

## 2.1 Report on legal documentation for “Experimental facility for conventionally raised animals”



### 1. DOCUMENT CONTROL SHEET

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### 1. VERSIONING AND CONTRIBUTING HISTORY

Version	Date	Revision Description	Responsible Person
v1	15. 10. 2021.	First draft	Ivan Milošević, Milica Stojić, Ljubomir Jovanović
v2	20. 11. 2021.	Final version	Danijela Kirovski

The project team analyzed the legal regulations that apply to the territory of the Republic of Serbia for the construction and registration of facilities for housing experimental animals. Construction and registration is regulated by: the Law on Animal Welfare ("Official Gazette of RS", No. 41/09) (serbian: *Закон о добробити животиња („Службени гласник РС”, број 41/09)*), further on in this document Law, and Rulebook on the conditions for entry in the register for animal experiments and the content and manner of keeping that register, the training program on the welfare of experimental animals, the application form for approval of animal testing, the manner of care, treatment and deprivation of life of experimental animals, as well as the content and the manner of keeping records on keeping, reproduction, trade, ie conducting experiments on animals ("Official Gazette of RS", No. 39/10) (serbian: *Правилник о условима за упис у регистар за огледе на животињама и садржини и начину вођења тог регистра,*

програму обуке о добробити огледних животиња, обрасцу захтева за одобрење спровођења огледа на животињама, начину неге, поступања и лишавања живота огледних животиња, као и о садржини и начину вођења евиденције о држању, репродукцији, промету, односно спровођењу огледа на животињама („Службени гласник РС”, број 39/10)), further on in this document Rulebook . In addition, the project team sought to harmonize the adaptation of the facility with European regulations in this area, primarily with Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. The conclusion was that the Faculty of Veterinary Medicine of the University of Belgrade has all the legal, technical and spatial reasons to form Experimental facility for conventionally raised animals.

Article 33 of the Law regulates who may perform experiments on animals in the Republic of Serbia and under which conditions. Animal experiments can be performed by formal and individual persons registered in the Register for Animal Experiments, which is kept by the Ministry. Thus they have the right to be entered in the Register for animal experiments, if they meet the requirements in terms of facilities, equipment and training on the welfare of experimental animals. The request for be registrated in the Register for animal experiments is submitted to the Ministry of Agriculture, Forestry and Water Economy of the Republic of Serbia.

The register for animal experiments shall contain:

- 1) average number of the animals;
- 2) name and place of the legal entity, ie name and surname and address of the individual person performing animal experiments;
- 3) name and place of the legal entity or entrepreneur, ie name and surname and address of the individual person engaged in keeping, reproduction and trade of experimental animals.

Entry and deletion from the Register for Animal Experiments shall be performed on the basis of a decision signed by the Minister, within 30 days from the day of submission of the request for entry, ie occurrence of conditions for deletion from the Register for Animal Experiments. The Minister prescribes more detailed conditions in terms of facilities and equipment, the Rulebook on the welfare of experimental animals, as well as more detailed content and manner of keeping the Register for animal experiments.

Conditions regarding facilities and equipment for entry into the register for animal

experiments and training program on the benefits of experimental animals in accordance with the Rulebook will be set out below.

The facility for experimental animals keeping must be constructed in such a way to provide conditions appropriate to each individual species of animal living in it and to prevent the escape of animals, as well as to perform the experiments as efficiently as possible, with the latest results, the use of a minimum number of animals. Degree of pain, suffering, stress or permanent injury to animals. The ceilings and walls of the facility must be made of a material that is resistant to cleaning and disinfection, with smooth, impermeable surfaces that are easy to wash, clean and disinfect. The floors of the facility must be smooth, impermeable, made of non-slip material, which is easy to wash, clean, disinfect and that can withstand the weight of feeders, animals and other heavy equipment. The material from which the ceiling, walls and floors of the facility, as well as the accommodation place for animals, must be such that can not have a significant effect on the health of the animals and does not cause injuries. The drains of the facility must be fixed and covered in a way that prevents free access of animals. The corridors of the facility must be wide enough to allow easy use of mobile equipment. Door connections, ducts, sockets, pipes, cables, equipment and devices in the user facility must be additionally protected, so that the animals do not damage or injure themselves. If the user facility has doors and windows, they must be constructed and protected, in order to prevent the entry of other animals and pests. If the user facility has an outlet, special protection measures must be provided to prevent the animals from escaping.

The user facility must be physically separated and protected from other facilities in the complex, with a limited number of entrances in order to prevent access by unauthorized persons and to have:

- 1) accommodation place for animals;
- 2) laboratories and rooms for general and special inspections;
- 3) auxiliary rooms, as follows:
  - a) food storage room and mat,
  - b) room for storing clean cages, instruments and other equipment,
  - c) room for cleaning and washing cages and equipment,
  - e) room for the disposal and hygienic storage of animal carcasses and waste of animal origin.

The facility must have devices and equipment appropriate to the species of animals

used, as well as the performance of the experiments carried out in those facilities. The facility must have a facility and equipment maintenance plan.

The facility must provide accommodation for animals that corresponds to the type of animal and which:

- 1) has a surface that allows at least a minimum of freedom of movement that is appropriate for the species of animals, as well as the manifestation of the natural behavior of animals;
- 2) enables observation of animals, with its minimal disturbance;
- 3) it is constructed in such a way to facilitate the handling of the animal;
- 4) it is compatible with the purpose of using animals in experiments, in order to ensure the obtaining of valid scientific data. If possible, the interior of the living space should be provided with a special space for performing less demanding inspection procedures.

Animal housing, which is named for keeping rodents, can also be used to keep larger species, provided that it is technically adapted to the species of animals that will be kept in it.

In the accommodation space, animals are kept in cages, boxes, stables or stables / drains, depending on the type of animal. Cages, boxes, stables and stables / outlets must be built and constructed to meet the ethological needs of the animals (the need to believe, hide, make a temporary shelter). Cages, with the exception of single-use cages, boxes, stables and stables / drains must be made of resistant material, which is easy to wash, clean and disinfect. Cages must have floors that are constructed and constructed in a manner appropriate to the species and age of the animal and such that excrement can be easily removed. Animal housing must have a ventilation system, which ensures the supply of fresh air to the accommodation, the reduction of levels of unpleasant odors, harmful gases, dust and pathogens, and the removal of excess heat and moisture. The ventilation system referred to in paragraph 1 of this Article must:

- 1) be such as to ensure the supply of fresh air in the accommodation space at regular time intervals, so that the degree of ventilation is 15 to 20 air changes per hour, or 8 to 10 air changes per hour at lower population density of animals in the accommodation space, and without causing a draft;
- 2) has an adequate capacity to achieve heating and cooling of the air.

The accommodation for animals must be provided with a temperature and humidity that is adapted to the needs of each individual species of animals. The relative humidity

referred to in paragraph 1 of this Article in the accommodation for animals must be maintained at an average value of  $55\% \pm 10\%$ , where if there are justified deviations from that value, values below 40% and above 70% should be avoided for a longer period of time. period.

Artificial lighting that meets the biological requirements of each species must be provided in the accommodation, if the accommodation for animals does not have windows. Artificial lighting must be such as to enable the regulation of the intensity of light and the cycles of light and darkness, as well as their control.

Housing for animals, laboratories and rooms for usually conducted and special experiments must be protected from sources of audible and high frequency noise, in order to prevent disturbance of animals, changes in the behavior and physiology of animals.

The accommodation for animals must have an alarm system that does not disturb the animals, as well as:

- 1) alarm device for detection of possible fire, entry of unauthorized persons, detection of failures in the ventilation system, heating system, as well as failures in the water supply of the pool or aquarium;
- 2) a generator to support the system for maintaining the life of animals, as well as lighting in case of failure or interruption of power supply;
- 3) instructions for emergencies, which are clearly and visibly displayed.

Laboratories and rooms for usually conducted and special experiments must have space for performing simple diagnostic tests, post-mortal examinations, ie collecting samples that will be subjected to extensive laboratory tests elsewhere; separate rooms for recovery and postoperative treatment of animals; separate rooms for conducting inspections or observations which are not desirable to be performed in animal accommodation facilities; minimal laboratory equipment. To perform surgical procedures in aseptic conditions, laboratories and rooms for general and special examinations must be provided with one or more separate rooms.

The room for storing food and mats must be cool, dry and protected from insects and pests. If materials that can be easily contaminated and pose a risk are stored in the user facility, the facility must have a special room for storing these materials. The room for cleaning and washing cages and equipment must be large enough to accommodate devices for cleaning and disinfection of used equipment, and the corridors between the rooms must be wide enough to allow easy transfer of mobile equipment. The walls and



floors of the room for cleaning and washing cages and equipment must be covered with a resistant material, and the ventilation system must be of sufficient capacity to remove excess heat and moisture.

Considering the legal basis, the project team concluded that Faculty of veterinary medicine, University of Belgrade has conditions in terms of facilities, equipment and personnel to establish the **Experimental facility for conventionally raised animals**. In addition to the standards required by the regulations in the Republic of Serbia, the project team will be guided by the advice of expert from the diaspora and use the knowledge and skills gained during trainings at the University of Graz in accordance with the reports 1.2, 1.3, 1.4.