**Articles**

Studia Iuridica Lublinensia vol. XXX, 3, 2021
DOI: 10.17951/sil.2021.30.3.133-146

Grzegorz Lubeńczuk
Maria Curie-Skłodowska University in Lublin, Poland
ORCID: 0000-0001-5028-8020
lubenczuk@umcs.pl

# Admissibility of the Use of Animals for Scientific Purposes in the Light of International Public Law and EU Law*

## *Dopuszczalność wykorzystywania zwierząt do celów naukowych w świetle prawa międzynarodowego i prawa Unii Europejskiej*

ABSTRACT

The article is aimed at assessing the regulations of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes, opened for signature in Strasbourg on 18 March 1986, and 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 in the context of their impact on the number of procedures which set out a model for the protection of animals used for scientific purposes in European countries, in the perspective of their impact on the reduction of the number of scientific procedures using animals carried out in European countries, including especially those involving the highest degree of suffering for animals. The starting point for this assessment was the identification of rules determining the admissibility of scientific use of animals in European countries and the impact that certain measures implemented under these rules may have

CORRESPONDENCE ADDRESS: Grzegorz Lubeńczuk, PhD, Assistant Professor, Maria Curie-Skłodowska University (Lublin), Faculty of Law and Administration, Institute of Law, Plac Marii Curie-Skłodowskiej 5, 20-031 Lublin, Poland.

* Publication has been prepared as part of the research project entitled "The Administrative Law Model of Animal Protection", covered by the application registered with the Funding Stream Support system administered by the National Information Processing Institute, as no. 2016/23/D/HS5/01820 and accepted for financing as part of the competition SONATA 12 held by the National Science Centre, Poland, under the decision of the Director of the National Science Centre in Kraków of 16 May 2017 (decision no. DEC-2016/23/D/HS5/01820, agreement no. UMO-2016/23/D/HS5/01820).

on the reduction of the number of procedures involving animals. In principle, the analysis of these solutions is to specify the directions of further development of regulations aimed at protecting animals used for scientific purposes.

**Keywords:** animals; scientific purposes; scientific procedures with the use of animals; admissibility; Strasbourg Convention; Directive 2010/63/EU

## INTRODUCTION

The possibility of using animals for scientific purposes raises many ethical, philosophical, biological, medical and even economic concerns. The manner in which animals are treated, especially with regard to humanitarian protection, i.e. based on ethical (non-economic) considerations, is regarded as one of the measures of civilisational development.[1] In the contemporary literature, animals are referred to as victims of science,[2] and Article 8 (a) of the World Declaration of Animal Rights, proclaimed by the United Nations Educational, Scientific and Cultural Organisation in Paris on 15 October 1978, refers to animal experimentation that involves physical or mental suffering, whether these are medical, scientific, industrial or any other experiments, as an infringement of animal rights. Despite this, the number of animals used for scientific purposes remains very high. According to data contained in the reports on the use of animals for scientific purposes, which the European Commission periodically submits to the Council and the European Parliament, the total number of cases of use of animals for research and testing in the European Union Member States was as follows: 11.79 million in 1991 (the first ever report covering 10 Member States),[3] 12 million in 2008 (the first report covering 27 Member States)[4] and 9.58 million in 2017 (the latest report available).[5] It should also be noted that a very high proportion of this number consists of cases where animals are used for procedures with high degree of pain, suffering and distress. Data from recent years show that approximately 51% of animals are used in procedures defined as "mild", approximately 32% in procedures defined as

[1] Cf. E. Kruk, *Polish and Estonian Regulations on Homeless (Stray) Animals*, "Studia Iuridica Lublinesia" 2021, vol. 30(1), p. 145.

[2] R.D. Ryder, *Victims of Science: The Use of Animals in Research*, London 1975, passim.

[3] First Report from the Commission to the Council and the European Parliament on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes COM(94) 195, final.

[4] Sixth report on the statistics on the number of animals used for experimental and other scientific purposes in the Member States of the European Union. Report from the Commisson to the Council and the European Parliament, COM (2010) 511 final.

[5] Report from the Commission to the European Parliament and the Council. Report on the statistics on the use of animals for scientific purposes in the Member States of the European Union in 2015–2017, COM(2020) 16 final.

"moderate", approximately 11% in procedures defined as "severe" and about 6% in "non-recovery" procedures under general anaesthesia after which the animal has not regained consciousness.[6] These figures show the extent of the use of animals for scientific purposes and the degree of suffering by animals, but also the significance of the use of animals in modern science.

It is clear that the persistently high number of cases of animals used for scientific purposes and the high proportion of procedures involving high degree of animal suffering are the result of a combination of factors, including the ever-increasing pace of scientific development and the approach of the scientific community. Undoubtedly, one of the key factors influencing the extent and manner of the use of animals for scientific purposes is the legislation in force in this area. This is so, because it is the applicable law which determines, in every case, the impassable limits to the legal use of animals for such purposes. This raises the question of how effective the current model of legal protection of animals in European countries is, and in particular, whether it properly defines the limits of permissible use of animals for scientific purposes.

## THE MODEL OF PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES IN EUROPEAN COUNTRIES

The regulations governing the admissibility and use of animals for scientific purposes are similar in a large part of European countries. This situation is a consequence of the adoption of regulations setting out rules for the use of animals for scientific purposes at the level of the Council of Europe and the European Union.

The first transnational act in Europe to comprehensively regulate the use of animals for scientific purposes was the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes, opened for signature in Strasbourg on 18 March 1986.[7] The Convention entered into force on 1 January 1991 and has been in force since then. Pursuant to Council Decision 1999/575/EC of 23 March 1998 concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes,[8] the Convention was approved by the European Community. Since the entry into force of the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed on 13 December 2007,[9] which granted legal personality to the European Union

[6] *Ibidem*.
[7] OJ EU L 222, 24.08.1999, pp. 31–37, hereinafter: the Strasbourg Convention.
[8] OJ EU L 222, 24.08.1999, pp. 29–30.
[9] OJ EU C 306, 17.12.2007, pp. 1–271.

and identified it as the legal successor of the European Community, the European Union has been a party to the Convention.

The first rules on the use of animals for scientific purposes in Community law were laid down in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes.[10] Following the accession of the European Community to the Strasbourg Convention, Directive 86/609/EEC was amended by Directive 2003/65/EC of the European Parliament and of the Council of 22 July 2003 amending Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes.[11] The changes were aimed at, i.a., adaptation of the provisions of Directive 86/609/EEC to the provisions of the Strasbourg Convention. On 9 November 2010, 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[12] entered into force, replacing Directive 86/609/EEC.

It is pointed out that the Strasbourg Convention and Directive 86/609/EEC was the basis on which the European standard for animal experimentation was developed.[13] The foundations of this standard are defined by the principles of the Three Rs (3Rs) formulated by R.L. Burch and W. Russell, i.e. replacing, reducing and improving the use of animals,[14] which assumes the use of research methods that allow replacing the use of animals for scientific purposes with alternative methods, as well as to reduce the total number of animals used for scientific purposes and to reduce pain, suffering, distress or the risk of permanent injury which significantly improves their welfare.[15]

The assumptions on which the Strasbourg Convention and Directive 2010/63/EU are based also correspond to the rules of the use of animals for scientific purposes formulated as early as in 1835 by M. Hall, who pointed out that:

- an experiment should not be conducted if the necessary information can be obtained by observation,

[10] OJ EU L 358/1, 18.12.1986, hereinafter: Directive 86/609/EEC.

[11] OJ L EU 230, 16.09.2003, pp. 32–33.

[12] OJ L EU 276, 20.10.2010, pp. 33–79, hereinafter: Directive 2010/63/UE).

[13] As proposed, i.a., by W. Rakoczy, *Ustawy o ochronie zwierząt. Komentarz*, Warszawa 2015, p. 270; idem, *Ustawa o ochronie zwierząt. Komentarz*, Wrocław 2003, p. 100; M. Micińska-Bojarek, *Europejski standard doświadczeń na zwierzętach. Aspekty humanitarno-prawne*, "Przegląd Prawa Ochrony Środowiska" 2012, no. 3, p. 111 ff.; M. Walczak, Z. Bonczar, *Etyczne i prawne aspekty doświadczeń na zwierzętach*, "Wiadomości Zootechniczne" 2015, no. 4, p. 151.

[14] R.L. Burch, W. Russell, *The Principles of Humane Experimental Technique*, Potters Bar 1959, passim.

[15] For more details of the 3Rs principles, see A. Schollenberger, *Zasada 3R w ochronie zwierząt wykorzystywanych do badań naukowych*, "Życie Weterynaryjne" 2017, no. 92, p. 424 ff.

- an experiment should not be performed without a clearly defined and achievable purpose,
- experiments that have already been conducted by other researchers should not be repeated,
- experiments should be conducted with causing the least possible suffering,
- an experiment should be conducted in conditions that allow adequate observation and documentation of the results and allow getting results as clear as possible, thus reducing the need for repetition.[16]

The literature points out that the elements that set the standard for the use of animals for scientific purposes that was established under the Strasbourg Convention and Directive 86/609/EEC were:

- the principle that an experiment can only be justified by an approved purpose explicitly provided for as permissible in the provisions of the Strasbourg Convention or Directive 86/609/EEC (Article 6 (1) of the Strasbourg Convention and Article 7 (2) of Directive 86/609/EEC),
- the principle of subsidiarity, according to which an experiment may not be conducted if it is reasonable and practicable to use a method which is scientifically satisfactory and does not involve the use of animals (Article 29 of the Strasbourg Convention and Article 22 (1) of Directive 86/609/EEC),
- subjective restrictions including: the principle that only purpose-bred laboratory animals may be used in experiments (Article 21 (2) of the Strasbourg Convention and Article 21 of Directive 86/609/EEC); the prohibition to use wild animals (Article 7 (3) of Directive 86/609/EEC); the prohibition to use stray animals (Article 21 (3) of the Strasbourg Convention and Article 19 (4) of Directive 86/609/EEC),
- the principle of the minimisation of pain and suffering as manifested in the requirements to use the minimum number of animals, to use animals with the lowest degree of neurophysiological sensitivity, to cause the least pain and suffering to the animals, to perform experiments which cause the least possible distress and lasting harm to the animals, to perform experiments which are most likely to bring satisfactory results (Article 7 of the Strasbourg Convention and Article 7 (3) of Directive 86/609/EEC), to conduct experiments under anaesthesia or with at least analgesia (Article 8 of the Strasbourg Convention and Article 8 of Directive 86/609/EEC), to take care of animals which are left alive at the end of the procedure and to euthanise humanely and as soon as possible animals which are not to be kept alive at the end of the procedure (Article 11 (3) of the Strasbourg Convention and Article 7 (3) of Directive 86/609/EEC),

[16] M. Hall, *A Critical and Experimental Essay on the Circulation of the Blood: Especially as Observed in the Minute and Capillary Vessels of the Batrachia and of Fishes*, Philadelphia 1835, pp. XVII–XX.

- making the possibility of conducting experiments dependent on the authorisation of the relevant authorities (Article 13 of the Strasbourg Convention and Article 7 (1) of Directive 86/609/EEC),
- compliance with detailed rules on the conditions of breeding and handling of animals before and after the experiment (Article 5, Article 11 (3) and Articles 19 to 20 of the Strasbourg Convention and Article 5, Article 9 (2) and Article 19 of Directive 86/609/EEC).[17]

While generally accepting the distinction of these elements of the standard laid down under the Strasbourg Convention and Directive 86/609/EEC, their catalogue should be supplemented by the following principles: the principle of restricting the admissibility of procedures using vertebrate animals and larval forms capable of living, reproducing or eating independently (Article 1 (1) in conjunction with Article 1 (2) of the Strasbourg Convention, and Article 1 in conjunction with Article 2 (a) of Directive 86/609/EEC); the principle of recognition of the results of procedures carried out in the territory of other States (Article 29 of the Strasbourg Convention and Article 22 of Directive 86/609/EEC); the principle of encouraging the use of alternative methods (Article 23 of Directive 86/609/EEC).

The provisions of Directive 2010/63/EU have significantly detailed the existing regulation, to some extent modifying the existing solutions and, above all, introducing a number of new ones. The analysis of the provisions of the Directive allows the catalogue of elements defining the standard of use of animals for scientific purposes to be supplemented with other principles, including:

- limitation of the admissibility of procedures using cephalopods (Article 1 (1) in conjunction with Article 1 (3) of Directive 2010/63/EU),
- the possibility of carrying out procedures for both applied and basic research (Article 5 of Directive 2010/63/EU),
- the possibility of carrying out procedures involving severe, prolonged and unrelieved pain, suffering or distress only for exceptional and scientifically justified reasons as part of provisional measures applied by a Member State authorising such a procedure (Articles 15 and 55 of Directive 2010/63/EU),
- the prohibition of administering to animals any pharmaceuticals to stop or restrict their showing pain without an adequate level of anaesthesia or analgesia (Article 14 (3) of Directive 2010/63/EU),
- the restriction on the possibility of using in the procedures the endangered species listed in Annex A to Council Regulation (EC) no. 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein[18] which have not been born and bred in captivity or have not been artificially propagated (resulting from Article 7 of Directive 2010/63/EU),

[17] Cf. W. Rakoczy, *Ustawy*..., p. 270 ff.; idem, *Ustawa*..., p. 100 ff.
[18] OJ EU L 61, 3.03.1997, pp. 1–69.

- the restriction on the possibility of use of non-human primates in procedures, including in particular great apes (Article 8 of Directive 2010/63/EU),
- a requirement that, except in scientifically justified cases, non-human primates may only be used in procedures if they are the offspring of animals bred in captivity or taken from self-sustaining colonies (Article 10 (1) and (3) of Directive 2010/63/EU),
- the possibility for the Member States to ban the use of non-human primates in procedures involving severe, prolonged and unrelieved pain, suffering or distress (Article 55 of Directive 2010/63/EU),
- allowing the use of stray animals of domestic species in procedures, where there is an essential need for studies concerning the health and welfare of the animals or serious threats to the environment or to human or animal health, and there is scientific justification to the effect that the purpose of the procedure can be achieved only by the use of a stray or a feral animal (Article 11 of Directive 2010/63/EU),
- the obligation for all breeders, suppliers and users to be authorised by and registered with the competent authority (Article 20 (1) of Directive 2010/63/EU),
- making the possibility of conducting a procedure conditional on obtaining the authorisation of the project under which the procedure is to be carried out (Article 36 of Directive 2010/63/EU),
- the requirement to collect and maintain, in the form of a separate file, information on the identification data, place and date of birth and whether the animal is bred for use in procedures, for each dog and cat and, for non-human primates, also information on whether it is the offspring of non-human primates that have been bred in captivity (Article 31 of Directive 201/63/EU),
- the obligation to carry out a retrospective assessment of projects involving the use of non-human primates and projects involving procedures classified as "severe" and where such obligation is imposed in the project authorisation (Article 39 of Directive 2010/83/EU),
- the obligation to submit non-technical project summaries for publication (Article 43 of Directive 2010/83/EU).

These rules for the use of animals for scientific purposes in European countries have been developed in a harmonised way for more than 30 years. Directive 2010/63/EU was implemented by all the Member States of the European Union.[19] Apart from the European Union, the Strasbourg Convention was also ratified by Norway, North Macedonia, Serbia, Switzerland and the United Kingdom, and signed by Ukraine and Turkey. This means that the rules on the use of animals for

[19] Report from the Commission to the European Parliament and the Council on the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes in the Member States of the European Union, COM(2020) 15 final.

scientific purposes set out in the Strasbourg Convention and Directive 2010/63/EU are implemented in two-thirds of European countries. This makes it possible to state that there is a certain standard defining admissibility of the use of animals for scientific purposes in European countries.

## CLASSIFICATION OF MEASURES FOR THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES AND ASSESSMENT OF THEIR IMPACT ON THE REDUCTION OF THE NUMBER OF PROCEDURES IN WHICH ANIMALS ARE USED

This list of the principles on which the current model of protection of animals used for scientific purposes is based shows that the Strasbourg Convention and Directive 2010/63/EU use a broad catalogue of measures of varied nature and aim. Examination of the structure of these measures allows us to propose their classification into four groups: measures of an objective nature, measures relating to the species and individual characteristics of the animal, personal restrictions and measures of a procedural nature. The aim of this classification is that measures of a similar nature have a similar effect on the number and use of animals for scientific purposes.

Measures of an objective nature are based on the determination of the acceptability of the use of certain scientific and experimental procedures, taking into account, on the one hand, the impact they may have on the welfare of the animal and, in particular, the possibility of causing pain, suffering, distress or the possibility of causing lasting harm, and, on the other hand, their scientific and practical value, assessed on the basis of the objective and its feasibility.

The essence of the restrictions related to the characteristics of an animal in terms of its species is to rule out the possibility of using animals of certain species for scientific purposes, or to make their use conditional on the purpose of the action taken, the fulfilment of additional conditions or the existence of specific circumstances, taking into account the suitability of the animals of the species concerned for the attainment of a specific purpose and the species-determined resistance to pain and stress.[20] Restrictions related to individual traits boil down to excluding the possibility

[20] The measures introduced based on the species characteristics or individual characteristics of the animal are referred to in the literature as objective restrictions (as proposed in, i.a., W. Rakoczy, *Ustawa…*, pp. 101–102; M. Micińska-Bojarek, *op. cit.*, p. 120), but taking into account the nature and scientific justification of the use of these measures, and partly also due to acceptance of the concept of animal dereification, which postulates to abandon treating animals as things, the use of such a term does not seem accurate. Therefore, it should be proposed to use the expression of restrictions related to the species or individual characteristics of the animal. On the other hand, the concept of "objective restrictions" may refer to measures relating to the object of scientific research involving the use of animals.

of using a particular animal because of its individual features, which may translate into reactions of the animal and its body to consecutive stimuli and thus affect the test results. Such features may include, in particular, the origin of the animal, which is crucial for determining its genetic, biological and behavioural characteristics, the health condition of the animal or the fact that it has been used in scientific procedures.

Subjective restrictions are requirements that apply to entities that use animals for scientific purposes. These requirements may relate, in particular, to the employment of appropriate personnel and the use of appropriate equipment and conditions for the keeping and testing of animals.

Procedural restrictions consist in making the possibility of using an animal for scientific purposes conditional on the fulfilment of certain administrative obligations. Specifically, they may consist in notifying the appropriate authorities of the intention to take specific actions or obtaining an administrative decision with specific content.

The analysis of the structure of individual measures for the protection of animals used for scientific purposes leads to the conclusion that they are aimed at achieving two basic goals, namely: reducing the number of procedures and minimising pain, suffering and distress in animals used in procedures. It seems that the measures classified according to the proposed classification as objective measures are of fundamental importance. Their application results in the exclusion of the possibility of performing procedures in a situation where their intended results have already been achieved or can be achieved by methods that do not cause pain, suffering and distress, and when the degree of pain, suffering and distress in the animals used in them is unjustified in the context of their scientific significance or usability of the assumed results of the procedure. As a result, the application of these measures has a direct impact on reducing the general number of procedures carried out, as well as reducing the number of procedures that are most oppressive for animals.

Measures relating to species characteristics and individual characteristics, as well as subjective measures, may also contribute to the achievement of the indicated goals, but only indirectly by improving the effectiveness of procedures, understood as increasing the predictability of their results, and by ensuring the procedures to be conducted in a manner so as to reduce suffering experienced by animals. Procedural measures should be considered as secondary and ancillary to other ones and their role in fulfilment of the goals of reducing the number of procedures and minimising pain, suffering and distress in animals used in procedures boils down to ensuring the efficient application of other measures.

Considering the above and the catalogue of principles implemented by the provisions of Directive 2010/63/EU in the system of protection of animals used for scientific purposes, it should be noted that when adopting that Directive, the EU legislature placed particular emphasis on the development of measures relating to the species and individual characteristics of animals used in procedures, as reflected by covering by the Directive also cephalopods, as well as the introduc-

tion of restrictions on the use in procedures of animals of endangered species and non-human primates, including in particular great apes. As mentioned earlier, such measures, if appropriately designed, may reduce the number of animals used in procedures, i.a., by increasing the certainty of the results obtained, but the solutions adopted in Directive 2010/63/EU do not focus on the reduction of the number of procedures performed but solely on the protection of animals of certain species. Without questioning the need to protect these animals and the respective solutions, it should be stressed that the solutions proposed in this regard in the provisions of Directive 2010/63/EU in no way result in a reduction in the suffering of animals used for scientific purposes, but only transfer this suffering to animals of other species. It should be pointed out here that there is no justification for introducing *a priori* restrictions on the use of animals of specific species or animals with specific individual characteristics for scientific purposes. This is so, because the future necessity of subjecting such animals to procedures cannot be predicted. This is somewhat confirmed by the fact that, while the provisions of Directive 86/609/EEC provided for a total ban on the use of stray animals in procedures, Article 11 (2) of Directive 2010/63/EU allows such use, recognising the need for testing the health and welfare of those animals and their possible usability in procedures in the event of a serious risk to the environment or to human or animal health.

Taking the above into consideration, solutions that lead to a closer link between the feasibility of the procedure and the assessment of the practical and scientific usefulness of the effects of the procedure and the species-related or individual immunity to pain, suffering, distress or damage should be deemed far more appropriate.

In this perspective, it should be noted that Article 5 (a) of Directive 2010/63/EU has broadened admissibility of the use of animals for scientific purposes by introducing the possibility of their use in procedures carried out for basic research. Of course, such a change may lead to an increase in the number of procedures in which animals are used, but from the point of view of the whole regulation on the rules of scientific use of animals, this solution should be fully accepted. It is aptly pointed out that, although this research is not directly aimed at achieving any important practical objective, they often produce results that significantly speed up progress in many fields of science[21] and are necessary to achieve practical progress and are also as fundamental as practical discoveries.[22]

[21] Cf. Ł. Smaga, *Ochrona humanitarna zwierząt*, Białystok 2010, p. 170.

[22] W. Paton, *Człowiek i mysz*, Warszawa 1997, p. 115.

## CONCLUSION

Although the question of the possibility of completely abandoning the exploitation of animals for scientific purposes is increasingly being raised in the scientific debate,[23] it seems that such a solution will not be possible in the foreseeable future. According to certain opinions, the very likely effect of eliminating research with the use of animal testing would be the exposure of many living beings (both animals and humans) to severe inconvenience and suffering in the future.[24] Therefore, one should agree with the view that the only way currently possible is to seek to progressively push the boundaries of all possible legislative compromises towards minimising the presence of animal procedures, minimising the suffering of animals involved, and improving the methods of supervision of their implementation.[25] This postulate should indicate the direction for the further development of the European system for the protection of animals used for scientific purposes. In order for this demand to be implemented, it is necessary to adopt appropriate measures.

The common methodological basis, as well as the uniformity, consistency and universality of application of the principles set out in the provisions of the Strasbourg Convention and Directive 2010/63/EU, make it possible to speak of the existence of a model of animal protection in European countries, which is intended to reduce the number of procedures in which animals are used. However, statistical data shows that, despite the systematic implementation of European regulations to protect animals used for scientific purposes, the number of animal procedures has not been significantly reduced, while the proportion of procedures that are classified as the most oppressive. This fact should suggest that the solutions used under this model are not sufficiently effective. This may be due to the fact that they are based, in many cases, on certain preconditions, which concern both the reasonableness of conducting procedures for specific purposes and the usability of animals with specific species-related or individual characteristics for these procedures. The inaccuracy of these assumptions may be evidenced by the fact that after many years of application of unaltered Directive 86/609/EEC in force, it was only the provisions of Directive 2010/69/EU which allowed the use of animals for basic research, or the fact that those provisions substantially mitigated the prohibition on the use of stray and feral animals in procedures, which under Directive 86/609/EEC was as a rule of an absolute character.

---

[23] Cf., i.a., R. Węgrzynowicz, M. Romańska, *Ochrona zwierząt w świetle prawa i norm etycznych*, [in:] *Prawna ochrona zwierząt*, ed. M. Mozgawa, Lublin 2002, p. 89.

[24] M. Ścibor, *Korzyści i negatywne skutki przeprowadzania doświadczeń na zwierzętach*, https://docplayer.pl/6249800-Korzysci-i-negatywne-skutki-przeprowadzania-doswiadczen-na-zwierzetach.html [access: 10.05.2021].

[25] As proposed by, i.a., Ł. *Etyczne i prawne aspekty dopuszczalności przeprowadzania doświadczeń na zwierzętach*, „Przegląd Prawa i Administracji" 2017, no. 108, p. 155.

Regardless of the doubts about the accuracy of individual solutions, a kind of conservativeness in the regulations on animal protection used for scientific purposes is worth noting. Both the desire to provide the widest possible protection for animals or at least for selected species and the fear of introducing solutions that would hinder further scientific development can be seen from the content of this regulation. On the one hand, those provisions define a broad (containing several dozen items) catalogue of principles governing the admissibility of the use of animals in procedures, and, on the other hand, they introduce more or less extensive exceptions to most of them, which ultimately results in the weakening of the system as a whole.

As an alternative to the current direction of development of regulations aimed at the protection of animals used for scientific purposes, it may be proposed abandoning further development of various types of casuistic restrictions of an objective nature, in particular those relating to the species-related and individual characteristics of animals, and to base the system on a fundamental rule, according to which each animal may be used in the procedure, provided that this is justified by the purpose of the procedure and provided that the procedure does not cause disproportionate suffering to the animal, i.e. not justifiable by the possible practical or scientific benefits that may result from this procedure, taking into account the possibility of achieving the same benefits with methods that do not require using live animals. It would also be worth establishing a strong institutional and procedural framework for the procedure under which such an assessment could be made.

Such changes would fall within the framework of the model for the protection of animals used for scientific purposes, as set out in the provisions of the Strasbourg Convention and Directive 2010/63/EU, based on the principles of the 3Rs and the methodological guidelines proposed by M. Hall, but it would require a far-reaching reconstruction of the regulations contained in both acts. However, under the current regulation, measures can be taken at national level to strengthen the system for recognizing the results of procedures conducted with the use of animals, as well as measures to further improve standards of animal care and handling before and after the procedure.

## REFERENCES

### Literature

Burch R.L., Russell W., *The Principles of Humane Experimental Technique*, Potters Bar 1959.

Hall M., *A Critical and Experimental Essay on the Circulation of the Blood: Especially as Observed in the Minute and Capillary Vessels of the Batrachia and of Fishes*, Philadelphia 1835.

Kruk E., *Polish and Estonian Regulations on Homeless (Stray) Animals*, "Studia Iuridica Lublinesia" 2021, vol. 30(1), **DOI: http://dx.doi.org/10.17951/sil.2021.30.1.145-166**.

Micińska-Bojarek M., *Europejski standard doświadczeń na zwierzętach. Aspekty humanitarno-prawne*, "Przegląd Prawa Ochrony Środowiska" 2012, no. 3, **DOI: https://doi.org/10.12775/PPOS.2012.016**.

Paton W., *Człowiek i mysz*, Warszawa 1997.

Rakoczy W., *Ustawa o ochronie zwierząt. Komentarz*, Wrocław 2003.

Rakoczy W., *Ustawy o ochronie zwierząt. Komentarz*, Warszawa 2015.

Ryder R.D., *Victims of Science: The Use of Animals in Research*, London 1975.

Schollenberger A., *Zasada 3R w ochronie zwierząt wykorzystywanych do badań naukowych*, "Życie Weterynaryjne" 2017, no. 92.

Smaga Ł., *Ochrona humanitarna zwierząt*, Białystok 2010.

Walczak M., Bonczar Z., *Etyczne i prawne aspekty doświadczeń na zwierzętach*, "Wiadomości Zootechniczne" 2015, no. 4.

Węgrzynowicz R., Romańska M., *Ochrona zwierząt w świetle prawa i norm etycznych*, [in:] *Prawna ochrona zwierząt*, ed. M. Mozgawa, Lublin 2002.

Żukowski Ł., *Etyczne i prawne aspekty dopuszczalności przeprowadzania doświadczeń na zwierzętach*, "Przegląd Prawa i Administracji" 2017, no. 108, **DOI: https://doi.org/10.19195/0137-1134.108.11**.

## Online sources

Ścibor M., *Korzyści i negatywne skutki przeprowadzania doświadczeń na zwierzętach*, https://docplayer.pl/6249800-Korzysci-i-negatywne-skutki-przeprowadzania-doswiadczen-na-zwierzetach.html [access: 10.05.2021].

## Legal acts

Council Decision 1999/575/EC of 23 March 1998 concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (OJ EU L 222, 24.08.1999, pp. 29–30).

Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ EU L 358/1, 18.12.1986).

Council Regulation (EC) no. 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJ EU L 61, 3.03.1997, pp. 1–69).

Directive 2003/65/EC of the European Parliament and of the Council of 22 July 2003 amending Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ L EU 230, 16.09.2003, pp. 32–33).

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 (OJ L EU 276, 20.10.2010, pp. 33–79).

European Convention for the protection of vertebrate animals used for experimental and other scientific purposes, opened for signature in Strasbourg on 18 March 1986 (OJ EU L 222, 24.08.1999, pp. 31–37).

Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community signed on 13 December 2007 (OJ EU C 306, 17.12.2007, pp. 1–271).

## Reports

First Report from the Commission to the Council and the European Parliament on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes COM(94) 195, final.

Report from the Commission to the European Parliament and the Council. Report on the statistics on the use of animals for scientific purposes in the Member States of the European Union in 2015–2017, COM(2020) 16 final.

Report from the Commission to the European Parliament and the Council on the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes in the Member States of the European Union, COM(2020) 15 final.

Sixth report on the statistics on the number of animals used for experimental and other scientific purposes in the Member States of the European Union. Report from the Commisson to the Council and the European Parliament, COM (2010) 511 final.

ABSTRAKT

Celem artykułu jest ocena regulacji Europejskiej Konwencji w sprawie ochrony zwierząt kręgowych wykorzystywanych do celów doświadczalnych i innych celów naukowych, sporządzonej w Strasburgu w dniu 18 marca 1986 r., oraz dyrektywy Parlamentu Europejskiego i Rady 2010/63/UE z dnia 22 września 2010 r. w sprawie ochrony zwierząt wykorzystywanych do celów naukowych w kontekście ich wpływu na liczbę procedur, które wyznaczają model ochrony zwierząt wykorzystywanych do celów naukowych w państwach europejskich, w perspektywie ich wpływu na ograniczenie liczby procedur naukowych z wykorzystaniem zwierząt przeprowadzanych w państwach europejskich, w tym w szczególności procedur wiążących się z najwyższym poziomem doznawanych przez zwierzęta cierpień. Punktem wyjścia do tej oceny było określenie zasad determinujących dopuszczalność wykorzystania zwierząt do celów naukowych w państwach europejskich, a także wpływu, jaki określone środki wdrażane w ramach tych zasad mogą wywierać na ograniczenie liczby procedur z wykorzystaniem zwierząt. W założeniu analiza tych rozwiązań ma pozwolić na wskazanie kierunków dalszego rozwoju regulacji mających na celu ochronę zwierząt wykorzystywanych w celach naukowych.

**Słowa kluczowe:** zwierzęta; cele naukowe; procedury naukowe z wykorzystaniem zwierząt; dopuszczalność; konwencja strasburska; dyrektywa 2010/63/UE