Legal Regulation of Animal Experiments

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Summary. The authors summarise the Hungarian legislation relating to animal experiments: The rules of the amended animal welfare act and the conditions relating to carrying out experiments to breeding and transporting experimental animals, to Animal Welfare Advisory Committee and sanctions. They present the definition, aim and authorisation of experiments and the applied anaesthesia. They briefly summarise the convention of the Council of Europe and the legislation of the European Union in the field of animal experiments. They emphasise the areas in which, according to their opinion, Hungarian legislation is inadequate: regulation of educational requirements and the support of research aiming at the replacement of animal experiments are missing. In spite of wide-scale legal regulation they deem it necessary to continue social conversation about the acceptance and refinement of animal experiments.

The first animal protection act, which also covered animal experiments entered into force in 1876 in Great-Britain; The Cruelty to Animals Act – a law against torture to animals – was born as a result of a long conversation between the representatives of science and animal protectionists. Great-Britain was the first and for a long time the only country, where experimental animals were protected by law. Doubts related to experimental animals, have however, continued to increase ever since, and have put the topic in the focus of political interest in many other countries.

In Hungary animals are protected since January 1, 1999, by Act XXVIII of 1998 (modified by Act LXVII in 2002). The aim of this law is “to enhance the protection of the specimen of animal life, increase the responsibility-awareness of people for the benefit of humane treatment of animals, and to determine the essential rules of animal protection”. Among others, the act covers „animals serving experimental purposes, animals kept for the purpose of testing, vaccine-production, treated as gene bank, as well as the spreading of scientific information and demonstration in the course of education.”

Legislation in Hungary related to animal experiments

The legal regulation of animal experiments is diverse

A number of regulations have been issued in our country in order to implement the animal protection act. From the aspect of laboratory animal-science, the most outstanding ones are the Government Regulation 243/1998 (XII.31.) as modified by Government Regulation 103/2002 (V.10.) and Government Regulation 186/2003 (XI.5.) on the performance of animal experiments, Government Regulation 244/1998 (XII.31.) as modified by Government Regulation 2002/98 (V.5.) on the animal protection penalty, FVM (Ministry of Agriculture and Rural Development) Decree 10/1999 (I.27.) on the Animal Welfare Advisory Committee, as well as joint-FVM-KöM-GM Decree 36/1999 (IV.2.) (Ministry of Agriculture and Rural Development-Ministry of Environmental Protection-Ministry of Economy) as modified by joint Decree FVM-KvVM-GM 58/2002 (VII.17.), on the breeding, keeping, shipping and sales conditions of experimental animals, furthermore, Act IV. of 1978 modified several times on the Code of Penal Law.
The concept of animal experiments

Point 9 of Paragraph 3 of the animal protection act (hereafter called: „Ávt“) contains the definition of animal experiments: „the use of an animal for experiments or other scientific purposes, which may eventually cause the animal pain, suffering, constant deprivation, or persistent impairment – also including any activity in the course of the experiment, which results in the birth of an animal under such circumstances -, and, which begins with the preparation of the animal for the experiment, and ends, when no further observation is performed for the benefit of the experiment; such use of the animal is qualified as an experiment, even if, in order to eliminate pain, suffering, constant deprivation, or persistent impairment, narcosis, anaesthesia, or other methods are successfully used; operations of non-experimental nature, agricultural or veterinary activities are not qualified as experiments, nor the application of scientifically accepted, modern, said to be less painful methods of animal slaughter or earmarking.“

Aim of animal experiments

Animal experiments may only be conducted for scientific purposes and based on licence

The aim of animal experiments is defined in Paragraph (4) of Article 25 of the Ávt, and Paragraph 3. of Government Decree 243/1998 (XII. 31.) (hereafter called: „Ákr“). Based on this, animal experiments may only be performed for the following purposes:
- the prevention, avoiding, identification and remedy of man, invertebrate and vertebrate animals or plants from illnesses, pathologic health status, other defects, as well as with the aim of revealing, exploring, regulating or modifying their physiology, the development, production, qualification, testing the efficacy and harmlessness of drugs, foodstuffs, other additives or products;
- The protection of natural environment for the benefit of the health and welfare of man or animals.
- Scientific research;
- Education and practical training;
- Forensic medicine

Prohibited aims
Ávt defines the objectives from which regard no animal experiment are not to be performed [Paragraphs (2) and (3) of Article 25 of the Ávt]: „for the manufacture of beauty products, tobacco and other items of delight, as well as weapons, their spare-parts and furthermore munitions“.

Notification and/or licensing obligation
Animal experiments are to be performed exclusively in registered institutions, and on the basis of a licence. This licence can be of a case-by-case basis, or can be of general effect. [Paragraphs (2) and (3) of Article 25 of the Ávt]. Institutions are registered by the county (metropolitan) Animal-Health and Food-Control Station (hereafter called: „station“), who invests them in a licence with the right to conduct animal experiments.

Submission for the right to conduct animal experiments
The submission is to be presented on the sample as per Enclosure 2 of the Ákr. The following are to be named in the application
- institution and its manager;
- registry number of the institution;
- denomination of the institution and the purpose of the experiment;
- validity of the licence;
- precedents of the experiment;
- brief description of the experimental activity, scientific justification;
- Expected pain, applicable anaesthetic methods, method of extermination of the animals;
- species, number of the animals to be utilized;
- standpoint of the Workplace Animal Experiment Committee (hereafter called: „MÁB“);
- education of those involved in the experiment;
- availability of veterinary care to the animals;

Submissions are equipped by the Station with the opinion of the Scientific Ethical Council of Animal Welfare Advisory Committee (hereafter called: “ethical council“)
Approval of the specific experiments

In institutions authorized for animal experiments animal protection boards are operated. The specific animal experiments to be performed in registered institutions invested with the right to conduct animal experiments are to be submitted to MÁB for approval. The members of MÁB are assigned by the manager of the institution.

The tasks of MÁB:
- elaboration of the workplace animal experiment regulation (ethical code);
- control of the execution of the regulations;
- approval of the specific animal experiments;
- organizing the training and education of those performing animal experiments within the institution;
- evaluation of the extent of pain caused to the animals in the course of experiment.

If according to MÁB the planned experiment is to cause especially great pain, a special permit is to be issued by the station. So as to judge the approval application, the station is to obtain the opinion of the ethical council.

Professional qualification

The Minister of Education has been our debtor with the definition of qualification conditions for 6 years. The experiment is to be carried out exclusively under the leadership of a qualified person, who disposes with the education and experience defined in a specific statute, is aware of the ethic principles and legal regulations of animal experiments. Animal experiments may be conducted, experimental animals may only be tended by those, who have undergone qualifying education (Paragraph 30 of Ávt). In Hungary according to Paragraph (4) e of Article 49 of Ávt, it is the task of the Minister of Education to regulate within a joint decree together with the Minister of Agriculture and Rural Development, the Minister of Economy, the Minister of Environmental Protection and with the Minister of Health, the conditions of the education necessary for the execution of Ávt, which, however, is still waiting to be done.

Selection of animal species

For the purpose of experiments - without a special permit in hand – only animals bred for this purpose at controlled places (laboratory animals) may be used. Stray specimens of domesticated animals are not to be used for experiments (Paragraph 31 of Ávt). Livestock and mate animals may be used for animal testing when provided from breeding sites under continuous control. Humanoid, non-human primates (gorillas, orang-utans, chimpanzees and gibbons) are not to be used for experimental purposes. On specimen of protected animals, only those tests can be conducted that are of environmental protection or major medical research interest, but in the latter case only on second-generation, bred specimen. The use of outback animals is subject to the permit of the environmental protection authority. (Paragraph 7 of Ákr).

Experiments may only be conducted on animals bred for experimental purposes

During and after the animal experiment, adequate keeping, attendance, care and continuous medical care of the animals must be ensured. Under adequate - keeping, accommodation according to the needs of the animal, necessary freedom of motion, on the other hand, under attendance - adequate feed, drinking water, as well as care, satisfying the health status and good feeling of the animals, furthermore, professional supervision are meant. Enclosure 2 to the Ákr contains the detailed regulations related to the care and accommodation of laboratory animals, covering the facility, aerial conditions, temperature and humidity, furthermore, regulating the questions of lighting, noise and vibration, feed, water supply and littering.

Keeping of records

Animal experiments are to be recorded and reported.

Collection and/or supply of data in relation to animal testing are to be carried out in four fields.

1. Facilities breeding, propagating, keeping, supplying and selling experimental animals are to keep records.
   - on the species, number, origin, time of change in site, as well as the name and address of the receiving party of incoming and outgoing animals;
   - On the name, identification data of occasional suppliers, the quantity of animals purchased from them (in a separate register);
   - On illnesses occurring and mortality, as well as individual and group-level treatments (registered in an animal species break-down);
2. The conductor of the animal experiment is obliged to carry forth detailed reports on the experiments and the interventions performed on the animals [Paragraph 2 of Article 27 of Ávt].
3. MÁB is to keep records of the experiments approved by them, and moreover of the data (thematic, attendance) of the training conducted in the institution on animal protection.

4. MÁB is obliged to compile for statistical purposes to the Ministry of Agriculture and Rural Development, the annual summary data on the animals used, suffering pain, distress or persistent impairment in a species – number - nature and aim of the experiment break-down. The summary data are annually published by the Ministry of Agriculture and Rural Development. The records, reports and statistical data are to be retained for 5 years.

**Decreasing the number of animals involved in experiments**

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<td>- the number of animals</td>
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<td>- causing of pain</td>
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<td>- physical and neurological impairment</td>
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In order to substitute the animal experiments – provided alternate adequate method is available – the scientific procedure to be used should be the one that does not require experiments to be conducted on living animals. The number of the animals utilized in the course of animal experiments is to be reduced to the absolutely necessary level. The method of preference should be the one foreseen to cause the least pain and/or that, which may be conducted with the least physiological, neural or behavioural impairment.

In view of all the above, it is necessary for the leader of the experiment, in the application to MÁB for the approval of the animal experiment, to backup the number of animals (5) with biometric data, as well as to describe in detail the intervention planned with the animals.

**Pain, distress and impairment during the experiment**

Pain, distress and impairment of the animals are to be avoided, or to be reduced to the minimum. For this reason, in the course of experiments entailing pain, distress or impairment, local or overall anaesthesia is to be applied. The only exception is the case is when the application of anaesthesia causes the animal greater strain than its omission, moreover, those experiments, where anaesthesia would result in the invalidity of the experiment (e.g. the testing of analgesic agents).

The Hungarian animal protection regulations – contrary to the practice of other countries – do not provide the definition of lower or higher level of pain, distress or impairment, nor that of shorter or longer endurance. What is more, nor are there data provided for the evaluation of these concepts.

The reader can find data for the recognition, as well as the evaluation of the extent of pain, distress and impairment in the recommendations of FEKETE (1, 2), RUDAS (6) and/or FELESA (4). Objective evaluation is nevertheless necessary both in the professional work related to animal torture, and also due to the fact that Hungarian legislation also forbids the repeated use of animals having already undergone experiments entailing pain, distress and impairment, for similar experiments with no anaesthesia applied.

**Extermination of the animals**

Extermination without pain of the animals does not belong to the concept of animal experiment; however, there are experiments, where the painless extermination of animals is inevitable. After completion of the experiments, the life of definitely or heavily impaired animals is to be extinguished in a humane manner.

**Penal provisions**

Animal protection penalty may be levied on those, who - with their operations or negligence - infringe the regulations of the legislation or authoritarian resolution relevant to the protection and humane treatment of animals. The amount of the penalty lies between HUF 5000 and 150 000. The penalty - with regard to the animal experiments in the first place – may be levied upon those, who

- cause unnecessarily substantial pain, long-lasting distress, bodily impairment to the animals;
- carry on selling of animals without a licence;
- conduct animal experiments without a licence, or performs these in a manner that differs from the contents of the licence;
- Fail to care for the regular satisfaction of the animals under their supervison, or functions unprofessionally in respect of their keeping, feeding and supplying them with drinking water, as well as their care and hygiene, furthermore, their motion requirements.
- Fail to, or satisfy defectively the data supply obligation prescribed in the course of animal experiments [Government. Decree 244/1998 (XII.31.)].
European regulation of the protection of experimental animals

Two important European legal documents were born in the mid 1980ies for the regulation and control of animal experiments.

Protection of experimental animals was regulated by the European Council in 1985 and the European Community in 1986

The first is convention No. 123 of the European Council, published in 1985 after several years of reconciliation, and accepted by 26 countries, entitled the Convention for the Protection of Vertebrate Animals used for Experimental ant other Scientific Purposes. The modification of the convention was accepted in 1988, which was also ratified by the EU in November, 2005. This agreement is of non-binding legal force. The guiding principle was for the member states to organise multilateral consultations to discuss the realisation of the contents of the convention, and to review the necessity of re-working or extending the convention in view of new knowledge. The other European document is the Directive No. 82/609 of the EU for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes. This directive was last modified by EU Directive No. 2003/65.

The text of the Directive of the EU Council is almost identical to that of the EC Convention; however, its legal force is completely different. This directive had to be integrated by the EU member states in their own national legislation (national regulations of binding force has to be issued). The basis for the national regulations was the text of the directive as minimum requirement. The member states are entitled to implement more rigorous national regulations, but not more moderate ones.

Professional training

Adequate and ethic animal experiment behaviour must be educated

Requirements related to professional training are to be treated with special attention. The legal regulations of various level are but little capable of emphasizing the necessity for humane and responsible modes of intervention towards experimental animals. Training and practice serve as good opportunity for acquiring good and ethical conduct in animal experiments.

Article 7 of the EU Directive prescribes that animal experiments can only be conducted or supervised directly by trained personnel. This regulation is supplemented by Article 14, which prescribes that persons conducting, participating in animal experiments, or tending experimental animals (including their surveillance as well), are to have undergone adequate training and are to dispose with sufficient experience. It is also inevitable that the persons involved in the planning and implementation of animal experiments should have a proof of their scientific qualifications related to experimental work. They are to have knowledge in the field of the care of experimental animals as well.

Every member state must provide feedback to the Committee of the EU on the implementation in their national legislation of the prescriptions concerning professional training. The recommendation regarding the necessary professional training of scientific researchers has been compiled by FELASA (Federation of European Laboratory Science Associations) (4). The member states have elaborated their own legislation on this basis. A generally valid concept in these, since the passing of Ävt on March 16, 1998 is that the non-blood-evolving interventions can only be performed by veterinarians, physicians or other graduates of natural sciences, blood-evolving interventions can only be carried out by veterinarians, physicians or biologist specializing in zoology. Beside relevant university studies the performer of the experiment is to dispose with special professional knowledge in the field of animal experiments. In special cases (e.g. university graduates preparing their thesis) the animal protection authority may grant an exemption.

Alternate methods

Research of methods substituting animal experiments would need public funds

The substitution of animal experiments was first widely summarized by RUSSEL and BURCH. According to Article 7 of the Directive it is impossible to conduct animal experiments when the accomplishment may be reached without the use of animals as well. If there is no alternate method, the animal species to be chosen should be of the lowest possible neuro-physiological sensitivity or pain responsiveness with which, however, adequate accomplishments may still be achieved.

All experiments are to be planned in such a way that the pain and distress can be kept at the lowest possible level. Article 23 of the Directive states that the Committee of the EU and the member states are obliged to work on the research, development and unification of alternate methods. The periodical ATLA (Alternatives to Laboratory Animals) serves for the publication of data.
Primarily in default of public financial funds – in our country the research of alternate methods is unfortunately insignificant.

Importance and limits of legislation

All previous legal regulations are based on the presumption that under certain circumstances the use of animals for experiments or other scientific purposes is morally acceptable (8).

In 1876 the royal committee of the United Kingdom defined the main purpose of the law created for the control of animal experiments as follows: "...to reconcile the requirements of science with the rightful assertions of humanity." This became the guiding principle of the constituents of the law against animal torture then in force (Cruelty of Animals Act) and all legal rules, regulations and guidelines born ever since are also based on the same principle.

How the desired aim of the control of animal experiments is realized does not depend only on the efficacy of the administration, e.g. effective supervision or specific institutional control system, but to a large extent on the behaviour, attitude and state of mind of those, who conduct the experiments and tend the animals. A very considerable element of the control system is therefore the adequate training and knowledge, which do not only mean practical capabilities, but the awareness of alternate methods, and the ethical approach towards animal experiments.

Besides legal regulations, professionalism and charitability of researchers is also necessary

No legal regulation could be effective, if the researchers were indifferent, or searched for the possibilities of evading the regulations. The reality is that in the past decades, since we speak about the control of animal experiments, in the scientific circles a constant increase of the attention towards practical and ethical aspects may be observed. In the meantime the interest of researchers has also focused on the application and implementation of control systems. Legislation can set up regulations, but these regulations remain ineffective if the self-control of the institutions does not operate or efficiency is not satisfactory. Legislation can only be as effective as its practical implementation is realised. Adequate daily care and reasonable realisation of experiments must be assured by the institutions themselves.

Central control can only guarantee that animal experiments are only permitted if their reason, purpose and necessity are well-founded, and the adequate attendance of the animals is ensured by trained personnel, within adequate institutional frames and professional conditions. When submitting their licence applications, conciliation with the authorities or requesting the opinion of the institutional committee for their application, researchers must concentrate their efforts on minimizing the number of animals, seek alternate methods, and find the means and possibilities for reducing to minimum the pain and distress caused during and after the experiments.

Legislation has created a brand new conversation among researchers, veterinarians, the technical personnel and the competent authorities. In fact the appearance of a legal regulation aiming at the amelioration of animal experiments does not immediately bring forth spectacular changes. Visible development can be observed in the field of anaesthetics, application of analgesics, or the refinement of the realisation of experiments, which are the outcome of reconciliatory meetings prior to issuing licences for experiment applications, or the debates organized at scientific meetings.

Multilateral information and social conversation are inevitable

The purpose of the experiment is an important question in the course of judging animal experiment applications by the competent authority or workplace committee. In some national legal regulations, by prescription the competent authority or workplace committee is to judge on one hand the expected expediency indicated by the applicant (e.g. new medical or scientific accomplishments), on the other hand the extent of pain or distress caused during the experiment. It may therefore happen that the planned experiment is not permitted, if its scientific achievement is little, or the foreseen extent of the impairment of the animals is likely to exceed the value prescribed by law, or the expected outcome and the extent of impairment are not proportionate. All this, however, does not mean that the law would basically ban the use of animals for scientific purposes. The opponents of animal experiments consider the major defect of all regulations, and argue that the current legal regulations the question in focus is not whether animal experiments are to be permitted at all, e.g. for consumers, it is not important for the trial of new products.

Social sensitiveness regarding the use of experimental animals is just as changeable as the moral attitude of the society in all similar questions. This is a part of the development of social consciousness, and is expected to raise further medical-ethical questions. In view of the above basic questions concerning the severe legal regulations related to the use of animals that continue to improve the execution and control of experiments, further discussions need to be continued.
LITERATURE


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Supplement – Comment

For the aim of realising the training mentioned in the article, for 10 years the SZIE-ÁOTK has been organising 80 hour courses entitled „Laboratory Animal-science and experiment organisation” for university graduates of biology type. For the PhD students of the Veterinarian Doctor school, the course is obligatory. The course is equivalent to the „C” level FELESA qualification of leaders of experiment; its accreditation is expected for September this year.

The management of ÁOTK – in reply to the challenges of our age - a 30 hour course was implemented in 2005 entitled „Laboratory Animal-science and experiment organisation”. This is in practice equivalent with level „B” (technician) of the FELESA requirements. The education of both subjects is hindered by the fact that there is no tutorial material in available in Hungarian, the lack of which is meant to be alleviated by the present article.

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