

## Legislation on the protection of experimental animals

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The aim of this paper is to establish the current situation in the field of legislation on the protection of experimental animals in Slovenia. The protection of experimental animals has been regulated by the provisions of the Protection of Animals Act.<sup>1</sup> On the basis of this act, the Instructions on Conditions for the Issuing of Authorisations for Experiments on Animals for Scientific and Research Purposes<sup>2</sup> and the Rules on the Ethics Commission for Experiments on Animals<sup>3</sup> have been used.

The basic protection of experimental animals is provided for by a system of permits for experiments on animals. Permits for experiments on animals are granted by the administrative authorities responsible for veterinary medicine in cases where experiments are urgently required for medical, veterinary medical, or scientific and research purposes and the results are expected to produce important new knowledge, or when the suffering of animals is ethically acceptable in comparison with what the experiment is expected to achieve; where, in cases of basic research, experimental aims cannot be achieved by any other method or procedure, the experiment is performed on the minimum possible number of animals of the lowest neurophysiological sensitivity and a method is used that causes the minimum level of suffering, pain or lasting harm. Staff involved in the execution of experiments or in the care and nursing of animals, the premises for the accommodation or rearing and provision of animals, and the installations and devices used must all comply with the set conditions.

With the adoption of the Act, which has been harmonised with EU regulations, legislation on the protection of experimental animals has been put into effect. As laid down by the act<sup>1</sup>, the implementing regulations will lay down the conditions for the issuing of permits for experiments on animals, the procedure, documentation, records, reports and responsibilities of experts on the protection of animals, and staff and other conditions relating to the execution of experiments and procedures involving animals.

*Key words:* animals, laboratory; animal husbandry; animal rights; legislation

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## Introduction

The above cited parts of the legislation on the protection of experimental animals in Slovenia have been reviewed. The protection of animals used for experimental purposes is an increasingly important area. In most developed European countries, extensive legislative activities in this area began back in 1986. With the adoption of the Protection of Animals Act<sup>1</sup> (which came into effect on 18 December 1999), legislation regulating the protection of experimental animals finally entered into force in Slovenia.

The act not only provides protection for animals against cruelty but also lays down the principles of animal welfare. In the general provisions section, the act defines public responsibility for the protection of animals and their life, health and welfare by stressing the following basic principle: "No man shall be allowed to cause suffering, illness or death to an animal without a well-substantiated reason."

### Data from the legislation in force in Slovenia

The field of protection of experimental animals in Slovenia is regulated by the Protection of Animals Act<sup>1</sup>, the Instructions on Conditions for the Issuing of Authorisations for Experiments on Animals for Scientific and Research Purposes<sup>2</sup>, and the Rules on the Ethics Commission for Experiments on Animals.<sup>3</sup> All animals with a developed nerve system that enables them to feel painful external influences must be dealt with under the terms of this act. The provisions of the act must always be taken into consideration when working with vertebrate animals and, depending on their level of sensitivity, with all other animals. There is a special chapter in the act: Experiments on Animals (Articles 21-24). Basic protection for

experimental animals is provided for by a system of permits for experiments on animals which are issued by the administrative authorities, competent for veterinary medicine.

Experiments on animals may only be carried out by organisations registered to perform experiments on animals and granted permission by the Veterinary Administration of the Republic of Slovenia (VARŠ). Any organisation performing experiments on vertebrate animals must appoint an animal protection expert with the appropriate qualifications. The expert provides the explanations needed in order to obtain approval for the experiment and is responsible for ensuring that experiments are carried out in compliance with the law.

Permission for an experiment is granted only if the experiment is truly necessary, and if:

- the experiment is required for medical, veterinary or general, scientific and research purposes, it is expected that the results will yield new and important findings, and it is expected that animal suffering will be ethically acceptable in comparison with what the experiment is expected to achieve;
- it is basic research;
- the goal of the experiment cannot be achieved by any other methods and procedures;
- the lowest possible number of animals with minimal neuro-physiological sensitivity and methods that cause the lowest amount of suffering, pain or permanent injury are used in the experiment;
- the animal is anaesthetised before the start of the experiment, unless the pain caused by the experiment is lower than the pain caused by anaesthesia or the anaesthetisation of the animal is against the purposes of the experiment;
- the animal will be properly treated or killed after the experiment is completed, if suffering cannot be prevented;

- the persons who carry out experiments or take part in them and the persons who take care of the animals, including duties of a supervisory nature, have attained the appropriate level of education;
- the animals used in the experiment come from well-organised and registered breeding establishments; in exceptional cases, when the experiment is necessary for the preservation of an animal species and the animal is the only one suitable for the experiment or when it cannot be bred, the competent authority may issue permission for the experiment in compliance with the Regulation on the Protection of Endangered Animal Species.<sup>4</sup> Experiments on equine animals, bi-ungulates, dogs or cats may only be performed when it is not possible to achieve the envisaged aim by experimenting on other animals.<sup>2</sup>

A special permit from VARS is required for each individual experiment. The person who will conduct the experiment must have the proper qualifications.<sup>1</sup> Only persons with adequate qualifications in veterinary and human medicine, biology and animal husbandry may perform experiments on animals.<sup>2</sup> An authorisation is not necessary for experiments that have been prescribed by a legal act or ordered by a court of law or a competent inspector on the basis of a legal act, or in the execution of vaccinations or diagnostic investigations, the collection of blood or other material, or the detection of injuries and diseases.<sup>1</sup> The performance of experiments on animals in order to test chemical agents used in war, cosmetic preparations, alcohol or tobacco products, or of experiments in which muscle-paralysing agents are used and performed without the use of anaesthesia are prohibited.<sup>1</sup> Surgical operations for educational purposes which cause suffering and harm to or even the death of the animal are also prohibited. These can be performed only exceptionally by university or scientific and

research institutions in cases where they are necessary in the course of the regular training of doctors of human or veterinary medicine, biologists or pharmacists, and where their objective cannot be achieved by any other means of training (films, photographs, models, etc).<sup>1,2</sup>

The Rules on the Ethics Commission for Experiments on Animals lay down the procedure of examining and processing opinions on the necessity of a certain experiment in order to grant permission to carry it out on an animal.<sup>3</sup> The rules lay down in detail the composition, tasks, competence and method of work of the ethics commission for experiments on animals.

Immediate inspection and control of the implementation of the law and other regulations and international agreements on the protection of animals against suffering is carried out by veterinary inspection and control services. The Veterinary Practice Act<sup>5</sup> and the Protection of Animals Act<sup>1</sup> define the competence of the veterinary inspection and control service to order measures to protect animals against suffering, and the penalties for violations of the legislation. A veterinary inspector has the right and duty to prohibit the performance of any procedures on animals which are not permitted or which violate the provisions of the Protection of Animals Act, order such experiments to be discontinued, or prohibit the carrying-out of experiments on animals which are carried out in violation of the provisions of the act, or when any existing deficiencies have not been eliminated by the prescribed deadline. The performance of experiments on animals in violation of the regulations is punishable by a fine under the Protection of Animals Act<sup>1</sup> and, when premeditated, is considered as having caused suffering to the animal in question, which as such is punishable under the Penal Code.<sup>6</sup> The penalty envisaged for such an offence is a prison sentence of up to three months.

A fine of between SIT 100,000 and 150,000 under the act<sup>1</sup> is imposed on an individual carrying out an experiment on animals in violation of Article 21 of the Act (without permission and in an organisation that has not been registered for such an activity) or when experimenting on animals in violation of Article 22 of the act (procedures for educational purposes without an approval). A fine of between SIT 150,000 and 10 million is imposed on a legal entity for the same violation.

A fine of between SIT 150,000 and 10 million is imposed on an individual who conducts painful procedures on vertebrate animals without the use of appropriate anaesthesia or when conducting experiments on vertebrate animals in violation of Article 23 of the Act (when the organisation in question fails to appoint an expert on the protection of animals). A fine of between SIT 25,000 and 500,000 is imposed on the responsible person of the legal entity which committed such a violation.

### Discussion

There is direct and indirect links between animals and human beings – they are of vital importance to us. We should never forget that animals are living creatures with senses and are capable of expressing their feelings. We should handle them in a humane manner and with a due level of responsibility. Well-regulated legislation is of great importance for animal protection. Major progress at the international level in the legal regulation of the protection of experimental animals was made in the 1980s. An important turning point was the 1986 Convention of the Council of Europe on the Protection of Animals Used for Experimental and Other Scientific Purposes.<sup>7</sup> A contribution towards increased protection for experimental animals was also made by the European Union (then the European Economic Community) with the

adoption of Directive 86/609/EEC<sup>8</sup>, which in essence does not differ from the European Convention. The objective of the Directive and of the European Convention is to ensure that the provisions on the protection of experimental animals are harmonised in the national legislation of the member states. The European Convention<sup>7</sup> and the European Union Directive<sup>8</sup> define in different chapters the essential principles of use of animals in experiments and the conditions for rearing and accommodating the animals, with the minimum recommended housing areas for individual animal species and the micro-climatic conditions. By incorporating the proposed standards, any departures from the norm will be eliminated; by prescribing conditions for the rearing, accommodation and use of animals in experiments, measures for the protection of experimental animals will be made uniform. Most importantly, by granting mutual recognition to the test results of experiments performed on animals, the unnecessary duplication of experiments will be prevented.

Slovenia is undergoing accelerated legislative activities to protect experimental animals. Experiments on animals carried out for scientific and research purposes have been regulated and subject to restrictions in Slovenia since 1985, when the Instructions on Conditions for Granting Authorisations for Experiments on Animals for Scientific and Research Purposes were issued.<sup>2</sup> These instructions include certain provisions that were laid down later on by the European Convention<sup>7</sup> and EU Directive.<sup>8</sup> According to the instructions, any organisation intending to use animals in experiments that cause pain, suffering or lasting harm must obtain the approval of the competent administrative authority, provide conditions in which such experiments may be carried out, restrict the use of domestic animals in experiments and for educational purposes, and keep a protocol of the experiment and a report on the experi-

ment by the person in charge of it. A drawback to these instructions was that the penalties they prescribed were low and the execution of inspection and control ineffective.

By adopting the Protection of Animals Act<sup>1</sup>, progress has been made in regulation of the protection of experimental animals. The act includes some of the basic provisions of EU Directive 86/609/EEC<sup>8</sup> as follows:

- Experiments on vertebrate animals may be performed only when it is anticipated that the suffering of the animal will be ethically acceptable in the light of the envisaged results.
- Experiments on animals may only be performed by organisations registered to carry out experiments on animals and duly authorised by the competent administrative authority.
- Experimental animals may only originate from an organised and registered rearing establishment for the rearing of experimental animals;
- The person carrying out the experiments shall have appropriate professional qualifications.
- The person carrying out the experiments shall keep records on the number and species of animals used and the type of experiment, and notify the competent administrative authority thereof.

Slovenia has the Rules on the Protection of Experimental Animals, which transpose all other provisions of the EU Directive.<sup>8</sup> The rules lay down the detailed conditions for granting permits to carry out experiments on animals, the procedure, documentation, records, reports and obligations of professionals relating to the protection of animals, staff and other conditions for the execution of experiments, and the procedures relating to the use of animals in experiments. The rules lay down detailed conditions regarding the establishments involved in the rearing, supply and use of animals in experiments, and the premises, equipment and staffing thereof.

The rules include provisions concerning the planning of experiments under consideration of the 3R concept (1R – replacement, or replacement of a planned method with another; 2R – reduction, or selection of an experiment that requires fewer animals; 3R – refinement, or the conducting of an experiment to perfection so as to guarantee its success) and the use of alternative methods. The EU Directive<sup>8</sup> and the draft rules include the 3R concept in the following provisions:

- An experiment may not be repeated when any other scientifically satisfactory method is available that enables attainment of the envisaged result and does not require the use of animals.
- When an experiment is urgently necessary, the selection of animal species must be carefully studied. An experiment must be chosen which requires the minimum number of animals, and animals with the minimum neuro-physiological sensitivity, which causes the minimum pain, suffering, stress and lasting harm, and which in all probability will give satisfactory results.
- All experiments must be planned so as to avoid stress, avoidable pain and suffering on the part of experimental animals.
- Experiments causing lasting pain to animals are subject to a special application to the competent authority and their use must be justified.

Efforts have been made in Slovenia to ratify the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes (ETS 123).<sup>7</sup>

Data on the use of experimental animals in European countries (including Slovenia) shows a decline in the use of animals in experiments. The annual number of experimental animals used in Slovenia in the past three years has totalled approximately 22,000 (in 1996 it was still 30,000, and between 1993 and 1995 it was 33,000). Most of the experi-

ments are carried out on laboratory rodents by the chemical and pharmaceutical industries for substance testing in compliance with applicable legislation, regulations and international agreements. Institutes and laboratories of the faculties of medicine, veterinary medicine, biology, zootechnics and physiology use animals for basic research or scientific and research activities; these account for nearly one fifth of all experimental animals used. To a lesser extent, animals are also used in the diagnosis of disease and for education and training purposes. An important role in reducing the number of experimental animals is played by the applicable legislation, the replacement of animals with alternative methods (and a legal requirement to do so), the required permits for conducting experiments, ongoing staff training, successful co-operation between research institutions and researchers at national and international levels, active associations and societies, and increased responsibilities of the commissions for the protection of animals.

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