Abstract of Doctoral Dissertation

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The 3R principle in Polish experimental animals protection law

Animal experiments have been associated with many groundbreaking discoveries in the fight against diseases that plague humanity. However, the morality of human use of animals (including animal experimentation) is subject to philosophical and ethical debates. As living creatures that are capable of feeling, animals have certain interests (for example, to avoid suffering); their welfare and lives are morally relevant and are subject to legal protection. Due to growing moral demands and technical progress that has provided alternatives to animal experimentation, the discussion concerning the validity of continuing the current model of science is increasingly important. Therefore, changes in the sphere of legislation are inevitable. Intense discussing about regulating animal experimentation was renewed by the adoption of Directive 2010/63/EU of the European Parliament and of the Council of September 22, 2010 on the protection of animals used for scientific purposes. Implementing Directive 2010/63 into Polish law has made this issue a subject of public debate in Poland.

In the 1950s, zoologist William Russel and microbiologist Rex Burch formulated guidelines for humane, ethical animal experimentation; these guidelines are known as the 3R principle. This principle is considered the flagship principle concerning animal treatment. It contains detailed instructions about animal experimentation and can therefore at least partially solve the moral dilemmas associated with this activity.

The 3R principle contains three principles/standards/components. According to the first principle – replacement, animal experimentation is unacceptable when a scientifically satisfactory method or testing strategy that does not entail the use of live animals can be used. The second component, reduction, requires that the number of animals used in projects should be reduced to a minimum (without compromising the project's objectives). The last principle – refinement, ensures that breeding, accommodation and care, and procedural practices eliminate or reduce to the minimum any possible pain, suffering, distress, or lasting harm to the animals.

Through Directive 2010/63 and the Act of 15 January 2015 protection of animals used for scientific or educational purposes, the 3R principle became an original and autonomous legal requirement applicable to all participants of the animal experimentation system, not only during the experiment but also during all interactions with animals used or intended for use in the experiment. This dissertation explores the 3R principle as the guiding principle of Polish legislation concerning the protection of experimental animals.

Chapter 1 presents the historical determinants of the discussion about the ethical use of animals in scientific research. Furthermore it questions the scale and significance of this problem in contemporary (especially Polish) research practice and defines important terms specific to this area of legislation.

Chapter 2 explores the genesis of the 3R principle, searching for the principle's essence and contemporary understanding. The chapter compares this understanding of the 3R principle with the legal solutions implemented by the first legislation on the protection of experimental animals. This comparison will include the regulations enacted in several countries (the United Kingdom, Germany, the United States of America, Poland, etc.) and at the international level.

A similar review of legal solutions that are comparable with the standards contain in 3R principle is also presented in Chapter 3, which explores the development of legislation concerning the protection of experimental animals. This chapter analyzes European Convention No. 123 on the protection of vertebrate animals used for experiments, as well as the 1986 EU Directive 86/609 and Polish regulations. A detailed description of the current system protecting experimental animals (i.e., the regulations of Directive 2010/63 and the laws implementing this directive) is then given. The chapter questions how the 3R principle was incorporated into the Act of 15 January 2015 protection of animals used for scientific or educational purposes.

Chapter 4 investigates the 3R principle in contemporary Polish legislation in the perspective that the principle could indeed be recognized as a legal principle. This is preceded by a short review of select legal principle concepts from Polish legal theory. The possibility of characterizing the 3R principle as a general clause is also considered, as constructions containing general clauses often function independently as general principles of law in the literature and jurisprudence.

Chapter 5 explores the relationship between the 3R principle and the harm-benefit analysis. Directive 2010/63 introduced a breakthrough solution by imposing a compulsory ethical assessment weighing the harm to animals caused by the experiment against the experiment's benefits for humans, animals, or the environment. This assessment considers whether the animals' suffering, pain, and distress are justified by the expected results of the experiment.

Chapter 6 determines whether the 3R are a version of the proportionality principle. In the case of animal experiments, specific goods and values collide: the need for further scientific development is constantly in conflict with the need to protect the welfare and lives of animals used for such purposes. This part of the dissertation also addresses the issue of limiting the constitutional freedom of scientific research with regulations concerning the protection of experimental animals and assesses the status quo in this regard.

The last four chapters concentrate on the dogmatic and empirical–practical aspects of implementing the 3R principle and fulfilling it through individual institutions and tools of Polish law.

Chapter 7 is devoted to the characteristics of ethical committees for animal experiments and aims to determine whether the current regulations of these bodies allow the implementation of the 3R principle in a more comprehensive and effective way than previous legal states.

Chapter 8 aims to show that transparency of the system that protects experimental animals could be helpful in fulfilling the 3R principle. Some data and documents seem to show significant potential in this regard; however, ensuring public access to knowledge about ethically sensitive aspects of animal experimentation runs counter to the need to protect researchers' interests, because their intellectual property rights should be protected.

Chapter 9 focuses on the characteristics of the retrospective assessment, through which the ethics committee re-examines the experiment after its completion. The intention of this assessment is to review the experiment in terms of specific criteria aimed at drawing conclusions useful for better (scientifically and ethical) planning of future research, including better implementation of the 3R principle. The chapter explores the relationship between the design and operation of retrospective assessment and effective implementation of the 3R principle.

The last chapter of this dissertation is devoted to the methods for sanctioning violations of the 3R principle. The purpose of this chapter is to characterize and evaluate the tools that should ensure effective implementation of the 3R principle. It examines whether the current sanctioning system is more effective than the previous regulations, as current law has established sanctions that are administrative rather than punitive.

The conducted research confirmed that animal experiments are still widespread, and their number (including that in Poland) is not decreasing. At the same time, animal protection laws have always been consistent with the 3R principle (at least to some extent). However, until the adoption of Directive 2010/63, the 3R principle was not explicitly framed and recognized legally. The present research established that the 3R principle has features that make it recognizable as a principle of law, and the regulations imposed by the Act of 15 January 2015 for the protection of animals used for scientific or educational purposes fulfill the 3R principle in a continuous and organized way. The 3R principle is realizing primarily by ethical committees, but the animal experimentation system's transparency tools - particularly the retrospective assessment – also show considerable potential in 3R's development. Furthermore, present sanctions seem to be an effective incentive for implementing the 3R principle. The 3R principle allows for a gradual shift of the limits of possible compromises (including legislative ones) to minimized use and suffering of animals. It also encourages innovation and set trends in the development of science.

Assuming the use of its potential and due diligence in implementation, the 3R principle seems to be an effective tool for reducing animal suffering in experiments. An element closely related to the principle – one that complements its meaning and role – is the harm-benefit analysis. The factors considered by this analysis are closely related to the 3R principle, and the resulting application of detailed standards of conduct has a significant impact on the final result of the analysis, as it minimizes the negative consequences of the experiment. Final result is decision whether the experiment should or should not be carried out. Moreover, the similarity between the principle of proportionality and the 3R principle (as a principle of law) was confirmed; the similarity in content and structure was clear. Importantly, both of these principles are used to resolve conflicts of values or interests.