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## **Standards of legal protection for animals used in scientific research**

### **Standardy ochrony prawnej zwierząt wykorzystywanych do badań naukowych**

#### **Abstract**

The setting of appropriate standards of behavior allows a minimum degree of animal protection to be established<sup>1</sup>. As indicated in recital 1 of Directive 2010/63 on the protection of animals used for scientific purposes<sup>2</sup>, differences in national legislation may hinder trade in products and substances in the manufacture of which animal experiments are carried out. The way in which animal welfare is protected depends on the level of knowledge of the animals' ability to feel and respond to pain, so that, as a result, the standard of animal treatment is constantly improving. With the development of biological and medical sciences, the importance of animals has gradually increased and continues to be high due to the continuous use of living organisms in diverse scientific research. The establishment and development of bioethics has necessitated the creation of legal regulations to protect animals used in research and to guarantee their proper treatment.

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<sup>1</sup> In ethical strategies related to animal welfare, two standards are distinguished: the "Golden Standard" and the "Successive Standard". See: J. El-Jai, *Dobrostan zwierząt w naukach humanistycznych i przyrodniczych*, „Studia Ecologiae et Bioethicae” 2008, 6, p. 185.

<sup>2</sup> Directive of the European Parliament and of the Council 2010/63/EU of 22.09.2010 on the protection of animals used for scientific purposes, Official Journal of the European Union L2010.276.33.

This paper attempts to describe the current legal standards for the protection of animals used in scientific research and comments on possible changes.

**Keywords:** animal rights, laboratory animals, scientific research, bioethics.

## Streszczenie

Wyznaczenie i przyjęcie właściwych standardów postępowania pozwala określić minimalny zakres ochrony zwierząt<sup>3</sup>. Jak wskazano w motywie 1 Dyrektywy 2010/63 w sprawie ochrony zwierząt wykorzystywanych do celów naukowych<sup>4</sup> różnice w ustawodawstwie poszczególnych państw mogą stanowić przeszkodę w handlu wyrobami i substancjami, przy których wytwarzaniu przeprowadza się doświadczenia na zwierzętach. Sposób ochrony dobrostanu zwierząt zależy od poziomu wiedzy na temat ich zdolności do odczuwania i reagowania na ból, dzięki czemu standard postępowania ze zwierzętami podlega ciągłemu doskonaleniu. Wraz z rozwojem nauk biologicznych oraz medycznych znaczenie zwierząt stopniowo rosło i dalej utrzymuje się wysokim poziomie w związku z ciągłym wykorzystywaniem organizmów żywych do różnokierunkowych badań naukowych. Powołanie i rozwój bioetyki wymusiły opracowanie regulacji prawnych chroniących zwierzęta wykorzystywane do badań oraz gwarantujące im właściwe traktowanie. W niniejszym opracowaniu podjęto próbę opisanie obowiązujących obecnie standardów prawnych ochrony zwierząt wykorzystywanych do badań naukowych oraz zawarto uwagi dotyczące możliwych zmian.

**Słowa kluczowe:** prawa zwierząt, zwierzęta laboratoryjne, badania naukowe, bioetyka.

## 1. Introduction

The results of scientific research, including laboratory experiments and environmental studies, currently form the basis for many fields such as medical sciences, health sciences, agricultural sciences, as well as physical and natural sciences. The dynamic development of science is closely associated with the use of living organisms, including animals, for scientific purposes. In recent years, thanks to conducted experiments, scientists have been able to create artificial pancreas and intelligent patches, program artificial memories, construct specialized exoskeletons and bionic contact lenses, and develop an endoscopic capsule<sup>5</sup>. Despite the undeniable fact that the progress in biological and medical sciences would be impossible without conducting research on animals, opponents of such solutions are increasingly expressing their views. Considering the

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<sup>3</sup> W strategiach etycznych odnoszących się do dobrostanu zwierząt wyróżnia się: „Złoty standard” i „Sukcesywny standard”. Zob. J. El-Jai, *Dobrostan zwierząt w naukach humanistycznych i przyrodniczych*, „Studia Ecologiae et Bioethicae” 2008, 6, s. 185.

<sup>4</sup> Dyrektywa Parlamentu Europejskiego i Rady 2010/63/UE z dnia 22 września 2010 r. w sprawie ochrony zwierząt wykorzystywanych do celów naukowych (Dz.U. UE. L 2010.276.33).

<sup>5</sup> A. Białek, *Smartfony, social media, drukarki 3D. Które wynalazki XXI wieku zmieniły nasze życie na lepsze?* National Geographic Poland, <https://www.national-geographic.pl/artukul/wynalazki-xxi-wieku-20-wspanialych-odkryc-ostatnich-lat> [access: 30.10.2023].

well-being and respect for animals, they believe that scientists have given themselves the right to prioritize humans, thereby ignoring the well-being and rights of animals<sup>6</sup>.

Taking the above into account and considering that the use of animals for scientific or educational purposes involves constitutional issues such as freedom of scientific research, environmental protection, and public morality, discussions about the role of animals in our lives and the extent of their use have raised the standards of animal protection. However, reaching a compromise between using animals for research and ensuring the highest standards of welfare requires further legislative effort.

## 2. The journey of animals to the laboratory and the legal regulations associated with it

Animals have long been utilized by humans for various purposes. Initially, they served as a source of food or assisted in transportation. Later on, they were also bred for entertainment<sup>7</sup>. Over the years, animals were treated in a utilitarian way, and the law categorized them as things<sup>8</sup>. The perception of animals, their capacity to experience pain, and their role in human life have continually evolved. This chapter outlines the shift in the perception of animals, highlighting the evolution of thought that initiated the implementation of legal standards for the protection of animals, especially those used in scientific research.

Even in ancient Greece, there was an interest in animals as research models that facilitated a better understanding of human anatomy and physiology. One of the early significant researchers contributing to the development of biology was Aristotle<sup>9</sup>. He conducted numerous observations and studies on animals, meticulously describing his findings. In his treatise “Natural History of Animals”, he detailed

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<sup>6</sup> B. Mepham, *Bioetyka – Wprowadzenie dla studentów nauk biologicznych*, Wydawnictwo Naukowe PWN, Warszawa 2008.

<sup>7</sup> D. Krześniak, *Zwierzęta gospodarskie*, <https://mwmskansen.pl/zwierzeta-gospodarskie/> [access: 7.11.2023].

<sup>8</sup> See: K. Piernik-Wierzbowska, *Systematyka i zagadnienie własności zwierząt oraz ich statusu prawnego w kontekście problematyki odpowiedzialności za szkody przez nie wyrządzone*, „Studia Iuridica Toruniensia” 2015, Vol. XVI, p. 224 and following.

<sup>9</sup> At this point, it should be added that the Aristotelian hierarchy of beings introduced a division into less perfect entities (animals, plants), which serve more perfect beings – humans. The human soul possesses rational power, which is proper only to humans. See: T. Zawojska, *Arystotelesowska koncepcja człowieka podstawą racjonalnej działalności gospodarczej*, „Zeszyty Naukowe Szkoły Głównej Gospodarstwa Wiejskiego. Ekonomia i Organizacja Gospodarki Żywnościowej” 2017, No. 117.

important aspects of the external and internal structures of different animal species, distinguishing features such as the heart, liver, brain, lungs, etc. Additionally, through extensive animal research, he documented anomalies in their anatomical structures, linking them to specific diseases<sup>10</sup>. Another Greek scholar pioneering experimental research involving animals was Erasistratus of Ceos. He conducted the first vivisection<sup>11</sup>, an operation on a living animal for research purposes. In Roman times, Galen, a physician, performed dissections primarily on macaques, gaining renown in the scientific community for developing a schema of human anatomy<sup>12</sup>.

In European culture, animals were primarily treated in a utilitarian manner. According to Ulpian, natural law, the essence of which is the pursuit of “[...] order and harmony governing nature, as well as the good of all creatures [...]”<sup>13</sup>, is common to all beings<sup>14</sup>.

For centuries, an incalculable number of animals have crossed the thresholds of various laboratories. This gradual involvement of animals in scientific research has contributed to advancements in various scientific fields, particularly those crucial to human life, such as medical sciences. Consequently, the use of animals in scientific research has continuously expanded. Unfortunately, all too often, animals were treated inappropriately and inhumanely, lacking the due respect for organisms that contributed so much to humanity<sup>15</sup>.

The issue of animal subjectivity as a legal matter was first addressed in the 19th century by J. Bentham, who asserted that the fact that animals experience pain and pleasure justifies modifying the human-animal relationship and requires consideration of animal interests<sup>16</sup>.

It was only in the late 1970s, as a result of increasing social awareness and thinking beyond human selfishness, that a new interdisciplinary field of knowledge, bioethics, was established. Current data indicate that each year, approximately

<sup>10</sup> Aristotle, *Zoologia. Historia Animalium*, Warszawa 1982.

<sup>11</sup> *Słownik wyrazów obcych PWN*, Warszawa 1991, p. 907.

<sup>12</sup> V. Nutton, *Galen. Greek physician*, <https://www.taylorfrancis.com/books/mono/10.4324/9780429341380/galen-vivian-nutton> [access: 11.11.2023].

<sup>13</sup> P. Sadowski, *Filozofia prawa w życiu i nauczaniu Ulpiana*, „Zeszyty Prawnicze UKSW” 2008, 8.1, p. 101.

<sup>14</sup> D. 1,1,1,3; <https://droitromain.univ-grenoble-alpes.fr/Corpus/d-01.htm> [access: 30.10.2022].

<sup>15</sup> E. Krajewska-Kułak, C. Łukaszuk, A. Guzowski, J. Fiłon, *Relacje człowiek – zwierzęta dawniej i dziś* [in:] *Eksperymenty i badania na zwierzętach. Egoizm, koszt postępu czy przejaw okrucieństwa*, ed. E. Krajewska-Kułak, A. Guzowski, J. Brezcko, M. Wiśniewska, S. Surendra, Poznań 2021, p. 13.

<sup>16</sup> A. Kalisz, D. Pawlicka, *Od ochrony prawnej ku prawom zwierząt – między świadomością moralną a prawną. Ewolucja podejścia na przykładzie orzecznictwa sądownoadministracyjnego*, *Archiwum Filozofii Prawa i Filozofii Społecznej* 2022/2, p. 39 and the literature cited by the authors.

75–100 million mice, rats, guinea pigs, rabbits, birds, and fish participate in experiments<sup>17</sup>. Therefore, further development of bioethics and regulations governing the use of animals in laboratories is inevitable<sup>18</sup>.

According to the modern definition, laboratory animals, also known as experimental animals, are organisms with relatively small body sizes, characterized by high fertility, rapid maturation, and ease of cultivation in laboratory conditions. They are most commonly used in research in the fields of physiology, embryology, genetics, biochemistry, and pharmacology<sup>19</sup>. These animals come from special breeding facilities for laboratory animals. Currently, there are companies in the market that specialize in the “production” and sale of laboratory animals, such as various strains of mice, rats, hamsters, rabbits, guinea pigs, and gerbils. Rodents are most frequently used in experiments because they perfectly meet the requirements for laboratory animals. Moreover, in preclinical studies involving these animals, the etiology and symptoms of diseases are similar to those occurring in humans. Various animal models are available for sale, ranging from standard models to models of specific diseases, genetically modified models, and even those with specific surgical modifications<sup>20</sup>.

The legislator “can initiate and accelerate transformations in social life by introducing new solutions into the legal system”<sup>21</sup>. Legal protection, while placing humans at the centre, sets minimum standards for principles of conduct towards animals. A noticeable phenomenon is the adoption of consumer<sup>22</sup> and social attitudes characterized by high levels of moral standards<sup>23</sup>. As demonstrated by

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<sup>17</sup> *Animal experiments in research (Deutsche Forschungsgemeinschaft). Senate Commission on Animal Protection and Experimentation*, ed. U. Eysel, A. Haverich, G. Heldmaier, B. Hoffmann, W. Lower, S. Treue, H. Wagner, E. Wolf, F. Wollnik, C. Exner, H.J. Bode, K. Blumer, C. Giese, Deutsche Forschungsgemeinschaft – Bonn: Lemmens Medien GmbH, 2007, p. 1–44.

<sup>18</sup> V. Baumans, *Science-based assessment of animal welfare: laboratory animals*, “Scientific and Technical Review of the Office International des Epizooties”, Paris 2005, 2, p. 503–514.

<sup>19</sup> *Encyklopedia PWN*, entry: *Doświadczalne zwierzęta*, source: <https://encyklopedia.pwn.pl/haslo/doswiadczalne-zwierzeta;3893951.html> [access: 22.10.2022].

<sup>20</sup> Anima Lab website, *Zwierzęta laboratoryjne*, <https://animalab.pl/zwierzeta-laboratoryjne>.

<sup>21</sup> A. Nałęcz, *Ochrona zwierząt a postęp cywilizacyjny* [in:] P.J. Suwaj, J. Zimmermann, *Wpływ przemian cywilizacyjnych na prawo administracyjne i administrację publiczną*, Warszawa 2013, LEX.pl.

<sup>22</sup> „Rzeczpospolita”, *Konsumenci, choć oszczędzają, są bardziej świadomi ekologicznie*, <https://klimat.rp.pl/walka-o-klimat/art37512611-konsumenci-choc-oszczedzaja-sa-bardziej-swiadomi-ekologicznie> [access: 30.11.2022].

<sup>23</sup> In the literature, it is indicated that the so-called *Green Consumering*, which is effectively implemented, for example, through the promotion of appropriate attitudes among business entities and consumers, has the potential to influence the protection of values such as the natural environment. See: M.L. Li, *Review of Consumers’ Green Consumption Behavior*, “American Journal of Industrial and Business Management” 2020, Vol. 10, No. 3, p. 593, <https://www.scirp.org/journal/paperinformation.aspx?paperid=98897> [access: 30.11.2022].

the position of J. Bentham, moral awareness often precedes legal awareness, which generally contributes to the protection of animal rights<sup>24</sup>.

### 3. Current legal issues regarding experiments involving living organisms in Poland

Constitutional regulations regarding animals used in scientific research focus on the following issues: freedom of scientific research, public morality, and environmental protection. Animal protection rights in the fundamental law concentrate on the acknowledgment of the need to protect the natural environment, the pursuit of sustainable development, and ensuring ecological safety. It can also be perceived through the provisions formulated in Article 31, paragraph 3, of the Constitution of the Republic of Poland and the concept of public morality contained therein, justifying the limitation of rights and freedoms of citizens in the name of the humanitarian protection of animals as sentient beings capable of suffering<sup>25</sup>.

The sources of animal welfare standards should be sought in activities related to environmental protection<sup>26</sup>, but the starting point for legal protection of animals is the “right to freedom from suffering”, which implies protection of individual beings as living organisms with consciousness<sup>27</sup>. Therefore, it should be assumed that “[...] The axiology of provisions on animal welfare refers to moral limitations on harming them, rather than the need to maintain the natural environment in a sufficiently unimpaired state”.

Constitutional freedom of scientific research justifies the use of animals for research purposes, and the detailed rules for conducting experiments on animals are specified in the Animal Welfare Act<sup>28</sup>. The Act classifies animals into: animals used for entertainment, shows, films, sports, and special purposes – chapter 4; farm animals – chapter 3; and wild animals – chapter 6 of the Animal Welfare Act<sup>29</sup>. The legal classification of animals determines the manner of legal protection and the possibility of their use for human benefit<sup>30</sup>.

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<sup>24</sup> A. Kalisz, D. Pawlicka, *Od ochrony prawnej...*, *op.cit.*, p. 40 and 51.

<sup>25</sup> T. Pietrzykowski, *Moralność publiczna a konstytucyjne podstawy ochrony zwierząt*, Instytut Nauk Prawnych PAN, „Studia Prawnicze” 2019, No. 1, p. 5.

<sup>26</sup> See: T. Pietrzykowski, *Moralność publiczna...*, *op.cit.*, p. 10.

<sup>27</sup> A. Kalisz, D. Pawlicka, *Od ochrony prawnej...*, *op.cit.*, p. 39.

<sup>28</sup> The Act of August 21, 1997, Journal of Laws of 2019, item 122.

<sup>29</sup> S. Jarosz-Żukowska, Ł. Żukowski, *Wolność badań naukowych [in:] Realizacja i ochrona konstytucyjnych wolności i praw jednostki w polskim porządku prawnym*, ed. M. Jabłoński, Wrocław 2014, p. 728.

<sup>30</sup> See: K. Walkowicz, *Problematyka rozszerzania prawnej podmiotowości zwierząt*, „Studenckie Prace Prawnicze, Administratywistyczne i Ekonomiczne” 2021, 35, p. 191–193.

In recent years, one of the significant rulings of the Constitutional Tribunal, which reflects the perception of animals and addresses the possibility of protecting them from unnecessary suffering, pertained to ritual slaughter<sup>31</sup>. The Constitutional Tribunal emphasized at that time that the freedom to manifest religion and perform ritual slaughter should take precedence over the necessity to protect animals and does not pose a threat to public morality. Public morality encompasses “values, norms, and moral judgments that have become widespread and ingrained in a given society and its culture, considered as belonging not only to the »private« sphere of individual moral beliefs”<sup>32</sup>. K. Buratowska notes, however, that “ritual slaughter is classified as a form of manifesting religion without general recognition, undesirable, and conflicting with public morality”<sup>33</sup>. According to T. Pietrzykowski, basing the humanitarian protection of animals on the vague and ambiguous concept of public morality means that the legislator is not bound by the mandate to implement such protection<sup>34</sup>. However, it is in laws that one should look for specific guidelines on how to treat animals used in scientific research.

The recent changes in European Union law primarily involve modifications to the language used, such as replacing “animal protection” with the term “animal welfare”<sup>35</sup>. The introduction of principles for the replacement, reduction, and refinement of animal use (Article 4 of Directive 2010/63) is positively regarded as a high standard of animal protection.

Directive 2010/63, in Recital 12, indicates that animals should be treated as sentient beings, and their use in procedures should be limited to areas that can ultimately benefit human and animal health or the environment. The use of animals for scientific or educational purposes should only be considered when no other alternatives exist. The use of animals in scientific procedures in other fields under the Union's competence should be prohibited. Furthermore, in Recital 10, it is stated that the directive aims to facilitate and promote the development of alternative approaches and ensure a high level of protection for those animals that still need to be used in these procedures<sup>36</sup>.

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<sup>31</sup> Judgment of the Constitutional Tribunal dated December 10, 2014, case reference K 52/13, <https://trybunal.gov.pl/postepowanie-i-orzeczenia/wyroki/art/7276-uboj-rytualny>.

<sup>32</sup> T. Pietrzykowski, *Moralność publiczna...*, *op.cit.*, p. 14; K. Buratowska, *Glosa do wyroku Trybunału Konstytucyjnego z dnia 10 grudnia 2014 r., sygn. K 52/13*, „Roczniki Administracji i Prawa” 2021, XXI, issue 1, p. 295.

<sup>33</sup> K. Buratowska, *Glosa do wyroku...*, *op.cit.*, p. 295.

<sup>34</sup> T. Pietrzykowski, *Moralność publiczna...*, *op.cit.*, p. 21. The author also advocates the constitutionalization of animal protection. *Ibidem*, p. 21.

<sup>35</sup> A. Kalisz, D. Pawlicka, *Od ochrony prawnej...*, *op.cit.*, p. 43. The law and the vocabulary used in legal texts shape reality. See: A. Partyk, *Dr Dębska: Język prawa ma ukryte znaczenia*, <https://www.prawo.pl/prawnicy-sady/jezyk-prawa-wplywa-na-nasze-zycie,342940.html> [access: 30.10.2022].

<sup>36</sup> Directives only indicate the results that should be achieved by the member states. A. Kalisz, *Wykładnia i stosowanie prawa wspólnotowego*, Warszawa 2007, p. 75–78.

In Poland, the law concerning animal protection falls under administrative law. Currently, scholars in the field indicate the creation of a new branch of law that could form a specialized set of legal norms covering the protection of animals<sup>37</sup>. Two fundamental laws<sup>38</sup> regulate the treatment of vertebrate animals used for scientific or educational purposes: the Animal Welfare Act and the Act on the Protection of Animals Used for Scientific or Educational Purposes<sup>39</sup>, which is *lex specialis* in relation to the Animal Welfare Act. Article 2, paragraph 1 of the Animal Welfare Act specifies that in matters not regulated by the Act on the Protection of Animals Used for Scientific or Educational Purposes, the provisions of the Animal Welfare Act apply<sup>40</sup>, while matters not covered by the Animal Welfare Act are subject to the provisions concerning things (Article 1, point 2 of the Animal Welfare Act)<sup>41</sup>.

The Act on the Protection of Animals Used for Scientific or Educational Purposes implements the provisions of Directive 2010/63<sup>42</sup>. Its scope includes defining the principles and conditions for the protection of animals used for scientific or educational purposes. This involves specifying the methods for performing

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<sup>37</sup> Ministry of Justice, *Pojęcia i definicje. Gałąź prawa*, <https://isws.ms.gov.pl/pl/pojecia-i-definicje/letter,G,1.html> [access: 30.10.2022].

<sup>38</sup> Of course, there are many more legal acts regulating experiments on animals. See: Website of the Ludwik Rydygier Collegium Medicum in Bydgoszcz, *Akty prawne regulujące doświadczenia na zwierzętach*, source: <https://www.cm.umk.pl/37-wydzialy/jednostki-miedzywydzialowe/173-akty-prawne-regulujace-doswiadczenia-na-zwierzetach.html> [access: 30.10.2022].

<sup>39</sup> The Act of January 15, 2015, Journal of Laws of 2023, item 465.

<sup>40</sup> K. Kuszlewicz, *Ustawa o ochronie zwierząt. Komentarz, Wprowadzenie. Zasadnicze problemy ochrony zwierząt w Polsce*, Warszawa 2021, LEX.pl.

<sup>41</sup> Considering the nature of the study, the civil law understanding of animals as things is not the subject of analysis in this article. By stating that animals are not things, it should be assumed that the role of regulation will be "to construct appropriate human-animal relationships, within which humans will be obliged not only to refrain from actions harmful to animals but also to make efforts to create the best possible living conditions for them". M. Goettel, *Sytuacja zwierzęcia w prawie cywilnym*, LEX.pl 2013, <https://sip.lex.pl/komentarze-i-publicacje/monografie/sytuacja-zwierzecia-w-prawie-cywilnym-369273602>. B. Klimek, *Przemoc wobec zwierząt i prawna ochrona zwierząt w Polsce*, „Życie Weterynaryjne” 2018, 93(9), <https://www.vetpol.org.pl/dmdocuments/ZW-09-2018-01.pdf>.

M. Jarosz, *Ochrona zwierząt w Polsce na przestrzeni dziejów*, „Wiadomości Zootechniczne” 2016, R. LIV; M. Gabriel-Węglowski, *Przestępstwa przeciwko humanitarnej ochronie zwierząt*, <https://sip.lex.pl/komentarze-i-publicacje/monografie/przestepstwa-przeciwko-humanitarnej-ochronie-zwierzat-369197535>; P. Paleń, *Wybrane aspekty prawne ochrony zwierząt gospodarskich w Polsce*, „Kortowski Przegląd Prawniczy” 2017, No. 2, <https://wpia.uwm.edu.pl/czasopisma/sites/default/files/uploads/KPP/2017/2/5-10.pdf>; E. Nawrotek, *Zwierzę jako istota żyjąca – komentarz ekspercki*, <https://www.umcs.pl/pl/komentarze-eksperskie,22097,zwierze-jako-istota-zyjaca-komentarz-ekpercki,132861.chtm>.

<sup>42</sup> Directive of the European Parliament and of the Council 2010/63/EU dated September 22, 2010.



procedures and experiments, establishing principles for the activities of breeders, suppliers, and users, and setting guidelines for conducting inspections of breeders, suppliers, and users.

The Act on the Protection of Animals Used for Scientific or Educational Purposes defines a “procedure” as any form of using animals, including for research, development, and the production of medicinal products (Article 3 of the Act). A procedure may cause pain, suffering, distress, or lasting damage to the animal, equivalent to or more intense than needle pricking. Furthermore, these activities aim to or may result in the birth or hatching of an animal, or the creation and maintenance of a genetically modified line of animals under conditions of pain, suffering, distress, or lasting damage to the organism, equivalent to or more intense than needle pricking.

The implementation of the 3Rs principles (Replacement, Reduction, Refinement) outlined in Article 4 of Directive 2010/63 obliges breeders, suppliers, and users (Article 3a of The Act on the Protection of Animals Used for Scientific or Educational Purposes) to:

1. apply, whenever possible, methods or research strategies instead of a specific procedure that are scientifically satisfactory and do not involve the use of animals (Replacement);
2. minimize the number of animals used in procedures without compromising the purpose of these procedures (Reduction);
3. improve the breeding, maintenance, care, and methods used in procedures to eliminate or minimize potential pain, suffering, distress, or lasting damage to their organisms (Refinement)<sup>43</sup>.

The 3R principle undergoes continuous improvement, including the incorporation of qualified individuals into the euthanasia of animals<sup>44</sup>. Adhering to the above principles minimizes the distress experienced by animals and “[...] compels scientists to seek new, high-quality research methods, encouraging collaboration so that animals used in one experiment can also serve as a data source for another research group”<sup>45</sup>. Adherence to the 3R principle is also contingent on the development of appropriate procedures, which have been

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<sup>43</sup> The authors point out that the reliability of the results of scientific research depends to a large extent on the welfare of animals subjected to experiments. See: A. Schollenberger, *Zasada 3R w ochronie zwierząt wykorzystywanych do badań naukowych*, „Życie Weterynaryjne” 2017, 92(6), p. 424.

<sup>44</sup> A. Strządała *Znaczenie zasad 3R w trosce o dobrostan zwierząt wykorzystywanych do doświadczeń naukowych. Podstawy prawne, ich aksjologiczne przesłanki oraz praktyczne wskazówki*, „Kultura i Wartości” 2021, 32, p. 135.

<sup>45</sup> A. Schollenberg, *Zasada 3R...*, *op.cit.*, p. 426.

outlined in soft law sources – the so-called good practices – presented with a significant delay<sup>46</sup>.

Another way to maintain adequate welfare is to apply control by social entities that play a significant role in the process of legislating and enforcing laws, including reviewing draft laws<sup>47</sup> and verifying their welfare aspects<sup>48</sup>. Social organizations whose statutory purpose is the protection of animals (Article 40 of the Animal Welfare Act) could be crucial in the humanitarian protection of animals<sup>49</sup>. The authors point out the lack of regulations that could specify the collaboration between social organizations and relevant state and local institutions<sup>50</sup>. Supplementing the Animal Welfare Act with an appropriate procedure could eliminate this legal gap<sup>51</sup>. Among social organizations, two basic motivations can be distinguished, influencing their actions and societal reception. There are organizations whose goal is the welfare of animals and those that advocate for granting rights to animals. The former aim solely at improving welfare, while the latter include a demand to cease any exploitation of animals<sup>52</sup>. The latter motivation contradicts the tradition and a typical, object-oriented approach to treating animals in some cultures<sup>53</sup>.

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<sup>46</sup> See: Ministry of Education and Science. *Krajowa Komisja Etyczna do Spraw Doświadczeń na Zwierzętach*, <https://www.gov.pl/web/edukacja-i-nauka/krajowa-komisja-etyczna-do-spraw-doswiadczen-na-zwierzetach> [access: 30.10.2022]. Supreme Audit Office in the report: *Wykorzystanie zwierząt w badaniach naukowych*, source: <https://www.nik.gov.pl/plik/id,13608,vp,16043.pdf>, p. 9 [access: 30.10.2022]. The Supreme Audit Office, in the report, accused the National Ethics Committee of sluggishness in providing good practices. In the further part of the report, a series of procedural errors were identified, including the failure of district veterinary doctors to promptly inform the National Ethics Committee and local ethics committees of shortcomings found during inspections of the conditions of keeping experimental animals in experimental and breeding units. See: Supreme Audit Office, *Wykorzystanie..., op.cit.*, p. 12.

<sup>47</sup> A. Gdula, *Tajne eksperymenty na zwierzętach poza społeczną kontrolą*, <https://siecobywatelska.pl/tajne-eksperymenty-na-zwierzetach-pozza-spoieczna-kontrola/> [access: 30.10.2022]; A. Sucharska, *Prawo do informacji pomaga ratować zwierzęta*, <https://siecobywatelska.pl/prawo-do-informacji-pomaga-mi-ratowac-zwierzeta/> [access: 30.10.2022].

<sup>48</sup> According to Article 25 of the Act on the Protection of Animals Used for Scientific or Educational Purposes, the breeder, supplier, and user are obligated to establish a committee for animal welfare. This committee is responsible, among other things, for monitoring the welfare of animals and overseeing the conduct and results of experiments.

<sup>49</sup> See: E. Kruk, *Współdziałanie organizacji społecznych z właściwymi instytucjami państwowymi i samorządowymi w ujawnianiu oraz ściganiu przestępstw i wykroczeń określonych w ustawie o ochronie zwierząt*, „*Studia Prawnoustrojowe*” 2019, 43, p. 207–215.

<sup>50</sup> *Ibidem*, p. 211–212.

<sup>51</sup> *Ibidem*, p. 213.

<sup>52</sup> See: J. El-Jai, *Dobrostan zwierząt..., op.cit.*, p. 184.

<sup>53</sup> The attempt to introduce the so-called “five for animals” should be positively assessed. Unfortunately, due to reasons such as the lack of an appropriate *vacatio legis* for retraining entrepreneurs

Despite efforts over several decades, the implementation of new legal regulations and social controls that have contributed to improving the conditions of animals used in research, we cannot entirely forgo the “services” of animals. The legislator's goal should be a continuous pursuit of “providing animals with the best conditions and obtaining results of the highest cognitive value”<sup>54</sup>. The legislator should also strive for the highest level of transparency, including legal acts related to clinical research, by imposing an obligation to disclose results, preventing so-called forcing open doors<sup>55</sup>.

#### **4. Why does the law only protect vertebrate animals? Ethical and legal approach to differences in the use of vertebrates and invertebrates in scientific research**

While vertebrate animals remain a common subject of laboratory research, experiments involving this group of animals have certain limitations due to ethical considerations. Experiments involving vertebrates are strictly controlled, and their conduct requires the approval of the National Ethics Committee for Animal Experiments.

When planning “ethical” animal research, organisms with a lower capacity for feeling pain and suffering should be chosen. Thus, in preliminary studies, the use of invertebrates may serve as an alternative method<sup>56</sup>. For example, in research on neuron function, invertebrates are a suitable model because they have few but relatively large nerve cells. The simpler anatomy and physiology of the nervous system allow the observation of functional processes at the level of individual neurons or neural networks<sup>57</sup>. Invertebrates can be equally good model organisms

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and the absence of notification of the law before its adoption by the Sejm, the draft law was rejected. See: Website of the Commissioner for Human Rights, *Rzecznik do Senatu ws. „piątki dla zwierząt”*. *Trzeba dać przedsiębiorcom czas na przebranzwianie. A ustawę trzeba było notyfikować przed jej przyjęciem*, <https://bip.brpo.gov.pl/pl/content/opinia-rpo-dla-senatu-ws-piatki-dla-zwierzat> [access: 30.11.2022].

<sup>54</sup> A. Józkowicz, *Nauka bez wykorzystywania zwierząt w badaniach*, [https://nauka.uj.edu.pl/aktualnosci/-/journal\\_content/56\\_INSTANCE\\_Sz8leL0jYQen/74541952/148743541](https://nauka.uj.edu.pl/aktualnosci/-/journal_content/56_INSTANCE_Sz8leL0jYQen/74541952/148743541) [access: 30.10.2022].

<sup>55</sup> The legal issue concerning scientific research is the imposition of the obligation to publish research. Transparency in clinical trials is essential to avoid unnecessary adverse events that have been concealed so far. See: *Nauka w Polsce, Od 2016 r. większa jawność w badaniach klinicznych leków*, <https://naukawpolsce.pl/aktualnosci/news%2C407730%2Cod-2016-r-wieksza-jawnos-w-badaniach-klinicznych-lekow.html>. Unfortunately, research results not only have a scientific character but also utilitarian and commercial aspects. See more: J. Ożegalska-Trybalska, *Protection and ownership of research results*, “*Nowotwory J Oncol*” 2020, 70, p. 163–166.

<sup>56</sup> Directive of the European Parliament and of the Council 2010/63/EU dated September 22, 2010.

<sup>57</sup> B. Sadowski, *Biologiczne mechanizmy zachowania się ludzi i zwierząt*, Warszawa 2012, p. 584.

in diverse research directions<sup>58</sup>. Unfortunately, legal regulations regarding the use of vertebrate animals in research do not provide the same guarantees for invertebrates. This applies to both the lack of restrictions on conducting experiments on them and the permission to inflict pain on them (with the justification that they exhibit lower pain perception, if any)<sup>59</sup>. According to Elwood<sup>60</sup>, an accurate term in reference to lower animals is “experiencing pain”, which combines internal awareness and negative emotional feelings associated with tissue damage, for example.

In light of the described limitations, invertebrates are increasingly used in biomedical research aimed at understanding the molecular basis of various diseases or preliminary testing of substances used in treatment. This represents a new area of interest for scientists seeking to utilize these animals, for example, in studying the bioactivity of new active substances and determining the toxicity of substances used in the treatment of humans and animals. Many invertebrate species, such as *Caenorhabditis elegans*, *Aplysia californica*, or *Drosophila melanogaster*, have been used in various types of scientific research for a long time. They are increasingly finding applications, for instance, in educational activities related to the study of anatomy, genetics, developmental biology, or ecology<sup>61</sup>.

## 5. Summary

In accordance with the EU Directive on the protection of animals used for scientific purposes, when conducting experiments for scientific and educational purposes, efforts should be made to replace procedures involving live animals with alternative methods whenever possible. Many studies performed on living organisms in specific research procedures cannot be eliminated, and appropriate breeding and treatment conditions must be provided, taking into account their welfare. The choice of appropriate research methods is also crucial, involving not only the right species but also minimizing the number of individuals used (while ensuring reliable and valuable results).

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<sup>58</sup> Ch. Harvey-Clark, *IACUC challenges in invertebrate research*, “ILAR Journal” 2011, 52, p. 213–220; S.E. Wilson-Sanders, *Invertebrate models for biomedical research, testing, and education*, “ILAR Journal” 2011, 52, p. 126–152.

<sup>59</sup> P.L.R. Andrews, *Laboratory Invertebrates: Only spineless, or spineless and painless?* “ILAR Journal” 2011, 52, p. 121–125, J.A. Mathre, *Philosophical background of attitudes toward and treatment of invertebrates*, “ILAR Journal” 2011, 52, p. 205–212.

<sup>60</sup> R.W. Elwood, *Pain and Suffering in Invertebrates?*, “ILAR Journal” 2011, 52, p. 175–184.

<sup>61</sup> Ch. Harvey-Clark, *IACUC challenges in invertebrate...*, *op.cit.*, p. 213–220. S. E. Wilson-Sanders, *Invertebrate models...*, *op.cit.*, p. 126–152.

Despite the legal possibility of experimenting on animals, such procedures inflict pain on them and expose them to chronic stress and suffering<sup>62</sup>. The existing legal protection of animal rights is based on the establishment of norms in administrative law, shaped, among other factors, by cultural models. A noticeable trend in this field is the pursuit of standardizing the functioning of public administration<sup>63</sup>. The legal issues surrounding the protection of animals should be addressed in a new branch of law and jurisprudence<sup>64</sup>. The legislative process in determining standards for the use of animals for scientific purposes should take into account the advancements in biological sciences and involve social organizations to increase oversight. In this context, the application of the so-called 3R principle seems justified. This principle emphasizes the replacement of animal experiments with *in vitro* techniques or computer simulations, the reduction of the number of animals used, minimizing animal discomfort during experiments, and meeting their physiological requirements in breeding practices<sup>65</sup>.

Improvements in animal welfare should also be sought through the introduction and updating of best practices that define how laboratory animals should be treated<sup>66</sup>. Legislative initiatives such as the “Five for Animals” aim to significantly improve the fate of animals<sup>67</sup>, sparking discussions, and this should translate into consumer awareness and the development of so-called “green consumerism” – an attitude based on avoiding products harmful to health, the environment, and those causing significant damage to the ecosystem, etc.<sup>68</sup>.

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<sup>62</sup> Z. Gądzik, *Etyczne aspekty wykorzystywania zwierząt w procedurach doświadczalnych*. *Studia Ecologiae et Bioethicae*” 2021, 19, p. 17–30. DOI: 10.21697/seb.2021.19.1.02.

<sup>63</sup> A. Nałęcz, *Ochrona zwierząt...*, *op.cit.* and the literature quoted by the author.

<sup>64</sup> Cited from: K. Kuszlewicz, *Ustawa o ochronie zwierząt...*, *op.cit.*; T. Pietrzykowski, *Prawo ochrony zwierząt – między praktyką a teorią nowej gałęzi prawa*. *Artykuł recenzyjny*, “Krytyka Prawa” 2020, 2, Vol. 12, p. 224.

<sup>65</sup> See: V. Baumans, *Science-based...*, *op.cit.*, p. 503–514; B. Mepham *Bioetyka...*, *op.cit.*; Ch. Harvey-Clark, *IACUC challenges...*, *op.cit.*, p. 213–220.

<sup>66</sup> Good practices outline the way animals should be treated; however, they are not norms imposed through legislation. M. Iwaniec, *Soft law – współczesny instrument regulacji życia gospodarczego*, *iKAR* 2020, 5(9), p. 134.

<sup>67</sup> B. Michalski, „*Piątka dla zwierząt*”. *Ustawa dobra, ale...*, <https://prawo.gazetaprawna.pl/artykuly/1491087,piatka-dla-zwierzat-ochrona-zwierzat-uboj-rytualny-cyrki.html> [access: 30.10.2022].

<sup>68</sup> See: L. Witek, *Zachowania konsumentów na rynku produktów ekologicznych w Polsce i innych krajach Unii Europejskiej*, „*Handel Wewnętrzny*” 2014, 1, p. 283 and the literature quoted by the author.

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