clinical veterinary manipulations, including euthanasia and marking of the animals shall not be deemed an experiment.

11. "Experimental animals" shall mean animals used for scientific research and experimental purposes.

12. "Pain, suffering and lasting harm" means inflicting disturbances in the health (physical, mental and social) of the animals. This includes the causing of disease, trauma and physiological and mental discomfort at the time of conducting the experiment or afterwards (for example, after injecting carcinogenes).

13. "Distress" shall mean a condition resulting from inability or impossibility to adapt to the effect of irritating factors. The distress is normally associated with change in the mobility and may lead to stereotyping behaviour.

14. "Specially bred animals" shall mean those animals which are specially reared and bred at the establishments under items 8 and 9 specifically for the purpose of being used in experiments.

15. "Properly anaesthetized animals" shall mean animals deprived of sensation of pain by applying anaesthesia (local or general) as effective as those used in good veterinary practice.

16. "Vivarium" shall mean a premise at the establishments under Article 69 of the Law on Veterinary Activities, where the experimental animals are accommodated.

Final provisions

§ 2. This Ordinance has been issued pursuant to § 5 of the Law on Veterinary Activities.

§ 3. (Amended – SG, No. 73 of 2003) The Ordinance shall be enacted on 1 January 2004, with exception of Article 23, paragraph 3, item 6, which shall be enacted on 01.01.2006.

§ 4. At the latest by 31 December 2004 the existing establishments for breeding, keeping in stock and/or supplying experimental animals, as well as the establishments where experiments using animals are carried out, shall bring their operations in line with the requirements of this Ordinance.

§ 5. The implementation of this Ordinance is assigned to the Director General of the NVS.

Annex No. 1 to Article 8

List of experimental animals to be bred for use specifically for experimental and other scientific purposes

- Mouse - *Mus musculus*
- Rat (Norway rat) - *Rattus norvegicus*
- Guinea Pig - *Cavia porcellus*
- Golden Hamster - *Mesocricetus auratus*
- Rabbit - *Oryctolagus cuniculus*
- Non-human Primates
- Dog - *Canis familiaris*
- Cat - *Felis catus*
- Quail - *Coturnix coturnix*
- Frogs

Annex No. 2 to Article 14, paragraph 1

Guidelines for local quarantine periods at the establishments for experimental animals

Species	Days
Mouse	5 - 15
Rat	5 - 15
Gerbil	5 - 15
Guinea Pig	5 - 15
Syrian Hamster	5 - 15
Rabbit	20 - 30
Cat	20 - 30
Dog	20 - 30
Non-human Primates	40 - 60

Section I

Guidelines regarding the minimum area which must be provided to the animals in stock and during experiments

Animals should be provided with an opportunity to take exercise as often as possible. Regular contact should be maintained between the staff and the experimental animals so that the animals get accustomed to the human presence and activity and establish a sense of confidence. Where appropriate, time should be set aside for talking, handling and grooming the animals. The staff should treat the animals with sympathy and attention.

Table 1

Caging small rodents and rabbits

Species	Minimum cage floor area sq. cm	Minimum cage height cm
Mouse	180	12
Rat	350	14
Syrian Hamster	180	12
Guinea Pig	600	18
Rabbit 1 kg	1 400	30
2 kg	2 000	30
3 kg	2 500	35
4 kg	3 000	40
5 kg	3 600	40

When keeping the animals in stock and when preparing an experiment, consideration should be given to the potential growth of the animals to ensure adequate room according to this table in all phases of their growth. See also Figures 1 to 5 and 8 to 12.

Table 2

Caging small rodents in breeding

Species	Minimum cage floor area for mother and litter sq. cm	Minimum cage height cm
Mouse	200	12
Rat	800	14
Syrian Hamster	650	12
Guinea Pig	1 200	18
Guinea Pig in harems	1 000 per adult	18

Table 3

Caging breeding rabbits

Weight of doe kg	Minimum cage floor area per doe and litter sq. m	Minimum cage height cm	Minimum nest box floor sq. m
1	0,30	30	0,10
2	0,35	30	0,10
3	0,40	35	0,12
4	0,45	40	0,12
5	0,50	40	0,14

The minimum cage floor area per doe and litter includes the area of the nest box floor.

Table 4

Guidelines for housing cats
(during experiments and breeding)

Weight of cat kg	Minimum cage floor area per cat sq. m	Minimum cage height cm	Minimum cage floor area per queen and litter sq. m	Minimum pen floor area per queen and litter sq. m
0,5 - 1	0,2	50	-----	-----
1 - 3	0,3	50	0,58	2
3 - 4	0,4	50	0,58	2
4 - 5	0,6	50	0,58	2

The housing of cats in cages should be strictly limited. Cats confined in this way should be let out for exercising at least once a day, where it does not interfere with the experiment. Cat pens should be equipped with dirt trays, ample shelf room for resting and objects suitable for climbing and claw-trimming. In the cat cages the height means the vertical distance between the highest point on the floor and the lowest point in the top of the cage.

The minimum floor area may include the additional area provided as shelves. The minimum cage floor area per queen and litter includes the 0,18 sq. m. area of the kittening box.

When keeping the animals in stock and when preparing an experiment, consideration should be given to the potential growth of the animals to ensure adequate room according to this table in all phases of their growth. See also Figure 7.

Table 5

Housing dogs in cages
(during experiments)

Height of dog to point of shoulder	Minimum cage floor area per dog sq. m	Minimum height of cage cm
30	0,75	60
40	1,00	80
70	1,75	140

Dogs should not be kept in cages longer than it is absolutely necessary for the purpose of the experiment.

Caged dogs should be let out for exercise at least once a day unless it is incompatible with the purpose of the experiment. A time-limit should be set beyond which a dog should not be confined without daily exercise. Exercise areas should be large enough to allow the dog freedom of movement. Grid floors should not be used in dog cages unless the experiment requires it.

As a general rule the minimum cage height should be twice the height of the dog to the shoulder. The cage height means the vertical distance between the highest point on the floor and the lowest point in the top of the cage.

Table 6

Guidelines for housing dogs in pens
(in stock and during experiments)

Weight of dog kg	Minimum pen floor area per dog sq. m	Minimum adjacent exercise area per dog	
		up to 3 dogs sq. m	more than 3 dogs sq. m
< 6	0,5	0,5 (1,0)	0,5 (1,0)
6 - 10	0,7	1,4 (2,1)	1,2 (1,9)
10 - 20	1,2	1,6 (2,8)	1,4 (2,6)
20 - 30	1,7	1,9 (3,6)	1,6 (3,3)
> 30	2,0	2,0 (4,0)	1,8 (3,8)

Figures in brackets give the total area per dog, that is, the pen floor area plus the adjacent exercise area.

The dogs kept permanently outdoors should have access to a sheltered place to find protection against unfavourable weather conditions. Where dogs are housed on grid floors, a solid area should be provided for sleeping. Grid floors should not be used unless the experiment requires it. The partitions between pens should be such as to prevent dogs from injuring each other.

All pens must have a siphon on the floor or drainage system for waste removal.

Table 7

General guidelines for caging primates of the species most commonly used (superfamilies *Ceboidea*
and *Cercopithecoidea*)
(in stock and during experiments and breeding)

Weight of primate kg	Minimum cage floor area for one or two animals sq. m	Minimum cage height cm
<1	0,25	60
1 - 3	0,35	75
3 - 5	0,50	80
5 - 7	0,70	85
7 - 9	0,90	90
9 - 15	1,10	125

Because of the wide variations in sizes and characteristics of primates, it is especially important to match the shape and internal fittings (swings, catching rods, shelves at various heights) as well as the dimensions of the cages to the particular needs of the animals. The total volume of the cage is just as important for the primates as the floor area.

As a general principle, the height of a cage, at least for apes and other simians, should be its greatest dimension. Cages should be high enough at least to allow the animals to stand up erect.

The minimum cage height must be such as to allow them to swing in their full extension on the swings hanging from the ceiling without their feet touching the cage floor.

Where appropriate, perches, swings and shelf grounds should be fitted at various heights to allow the primates to use the upper part of the cage.

Compatible primates may be kept two to a cage. Where they cannot be kept in pairs, their cages should be so placed that they can see one another, but it should also be possible to prevent this when required.

The cage height is determined as the vertical distance between the highest point on the floor and the lowest point in the top of the cage.

Table 8

Guidelines for caging pigs
(in stock and during experiments)

Weight of pig kg	Minimum cage floor area per pig sq. m	Minimum cage height cm
5 - 15	0,35	50
15 - 25	0,55	60
25 - 40	0,80	80

The table would also apply to piglets. The pigs should not be kept in cages unless absolutely necessary for the purpose of the experiment and then only for a minimum period of time.

The cage height is determined as the vertical distance between the highest point on the floor and the lowest point in the top of the cage.

Table 9

Guidelines for accommodating farm animals in pens
(in stock and during experiments)

Species and weights kg	Minimum pen floor area sq. m	Minimum pen length m	Minimum pen partition height	Minimum pen floor area for groups sq. m / animal	Minimum length of feed rack per head m
Pigs 10 - 30	2	1,6	0,8	0,2	0,20

30 - 50	2	1,8	1,0	0,3	0,25
50 - 100	3	2,1	1,2	0,8	0,30
100 - 150	5	2,5	1,4	1,2	0,35
> 150	5	2,5	1,4	2,5	0,40
Sheep < 70	1,4	1,8	1,2	0,7	0,35
Goats < 70	1,6	1,8	2,0	0,8	0,35
Cattle < 60	2,0	1,1	1,0	0,8	0,30
60 - 100	2,2	1,8	1,0	1,0	0,30
100 - 150	2,4	1,8	1,0	1,2	0,35
150 - 200	2,5	2,0	1,2	1,4	0,40
200 - 400	2,6	2,2	1,4	1,6	0,55
> 400	2,8	2,2	1,4	1,8	0,65
Adult horses	13,5	4,5	1,8	-----	-----

Table 10

Guidelines for accommodating farm animals in stalls
(in stock and during experiments)

Species and weights kg	Minimum stall area sq. m	Minimum stall length m	Minimum stall partition height m
Pigs 100 - 150	1,2	2,0	0,9
> 150	2,5	2,5	1,4
Sheep <70	0,7	1,0	0,9
Goats <70	0,8	1,0	0,9
Cattle 60 - 100	0,6	1,0	0,9
100 - 150	0,9	1,4	0,9
150 - 200	1,2	1,6	1,4
200 - 350	1,8	1,8	1,4
350 - 500	2,1	1,9	1,4
> 500	2,6	2,2	1,4
Adult horses	4,0	2,5	1,6

Stalls should be sufficiently wide to allow the animal to lie comfortably and to stand up and turn around without difficulties.

Table 11

Guidelines for caging birds
(in stock and during experiments)

Species and weights g	Minimum area for one bird sq. cm	Minimum area for two birds sq. cm / bird	Minimum area for three or more birds sq. cm / bird	Minimum cage height cm	Minimum length of the feed trough per bird cm
Chickens					
100 - 300	250	200	150	25	3
300 - 600	500	400	300	35	7
600 - 1200	1000	600	450	45	10

1200 - 1800	1200	700	550	45	12
1800 - 2400	1400	850	650	45	12
(Adult males)					
> 2400	1800	1200	1000	60	15
Quails					
120 - 140	350	250	200	15	4

The area is calculated as the product of cage length and cage width measured internally and horizontally. The cage height is determined as the vertical distance between the highest point on the floor and the lowest point in the top of the cage.

Mesh size in grid floors should not be greater than 10 x 10 mm for young chicks, and 25 x 25 mm for pullets and adults. The wire thickness should be at least 2 mm. The sloping gradient should not exceed 14 % (8 °). Water troughs should be of the same length as the feed troughs. If nipples or cups are provided, each bird should have access to at least two water troughs or cups. Cages should be fitted with perches and allow birds in single cages to see each other.

Section II
Additional guidelines regarding the minimum cage floor area

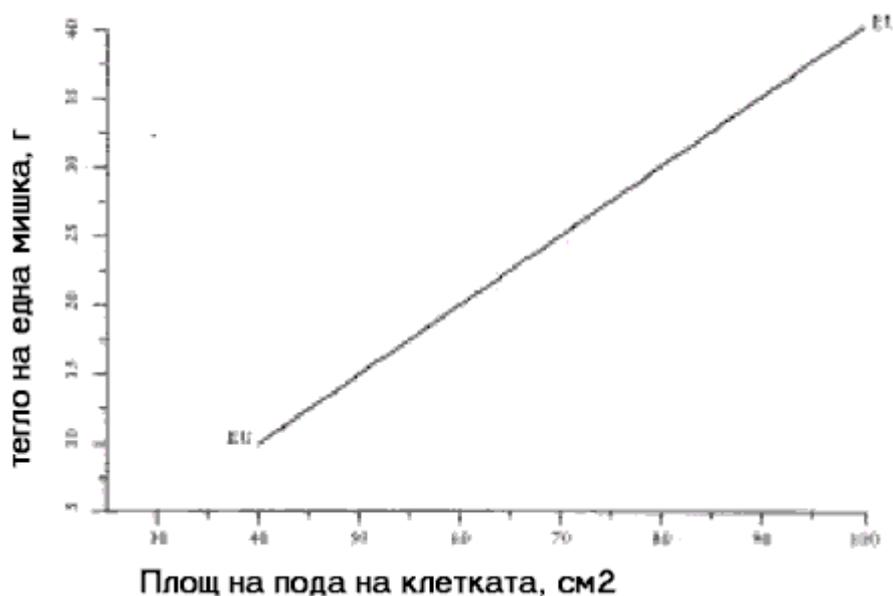


Figure 1. Minimum cage floor area to be allocated depending on the weight of the mice (in stock and during experiments). The full-drawn EU-EU line gives the minimum area that it should be allocated.

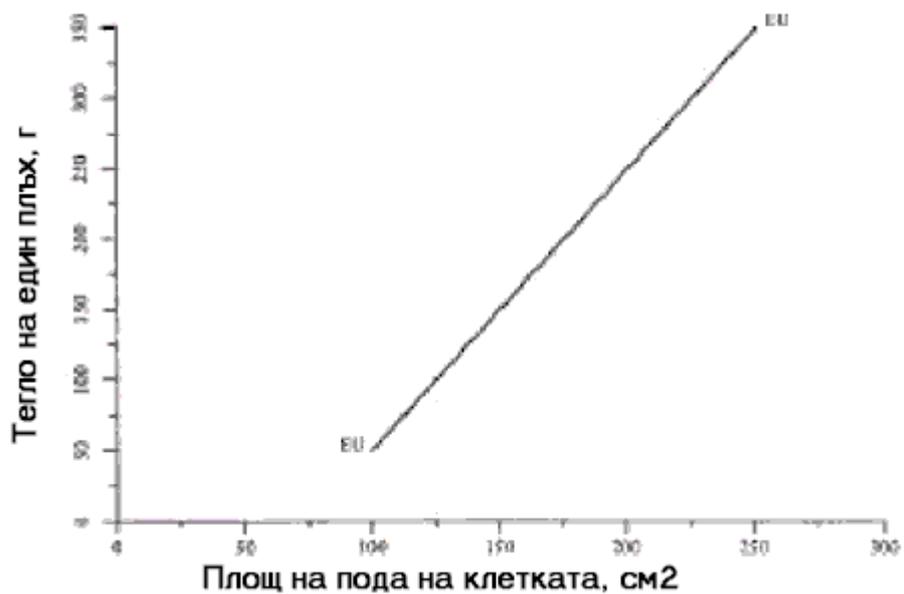


Figure 2. Minimum cage floor area, considering the weight of a rat (in stock and during experiments). The full-drawn line EU-EU gives the minimum area that it should be allocated.

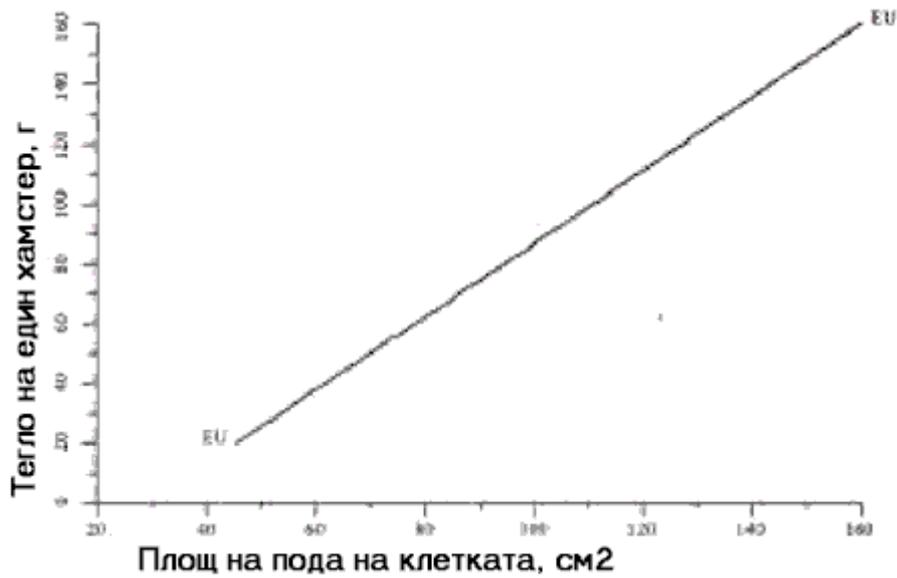


Figure 3. Minimum cage floor area, considering the weight of a Syrian Hamster (in stock and during experiments). The full-drawn EU-EU line gives the minimum area that it should be allocated.

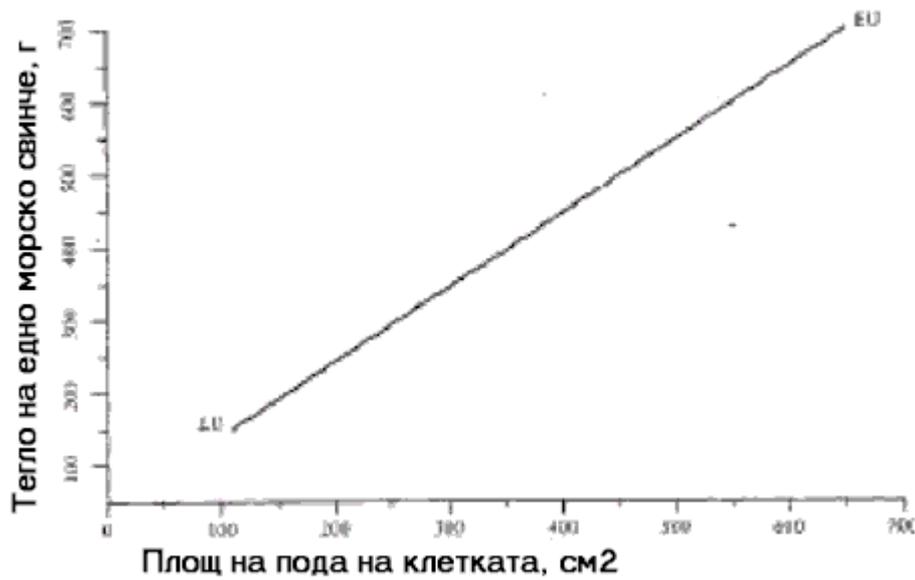


Figure 4. Minimum cage floor area, considering the weight of a Guinea Pig (in stock and during experiments). The full-drawn EU-EU line gives the minimum area that it should be allocated.

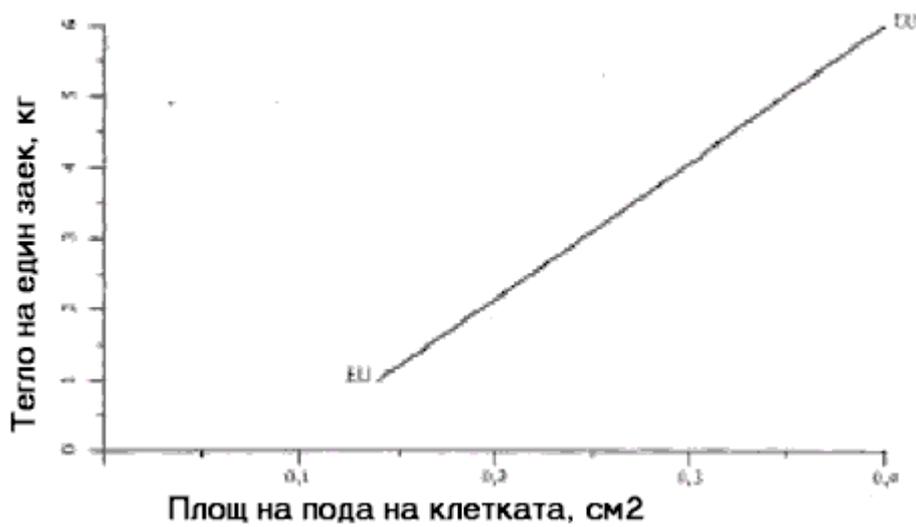


Figure 5. Minimum cage floor area, considering the weight of a Rabbit (in stock and during experiments). The full-drawn EU-EU line gives the minimum area that it should be allocated.

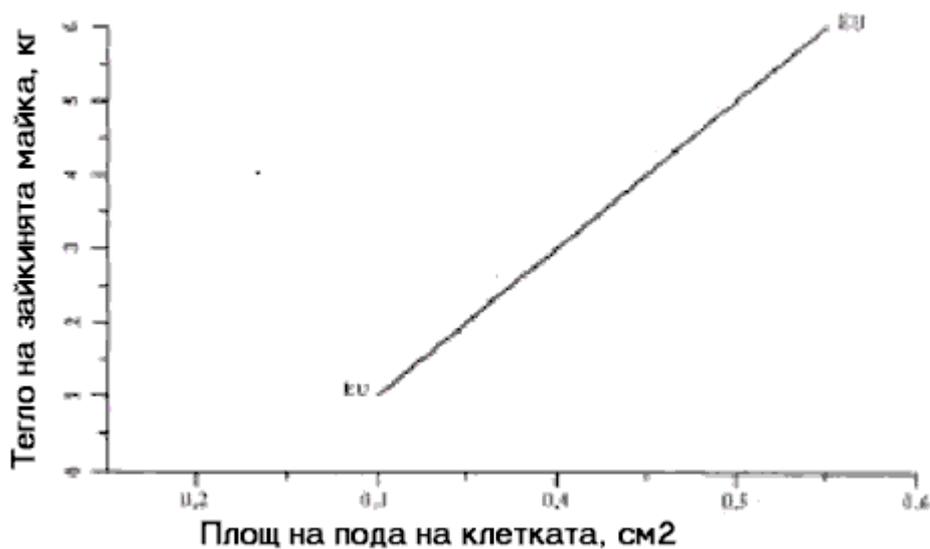


Figure 6. Minimum cage floor area for a doe with unweaned litter (in breeding). Considering the weight of the doe, the full-drawn EU-EU line gives the minimum area that it should be allocated.



Figure 7. Minimum cage floor area, considering the weight of a cat (in stock and during experiments). The full-drawn EU-EU line gives the minimum area that it should be allocated.

Section III
Guidelines regarding the density of the animals in the cages

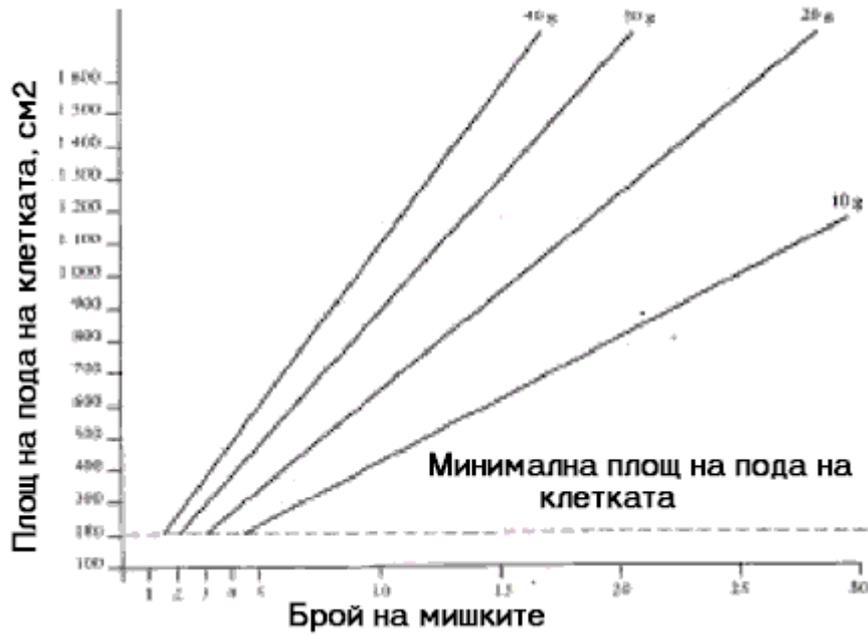


Figure 8. Guide to the relationship between number of mice per cage and cage floor area (in stock and during experiments). The lines represent the average weights and correspond to the EU-EU line in Figure 1.

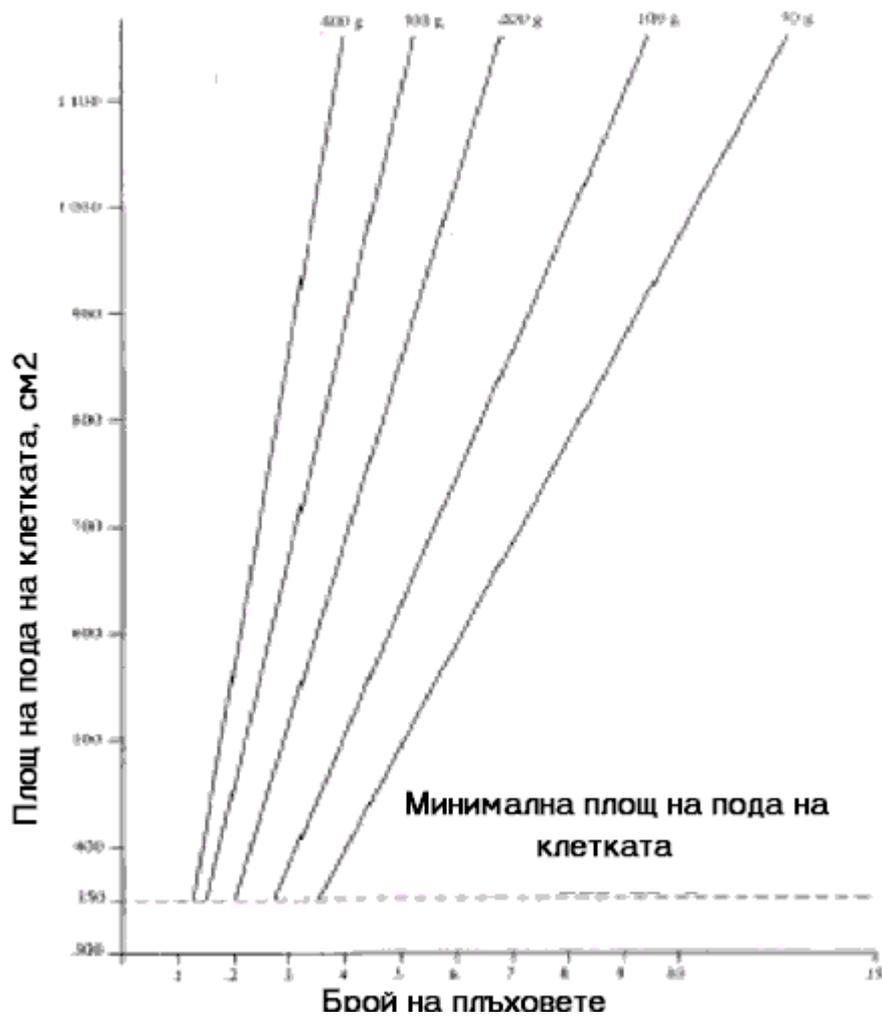


Figure 9. Guide to the relationship between number of rats per cage and cage floor area (in stock and during experiments). The lines represent the average weights and correspond to the EU-EU line in Figure 2.

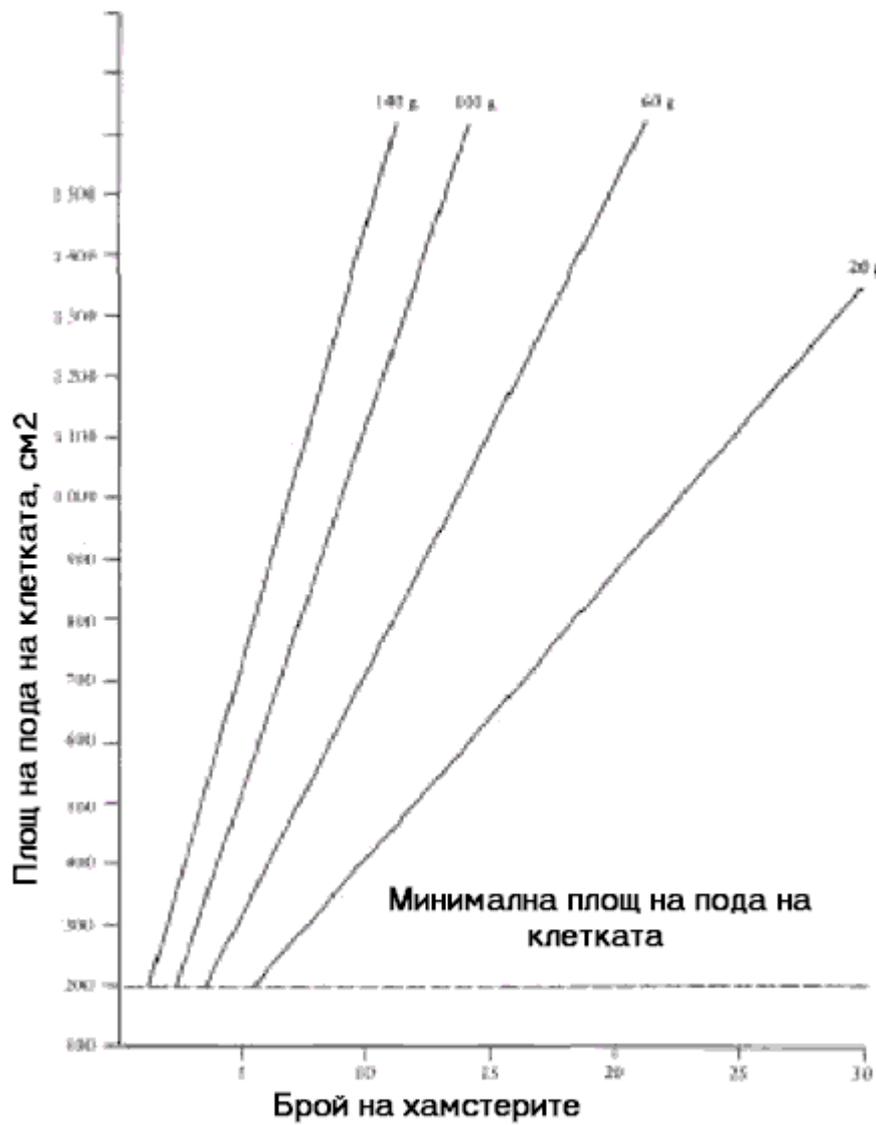


Figure 10. Guide to the relationship between number of hamsters per cage and cage floor area (in stock and during experiments). The lines represent the average weights and correspond to the EU-EU line in Figure 3.

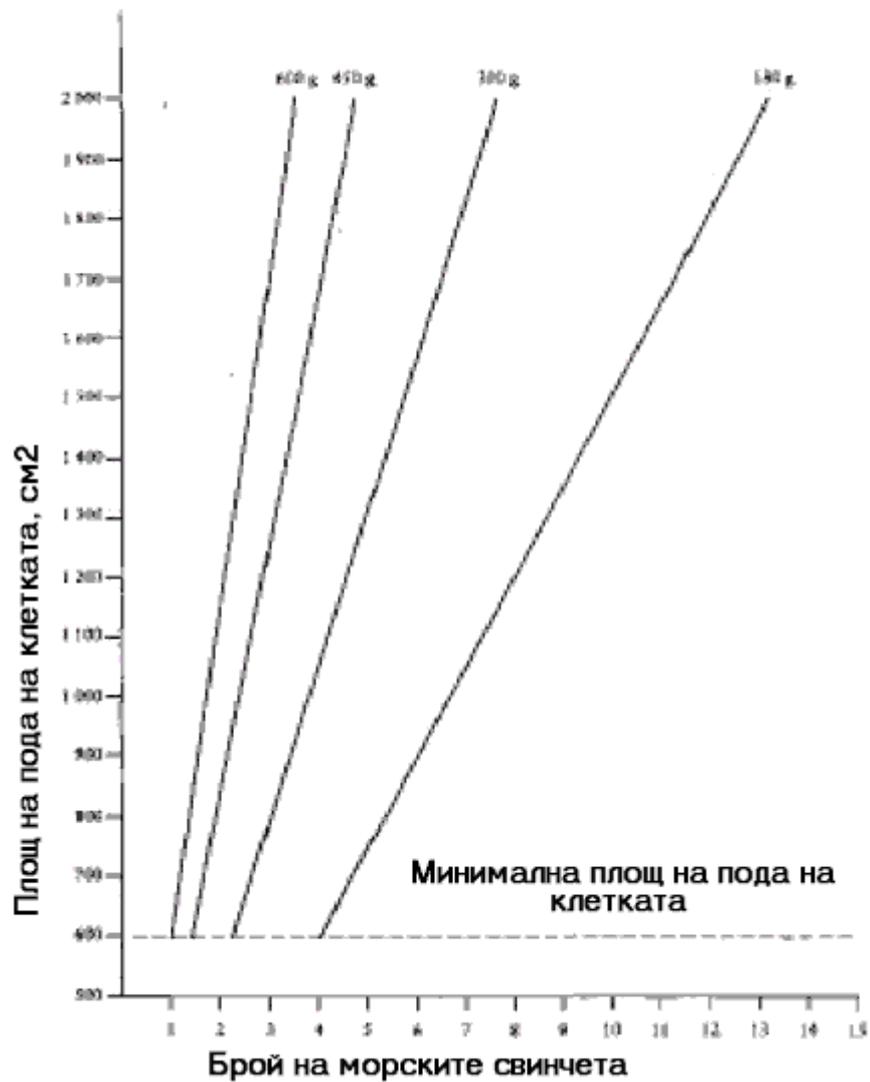


Figure 11. Guide to the relationship between number of guinea pigs per cage and cage floor area (in stock and during experiments). The lines represent the average weights and correspond to the EU-EU line in Figure 4.

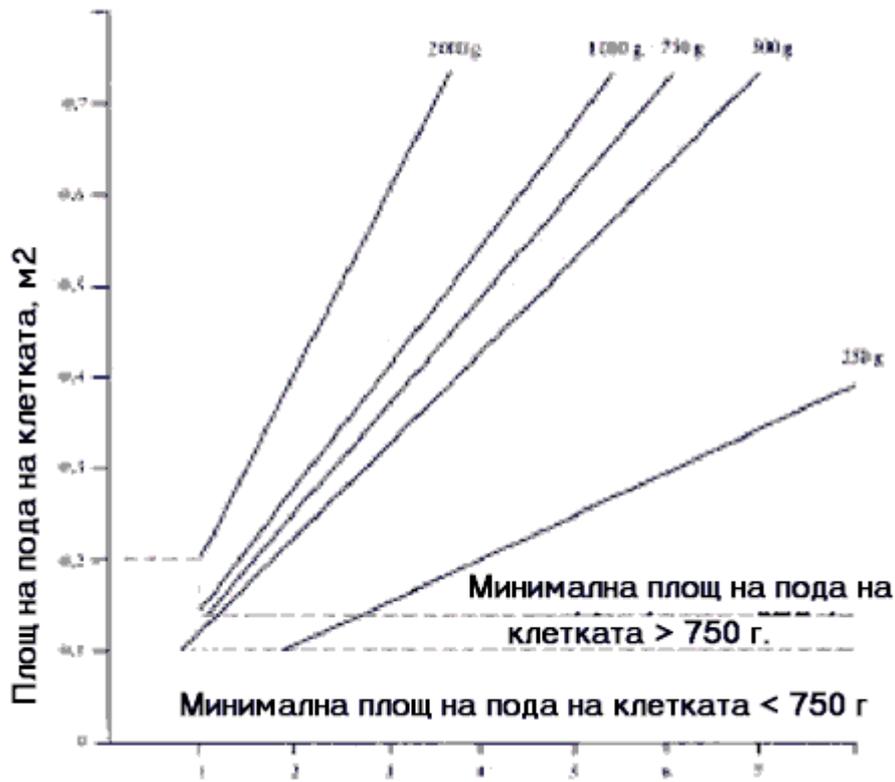


Figure 12. Guide to the relationship between number of rabbits per cage and cage floor area (in stock and during experiments). The lines represent the average weights and correspond to the EU-EU line in Figure 5.

Permissible methods of killing experimental animals

Methods of killing of animals other than fetuses, larvae and embryonic forms	Animal species for which the respective method is appropriate
A. Overdose of anaesthetic adequate to the size and animal species	All animals
B. Applying carbon dioxide	Rodents, rabbits up to 1,5 kg
C. Breaking the spine in the neck area	Rodents up to 500 g Rabbits up to 1 kg Poultry up to 3 kg
D. Mechanical blow over the cranium	Rodents and rabbits up to 1 kg Poultry up to 250 g Amphibians and reptiles (by destroying the cerebrum before regaining consciousness) up to 1 kg Pisces (by destroying the cerebrum before regaining consciousness)
E. The methods of killing provided for in Ordinance No. 20 on minimizing the suffering of animals at the time of slaughtering (State Gazette No. 55 from 2002)	Large and small ruminants, equine, swine and poultry

Annex No. 5 to Article 23, paragraph 3, item 2, item "a"

Guidelines for room temperature
(animals kept in cages, pens or cattle-sheds)

Species or groups of species	Optimal range °C
Non-human New World primates	20 - 28
Mice	
Rats	
Hamsters	
Gerbils (Gerbillinae)	20 - 24
Guinea Pigs	
Non-human Old World primates	
Quails	
Rabbits	
Cats	
Dogs	
Ferrets (Mustellidae)	15 - 21
Poultry	
Pigeons	
Swine	
Goats	
Sheep	10 - 24
Cattle	
Horses	

In the cases of very young or hairless animals, higher room temperatures than those indicated may be required, upon judgement of the veterinarian.

Table 1

Number and animal species used in procedures during (*year*) in (*country*)

Mice (<i>Mus musculus</i>)
Rats (<i>Rattus norvegicus</i>)
Guinea pigs (<i>Cavia porcellus</i>)
Other rodents (other Rodentia)
Rabbits (<i>Oryctolagus cuniculus</i>)
Apes (Hominoidea)
Other simians (<i>Cercopithecoidea & Ceboidea</i>)
Prosimians (<i>Prosimia</i>)
Dogs (<i>Canis familiaris</i>)
Cats (<i>Felis catus</i>)
Other carnivores (other Carnivora)
Horses, donkeys and cross-breeds (<i>Equidae</i>)
Swine (<i>Sus</i>)
Goats and sheep (<i>Capra & Ovis</i>)
Cattle (<i>Bos</i>)
Other mammals (other Mammalia)
Poultry (<i>Aves</i>)
Reptiles (<i>Reptilia</i>)
Amphibians (<i>Amphibia</i>)
Pisces (<i>Pisces</i>)
Total:

Each animal should be counted only once in one and the same table. The table should specify the total number of animals used in procedures, where this total number must be broken down by type and class of the animals.

Table 2

Number of animals used for particular purposes during (*year*) in (*country*)

Field of application	All animal species	Selected animal species		
		Rodents and rabbits	Dogs and cats	Primates
1. Biological (including medical) research of fundamental nature				
2. Discoveries, development and control of quality (including also safety assessment) for products or appliances for the humane and veterinary medicine				
3. Diagnostics of disease				
4. Protection of humans, animals and environment through toxicological or other types of safety assessments				
5. Education and training				

The table is intended to show the number of animals used in broad fields: fundamental research, design of new products, safety assessment, diagnostics of diseases, as well as for education and training. In item 1 the term "medical" includes the veterinary medicine too.

Table 3

Number of animals used in procedures for particular purposes for protection of humans, animals and environment through toxicological or other types of safety assessments during (*year*) in (*country*)

Detailed classification of item 4 from Table 2	All animal species	Selected animal species		
		Rodents and rabbits	Dogs and cats	Primates
1	2	3	4	5
1. Substances used or intended for use mainly in agriculture				
2. Substances used or intended for use mainly in industry				
3. Substances used or intended for use mainly in households				
4. Substances used or intended for use mainly in cosmetics or for personal hygiene				
5. Substances used or intended for use mainly as additives to the foodstuffs for human consumption				
6. Potential or existing hazards of polluting agents in the common/general environment				

The table is intended to give a detailed breakdown of the procedures carried out for general protection of humans, animals and environment, except for the medical purposes. Item 6 includes the hazardous radiation.

Table 4

Number of animals used for procedures related to diseases and ill-health during (*year*) in (*country*)

Field of application	All animal species	Selected animal species		
		Rodents and rabbits	Dogs and cats	Primates
1. Cancer (except for assessments of carcinogenic hazards)				
2. Cardiac-vascular diseases				
3. Nervous and mental disorders				
4. Other diseases relevant to humans and animals				

In those instances where a procedure covers the cancer on the grounds of each item from 2 to 4, its classification under "cancer" field should be considered as most appropriate.

The table is intended to show the number of animals used for medical purposes, including veterinary medicine, where particular attention should be paid to the three fields of the human diseases of major public importance.