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Ο επίσημος κτηνίατρος και ο ρόλος του στην εποπτεία των πειραμάτων σε ζώα σύμφωνα με την πολωνική νομοθεσία

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The official veterinarian and his role in the supervision of experiments on animals in the Polish legislation

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ABSTRACT. Polish legislation regulating the supervision of animals used for scientific purposes has undergone significant changes in the last several years. The most important achievement was delegating the supervision of laboratory animal breeding, supply and experiments to veterinarians employed by the Veterinary Inspectorate.

Initially, pursuant to the first regulations dating back to 1928, veterinarians were not assigned any role in the supervision of animals used for scientific purposes. Minor modifications in this respect were introduced in 1960. The first supervisory powers were introduced by the Act of 1997 involving approvals to be issued by veterinarians in compliance with the legal requirements of entities carrying out experiments on animals and entities breeding laboratory animals. The Act of 2005 on experiments on animals did not bring about significant changes in the powers of veterinarians supervising animals used for scientific purposes.

The above-mentioned legal acts did not provide the Veterinary Inspectorate with greater rights to supervise animals used for scientific purposes. When the Act on Freedom of Economic Activity was amended (in 2007), the supervision of economic operators became particularly difficult or sometimes even impossible.

The Act on the Protection of Animals Used for Scientific or Educational Purposes that was passed in Poland on 15 January 2015 is a legal act that delegates the right to comprehensive supervision of animals used for scientific purposes to one public authority, namely, the Veterinary Inspectorate.

Keywords: *experiments on animals, laboratory animals, veterinary supervision, veterinary legislation*

INTRODUCTION

The necessity of legal protection of animals is a result of scientific achievements and ethical considerations. Progress in natural sciences, especially in medicine, would not be possible without animals used for scientific purposes. While conducting such studies, the arguments of opponents of vivisection should not be overlooked and the objective of limiting animal suffering should also be considered (Babińska et al., 2007a). With these points in mind, it is necessary to carry out

experiments on animals with the most extensive and effective inspections possible, which requires providing the supervising authorities with the rights and means to ensure effective enforcement of the legislation. These needs are the basis for amending the legislation on protection of animals used in scientific projects together with clear-cut supervisory procedures (Babińska et al., 2007b; Felsmann et al., 2013, Felsmann et al., 2014; Felsmann et al., 2015; Radecki, 2003, Radecki, 2007; Wawrzyniak, 2001).

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The Polish legislation that regulates experiments on animals has undergone particularly dynamic changes in the last several years (Babińska et al., 2007b; Felsmann et al., 2013, Felsmann et al., 2014; Felsmann et al., 2015). In view of the increasing awareness of society of the need to protect animals against suffering, it is not surprising that the supervision of experiments on animals is delegated to the authorities appointed by the state which are granted statutory rights to inspection and take appropriate decisions in such matters (Act, 1997b, Act, 2002; Act, 2005; Act, 2015). The authors analyzed the evolution of Polish legislation governing the supervision of animals used for scientific purposes, particularly the role of official veterinarians in these inspections, to the adoption of Directive 2010/63/EU (Commission Recommendation, 2007; Council Decision, 1998, Council Decision, 2003; Council Directive, 1986; Directive, 2003, Directive, 2010; European Parliament Resolution, 2004; Felsmann et al., 2014, Felsmann et al., 2015).

Regulation of the President of the Republic of Poland of 22 March 1928 on animal protection

In Poland, the Regulation of the President of the Republic of Poland of 22 March 1928 on Animal Protection was the first legal act that comprehensively addressed the issue of animal protection (Regulation of the President, 1928). This normative act (with minor additions introduced in 1932) was in force for nearly 70 years (Act, 1932; Regulation of the President, 1928).

This regulation included only several articles, two of which directly applied to experiments conducted with animals (Act, 1932; Regulation of the President, 1928). Despite being in force for several decades, only three executive acts to this regulation were issued (Regulation of the Minister of Higher Education, 1959; Regulation of the Minister of the Interior, 1930; Regulation of the Minister of Justice, 1957) as well as intra-departmental rules (Ordinance of the Chief Quartermaster, 1963; Regulation of the Minister of National Defence, 1963). Only Regulation of the Minister of Higher Education related directly to animal experiments, but no role was marked by veterinarians and the Veterinary Inspectorate. This normative act together with the Regulation of the President of the Republic of Poland issued in 1928 formed the basis for issuing intra-de-

partmental rules, based on which each departmental experimental facility in the institutions and units subordinate to the Minister of Defense was supervised by an appointed veterinary officer (Ordinance of the Chief Quartermaster, 1963; Regulation of the Minister of National Defence, 1963). The Head of the Veterinary Service of the Polish Army was responsible for supervising the compliance with provisions for animals used for scientific purposes. The Head of the Veterinary Service appointed a military veterinarian to supervise each military establishment performing experiments on animals. The supervising veterinarian controlled facility and rooms, animal welfare, experience of research personnel and overlooked the experiments. The supervising veterinarian was entitled to raise objections against the scientific projects (Ordinance of the Chief Quartermaster, 1963; Regulation of the Minister of National Defence, 1963). According to military veterinarians, including one of the authors, this method resulted effective supervision. At that time, only the military veterinarians had the right to supervise animals used for scientific purposes.

Act of 21 August 1997 on animal protection and administrative acts issued on the basis of this act

This Act was the first legal act in Poland that contained references to administrative supervision of experiments conducted on animals. This legal act, however, did not directly designate veterinarians as the profession with specified tasks or rights for the supervision of animals used for scientific purposes (Act, 1997b, Act, 2002). Article 3 generally ordered cooperation between governmental and council authorities and the Veterinary Inspectorate in effectuating these legal rules (Act, 1997b). Some of the articles on experiments on animals that had been originally included in the Act (articles 28-32) contained a number of dead letters that had never been enforced.

The only executive acts issued by the Cabinet resulting from article 23 of the Act were regulations (1999 and 2003) on ethical committees dealing with experiments on animals (Regulation of the Council of Ministers, 1999, Regulation of the Council of Ministers, 2003). Apart from these regulations, since none of the required executive acts were issued for years, veterinarians remained without any rights or procedures to supervise directly experiments conducted on animals.

The Act of 2002 on the Change of the Act of 1997 introduced new provisions that settled the issue of conducting animals used for scientific purposes, by elaborating on some disputable and unclear articles of the original Act (Act, 2002). Despite these changes, the supervision of animals used for scientific purposes was delegated to a person appointed by the manager of the experimental facility (article 28, section 8a). Such persons were rarely veterinary professionals (Act, 1997b). The role of veterinarians, according to the amended act, amounted to controlling documentation. The regulations obliged experimental facilities to record and store documentation on animals used for scientific purposes and to allow the Veterinary Inspectorate access to such documents (article 28, section 8b). Hence, the Act of 1997 on Animal Protection, even with the amendments made in 2002, did not authorize veterinary authorities to supervise directly experiments or tests on animals.

The paragraph 18 point 1 of the regulation of 2003 on ethical committees granted a local ethical committees the right to issue opinions on husbandry conditions in laboratory animal breeding facilities (Regulation of the Council of Ministers, 2003). This was a dead letter, as both in the parental act and in the executive acts the members of a local ethical committees are not authorized to supervise the breeding of laboratory animals; furthermore, at the time this regulation was issued, there was no regulation on the conditions of laboratory animal breeding (as dictated by article 29, section 4 of the Act). It should be noted that a local ethical committees did not have to include veterinarians. The Regulation of the Minister of Agriculture on the Husbandry Conditions for Laboratory Animals was issued in 2005 when the Act on Experiments on Animals, released in the same year, was already in force (Regulation of the Minister of Agriculture, 2005). It should be emphasized that, as dictated by the Act on Animal Protection, a facility conducting experiments on animals could be entered into the registry of the Minister of Science and Higher Education only after specific administrative procedures were followed by veterinarians to confirm that statutory requirements had been met (Regulation of the Minister of Science, 2003). A district veterinarian, as a government authority, was obliged to issue an appropriate opinion according to article 217 of the Code of Administrative Proceedings (Act, 1960). Considering other statutory orders, including the necessity to provide supervision of some economic

activities, the process of applying need to be entered on the list of authorized facilities to conduct experiments on animals required the supervision of a district veterinarian acting as a Veterinary Inspectorate unit. It should be noted that this supervision only applied to husbandry conditions for laboratory animals and not to an experiment *per se*.

Act of 21 January 2005 on experiments on animals

The implementation of legal regulations on experiments on animals specified by the above-mentioned act did not extend the role of a veterinarian to include the supervision of an experiment (Act, 2005). The new legislation allowed for direct inspection over an experiment by the authorities (local ethical committees) but did not include obligatory membership of veterinarians in these bodies.

This legal Act clearly laid out that it was necessary to obtain a permit, issued by a district veterinarian, for breeding and supplying laboratory animals (article 13). Such settlement dispelled all doubts as to this issue, as the lack of similar rules in the previous act (detailed act) could give rise to controversy over such supervision executed by the Veterinary Inspectorate due to a lack of common references to other acts of a general nature (Act, 1997a, Act, 2004a, Act, 2004b). The respective permit was obtained as specified by the Code of Administrative Proceedings and covered breeders and suppliers of laboratory animals with veterinary administrative supervision. The possible withdrawal of such a permit required providing notification to the Minister of Science (article 14).

Similar to the previous act, conducting an experiment required consent of a local ethical committees (article 20) and an experimental facility had to be entered into the register of experimental facilities held by the Minister of Science (article 22). Entering an experimental facility to the ministerial register required, as in the case of the previous act, submission of the attestation of the respective district veterinarian confirming that specific requirements had been met. Under the new act, this requirement also applied to breeders and suppliers of laboratory animals (article 25).

The act (article 24) defined the cases in which an experimental facility could be removed from the register. One of the reasons was unmet requirements for animal husbandry, as demonstrated by the Veterinary

Inspectorate. A similar situation applied to breeders and suppliers of laboratory animals (articles 14 and 25) who were also supervised by the Veterinary Inspectorate.

The discussed legal act clearly defined the scope of administrative supervision exercised by the Veterinary Inspectorate (article 33). Article 33 authorized representatives of the Veterinary Inspectorate to access facilities and rooms in which animals, including those used for experiments, are bred and kept. Veterinarians of the Veterinary Inspectorate were still not authorized to exercise supervision of experiments.

The obligation to observe the Act on Freedom of Economic Activity (article 34a, introduced with an amendment in 2007) was a significant obstacle for exercising supervision of economic operators, both for the Veterinary Inspectorate and local ethical committees (Act, 2004c). According to this act (article 79), the supervising authorities were obliged to notify a controlled entity as for the intention and date of an inspection. Such regulations enabled a supervised entity to postpone the date of an inspection or even to avoid it.

Act of 15 January 2015 on the protection of animals used for scientific or educational purposes

Difficulties with effective supervision of animals used for scientific purposes were reported not only in Poland. Such difficulties were also noted in the agencies and institution of other Member States of the European Union. The consequence, *inter alia*, of such abnormalities was a directive adopted in 2010 which required the EU Member States to adopt updated regulations on the supervision of animals used for scientific purposes, by 1st January 2013.

This act has been recently adopted by the Polish Parliament after over two years since the date was defined in the directive (Directive, 2010; Felsmann et al., 2014, Felsmann et al., 2015). This Act implements into Polish legislation the Directive 2010/63/EU. New legislation increases the importance of veterinary inspectorate in supervising animals used for scientific purposes.

This legal act enables more extensive and, thus, more effective, veterinary administrative supervision of animals used for scientific purposes (Act, 2015). The supervision of animals used for scientific purposes, as well as laboratory animal breeding,

rearing and supply, is now delegated to veterinarians employed by the Veterinary Inspectorate. From the veterinary point of view, this is the most important novelty that meets the demands of the profession (Felsmann et al., 2014, Felsmann et al., 2015). Moreover, when the new legal regulations were adopted, changes in other acts were made which, in turn allowed administrative supervision of an experiment without procedural obstacles. Importantly, there was a modification to the Act on Freedom of Economic Activity that now makes economic operators and state institutions equal by lifting the obligation to provide notification of the date of a planned inspection (article 76).

The Act has also changed the rights of the national and local ethical committees that are now entitled to issue opinions on scientific projects and grant permits for conducting experiments (articles 47-50). The committees have been deprived of inspecting husbandry conditions of laboratory animals and of supervising the experiment itself. These rights have been assigned to the Veterinary Inspectorate (articles 54-63).

In accordance with the article 54 of the Act, a district veterinarian, depending on the location of a facility of a breeder, supplier or user, may conduct an inspection of the controlled entities within the requirements of the Act. Importantly, the supervision of a user is conducted by the district veterinarian for the location in which the experiment will be conducted.

The opportunity for an expert to participate in an inspection is an additional convenience for the Veterinary Inspectorate (article 55). This possibility strengthens the substantive importance of an inspection, as there are increasingly more certified veterinarians, especially those qualified in the use and pathology of laboratory animals.

The supervision of experiments is strengthened by the fact that a district veterinarian, in case of non-observance of the legislation, is entitled to issue with immediate effect, enforceable orders for controlled entities (breeders, suppliers, users) (article 57).

This Act and implementing regulations, continue to ignore the need to recognize the unique role of the veterinarian in the supervision of animals used for scientific purposes, despite the fact that this highlighted in many countries of the European Union (Poirier et al., 2015). The Directive of 2010

establishes the role of the veterinarian in animal experiments (Art. 9, 16, 17), especially for designated veterinarian (art. 25). The Act of 2015 also contains such rules (Art. 11, 12), but they are not clear. The best proof is the lack of requirement for employment of the veterinarian the breeder, supplier and user. The Act requires only the signature of a general agreement with a veterinarian (Art. 23) and completely ignores the role of designated veterinarian and laboratory animal veterinarians. The ethics committees still does not include obligatory membership of veterinarians in these bodies (Act, 2015; Regulation of the Minister of Science and Higher Education, 2015).

Despite these imperfections, the Act of 2015 Veterinary Inspectorate gives new powers to the effective supervision for animals used for scientific purposes.

Conclusions

Polish legislation on the protection of animals used for experiments has a long tradition. Over the years the role of veterinarians (Veterinary Inspectorate) in supervising the experiments was growing. The last Act of 2015 was another positive changes in this area. Importance of Veterinary Inspectorate supervising the experiments on animals is still inadequate. Knowledge of the veterinarians is disregarded in the assessment of scientific projects and supervision of animals used for scientific purposes.

CONFLICT OF INTEREST

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