

Bartosz Rakoczy*

Act on the Protection of Animals Used for Scientific or Educational Purposes – legal regulation review

Ustawa o ochronie zwierząt wykorzystywanych do celów naukowych lub edukacyjnych – przegląd regulacji prawnej

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Abstract

On 15 January 2015 the Act on the Protection of Animals Used for Scientific or Educational Purposes¹ was adopted in Poland. This act implements Directive 2010/63/EU of the European Parliament and the Council of 22 September 2010 on the protection of animals used for scientific purposes². The Act on the Protection

* Professor Doctor Habilitated in Environmental Protection Law, Professor of the Kazimierz Wielki University, Head of the Chair of Environmental Protection Law at the Nicolaus Copernicus University in Toruń.

¹ Dz.U.2015.266.

² OJ L 276 of 20 October 2010, p. 33.

of Animals Used for Scientific or Educational Purposes is not the first legislative act governing the presumption of acceptability of using animals for scientific and educational purposes. The first legislative act in the system of Polish law regulating the above-mentioned issues was the Experiments on Animals Act³ of 21 January 2005. However, it must be emphasized that the Act on the Protection of Animals Used for Scientific and Educational Purposes is not the only one legislative act regulating animal protection issues. Apart from the said Act there is the Animal Protection Act⁴ of 21 August 1997 and the Act of 11 March 2004 on the Protection of Animal Health and Control of Infectious Diseases of Animals⁵. Thus, in the Polish legal system animal protection is a very elaborate issue and is split concurrently between three underlying legislative acts.

Keywords: Environmental law; animals protection.

Streszczenie

W dniu 15 stycznia 2015 roku została przyjęta w Polsce ustawa o ochronie zwierząt wykorzystywanych do celów naukowych lub edukacyjnych. Akt ten wdraża dyrektywę 2010/63/ UE Parlamentu Europejskiego i Rady z dnia 22 września 2010 roku w sprawie ochrony zwierząt wykorzystywanych do celów naukowych. Ustawa o ochronie zwierząt wykorzystywanych do celów naukowych lub edukacyjnych nie jest pierwszym aktem prawnym regulującym domniemanie dopuszczalności wykorzystywania zwierząt do celów naukowych i edukacyjnych. Pierwszym aktem prawnym w systemie prawa polskiego regulującym powyższe kwestie była ustawa z dnia 21 stycznia 2005 roku o doświadczeniach na zwierzętach. Jednak należy podkreślić, że ustawa o ochronie zwierząt wykorzystywanych do celów naukowych i edukacyjnych nie jest jedynym aktem prawnym regulującym kwestie ochrony zwierząt. Oprócz tej ustawy obowiązuje ustawa o ochronie zwierząt z dnia 21 sierpnia 1997 roku oraz ustawa z dnia 11 marca 2004 roku o ochronie zdrowia zwierząt oraz zwalczaniu chorób zakaźnych zwierząt. Tak więc polski system ochrony prawnej zwierząt jest bardzo złożonym problemem i jest zawarty w trzech podstawowych aktach ustawodawczych.

Słowa kluczowe: Prawo ochrony środowiska; ochrona zwierząt.

³ Dz. U. No. 33 item 289 as amended.

⁴ Dz.U.2013.856, consolidated text.

⁵ Dz.U.2014.1539, consolidated text.

The new Act on the Protection of Animals Used for Scientific or Educational Purposes complements the animal protection system guaranteed under the above-mentioned legislative acts. Simultaneously, the Polish legislator declares that this act implements the above-indicated directive. Such a declaration of the Polish legislator makes one reflect whether or not the directive has been successfully implemented and how its provisions compare to other legislative acts regulating the issues of animal protection. Thus, this article will on the one hand attempt to evaluate the implementation of directive 2010/63/EU, and on the other establishing how the provisions of this act correspond to other legislative acts related to the protection of animals.

The issues of animal protection are given significant coverage in the Polish legal system. In the Polish environmental protection law this issue has had the status of a separate division of the environmental protection law, which is reflected in numerous handbooks which generally discuss animal protection separately. The underlying legislative act governing the issues regarding animal protection is the Animal Protection Act of 21 August 1997. The animal protection system also consists of a separate Act of 11 March 2004 on the Protection of Animal Health and Control of Infectious Diseases of Animals. The Act on Maintaining Cleanliness and Order in Municipalities⁶ of 13 September 1996 also contains certain elements. As regards competent authorities in charge of animal issues, the basic authorities are veterinary bodies such as the Poviats Veterinary Surgeon, Voivodeship Veterinary Surgeon and the National Veterinary Surgeon acting under the Veterinary Inspection Act of 29 January 2004. Certain obligations, in particular care of homeless animals, are also charged to the municipality, and specifically to the poviats governor or mayor.

The Act on the Protection of Animals Used for Scientific and Educational Purposes was preceded by the Experiments on Animals Act of 21 January 2005 referred to above. The Act on the Protection of Animals Used for Scientific or Educational Purposes sets forth the rules and conditions for the protection of such animals, including:

- a) rules for carrying out procedures and experiments,
- b) rules for the activity of breeders, suppliers and users,
- b) rules for the control of breeders, suppliers and users,

⁶ Dz.U.2013.1399, consolidated text.

- d) conditions of keeping animals used for scientific or educational purposes and dealing with such animals,
- e) tasks and powers of ethical committees for experiments on animals.

Thus the Act has a broad scope. It is described in article thereof. The key terms in the Act are ‘animal’ and ‘animal protection’. The Polish Animal Protection Act defines an animal as “live vertebrates, including independently feeding larval forms and mammalian embryos in the last third of the period of foetal development or at an earlier stage of development when, as a result of procedures performed, after the last third part of the period of foetal development has been reached, they can experience pain, suffering and distress or lasting harm, and live cephalopods”.

In addition to the general term of an ‘animal’, the Act distinguishes between laboratory animals, wildlife and livestock. The definition of laboratory animals encompasses:

- a) the following species of animals: house mouse (*Mus musculus*), common rat (*Rattus norvegicus*), guinea pig (*Cavia porcellus*), golden (Syrian) hamster (*Mesocricetus auratus*), Chinese hamster (*Critetulus griseus*), Mongolian gerbil (*Meriones unguiculatus*), European rabbit (*Oryctolagus cuniculus*), domestic dog (*Canis familiaris*), domestic cat (*Felis catus*), common frog (*Rana temporaria*), northern leopard frog (*Rana pipiens*), African clawed frog (*Xenopus laevis*), Western clawed frog (*Xenopus tropicalis*), and zebrafish (*Danio rerio*),
- b) the offspring of primates held in captivity.

In turn, the legislator makes reference to other legislative acts in which wildlife and livestock are defined. Following the European lawmaker, the Polish legislator indicates the acceptable uses of animals. These uses comprise:

- 1) research:
 - a) basic research according to article 2 section 3 letter a of the Act on the Principles of Financing Science⁷ of 30 April 2010,
 - b) according to article 2 section 3 letter b of the Act on the Principles of Financing Science of 30 April 2010, including translational research which applies animal testing findings to enhance clinical practice for the purposes of:

⁷ Dz. U. of 2014, item 1620.

- preventing diseases, diagnosing or treatment of diseases or dysfunctions in humans, animals or plants,
 - assessing, detecting, regulating or modifying physiological conditions in humans, animals or plants,
 - c) aiming at species preservation,
 - d) related to forensic medicine;
- 2) ensuring animal welfare or improving livestock rearing or breeding conditions;
 - 3) developing and manufacturing therapeutic products, foodstuffs within the meaning of the Act on Safety of Food and Nutrition⁸ of 25 August 2006, animal feed or other substances or products, or verification of their quality, effectiveness or safety use carried out for the purposes referred to in section 1 letter b and section 2;
 - 4) protecting the natural environment for the sake of human and animal health or welfare;
 - 5) academic education or training in order to acquire or improve vocational skills.

The use of animals for the above-mentioned purposes is defined by the lawmaker as a procedure. More accurately, a procedure is “any form of use of animals for the purposes set out in article 3, which may cause the animal a level of pain, suffering, distress or lasting harm, to the extent equivalent to, or higher than that caused by the introduction of a needle. This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation or maintenance of a genetically modified animal line in any such condition in the conditions of pain, suffering, distress or lasting harm, to the extent equivalent to, or higher than that caused by the introduction of a needle. The killing of an animal solely for the use of their organs or tissues for the purposes referred to in article 3 shall not be deemed a procedure”.

The Polish Act on the Protection of Animals Used for Scientific or Educational Purposes implies that an animal must not be used for such purposes. This implication follows from article 3 and 5; the first indicates the sole purpose of the procedures, while the other provision determines when the procedures can be performed.

⁸ Dz. U. of 2010 No. 136, item 914, as amended.

The procedures can be used only in three situations referred to as principles by the lawmaker. The first one is the principle of replacement. It excludes the application of a research method which makes it possible to achieve the purpose without using animals. The second principle – the reduction principle – means that the number of animals used in the procedures will be limited to a level required to achieve the purpose. Finally, the third principle, referred to as the principle of refinement, determines that the animals used for the procedures are kept in conditions adequate to their species, and that the research methods used in the procedures were selected so as to reduce to a minimum or eliminate any possible pain, suffering, distress or lasting harm to such animals. Regardless of the aforementioned principles, the procedure is not acceptable if it is associated with severe pain, suffering or distress which can be long-lasting and cannot be alleviated. In addition, generally the procedure cannot be carried out to obtain data that has already been obtained by other Member States of the European Union, which must be deemed fully justified.

In a situation when the procedures can be selected, article 5 section 4 determines that first the procedure assuming the use of the smallest number of animals and the use of animals that are likely to experience the least pain, suffering, distress or effects of lasting harm should be chosen. The lawmaker also indicates that the procedure causing the least pain, suffering or distress or entailing the lowest risk of lasting harm for the animals should be given the priority. In addition, the Polish lawmaker indicates that the procedure makes the achievement of the planned result of the procedure most likely.

In article 6 section 1 the lawmaker indicates that generally death of an animal should not be the end-point of the procedure and it should be considered the last resort. The Polish legislator, following the European lawmaker, gives a detailed description of the whole procedure. The suffering, pain or distress of the animal and its injury are further minimised by the requirements to be met by the entity carrying out activities using animals for scientific or educational purposes. Thus, not every entity can carry out activities using animals for scientific or educational purposes – this is only possible for an entity meeting the criteria defined by law. One of the basic obligations of such an entity is the obligation to keep the animals in an environment appropriate for the specific species, including the possibility to satisfy physiological and ethological needs of the animals, and provide equipment adapted

to the needs and characteristics of animals kept in such an environment. Furthermore, the entity is required to ensure suitable care or transport of animals.

The addressees of separate obligations are breeders, suppliers and users. Article 2 section 10 and 11 of the Act on the Protection of Animals Used for Scientific or Educational Purposes specifically determines who the supplier is and who the user is. A supplier means any “natural person, legal person or an unincorporated unit of organisation other than a breeder, supplying animals with a view to their use in procedures or for the use of their tissues or organs for the purposes referred to in article 3”. In turn, a user means any “natural person, legal person or an unincorporated unit of organisation using animals in procedures”.

The breeder should be interpreted as an entity breeding animals. Both breeders and suppliers, as well as users, must be entered into a relevant register. This way the entities are identified and can be covered by protection. The fundamental obligation of breeders, suppliers and users is to maintain records of animals detailed in article 30 of the Act on the Protection of Animals Used for Scientific and Educational Purposes. The second obligation of the breeder, supplier or user is the obligation to identify the dog, cat or primate with a permanent, individual identification mark.

Ethics committees for experiments on animals play an important role in the system for the protection of animals used for scientific or educational purposes. Such committees are in charge of granting and amending experiment approvals. These committees have a two-level structure. There is a National Ethics Committee for experiments on animals and there are local ethics committees for experiments on animals. The tasks of the national committee comprise:

- “1) formulating and presenting:
 - a) to breeders, suppliers and users – the opinions and findings concerning the protection of animals used for scientific or educational purposes,
 - b) to users – the opinions concerning cooperation to the extent of exchanging organs and tissues collected from animals,
 - c) to breeders – guidelines concerning an increase in the percentage of animals being the offspring of primates held in captivity;
- 2) developing good practices and sharing them with users, in particular as regards planning and executing procedures, using the replacement, reduction and refinement principles and alternative methods;

- 3) presenting the findings from the annual summary of the results of inspections carried out among breeders, suppliers and users to the minister in charge of science and the minister in charge of agriculture;
- 4) appointing and dismissing members of local committees;
- 5) cooperation with the European Commission during:
 - a) preparation and approval of research methods which make it possible to obtain, without using animals or when using a smaller number of animals or in a manner that is less painful to animals, the same or a wider scope of information that would have been obtained if the procedures were performed using animals (alternative methods),
 - b) appointing laboratories performing tests to approve alternative methods for the needs of the Union Reference Laboratory being the European centre for validation of alternative methods;
- 6) sharing and propagating information about alternative methods;
- 7) presenting to the person or persons referred to in article 25 section 2, opinions concerning the acquisition, breeding, accommodation and use of animals in procedures and concerning the care of such animals as well as sharing related good practices;
- 8) exchanging information with the competent authorities of other member states of the European Union regarding tasks of the Committee and regarding tasks to be performed at the breeder's, supplier's and user's site as referred to in article 25 section 1, and sharing related good practices”.

The national committee is a collegial body and its term of office is 4 years.

In turn, the tasks of the local committee comprise:

“1) approvals of:

a) experiments, including:

- re-use of the animal in the procedure – in circumstances referred to in article 12 section 2 point 2,
- executing the procedure without general or local anaesthesia – in circumstances referred to in article 13 section 3,
- giving the animal medicinal products or medicinal products for veterinary use which prevent or make difficult the demonstration of pain – in circumstances referred to in article 14 section 1 point 2,

- using animals referred to in article 7 and 8 section 1 point 2 and 3 in the procedure,
- b) modifying the experiment – in circumstances referred to in article 51 section 1;
- 2) withdrawing approvals of experiments;
- 3) checking the experiment according to criteria specified in article 53 section 2, hereinafter referred to as the “retrospective assessment”, and storing the results of retrospective assessment;
- 4) submitting information required to ensure correct inspection, at the request of the poviats veterinary surgeon carrying out inspection of the user to the extent of the experiment;
- 5) publishing non-technical summaries of experiments in the Public Information Bulletin on the respective site of the minister in charge of science”.

The Polish legislator guarantees that members of the national committee and local committees will be independent from public administration authorities, breeders, suppliers and users.

A significant element of the matter regulated in the Act is the rules of experiments. As a rule the experiments are carried out upon the approval of the local committee referred to above. The local committee, at the request of the user, will issue the approval accompanied by documents required by law such as for example, a non-technical summary of the experiment. Having performed the assessment the local committee adopts a resolution expressing its position. In such a resolution it can either approve or refuse to approve the experiment. The powers and responsibilities of the committee must be differentiated from the tasks of the public administration body such as the Poviats Veterinary Surgeon and, respectively, the Voivodeship Veterinary Surgeon as the second-instance authority. The Poviats Veterinary Surgeon has been awarded the powers of controlling the breeders, suppliers and users to the extent of activities entered into the above-mentioned register.

The Polish Act on the Protection of Animals Used for Scientific or Educational Purposes also determines the scope of inspection that the Poviats Veterinary Surgeon is entitled to carry out. The Poviats Veterinary Surgeon is also required to cooperate with the local committees. If, as a result of an inspection, the Poviats Veterinary Surgeon finds a breach of the regulations, he can issue an administrative decision ordering that the experiment be discontinued. Such a decision can be issued when

the Poviats Veterinary Surgeon determines that the procedure using animals is not covered by the approved experiment. In turn, if it is found that the user actually obtained an approval but has been breaching its terms and conditions, the Poviats Veterinary Surgeon will appoint the date by which the irregularities should be removed or possibly issue an administrative decision ordering that the procedure be suspended until the irregularities are removed. Significantly, the above-mentioned decisions are immediately enforceable.

If the user fails to remove the irregularities within the appointed term, the Poviats Veterinary Surgeon will apply to the local committee for withdrawing the approval.

Compliance with the obligations set forth in the Act is guaranteed both by criminal and administrative sanctions. Criminal liability is determined in article 66 and 67 of the Act stating respectively that:

“1. One who in connection with its activity using animals for scientific or educational purposes:

- 1) causes unnecessary pain, suffering, distress or lasting harm to animals,
- 2) uses animals in experimental procedures without an approval to use them, shall be liable to a fine, community sentence or imprisonment for up to 2 years.

2. Who, in circumstances referred to in section 1, causes the death of an animal shall be liable to imprisonment for up to 3 years.”

“1. One who prevents or hinders inspections carried out according to the Act shall be liable to a fine, community service or imprisonment for up to one year.

2. The same penalty shall be applied to those using information obtained in connection with the inspection for purposes other than the protection of animals used for scientific or educational purposes.”

On the other hand, an administrative penalty in cash up to a maximum amount of 50 thousand zlotys is charged for minor infringements.

Email

kpos@umk.pl