Protection of animals used in experiments in Polish law – history, present day and perspective: a review

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ABSTRACT: The aim of EU legislators with respect to experiments on animals was to reduce to an absolute minimum both the number of animals used in experiments and their suffering. This study presents, from a historical point of view, expectations related to the coming into force on 1 January 2014 of Directive 2010/63/EU adopted on 22 September 2010. At the same time, it points out that, in some situations, carrying out experiments on animals in practice is different than in theory. The study calls attention to the issue of mere literal conformity of the Polish law with EU directives, illustrating it with examples and takes a critical view of the omission of veterinarians (Veterinary Inspection) from the supervision of experiments.

Keywords: laboratory animals; experiments on animals; animal rights; animal welfare

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1. Application of national law (1928–2005)

The turbulent history of Poland in the first half of the twentieth century did not allow rapid scientific development and, consequently, the use of animals for experiments. However, only 10 years after Poland regained its independence, the Regulation of the President of the Polish Republic of 22 March 1928 on Animal Protection (Anonymous 1928) was published, amended later by the Act of 25 February 1932 on amending the Regulation of the President of the Polish Republic of 22 March 1928 on Animal Protection (Anonymous 1932). The issue concerning experiments on animals was covered in Article 3 of this Regulation. However, it restricted their performance to research and military establishments, and experiments could only be carried out "…for important work and scientific research". The experiments could be performed only by persons holding permits of the Minister of Religions and Public Enlightenment or the Minister for Military Affairs (Anonymous 1928).

The Regulation of the Minister of Higher Education of 16 November 1959 on Conditions and Manner of Conducting Experiments on Animals and the Method of Issuing Permits for Carrying out these Experiments, finally filled the 30-year gap regarding the lack of provisions to the abovementioned Article 3 concerning laboratory animals (Anonymous 1959). This short regulation briefly described the conditions allowing the performance of experiments on animals and specified the general aims that these experiments might serve, listed the institutions that could carry out such experiments,

as well as limited their conduct. The regulations included a requirement for keeping records of animals used in experiments only in relation to animals "with high development of psychological activities" and permitted the performance of experiments only by persons employed in establishments authorised to carry out such experiments. It required experimenters to hold an appropriate permit and vaguely-described "proper qualifications". The regulation did not specify the method of supervising the accommodation of experimental animals or the course of the experiment itself (Anonymous 1959). The only exceptions were internal regulations of the Ministry of National Defence, in which each military establishment performing experiments with the use of animals was assigned an officer (a veterinary surgeon) to supervise the welfare of animals and the course of the experiment. Such a person was actually authorised to stop the experiment (Anonymous 1963a; Anonymous 1963b).

This legal status lasted another 40 years until the Act of 21 August 1997 on Animal Protection was passed. This act (Art. 28–32), described the experimental procedures with the use of animals in a very similar way as in the regulation of 1928 (Anonymous 1928; Anonymous 1997). A significant part of the new content applied to administrative issues related to the appointment and operation of National (KKE) and Local (LKE) Ethical Committees on Animal Testing and to the responsibilities of ministers for issuing implementing provisions. The act did not specify the state organs authorised to supervise experiments with the use of animals and did not indicate the forms of such supervision (Anonymous 1997). Despite the statutory requirements, no regulations specifying the conditions or manner of issuing or withdrawing of permits to perform experiments were issued, no qualifications of persons managing the experiments were specified and no provisions governing the conditions of carrying out the experiment and the mode and manner of supervision of the experiment (Anonymous 1997) were published.

The only implementing act directly related to experiments on animals was the Regulation of the Minister of Agriculture and Rural Development of 24 February 2005 on the Specific Conditions of Keeping Animals in Laboratory Animal Farms and in Entities Carrying out Experiments and Tests (Anonymous 2005b). This was the first regulation describing the specific living conditions of laboratory animals and was aimed at ensuring their welfare. It also identified the Veterinary Inspectorate as the authority supervising the conditions under which laboratory animals were kept, but without the possibility of controlling the course of the experiment (Anonymous 2005b). This supervision was also required under the Act on Veterinary Inspection (Anonymous 2004a).

The Act on Animal Protection, it should be emphasised, did not require the obligatory presence of veterinarians on ethical committees. It should be noted that representatives of higher education institutions directly involved in animal experimentation, either by directly carrying out experiments on animals or by managing the sites carrying out the experiments worked in Local Ethical Committees. As has also been observed by other authors, the legal status described here made it possible to carry out experiments on animals without absolute compliancy with the "3R" principles (refining, reducing and replacing), but in conformity with the letter of the law (Wawrzyniak 2001; Pietrzykowski 2011).

2. Application of EU and national law (2005–2012)

At present, Poland is a rather exceptional state – all issues concerning the performance of experiments on animals are governed by a legal act of the highest importance – the Act on Experiments on Animals of 21 January 2005. In theory, this statute allows full and independent supervision of experiments with the use of animals (Anonymous 2005a). However, in reality, it has been characterised by a certain arbitrariness in its implementation. The authors, from the perspective of their extensive experience, both in performance and in supervision of experiments on animals, have analysed the abovementioned act, focusing on aspects raising the strongest controversies. When we look only at its literal wording, the Act satisfies the requirements of 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; 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, as well as 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 (Anonymous 1986; Anonymous 2003; Anonymous 2010a), applicable since 1 January 2013. However, if we look into this matter from the practical point of view, the Act does not ensure full supervision of the experiments, since it permits that the experimenters or persons interested in carrying out the experiment can perform the inspection activities. In practice, it ensures the possibility of performing any experiment if the performer convinces the LKE that this experiment is necessary for attaining the aim set by the experimenter himself/herself (Anonymous 2005a; Mroczkowski and Frieske 2013).

Also other legal possibilities and statutory provisions should be considered to prevent the unnecessary suffering of animals.

In Poland, the profession of veterinarian is governed by the Act of 21 December 1990 on the Veterinarian Profession (Anonymous 2003). Pursuant to this act, performance of this profession consists, among others, of examining animals, diagnosing, preventing and fighting animal diseases, treating animals and performing surgery procedures (Art. 1.1). Veterinarians are required to carry out their profession with particular care, based on principles of ethics and veterinary deontology (Art. 4). They are also professionally accountable before veterinarian self-regulating authorities (Art. 45) (Anonymous 1990). Pursuing the profession of veterinarian requires high qualifications and skills to assess the health conditions of animals and abilities to assess the level of animal suffering. Thus, entrusting veterinarians to supervise the compliance with the Act on Animal Protection seems to be necessary (Art. 34a) (Anonymous 1997).

The Act on Experiments on Animals of 21 January 2005, as the title suggests, deals with the regulation of a specific issue, which is the performance of experiments on animals (Anonymous 2005a). Although it coexists with the Act on the Profession of Veterinarian and the Act on Animal Protection, experiments are still not subject to the obligatory inspection of veterinary surgeons. This is particularly incomprehensible in the case of experiments related to surgical intervention, the need to apply anaesthesia and execution of analgesia procedures after the experiment.

As mentioned above, the Act on Experiments on Animals in its literal formulation fully protects animal welfare as described in the Universal Declaration of Animal Rights and in EU directives, but in practice, it remains a quite ostentatious law (Anonymous 1986; Anonymous 2003; Singer 2011). This law requires the acquisition of information in a given field from all available international sources in order to eliminate unnecessary repetition of experiments (Art. 3) (Anonymous 2005b). However, this requirement does not specify for whom those sources are to be available and, even in the days of the Internet, not yet everyone knows how to use the electronic resources of research institutions.

Experiments should be carried out in a manner that does not expose animals to unnecessary pain, suffering and distress, or lasting harm to their bodies (Art. 6.2) (Anonymous 2005a). However, pursuant to the requirements of the act, the experiments on animals, even those consisting in surgical interventions, can be performed by persons who are not veterinarians. They are not required to demonstrate a thorough knowledge of anatomy or physiology of the species of animals used in the experiment, or the principles of anaesthesia.

The law under discussion requires the proper use of anaesthetics in the experiment, means and methods for reducing pain, suffering and distress, and requires humanitarian killing of animals if their pain and suffering cannot be reduced. Reliable fulfilment of this requirement involves the knowledge and skills of veterinarians, while in practice the performance of the above-mentioned duties are left to lay people.

The Act requires the ensuring of constant care of experimental animals by a veterinary surgeon (Art. 18) (Anonymous 2005a). In the opinion of the lawyers, this provision by no means requires that the veterinarian should be continuously present at the experimental site (Radecki 2003). In reality, a civil law agreement confirming the readiness of a veterinarian to arrive at the experimental site satisfies this requirement.

The article requiring maintenance of animal records (Art. 18) remains a dead letter, since there are no specific directions concerning the method of keeping records of experimental animals (Anonymous 2005a). On the other hand, the compliance of the experiment with the project is confirmed by a person supervising the course of the experiment. Such a person is appointed by the head of the experimental establishment (Anonymous 2005a).

The lack of statutory provision concerning the obligatory presence of veterinarians in the com-

position of the Local Ethical Committee seems to be important for the process of the LKE to approve the planned experiment (Anonymous 2005a).

An interesting social engineering procedure is applied in the statement on the LKE's supervision of the performance of the experiment, as set forth in Chapter 6 (Art. 30.1.2) of the Act on Experiments on Animals, while Chapter 7 of the Act (Art. 33–27) bears the following title: "Supervision over observance of this act". The beginning of the content of Article 33 seems to indicate that the Veterinary Inspectorate is the authority supervising the observance of the provisions of the Act "The Veterinary Inspectorate supervises the accommodation, breeding, keeping records ...". Unfortunately, as mentioned above, the powers of the Veterinary Inspectorate are limited to the supervision of conditions in which animals are kept and the control of documents (Anonymous 2005a). Moreover, Local Ethical Committees, as bodies statutorily authorised and obliged to carry out inspections, perform those activities extremely rarely (Pietrzykowski 2011). The issues concerning the separation of powers of the Veterinary Inspectorate and members of LKEs are reflected in legal comments to the Act (Radecki 2003; Radecki 2007).

In case the LKE finds any irregularities in the course of the experiment, it can issue an order to remove infringements or to even suspend the experiment. This occurs by means of an administrative procedure, which provides the possibility to appeal to the National Ethical Committee. However, pursuant to the Code of Administrative Procedure, this can take many weeks (Anonymous 1960; Anonymous 2005a). In comparison, the Act on Animal Protection makes it possible to take away an animal from its owner even for reasons of improper care, with immediate enforceability (Art. 7) (Anonymous 1997).

Several implementing regulations have been issued to the Act on Experiments on Animals. The Regulation of the Minister of Science and Computerisation of 29 July 2005 on Qualifications of Persons Supervising Experiments on Animals, Carrying out the Experiment, Participating in the Experiment, and the Form of Individual Permits for Persons Carrying Out Experiments, issued pursuant to Art. 16.5 of the Act on Experiments on Animals, specifies selected issues set forth in the act (Anonymous 2005b). The Regulation does not specify the actual knowledge or skills of the person supervising the experiment, but focuses only on the requirement that such a person should hold a scientific degree in one of five fields of science (biology, pharmacy, medicine, veterinary medicine and agriculture) (§ 1.1) (Anonymous 2005b). Pursuant to the regulation, job seniority with the possibility of acquiring practical skills (which is not equivalent to their acquisition) satisfies this condition. The law does not specify in detail the skills or knowledge which must be acquired by a potential experimenter. The act delegates issues concerning the supervision of experiments on animals in establishments outside the research institutes to persons holding any master degree diploma and having knowledge of experiments on animals gained during the courses (§ 1.2) (Anonymous 2005b). After completing the course, the experimenter can perform anaesthetic procedures and assess the correctness of their execution (Art. 8 of the Act on Experiments on Animals) (Anonymous 2005b). The regulation expands the qualifications of persons who completed the courses to train other persons to perform experiments on animals (§ 1.3). At the same time, after completing the above-mentioned courses, such a person can supervise any experiment (§ 2) (Anonymous 2005b).

The Regulation of the Minister of Agriculture and Rural Development of 10 March 2006 on Detailed Conditions of Accommodating Animals in Laboratory Animal Breeding in Experimental Establishments, Breeding Sites and at Suppliers, seems to provide clear and precise guidelines concerning welfare conditions of experimental animals as well as the conditions and manner of supervising the keeping of laboratory animals (Anonymous 2006). An interesting issue is posed by § 28 of the regulation, which permits the person taking care of animals to make the decision about the need to kill the animal, along with implementation of this need (Anonymous 2006). This is contrary to the Regulation of the Minister of Agriculture and Rural Development of 9 September 2004 on the Qualifications of Persons Entitled to Professional Slaughter and Conditions and Methods of Slaughter and Killing of Animals, issued pursuant to the Act on Animal Protection (Anonymous 1997; Anonymous 2004c).

The Act of 29 January 2004 on Veterinary Inspection specifies a broad scope of operation of the Veterinary Inspectorate in various aspects concerning the welfare of animals, but it does not include provisions concerning the supervision over experiments with the use of animals, which is surprising for many veterinary surgeons (Art. 3) (Anonymous 2004a).

The application of the Act on Experiments on Animals requires taking into consideration other

legal regulations, including the Act of 2 July 2004 on the Freedom of Business Activity. Pursuant to this law, supervision of experiments using animals and the breeding of experimental animals is significantly restricted (Anonymous 2004b). Pursuant to the Act on Freedom of Business Activity, the controlling authority is obliged to inform the business, including the breeder of experimental animals and a private entity carrying out experiments on animals, about the intention to carry out an inspection at least seven days before conducting it, and to conduct it no later than within 30 days of the notification (Art. 79) (Anonymous 2004b).

3. Requirements of the EU law and their reflection in the national law (from 2013 onwards)

The above-described disparities between the provisions of Directive 86/609/EEC of 24 November 1986 and practical application of the national law based on its requirements not only occur in Poland. The application by some EU states of only the minimum requirements specified in the Directive of 1986 and the failure to enforce requirements of the Directive by other states was reflected by the position of the European Union authorities. The Commission of the European Communities issued on 18 June 2007 Guidelines for the Accommodation and Care of Animals Used for Experimental and Other Scientific Purposes (Anonymous 2007). These guidelines described in detail all aspects concerning the welfare of animals used for experiments. This document is far more detailed and precise than the Polish regulations governing the welfare of animals used for experiments issued before 2007.

Issues concerning the failure to comply with Directive 86/609/EEC in some countries, with respect to animal experimentation, was reflected in the Directive of the European Parliament and of the Council of 2010/63/EU of 22 September 2010 on the Protection of Animals Used For Scientific Purposes, regulating in detail issues concerning the protection of animals used for experiments (Anonymous 2010a; Anonymous 2010b). The purpose of this legal act is to standardise the treatment of animals used for experiments. Its authors define in detail certain requirements in relation to the previous regulation, and specify the date on which the new directive comes into force, i.e. 1 January 2013.

Although Directive 2010/63/EU emphasises the application of the "3 R" principle towards animals used for experiments, the effectiveness of its introduction in Poland should be considered. Without new regulations, the LKE will continue to be the leading authority. In practice, inspections carried out without previous notice will meet with the resistance of entrepreneurs, since the provision in the Act of Freedom of Business Activity is very precise and expanded in relation to the statement – "an appropriate portion of the inspection shall be carried out without prior warning" (Art. 34.4). The directive still does not specify who can assess the occurrence of pain and suffering in animals, including severe pain and correctness of anaesthetic procedures and pain suppression. It does not provide any further details concerning the training and educational background of the personnel participating in experiments, leaving the statement "adequately educated and trained" unclear and vague.

The new directive in Article 25 raises the issues of participation of the veterinarian in the breeding of experimental animals, at the supplier and the user. Unfortunately, the wording – "has a designated veterinarian" – with reference to the entities mentioned, does not bring about the need to introduce new regulations in Polish legislation. This means that the above-described issues regarding the form of employing the veterinarian are unchanged. Article 38 of the Directive, imposing the obligation to seek the advice of a veterinarian specialising in laboratory animal science or wild animals in the evaluation of the experimental project, is also worth mentioning. The existing Polish legislation does not provide for such a necessity, and the LKE does not have a veterinarian in its composition.

Before the entry into force of Directive 2010/63/EU, no drafts of legal acts concerning experiments on animals were presented in the Polish Parliament, which, in view of the needs specified in Article 61 of the Directive, means that the Polish law remains unchanged in this regard (Anonymous 2010a). Therefore, despite another high-level EU regulation, experiments with the use of animals in Poland will continue to stay beyond full control, since the law, unclear in some parts, will still apply.

4. CONCLUSIONS

Virtually any experiment on animals can be carried out in Poland. Legal loopholes in the Polish

law concerning experiments on animals create favourable conditions for the experiment to remain beyond independent, objective supervision. The participation of the Veterinary Inspectorate in the supervision of the experiment is excluded.

To ensure the full protection of animal rights, institutions carrying out experiments on animals should employ veterinarians on an on-going basis (in particular, specialists in the field of laboratory animal science) and the Veterinary Inspectorate should be able to control not only the conditions under which experimental animals are kept, but also the course of the experiment, at each of its stages, without previous notice of inspections.

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