

## LEGAL PROTECTION OF EXPERIMENTAL ANIMALS IN THE EUROPEAN UNION AND THE REPUBLIC OF SERBIA \*

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**Abstract.** *Despite the state-of-the-art achievements of modern technology, live animals are largely used today in diverse experimental procedures. The author of this paper shall not discuss the issues related to man's cruelty to experimental animals, the inadequacy and actual uselessness of these experiments for human beings, nor the fact that these experiments may actually be an impediment to scientific discovery. In this article, the author analyses the legal aspects concerning the protection of experimental animals in the European Union and in the Republic of Serbia. In anticipation of the forthcoming harmonization of the national legislation in this area with the EU legislation, the author eventually suggests some measures for the protection of experimental animals in Serbia.*

**Key words:** *Experimental animals, EU law, Serbian legislation.*

*On the event of 24<sup>th</sup> April,  
World Day of Laboratory Animals*

### INTRODUCTION

In the quest for scientific knowledge, health and profit, man has been using animals for experimental purposes for decades. The practice of running experiments on living animals (vivisection)<sup>1 2</sup> has been underway for quite a while. Animals are believed to

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<sup>1</sup> The term "vivisection" is a compound derived from the Latin terms "vivi" (meaning "alive") and "sectio" (meaning "cutting") and it literally means "cutting of alive tissue". For more information on the meaning of the term, see the website of the Encyclopedia Britannica; <http://www.britanica.com/ebc/article-9382118?>

have been used for experimental purposes ever since the times of the Ancient Greece and Rome.<sup>3</sup>

The brutal statistics of such practices today show that millions of animals are annually used in Europe for experimental purposes.<sup>4</sup> Animals are used in examining nearly all new medicines, food additives, cosmetics, cleansing agents, chemicals used in agriculture, as well as in experimental procedures for educational, training or military purposes.

The extensive use of animals for experimental purposes and their largely inhuman treatment in such experiments, which often prove to be illegal and unnecessary, has served as an incentive for some scholars<sup>5</sup> and animal rights' movement activists to voice their claims on the need to set limitations to the experimental use of animals and, most recently, to abolish animal experiments.<sup>6 7</sup>

Consequently, this has given rise to the legal protection of experimental animals. Ever since the adoption of the British Cruelty to Animals Act of 1876, experimental animals have been more or less legally protected in most European states.<sup>8</sup>

In this paper, the subject matter of the author's research is the legal protection of experimental animals, perceived in light of the European Convention on the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes, the relevant EU regulations on the issue and the related legislation of the Republic of Serbia.

<sup>2</sup> Unlike vivisection which may be used only on live animals, dissection implies cutting or operating on deceased animals. For more, see the website: [http://www.veganvanguard.com/vegism/experiment\\_lexicon.html](http://www.veganvanguard.com/vegism/experiment_lexicon.html).

<sup>3</sup> According to the available historical data, Aristotle (384-322 BC) and Erasistratus (304-258 BC) were the first to perform experiments on living animals. The Roman physicist Galen, who vivisected goats and pigs in 2<sup>nd</sup> century, is considered to be the forefather of vivisection. See: Laboratory Primate Advocacy, History of Non-human Animal Research, at the website <http://www.lpag.org/layperson/layperson.html#history>

<sup>4</sup> The Fifth European Commission Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the EU member states shows that the total number of animals used for these purposes in the 25 EU member states amount to 12, 1 million animals in the year 2005, whereby the 10 new EU member states participated with 8, 6 % of the total number of experimental animals, whereas Malta reported that no experiments on animals were performed on its territory in 2005. The most frequently used animals in these experiments were rodents and rabbits (78%), cold-blooded animals such as reptiles, insects, amphibians and fish (15 %), birds (5%) and other animals (2%). No big apes were used in the experiments in the EU in the year 2005. For more data on the experiments in the EU member states, see Fifth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member State of the European Union [SEC (2007) 1455], at the website

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52007DC0675:EN:...>

<sup>5</sup> See, P. Singer, *Animal Liberation*, New York, 1975; R. G. Frey, *Interest and Rights: The Case against Animals*, Oxford, 1983; R. Sharpe, *The Cruel Deception: The Use of Animals in Research*, London, 1988; T. Regan, *Defending Animal Right*, Chicago, 2001.

<sup>6</sup> More details at the website: [http://www.scienceclarified.com/Vi-Z/Vivi\\_section.html](http://www.scienceclarified.com/Vi-Z/Vivi_section.html).

<sup>7</sup> In particular, the proponents of this idea are two non-governmental organizations: PETA (People for the Ethical Treatment of Animals) and BUAV (British Union for the Abolition of Vivisection), whose requests for for the abolition of experiments on animals are substantiated by the following reasons: animal experiments show man's excessive cruelty towards lower species; in such experiments, animals are not used but actually abused; such experiments are frequently unreliable and give misleading results in terms of human health; the legal regulation of this issue is rather poor and insufficient; animal experiments yield more costs than benefits; animal experimentation is directly opposed to the animals' inherent right to live without pain and suffering. For more, see the websites <http://www.peta.org/about/faq-viv.asp>; <http://www.buav.org/pdf/VivisectionFAOs.pdf>.

<sup>8</sup> For more details, see: M. Пауновић, Упоредноправни преглед заштите права и добробити животиња, Страни правни живот, бр. 1/2004, стр. 27-60. (M. Paunović, *Comparative Survey on the Protection of Animal Rights and their Well-being*, Foreign Legal Life (journal), no. 1/2004, pp 27-60

## 1. THE CONVENTION ON THE PROTECTION OF VERTEBRATE ANIMALS USED FOR EXPERIMENTAL AND OTHER SCIENTIFIC PURPOSES<sup>9</sup>

The Convention on the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (hereinafter referred to as: the Convention) was adopted in Strasbourg on 18<sup>th</sup> March 1986 under the auspices of the Council of Europe and it entered into force on 1<sup>st</sup> January 1991. Ever since, the Convention has been accepted by 26 European countries as well as by the European Community.<sup>10</sup> The Republic of Serbia has not signed the Convention yet.

In the preamble, the Convention highlights the need of the Council of Europe member states to achieve a greater unity and cooperation in the protection of experimental animals, and provides the rationale for the adoption of such a document. While recognizing and justifying man's need to use animals for scientific purposes, the Convention is primarily aimed at reducing the number of such experiments as well as the total number of animals used for experimental and scientific purposes and, if possible, at protecting experimental animals in such procedures considering their capacity to suffer and remember.<sup>11</sup> The Convention promotes the development of alternative scientific research methods by means of which the number of experiments on animals will be reduced to a minimum.<sup>12</sup>

Under the Convention, the experimental animal is defined as any live non-human vertebrate, including different larval forms but excluding other fetal and embryonic forms.<sup>13</sup>

For the purpose of reducing the overall number of experimental animals, the Convention introduces restrictions on the use of living organisms in experimental procedures and provides a list of specific purposes animals may be used for:

- a) avoidance or prevention of diseases, ill-health and other abnormalities or their effects on man, vertebrates, invertebrates or plants, including the production and quality, efficacy and safety of testing drugs<sup>14</sup>, substances or products;

<sup>9</sup> Hereinafter in this paper, the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (ETS No.123) will be referred to as: the Convention. The integral text on the Convention may be seen at the website: <http://conventions.coe.int>.

<sup>10</sup> The Conventions has been signed and ratified by Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Holland, Norway, Romania, Slovenia, Spain, Sweden, Macedonia, Great Britain, and the European Community. It has also been signed but not ratified yet by Estonia, Hungary, Ireland, Poland, Portugal and Turkey. Source: <http://conventionis.coe.int/Treaty/Commun/ChercheSig.asp?>

<sup>11</sup> Theoreticians involved in the study of animal psychology argue that mammals and birds have cognitive, communicative, emotional and other psychological abilities. These animals have the capacity to reason, feel, plan and choose among options. For more information, see: C. Cohen, In Defense of the Use of Animals, unpublished manuscript, 1996. Cited after: T. Regan, op. cit., p. 73). In addition, some theoreticians believe that the psychological life of primates, dogs and cats is much more prolific and versatile than the psychological life of some representatives of the human species (for example, a child born with an embryo of a human brain). For more on this issue, see: R. G. Frey, op. cit. Cited after: T. Regan, op. cit., стр. 16.

<sup>12</sup> For more details on the alternative methods that have been accepted in the EU as a "trustworthy" substitute for experiments on animals, see [http://ec.europa.eu/environment/chemicals/labanimals/alternative\\_en.htm](http://ec.europa.eu/environment/chemicals/labanimals/alternative_en.htm)

<sup>13</sup> See Article 1, paragraph 2 a of the Convention

<sup>14</sup> Due to physiological and anatomic differences between man and animals, numerous animal tests aimed at examining the efficiency of some prescription drugs have proven to be quite unreliable. Namely, the "bleak" statistics show that some prescription drugs, which proved to be relatively efficient when used on animals, have produced rather negative effects when used on man. Thus, although it successfully passed long-term testing on animals, the prescription drug *contergan* caused more than 10,000 miscarriages and intrinsic physical



vention contains detailed guidelines on the accommodation and protection of animals used for experimental and other scientific purposes.

The Convention also envisages strict rules on the experimental procedure involving one or more animals. Thus, the choice of animal species to be used in the experiment shall be carefully considered and, where required, explained to the responsible authority in a signatory state. While choosing among the procedures, signatory states shall select those which require a minimum number of animals and cause the least pain, suffering, distress or lasting harm, or those which are most likely to provide satisfactory results.<sup>19</sup>

The experimental procedure shall be performed under general or local anesthesia or analgesia, or some other methods which are most likely to eliminate or reduce pain, suffering, distress and lasting harm. Under the Convention, the use of these methods is prohibited in two cases: when their application poses a serious risk to the animal considering that the pain caused in the experiment is lesser than the impairment of the animal well-being, and when the use of anesthesia or analgesia is incompatible with the aim of the experimental procedure.<sup>20</sup>

In order to prevent a huge number of experiments causing animals severe or lasting pain, the Convention specifies that such procedures shall be officially declared and justified, and specifically authorized by the responsible authority in a signatory state.<sup>21</sup>

The Convention envisages that, at the end of the procedure, the responsible authority shall decide whether the experimental animal shall be kept alive or killed by a humane method as soon as possible. The animal which has already been subject to the procedure causing the animal severe or lasting pain, irrespective of whether the anesthesia or analgesia was employed, may be used in subsequent experiments only upon its complete recovery, *i.e.* once it has returned to good health and well-being. Under the letter of the Convention, there are two exceptions to this rule: in case the subsequent experiment is of such kind that the animal is subject to general anesthesia which is to be maintained throughout the procedure until the animal is killed, and in case the next experiment includes some minor interventions only.<sup>22</sup> Under the Convention, the responsible authority is also permitted to set an animal free provided that it is in line with the needs of the experimental procedure.<sup>23</sup>

The Convention specifically focuses on the establishments involved in breeding or supplying animals for experimental purposes,<sup>24</sup> as well as the so-called user establishments where animals are used in experimental procedures.<sup>25</sup>

The Convention obliges the signatory states to use the following animal species for experimental and other scientific purposes: mice, rats, guinea pigs, golden hamsters, rabbits, dogs, cats and quail. However, the signatory states are permitted to include other

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<sup>19</sup> See Article 7 of the Convention

<sup>20</sup> See Article 8 of the Convention

<sup>21</sup> See Article 9 of the Convention

<sup>22</sup> See Article 11 of the Convention

<sup>23</sup> See Article 12 of the Convention

<sup>24</sup> See Article 13-17 of the Convention

<sup>25</sup> See Article 18 -20 of the Convention

animal species, particularly primates. The Convention prohibits the use of stray animals (particularly dogs and cats) and domesticated animals for experimental purposes.<sup>26</sup>

In order to preserve the rare and endangered species and avoid the illegal purchase or acquisition of animals used for experimental purposes, the Convention instructs the signatory state to use animals from registered breeding or supplying establishments only.<sup>27</sup> This helps achieve some other significant goals underlying the proper experimental procedure, such as having healthy animals which have already been adapted to the laboratory environment, which certainly yields less suffering and distress.<sup>28</sup>

Part VI of the Convention specifically deals with the use of animals for educational and occupational training purposes. The Convention envisages that the responsible authority of a signatory state must be notified about the respective procedure, which shall be carried out by or under the supervision of a competent person. However, the Convention prohibits the use of animals for educational or training purposes in case when the objectives may be achieved by using comparably effective audio-visual or some other suitable methods.<sup>29</sup>

Under the provision in Article 27 of the Convention, all signatory states are obliged to collect statistical data on the performed animal experiments and, subject to the given parameters, to make them accessible to the general public.

In order to avoid the unnecessary repetition of procedures required by health and safety regulations of a specific state, all the member states which have signed and ratified this Convention are obliged to recognize, where practicable, the results of the experimental procedures previously carried out in the territory of another member state.<sup>30</sup>

The Convention includes two appendices. Appendix A contains guidelines for the application of Article 5 of the Convention on the accommodation and care of experimental animals. Appendix B contains instructions for the application of Articles 27 and 28 of the Convention concerning the collection and exchange of relevant statistical data.

Moreover, the signatory states are allowed to adopt more rigorous measures for the protection of experimental animals, to impose their own restriction on the procedures involving the use of animals for experimental and scientific purposes, and/or to introduce more stringent control system as compared to the one prescribed in this international document.<sup>31</sup>

There is no doubt that the Convention is aimed at providing a substantial degree of protection of experimental animals. However, the provision in Article 35 of this Convention most apparently reflects how far the signatory states are actually ready to go in accomplishing this objective; under this Article, when signing or depositing the instruments of ratification, acceptance approval or accession, the signatory states are allowed to

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<sup>26</sup> See Article 21 of the Convention

<sup>27</sup> See Article 22 of the Convention

<sup>28</sup> See the explanation on Article 22 of the Convention in Explanatory Report for European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes, at the website <http://conventions.coe.int/Treaty/en/Reports/Html/123.htm>

<sup>29</sup> See Article 25 of the Convention

<sup>30</sup> See Article 29 of the Convention

<sup>31</sup> See Article 4 of the Convention

make one or more reservations in respect of certain solutions envisaged in the Convention.<sup>32 33</sup>

As a matter of fact, the very absence of relevant control mechanisms demonstrates the scope of proclaimed willingness of the signatory states to consistently apply the letter of the Convention. Thus, the multilateral consultations of the signatory states, which are periodically held in order to ensure the application of the Convention as well as the justifiability of changing and amending some of its provisions, seem to be insufficient in terms of getting a comprehensive insight into the methods and the scope of actual protection of experimental animals in the territories of the signatory states.

## 2. THE PROTOCOL OF AMENDMENT TO THE EUROPEAN CONVENTION ON THE PROTECTION OF VERTEBRATE ANIMALS USED FOR EXPERIMENTAL AND OTHER SCIENTIFIC PURPOSES<sup>34</sup>

Being profoundly aware of the fact that the degree of animal protection laid down in the Convention needs to be in line with the advancement of scientific knowledge, the signatories to the Convention also agreed to adopt the Protocol amending this Convention. This legal document envisages a simplified procedure for amending and supplementing the provisions contained in the Appendices A and B of the Convention. Under the Protocol, the signatories to the Convention are authorized (subject to multilateral consultations) to adopt the proposed amendments on the provisions contained in the Appendices without a formal approval of the Committee of Ministers of the Council of Europe.<sup>35</sup>

## 3. THE EU REGULATIONS DIRECTLY RELATED TO THE PROTECTION OF EXPERIMENTAL ANIMALS

### a) Directive 86/609/EEC<sup>36</sup>

Upon the proposal of the European Commission, the Council of Europe adopted the Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes on 24<sup>th</sup> November 1986.

The preamble and Article 1 of this Directive clearly set out its primary objective: to approximate and harmonize the legislations of the EC member states on the protection of experimental animals, which is to contribute to eliminating varied approaches to this issue which directly reflected on the operation of the common market.

This Directive was significantly influenced by the formerly adopted European Convention on the Protection of Vertebrate Animals used for Experimental and other Scien-

<sup>32</sup> However, no reservations may be made in respect of Articles 1 - 14 and Articles 18-20 of the Convention.

<sup>33</sup> This right has been actually used by most of the signatories to the Convention. For more information, see the website <http://conventions.coe.int/Treaty/Commun/ListeDeclarations.asp?NT=123&CM=8&DF=1>

<sup>34</sup> The integral text of the Protocol of Amendment to the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific purposes (ETS No. 170) may be found at the website <http://conventions.coe.int/Treaty/en/Treaties/Html/170.htm>.

<sup>35</sup> See Article 2 of this Protocol

<sup>36</sup> Council Directive 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 (86/609/EEC) was published in the Official Journal L 358, 18. 12. 1986, p. 1-28.

tific Purposes, to such extent that most of the provisions contained in the Convention were transcribed and integrated in the Directive. Some provisions were amended and supplemented<sup>37</sup> but, on the whole, there were just a few brand-new solutions.<sup>38</sup>

A significant novelty introduced by this Directive is that the European Community endeavoured to improve the control on the use of experimental animals, to define the minimum standards for animal care and accommodation as well as a relevant training of personnel handling these animals, to encourage the use of a fewer number of animals in experiments as well as procedures causing animals less pain and distress, and to encourage the use of alternative methods that may ensure an equal or larger amount of research data and knowledge in comparison to the experiments performed on animals.<sup>39</sup>

Under the Directive, the national legislations may freely introduce more rigorous measures for the protection of experimental animals, set more stringent conditions for the experimental procedures control, and/or impose restrictions on the use of animals for experimental purposes.<sup>40</sup>

#### **b) Proposal for a Directive on the Protection of Animals used for Scientific Purposes<sup>41</sup>**

Apart from the obvious benefits of the Directive 86/609/EEC for the protection of experimental animals, in the course of its application it proved to have some drawbacks. Thus, in line with Article 34 of this Directive, some EU member states adopted a broad scale of measures in order to attain a high level of protection of experimental animals whereas other member states kept their legislations within the required minimum, which eventually resulted in unfair competition among member states in the field of industry and scientific research.

Moreover, the application of this Directive showed that many of its solutions were governed by political rather than regulatory requirements; they proved to be outdated and obsolete as they did not keep up with the contemporary trends in experimental procedures on animals; nor did they correspond to the ongoing changes related to animal welfare considering the fact that the EC Treaty<sup>42</sup> includes the Protocol on the Animal Protection and Welfare in transport, internal market and scientific research policy.

For all these reasons, upon the proposal of the European Parliament, the European Commission embarked on revising the existing Directive. Consequently, at the end of 2008, the European Commission adopted the Proposal revising the Directive 86/609/EEC, which was to be approved by the European Parliament and the Council of Europe.

As compared to the original Directive 86/609/EEC, the legal solutions contained in the Proposal for a Directive on the Protection of Animals used for Scientific Purposes (2008) were intended to significantly improve the treatment of animals used in experi-

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<sup>37</sup> See Articles 10, 15 and 22 (para. 1) of the Council Directive 86/609/EEC.

<sup>38</sup> See Articles 4 (para. 4), 22 (para. 3) and 26 of the Council Directive 86/609/EEC

<sup>39</sup> As a result, the European Commission established the European Centre for the Validation of Alternative Methods (ECVAM) in 1991.

<sup>40</sup> See Articles 24 of the Council Directive 86/609/EEC

<sup>41</sup> The integral text of the Proposal for a Directive on the Protection of Animals used for Scientific Purposes (SEC (2008)2410) (SEC (2008) 2411) may be found at the website

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52008PC=543:EN:NOT>

<sup>42</sup> Official Journal C 340, 10. 11. 1997, p.110.



ments, promote the quality of research in the European Union, and secure high healthcare standards for the protection of both people and animals, and their immediate living environment.<sup>43</sup>

In order to strengthen the existing EU regulation on the protection of experimental animals, the Proposal introduced the concept of three Rs<sup>44</sup> (replacement, reduction and refinement)<sup>45</sup> in the treatment of experimental animals. The first R implies the replacement of animal-using methods with some alternative methods that do not involve the use of live sentient animals. The second R stands for the reduction of a number of animals to be used in experiments to a minimum which would not jeopardize the quality of research results. The third R implies the refinement of the experimental procedure, *i.e.* the application of such methods which would eliminate or produce minimum pain, suffering, distress or lasting harm to animals, and improve the treatment and the living conditions for experimental animals.

As compared to the original Directive 86/609/EEC, under this Proposal each member state was obliged to institute an ethical assessment of the experimental procedures involving animals on its territory, which was to be performed by competent experts<sup>46</sup>, and to have each research project involving animals officially approved.<sup>47 48</sup>

Furthermore, the Proposal expanded the range of the animal species which might be used in experiments, including invertebrates as well as embryos in the last trimester of their development.<sup>49</sup> The Proposal also expanded the scale of goals for running experiments on animals, now including the basic scientific research, education and training, as well as forensic inquiry.<sup>50</sup>

In principle, the Proposal prohibited the use of big apes (chimpanzees, gorillas and orangutans) in experiments, except for the cases when such experiments are necessary for the preservation of the species, or when there is an absolute need for such an experiment, for example, in case of serious pandemics which affect the entire human population in Europe.<sup>51</sup>

Unlike the Directive 86/609/EEC, relying on the Recommendation 2007/526/EC<sup>52</sup> this Proposal firmly established the minimum requirements on the accommodation and

<sup>43</sup> For more details, see: Explanatory Memorandum annexed to the Proposal of a Directive for the Protection of Animals used for Scientific Purposes, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?>

<sup>44</sup> This rule was established in 1959 by the British scientists Russell and Burch in order to explain the essence of alternative methods as compared to *in vivo* experiments. Today, this principle is widely recognized in science and international industry in case of using animals in experimental procedures. For more details, see Explanatory Memorandum annexed to the Proposal of the Directive for the Protection of Animals used for Scientific Purposes, at the website <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?>

<sup>45</sup> See Article 4 of the Proposal for a Directive on the Protection of Animals used for Scientific Purposes (2008)

<sup>46</sup> See Article 37 of the Proposal

<sup>47</sup> See Article 32 of the Proposal

<sup>48</sup> In the Directive 86/609/EEC, such option was given to the EU member states. See Article 24 of Directive.

<sup>49</sup> See Article 2, paragraph 2 of the Proposal

<sup>50</sup> See Article 15 of the Proposal

<sup>51</sup> See Article 8 in conjunction with Article 50 of the Proposal

<sup>52</sup> Commission Recommendation of 18 June 2007 on guidelines for the accommodation and care of animals used for experimental and other scientific purposes 2007/526/EC (notified under document number C (2007)2525).

care of experimental animals, and provided more substantial measures for the protection of experimental animals and their well-being.<sup>53</sup>

As compared to the Directive 86/609/EEC, the Proposal for a Directive on the Protection of Animals used for Scientific Purposes has envisaged that the EU member states are obliged to prescribe penalties for the violation of the national provisions adopted in compliance with this legal document and to ensure their actual application in practice.<sup>54</sup>

**c) Directive 2003/65/EC**<sup>55</sup>

The Directive 2003/65/EC amended and supplemented the previous Directive 86/609/EEC by introducing the so called comitology procedure.<sup>56</sup> This legal document has actually ensured that the Annexes to the Directive would be more expediently kept up to date and that they would be in line with the latest scientific developments and achievements.

**d) Decision 1999/575/EC**<sup>57</sup>

By this Decision of the Council of Europe, the European Community was included as one of the signatories of the European Convention on the Protection of Vertebrate Animals used in Experimental and other Scientific Purposes. The Convention was approved subject to reservations related to the application of Article 28 (1) of the Convention.

**e) Decision 2003/584/EC**<sup>58</sup>

By this Decision of the Council of Europe, the European Community approved the Protocol amending the European Convention on the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes.

**f) Recommendation 2007/526/EC**

By the Recommendation 2007/526/EC, the European Commission introduced into the EC legislation the guidelines for the accommodation and care of experimental animals, which was actually the revised version of Appendix A of the European Convention on the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes.<sup>59</sup>

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<sup>53</sup> See Article 32 of the Proposal and Annex no.4 to this Proposal

<sup>54</sup> See Article 55 of the Proposal

<sup>55</sup> 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, published in the Official Journal L 16. 09. 2003, p. 32-33.

<sup>56</sup> The term "*comitology*" implies a set of procedures by which the committees assist the European Commission in applying the EU legislation at the Community level. For more on this issue, see the website [http://europa.eu/scadplus/glossary/comitology\\_en.htm](http://europa.eu/scadplus/glossary/comitology_en.htm).

<sup>57</sup> Council Decision of 23 March 1998 concerning the conclusion of the European Convention for the Protection of Vertebrate Animals use for Experimental and other Scientific Purposes (1999/575/EC), published in the Official Journal L 222, 24. 08. 1999, p. 29-30.

<sup>58</sup> Council Decision of 22 July 2003 concerning the conclusion of the Protocol of Amendment to the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (2003/584/EC), published in the Official Journal L 198, 06. 08. 2003, p. 10-12.

<sup>59</sup> This set of measures on the accommodation and care of experimental animals was changed in 2006 during

## 4. THE EU REGULATION INDIRECTLY RELATED TO EXPERIMENTAL ANIMALS

**a) Regulation (EC) 1907/2006**<sup>60</sup>

On the grounds of the action plan adopted at the World Summit on Sustainable Development held in Johannesburg on 4<sup>th</sup> September 2002, the European Union has been given a task which was to be completed by the year 2020; namely, the EU is required "to improve the substances" in chemical products manufactured and used in its territory, which is to significantly minimize their adverse effects on human health and environment.

In order to attain this goal, the EU has set out on a large project of reviewing more than 40 regulations and directives containing some legal provisions on the use of chemicals and, eventually, to consolidate all these provisions in a single legal document which would provide equal rules for the so-called "existing" and "new" chemical.<sup>61</sup>

In 2006, the European Parliament and the Council of Europe adopted the Regulation 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals produced and used in the EU territory, with an aim to minimize their negative impact on human health and environment.

In order to accomplish the objectives set forth in this legal document,<sup>62</sup> it is important to examine and evaluate a huge number of chemicals (about 3,000 in total) as we unfortunately do not have sufficient information on the adverse effects of their application on human health and environment.<sup>63</sup>

Although the Regulation persists on avoiding experiments on live animals (asserting that tests involving vertebrates shall be performed only as the last resort and for the purposes specified in the Regulation) and encourages the application of necessary measures to prevent duplication of experiments,<sup>64</sup> the prospects of animal protection are still uncertain. Considering that there are few alternative methods to be used in testing chemicals, it implies that plenty of animals will be used for testing certain chemicals in the forthcoming years.<sup>65</sup>

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the Fourth Multilateral Consultation of the signatories to the Convention. For more information, see the preamble of the Proposal for a Directive for the Protection of Animal used for Scientific Purposes, at the website <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52008PC=543:EN:NOT>

<sup>60</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; published in the Official Journal L 396, 30. 12. 2006, pp. 1-849.

<sup>61</sup> The so-called "existing" chemicals include more than 100,000 substances produced in chemical industry until the year 1981. The chemical substances that appeared on the market thereafter fall into the category of the so-called "new" chemical substances.

Source: [http://www.ec.europa.eu/environment/chemicals/reach/reach\\_intro.html](http://www.ec.europa.eu/environment/chemicals/reach/reach_intro.html).

<sup>62</sup> See Article 1 of the Regulation (EC) No 1907/2006

<sup>63</sup> Unlike the "new" chemicals which are subject to comprehensive testing prior to being placed on the market, the "existing" chemical substances did not have to comply with that requirement. For more information, see the website [http://www.ec.europa.eu/environment/chemicals/reach/reach\\_intro.html](http://www.ec.europa.eu/environment/chemicals/reach/reach_intro.html).

<sup>64</sup> See Article 25 of the Regulation (EC) No 1907/2006

<sup>65</sup> Christian Sailer, the Chief Prosecutor of the International Court for Animal Rights in Geneva believes that 50,000 animals will be used and poisoned for these purposes, including a total of 20,000 to 30,000 dogs. Source: „Слобода за животиње“, бр. 2-3/2008, Београд, стр. 15. (Freedom for Animals, no. 2-3/2008, Belgrade, p. 15)

### b) Directive 76/768/EEC <sup>66</sup>

The Directive 76/768/EEC, generally known as the Cosmetics Directive, primarily regulates the issues pertaining to the approximation and harmonization of national legislations of the member states on cosmetic products. However, this Directive is also important because it, as well as its subsequent amendments contained in the Directive 2003/15/EC, includes the provisions that prohibit:

1) selling cosmetic products whose final formula, in order to meet the strict requirements of this Directive, has been subject to animal testing even though the given experimental objective could be achieved by using some other alternative methods, validated and adopted at the Community level;

2) selling cosmetic products containing substances or combination of substances which, in order to meet the strict requirements of the this Directive, have been subject to animal testing even though the same objective could be achieved by using some alternative methods, validated and adopted at the Community level;<sup>67</sup>

3) animal testing of finished cosmetic products on the territory of any member state, performed in order to check their quality and meet the requirements of the Directive;

4) animal testing of substances or combinations of substances of a cosmetic product on the EU territory, performed in order to meet the requirements of the Directive.

The EU member states have been given the ultimate deadline for the implementation of these provisions, which shall be limited to six years from the date when the Directive 2003/15/EC enters into force, the ultimate deadline being the end of 2009.

Unfortunately, there are no alternative methods available for the tests involving the toxicity of substances.<sup>68</sup> For these test, the period for the implementation of the legal provisions given in items 1 and 2 above has been limited to a maximum of 10 years from the date when the Directive 2003/15/EC enters into force, the ultimate deadline being the year 2013.<sup>69</sup> However, given the strict requirements in this Directive, the ten-year period is most likely to be extended.<sup>70</sup>

Whether and to what extent shall the letter of this Directive be observed remains to be seen. France is the first country that has already taken the first steps to challenge its application. In order to protect its largest cosmetics company *L'Oreal*, France referred to the European Court of Justice in Luxembourg asking the Court to repeal these strict legal provisions. This part of the Directive has also been contested by the European Cosmetics Federation, composed of more than 70 cosmetic companies from Switzerland, Belgium, France, Germany and Italy.<sup>71</sup>

<sup>66</sup> Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (76/768/EEC), published in the Official Journal L 262, 27. 09. 1976, p.169. For the needs of this paper, the author used the consolidated version of this Directive, which includes all the consolidated changes, amendments and supplements.

<sup>67</sup> These two prohibitions have actually been introduced into the text of the Cosmetics Convention for the purpose of preventing the sale of cosmetics which has been tested in the non-EU member states. For more information, see the website [http://www.navs.org.uk/about\\_vivisection\\_27/43/1138/](http://www.navs.org.uk/about_vivisection_27/43/1138/) of 13. 02. 2009

<sup>68</sup> These tests include repeated-dose toxicity, reproductive toxicity and toxicokinetics

<sup>69</sup> See Article 4 a, para. 2 and 2.1 of the Cosmetics Directive

<sup>70</sup> See Article 4 a, para. 2,4 of the Cosmetics Directive

<sup>71</sup> For more information, see A. Osborn & A. Gentleman, Secret French move to block animal-testing ban, *na cajry* <http://www.guardian.co.uk/animalrights/story/0,11917,1021527,00.html>.

## 5. THE NATIONAL LEGISLATION ON THE PROTECTION OF EXPERIMENTAL ANIMALS

In the Republic of Serbia, the legal protection of animals and particularly experimental animals has not developed much as compared to the previous decade. Serbia has not signed and ratified the Convention on the Protection of Vertebrate Animals, nor its accompanying Protocol.

The Environment Protection Act,<sup>72</sup> which primarily deals with the protection, use and trade issues related to the wild flora and fauna,<sup>73</sup> does not contain any legal provisions on the protection of experimental animals.

The Veterinary Practices Act<sup>74</sup> generally refers to the welfare of experimental animals in only one of its provisions, stating that in experimental procedures "animals shall not be subject to ill-treatment and suffering."<sup>75</sup> However, this Act does not envisage any penalties for all the persons involved in the experimental procedures who may act otherwise.<sup>76</sup>

The Proposal for the Animal Welfare Act is currently in the Parliament procedure, pending its adoption. It will be the first act in these territories that will explicitly contain the legal solutions on the protection of experimental animals,<sup>77</sup> which are mostly in compliance with the legal provisions contained in the European Convention on the Protection of Vertebrate Animals used in Experimental and other Scientific Purposes as well as with the EU regulation on this issue.

## CONCLUSION

There is no doubt that the European Union has made a huge qualitative step forward in the protection of animals used for experimental purposes, which is made obvious in a number of legal documents which have already been adopted or are about to be adopted on this issue. The new course is most prominently substantiated in the Council Directive 76/768/EEC, generally known as the Cosmetics Directive, and the Proposal for revising the EU Directive 86/609/EC on the protection of animals used for experimental and other scientific purposes.

In spite of the proven validity of diverse alternative methods which may substitute for the use of animals in experimental testing, considering the current scientific developments it is rather certain that animals are not likely to be fully exempt from experimental testing in a recent future.<sup>78</sup>

<sup>72</sup> The Serbian Environment Protection Act, "Službeni glasnik RS", 6p. 135/2004 (the Official Journal of RS)

<sup>73</sup> See Articles 27 and 28 of the Serbian Environment Protection Act

<sup>74</sup> "Službeni glasnik RS", 6p. 91/2005. (the Official Journal of RS)

<sup>75</sup> See Article 138, para. 5 of the Veterinary Practices Act

<sup>76</sup> The Animal Healthcare Act (Official Journal RS", no. 37/1991, 50/1992, 33/1993, 52/1993, 53/1995, 52/1996 и 25/2000) served as the grounds for adopting the Book of Rules on the measures for the protection of animals from torture in the procedures involving animal healthcare, experiments on animals and other procedures, as well as the methods for a humane killing of animals (Official Journal of RS, no 44/1994). This Book of Rules (as well as the Act it was based on) ceased to be valid on the date when the Veterinary Practices Act entered into force. However, Article 138 of the Veterinary Practices Act does not authorize the competent Ministry to more specifically regulate the issue of experimental procedures on animals.

<sup>77</sup> See Articles 35 - 54 of the Proposal for the Animal Welfare Act

<sup>78</sup> For more details, see A. P. Worth, M. Balls (ed.), *Alternative (non-animal) Methods for Chemicals Testing*:

In order to enter the European Integration process, the Republic of Serbia has to sign and ratify a number of related documents, such as the European Convention on the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes, the Protocol amending this Convention, as well as all the other EU regulations on the protection of experimental animals adopted by the competent EU authorities.

In the meantime, the Serbian consumers must be duly informed about the nature of each product placed on the market, not only through the Internet and media but also through product labelling. The label should inform the consumers that the product has (not) been tested on animals and enable them to make an informed decision on whether to purchase such a product or not. Given the fact that companies are primarily driven by profit,<sup>79</sup> consumers may thus exert some influence on the business policies of the companies using experimental animals in testing their product.

## **PРАВНА ЗАШТИТА ŽIVOTINJA KOJE SE KORISTE U EKSPERIMENTIMA U EVROPSKOJ UNIJI I REPUBLICI SRBIJI**

**Nataša Stojanović**

*Čovek, i pored dostignuća savremene tehnologije, danas masovno koristi žive životinje u različitim eksperimentima. Ne upuštajući se u to, koliko ti eksperimenti mogu biti okrutni za životinje i beskorisni za čoveka, a koliko, pak, mogu predstavljati prepreku na putu otkrivanja naučnih istina, autor svoju pažnju usmerava na pravni aspekt zaštite oglednih životinja u pravu Evropske unije i srpskom pravu. U radu su predložene mere, kojima bi se eksperimentalne životinje, na teritoriji Republike Srbije, uzele u zaštitu, dok se ne usaglasi domaća legislativa sa evropskim zakonodavstvom.*

Ključne reči: *ogledne životinje, pravo Evropske unije, pravo Republike Srbije.*

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Current status and Future Prospects – A report prepared by ECVAM and the ECVAM Working Group on Chemicals. ATLA 30, Supplement 1, July 2002; and CSTEE Opinion of 8 January 2004 (Opinion on the BUAV-ECEAE report on "The way forward – action to end animal testing"), cited in Explanatory memorandum accompanying the Proposal for a Directive on the Protection of Animals used for Scientific Purposes, at the website <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52008PC=543:EN:NOT>

<sup>79</sup> Products such as Ajax, Ariel, Calgon, Domestos, Glade, Fairy, Lenor, Oust, Pantene, Persil, Palmolive, Rexona, Signal, Tide, Vanish and cosmetic lines such as Max Factor, Garnier, Maybelline, Lancôme, Oil of Olaz, ROC have all "successfully passed" tests on animals. For the lists of companies which do (not) test their products on animals, see the websites: <http://www.caringconsumer.com/pdfs/companiesDoTest.pdf>; <http://www.well.org.rs/testzivotinje.htm>; <http://www.prijatelji-zivotinja.hr/index.hr.php?id=81>.