

GENERAL PRINCIPLES CONCERNING THE HARMONIZATION OF ROMANIAN LEGISLATION WITH THE EUROPEAN UNION IN THE FIELD OF PROTECTION OF ANIMALS USED FOR SCIENTIFIC SCOPE

Cristin COMAN¹, Magda GONCIAROV²

¹National Institute for Microbiology and Immunology Cantacuzino,
Splaiul Independentei 103, District 5, 055190, Bucharest, Romania,

Phone 0212694091, Fax: 0214904652, Email: comancristin@yahoo.com;

²University of Agronomic Sciences and Veterinary Medicine of Bucharest,
59 Mărăști Blvd, District 1, 011464, Bucharest, Romania,

Phone: +4021.318.04.69, Fax: + 4021.318.04.98, Email: magdagonciarov@yahoo.com

Corresponding author email: comancristin@yahoo.com

Abstract

The introduction of alternative methods in the research, in the diagnosis of diseases and in the production of biopreparations, led over time to a drastic reduction in the number of animals used for scientific scope in Romania. However, our country has always aligned legislation in this area with the European Union. In this regard, last year was transposed into national law Directive 63/2010 which refers to animal protection used for scientific scope, transposition materialized by Law no. 43/2014. Although the law is very complex, including a large number of issues, including general and special requirements on the units, care and housing of animals, animal species that can be used in procedures, there are a number of issues for which the law requires the development of a secondary legislation in areas such as: authorize breeders and users of laboratory animals, create a bank of organs and tissues of animal origin, able to reduce the number of animals used in experiments, authorization of projects, setting and punishing contraventions and others. This law, new for Romanian legislative landscape, will determine an increase in the level of consciousness in the use of this category of animals and conducting scientific research of the best quality.

Keywords: animal, experiment, harmonization, protection.

INTRODUCTION

The idea of using animals in experiments concerning scientific research on the human body appeared at an early stage of medical research and the development of techniques and procedures regarding animal models was parallel to the development of medicine.

Since the 18th century experimental medicine started being regarded as a necessity in the increase of human welfare and living conditions. It became also clear that the development of medicine is dependent on the results of experimental medicine.

At the end of the nineteenth century, animal experimentation started exploding and becoming an integral part of biomedical research, and the factors that contributed to this were: the discovery of anesthetics in the first half of the nineteenth century and their use in animals exposed to painful experiments. The book published in 1859 by Charles Darwin „Origin of Species”, showed

a homology between humans and animals, thus providing a rational basis for the use of animals as a model for humans.

The book „Introduction to the study of experimental medicine” published in 1865 by Claude Bernard's describes the tools used in the design of experiments. It has become a „bible” of animal experimentation and also of development of microbiology, thus contributing to the production and testing of serums and vaccines.

The development of industry in the 20th century resulted in a rapid increase of the use of laboratory animals. Both the number and also the species of animals used increased. While, at the beginning, only domestic animals were used, in the early 20th century species like mice, rats and other mammals, reptiles, birds, amphibians and fish started being used.

Every year, 75-100 million animals are used throughout the world, of which 10-12 million in Europe.

Most animal experiments are performed in medical sciences, biological, veterinary medicine and agriculture. In biology, veterinary medicine and agriculture, experiments on animals are used to obtain information about the species that have been made experiments.

A large number of animals are still used for medical research and safety testing of drugs and vaccines. In these fields, the animals are almost exclusively used as a replacement or as a model for humans.

MATERIALS AND METHODS

Animal experiments have become a political issue by the emergence of legislation in this area. The rules regarding the protection of animals used for experimental and other scientific purposes is to put under the control of governmental authorities the breeding and the use of laboratory animals to ensure the welfare of this category of animals.

The regulations have emerged as a result of public and non-governmental organizations' pressure that fight to reduce animal testing on one hand, and of scientific society pressure on the other hand, to create a single framework for the use of laboratory animals.

In the European Union, by 2010, the legislation regarding protection of animals resulted in two acts, namely the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (Council of Europe, 1986) and the Council Directive 86/609/EEC (The Council of the European Communities, 1986). After signing the accession treaty to the European Union, Romania was required to adopt and implement the European Union legislation, including regulations related to animals used for scientific purposes (European Union, 2005).

In 2010 the European Union adopted a new directive for the protection of animals used for scientific purposes, Directive 2010/63/EU (European Parliament, 2010) which was transposed into the Romanian Law No. 43/2014 (of the Romanian Parliament, 2014). In addition to the implementation itself, the law comprises the preparation, adoption and

implementation of a complex secondary legislation.

Analysis on historical and legislative framework on the use of laboratory animals in our country is done in compliance with the European Union legislation and principles.

RESULTS AND DISCUSSIONS

Brief history of the use of laboratory animals in Romania

The use of animals in experiments is attested from the late nineteenth century and early twentieth century. Former students of Louis Pasteur and Robert Koch founded several institutes in Romania, in which animals are used in the production of serums and vaccines. The first experimental medicine department in Bucharest was founded in 1904. Animal experimentation in Romania began using animals in the production of vaccines and serums and biological control of these products.

Using the large number of animals in the production of therapeutic sera and vaccines began after a campaign of anti-cholera and anti-dysentery serumization among soldiers who fought in the Second Balkan War (1913). In 1921, the government of the time established the first institute to use laboratory animals, the Cantacuzino Institute, which was similar to Pasteur Institute in France.

During the communist regime (1945-1989), a strong increase in the number of animals used for experimental purposes could be observed, the reasons being: to pay for war reparations by selling serums and vaccines, to produce all medicines, serums and vaccines locally and to develop and establish new experimental research institutes.

The effects of this development of animal experimentation were: an increase in the number of animals used, the peak being reached in 1975 with 2.6 million animals used (Potorac, 1989), a higher number of users of laboratory animals (in 1975 there were 352 institutions and 27 breeders), a diversification of species used: rodents, monkeys, dogs, cats, ferrets, birds, reptiles and a continuous improvement and growth conditions of accommodation.

The highest number of animals was used in the production of vaccines and serums, safety control drugs and biological products, as well as diagnostic.

After the revolution in 1989, a dramatic reduction in the use of animals in experiments, has taken place, the main reasons being: reorganization, dissolution or privatization of research institutes, privatization and dismantling of most drug plants and animal facilities in research and development divisions, purchase of imported drugs and vaccines and implementation of alternative methods to animal experiments.

This decrease in animal experimentation reduced the number of animals used in experiments, restricting the number of species used and animal research.

In the last year of the communist regime the number of animals used was approximately 900,000. The first statistics after that year was made in 2002, the year when Romania began his road to the European Union. In 2007, the year of entry into the European Union, the number of animals used was approximately equal to that of 2002, but it was the first year without the use of non-human primates and carnivores. 2011 is the year of the third report to the Council of Europe of Romania. As it can be seen in table 1 the number of animals used is half compared to 2007 (Gonciarov 2014). This year there were also non-reported, cold-blooded animals used for scientific purposes, together with carnivores and non-human primates. The main reason for this reduction is the introduction of alternative methods in diagnosing diseases and in the production of biological products.

The main areas in which animals are used for scientific purposes are, in order of their numbers: production of biological products and their quality control; diagnostic, research and education. Romania filed in 2011 the third report on the statistics of the use of laboratory animals, according to the 2010/63/EU Directive.

The total number of animals represented 0.5% of the number of animals used in the European Union. Research used 10% of the animals; about 40% was used in diagnosis, 35% in production and quality control of human biological products and 10 % in

veterinary products and in safety studies (Figure 1).

Table 1 – The number of laboratory animals used in Romania

Species	Years			
	1989	2002	2007	2011
Mice	560.00 0	80.000	95.000	44537
Rats	150.00 0	15.000	9.000	5314
Guinea-pigs	130.00 0	12.000	12.000	6602
Others rodents	4.300	1.500	700	240
Rabbits	22.000	12.000	4.000	2166
NHP	17	2	0	0
Carnivores	286	57	0	0
Birds	4.500	3.000	2.000	1.203
Artio + perissodactyla	1.003	427	156	124
Cold blooded animals	237	136	54	0
Total	872.34 3	124.12 2	122.91 0	60.18 6

Purposes of experiments
Total number of the animals – 60186.

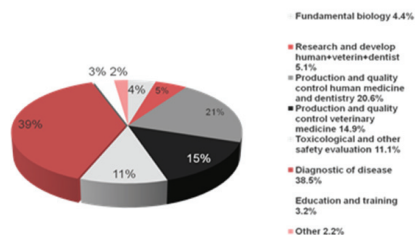


Figure 1 - Purposes of using laboratory animals in Romania

Romanian legislation on laboratory animals in Romania

Until signing the association agreement with the European Union, Romania had no specific legislation for animals used for scientific purposes. By signing the agreement for European Union membership Romania has assumed full adoption of the European Union legislation. In this respect, the European Union legislation on laboratory animals was adopted and then implemented (Gonciarov, 2011).

The first two laws transposing the 2010/63/EU Directive were the Government Ordinance No. 37/2002 adopted by Law No. 471/2002 on the protection of animals used for experimental and other scientific purposes. Other two laws (Law No. 205 / 2004 on the protection of animals, as amended by Law No. 9/2008 and the Order of the National Sanitary Veterinary and Food Safety Authority and Ministry of Interior and Administrative Reform No. 523/2008 approving the Methodological Norms for the application of Law No. 205/2004 on the protection of animals) contain specific provisions for the use of animals for scientific purposes in a comprehensive law for animal protection.

The 2010/63/EU Directive and its implementation.

Although the 2010/63/EU Directive had to be adopted by October 10, 2012 and be effective starting from 01.01.2013, Romania has transposed the directive quite late, by Law no. 43 of 11 April 2014 - Protection of animals used for scientific purposes, issuer: Romanian Parliament, published in Official Gazette no. 326 of May 6, 2014 – which entered into application starting with May 9, 2014.

Compared to the 471/2002 Law, this is much larger (if we look only at the number of pages, it is five times greater) and it is not like a law on national regulations, these regulations only give general principles and not content as does the present law. There was much talk about how to adopt, as government decision, a government ordinance.

The Directive was transposed by law (this is a rare procedure regarding Directives). The explanation was probably to avoid ordinances, as in ordinary laws; another reason is, in our opinion, that a legislation had to be replaced with another of the same or higher value to the first legislation.

Adoption of the 2010/63/EU Directive was made in a rush and Romania will enter in an infringement procedure (infringement of European Union law). As a result, the transposing law (43/2014 Law) is largely (approximately 75%) a simple translation of the directive, sometimes quite unclear. The competent authority on the protection of

animals used for scientific purposes is the National Sanitary Veterinary and Food Safety Authority, having the role of initiation of normative acts and additional national legislation in this area. For joint projects to be elaborated within the law, other central state bodies (Ministry of Environment and Climate Change, Ministry of Health, Ministry of Education) join forces. The great majority (90%) of tasks such as implementation responsibility, creation of welfare and ethics committees, project evaluation, training of specialized staff, creation of a material and technical base, are the tasks of the National Sanitary Veterinary and Food Safety Authority.

In order for the law to be implemented, the legislation has to regulate the following aspects of the law:

Authorization of breeders, suppliers and users of animals used for scientific purposes.

While until now there was only one piece of legislation regulating veterinary authorization of all operators, the appearance of the 43/2010 Law led to the imposition of adopting a different and specific legislation to regulate the licensing of various fields. The same will happen for producers and users of laboratory animals. Until then, permits are suspended. In order to prepare for authorization, an evaluation form containing requirements related to the use of animals for scientific purposes, and also requirements on environmental protection, fire safety etc. will need to be completed. There will be a total of about 50 requirements, differently marked. In the case that one of the conditions are not met, the authorization will not be granted.

An important part of the licensing documentation will be the name and competence of persons responsible for the welfare of the animals. The law provides comprehensive staffing structure that will provide staff training, welfare, care and ongoing supervision of their.

In the case of large units, this structure requires active collaboration between those involved in animal monitoring and those who use the animals. In the case of small units, cooperation agreements with experts and specialists in the field, without the requirement of a fixed work schedule will be

accepted. Concerning staff competence, the requirements are set out in Annex V of 2010/63/EU Directive.

Education and Training

Until now, training in this area was not compulsory. Due to the small number of people involved in the growth and use of laboratory animals, the training has been made at the place of work. After joining the European Union a large number of students and researchers were trained in universities in Western countries. The competent authority will authorize courses organized on three levels: caretakers, technicians and experts. The main purpose of the success of organizing such courses is that diplomas will be recognized in all European Union countries.

Authorization of projects

So far, the only projects approved are research projects. In this regard, research ethics committees were established at the site of each user of research laboratory animals, as imposed by Law 206/2004.

For obtaining authorization for the use of animals in other areas, new licensing structures will be created. Competent authorities issue authorizations after receiving a positive report from a committee of ethics. Further rules concerning the election of the commission's evaluation, confidentiality, conflicts of interest, etc will need to be set. A simplified administrative procedure for animal use in our country is expected to ease the approval process of projects. This procedure will be established jointly by key ministries.

Alternative methods to animal testing

The competent authority will contribute to the development and validation of alternative methods that could provide the same level of information as those obtained in in vivo studies. A reference laboratory for coordination and promotion of the use of alternative methods to animal testing will be established. The Institute for Diagnosis and Animal Health will provide national promotion and will publicize information about alternative methods, and will also provide training in this area. Over the next two years, several alternative methods will be implemented in Romania, especially in terms

of confirming diagnosis of disease, and some methods for testing the efficacy and safety of biological products. Also, in education, animals will be replaced with solid computer models, digital or similar.

The use of animals from the wild

Romania has a rich wildlife, and so far the use of wild animals for scientific purposes has not been subjected to any act regulations, protecting referring only to habitat protection and to avoid their hunting. The new law provides that this category of animals, when their use is for scientific purposes to be subject to authorization. The birds for the migratory bird communities are taken to monitor their blood for disease control, main transmitted by birds and through birds (meningoencephalitis, West Nile fever, avian flu, etc.). The huge number of wild mammals required monitoring in terms of disease incidence possible to be transmitted to domestic animals and humans.

We believe that implementation of this law requires the application of offenses which are currently not included in the law. The transposition will generate some costs, especially with the improvement of animal accommodation.

CONCLUSION

Most European countries already have a strong culture for caring of animals used for scientific purposes and operate with high standards with consideration on animal suffering. The 2010/63/EU Directive, the new regulatory landscape for Romania, will increase the level of consciousness in the use of this category of animals.

Even if the number of animal users is small, implementation of the Directive is challenging, and we hope that the implementation will be done properly without subsequent necessary corrections.

Correct implementation of the Directive is very important especially for making high-quality scientific research, but also to reduce the suffering of these categories of animals. We estimate that the entire adoption of secondary legislation and its implementation at the user level will be completed by the end of 2017.

The new Directive changes substantially the legal system for regulating animal experiments in Romania and the implementation of this Directive in Romania will introduce a unified legal framework, which will benefit definitely animals and professionals involved.

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