LAW AND THE USE OF LIVING BIOLOGICAL TISSUES FOR RESEARCH AND EXPERIMENTAL PURPOSES

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Abstract: *This paper focuses on the legal issues related to creation of hybrid robots that utilize living neural tissues and embed them into robotic devices. Its aim is to identify possibilities and limitations of creating these semi-living robots with regard to the legal regulation of use of living biological tissues for research and experimental purposes. The paper analyzes the international law, the EU law and the Czech law. It concludes that the Czech law does not provide clear conditions for using animal neural tissues for creating a hybrid robot.*

Keywords: *animal, biological tissue, human, hybrot, law, neurorobotics, neural tissue, research*

INTRODUCTION

Scientists have been using living biological tissues for a number of various research and experimental purposes. The most profound use is probably for the purposes of medical research. However, there are scientific fields that use living biological tissues in completely novel ways and, thus, also give rise to new societal and legal questions. A great example is the field of neurorobotics. Neurorobotics can be defined as "the science and technology of embodied autonomous neural systems".[1] Some of these neural systems are based on "actual biological systems (e.g. in vivo and in vitro neural nets)" and can be embodied in various machines.[2] Neural systems in vivo connect a brain of a living being with help of a brain-computer interface with a certain device or a robot that is consequently controlled by the brain activity of this being resulting in a brain controlled robot. Neural systems with in vitro neural nets connect a living neural tissue extracted from an animal or potentially a human with a computer chip and are often called hybrots. These systems represent a completely new type of existence. There are many legal questions related to their existence, including questions of their status, design and operation. Although the law does not presume existence of such entities yet, it regulates use of living biological tissues and experiments on animals as well as humans. The aim of this paper is thus to identify possibilities and limitations of creation of hybrots with regard to the legal regulation of use of living biological tissues for research and experimental purposes.

1. LEGAL REGULATION OF RESEARCH ON ANIMAL TISSUES

Research on animals is regulated on the levels of international law, European Union's law and the Czech law. This regulation primarily aims to protect animals from unnecessary

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[1] KAPLAN, F. Neurorobotics: An Experimental Science of Embodiment. *Frontiers in Neuroscience*. 2008, Vol. 2, No. 1, [2019-11-18]. Available at: <https://europepmc.org/articles/pmc2570082>.

[2] Ibid.

suffering and promotes humane approach to treating animals. In order to use living animal tissues, namely neural tissues for the purposes of neurorobotics, mice or rats are firstly anesthetized and later euthanized. After that their brains are removed and neural cells are isolated and cultured in vitro. Thus, most of the research takes place after the death of an animal.

With regard to the international law, there are efforts to come up with an alternative to the Universal Declaration of Human Rights in the form of the Universal Declaration on Animal Welfare[3] which is supported also by the EU.[4] A number of international conventions for protection of animals was adopted by the Council of Europe. The use of animals for experimental purposes is regulated by the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes.[5] This convention defines a term procedure that refers to an experimental or other scientific use of an animal. However, so called humane methods of killing are not considered to be included under this term.[6] Article 11 of the Convention outlines criteria for deciding whether an animal should be killed after the end of a procedure. The Convention does not focus on in vitro research at all.

With regard to use of animals for scientific purposes, in 2010 the European Union introduced the Directive 2010/63/EU on the protection of animals used for scientific purposes.[7] This directive established a number of protective measures for use of animals for scientific and educational purposes and repealed an older directive.[8] The new Directive specifies that it sets out rules for treating animals for the period of their life until their death.[9] However, the Directive also declares some rules regarding killing animals. First of all, an animal should "be killed only by a competent person using a method that is appropriate to the species."[10] Next, the Directive recognizes use of animal tissues for the in vitro research. Therefore, with regard to the principle of reduction of animals in research, the Directive appeals to the Member States to "facilitate the establishment of programmes for

[3] Universal Declaration on Animal Welfare. In: *Wikipedia* [online]. 3. 11. 2019 [2019-11-18]. Available at: <https://en.wikipedia.org/wiki/Universal_Declaration_on_Animal_Welfare>.

[4] COUNCIL OF THE EUROPEAN UNION. Council conclusions on a Universal Declaration on Animal Welfare. In: *Public register of Council documents* [online]. 13. 2. 2009 [2019-11-18]. Available at: <https://register.consilium.europa.eu/doc/srv?l=EN&f=ST%206430%202009%20ADD%201>.

[5] European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes. In: *Council of Europe* [online]. 18. 3. 1986 [2019-11-18]. Available at: < https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007a67b>.

[6] Art. 1, par. 2, letters c and j of the Convention.

[7] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance). This Directive was amended by the Regulation (EU) 2019/1010 of the European Parliament and of the Council of 5 June 2019 on the alignment of reporting obligations in the field of legislation related to the environment, and amending Regulations (EC) No 166/2006 and (EU) No 995/2010 of the European Parliament and of the Council, Directives 2002/49/EC, 2004/35/EC, 2007/2/EC, 2009/147/EC and 2010/63/EU of the European Parliament and of the Council, Council Regulations (EC) No 338/97 and (EC) No 2173/2005, and Council Directive 86/278/EEC (Text with EEA relevance).

[8] Council Directive 86/609/EEC 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.

[9] Art. 1, par. 2 of the Directive 2010/63/EU.

[10] Recital 15 and Art. 6 and 23, par. 2, letter (d) of the Directive 2010/63/EU.

sharing the organs and tissue of animals that are killed."[11] The Directive also stipulates that "the killing of animals solely for the use of their organs or tissues" cannot be considered a 'procedure' within the meaning of the Directive.[12] Article 6 of the Directive sets out rules for killing animals and refers to Annex IV., in which the appropriate methods are set out. Killing of an animal is foreseen for situations when after a procedure an animal "is likely to remain in moderate or severe pain, suffering, distress or lasting harm."[13] Number of killed animals must be recorded.[14] The Directive itself does not exclude killing animals solely for the use of their organs and tissues but promotes the principle of reduction.

Isolation of neural tissues from animals is in the Czech law regulated by the Act on the Protection of Animals Against Maltreatment.[15] This Act implements a number of EU directives, including the Directive 2010/63/EU. Among others, the Act defines the terms 'an experimental animal', 'killing' and 'an experiment'. In line with the above mentioned European Convention and the Directive 2010/63/EU, the Czech Act does not consider killing an animal only for the purposes of using its organs or tissues as an experiment.[16] As opposed to these documents, the Czech Act, however, states that an animal cannot be killed without a reason. An exhaustive list of possible reasons for killing an animal is provided in § 5, par. 2 of the Act. With regard to extracting neural tissues from animals, two of the reasons are relevant – "the use of animal products bred or kept for the production of food, wool, leather or other products", or "termination of an experiment on an experimental animal, unless otherwise specified in the experimental design". It is questionable though whether the first mentioned reason applies. The former regulation that was later implemented into § 5 of the Act formulated this reason as "the slaughter or killing of a livestock to use its products".[17] Unfortunately, the explanatory report to the act that amended the Act on the Protection of Animals Against Maltreatment does not provide any explanation for this change of formulation. Animals bread or kept only for production of neural tissues do not, however, fall under the definition of an experimental animal under the Czech law. Isolation of neural tissues from animals would be considered an experiment in case when such isolation would be performed on a living animal. This, however, contradicts the minimization of suffering of such animals. It is then questionable under which regime would be the neural tissues isolated. If it would be done in the regime of "the use of animal products", then the scientist would not have to request approval of an experimental design under § 16 et seq. of the Act which might be considered a lacuna in law as it is currently unclear whether a living neural tissue embedded in a computer chip and stimulated by electric signals can experience pain and suffering.

Probably the most reasonable approach would be to use neural tissues from animals that were used for an experiment and later killed. However, this might not be suitable for

[11] Recital 27 and Art. 18 of the Directive 2010/63/EU.
[12] Art. 3, par. 1 of the Directive 2010/63/EU.
[13] Art. 17, par. 2 of the Directive 2010/63/EU.
[14] Art. 30, par. 1, letter (f) of the Directive 2010/63/EU.
[15] Act No. 246/1992 Coll., on the Protection of Animals Against Maltreatment.
[16] See § 3, letter t) of the Act No. 246/1992 Coll., on the Protection of Animals Against Maltreatment.
[17] Ordinance of the Ministry of Agriculture No. 119/1993 Coll., laying down the reasons for the killing of the animal.

certain projects of creating hybrots, in which neural tissues should not be affected by any stress prior to their isolation.

2. LEGAL REGULATION OF RESEARCH ON HUMAN TISSUES

Apart from using animal neural tissues, at least in some experiments hybrots are presumed to be controlled by human neurons in the future as well.[18] The use of parts of the human body is regulated at the level of international treaties, European law and national law.

The main international document regulating experiments on humans and use of their body parts is the Council of Europe's Convention on Human Rights and Biomedicine.[19] The conditions of scientific research performed on humans are set out in Articles 15 – 18. Research in vitro is mentioned only in relationship to embryos in Art. 18. Removal of organs and tissues is mentioned only with regard to transplantation purposes (Art. 19 – 20). However, these provisions are not relevant for the construction of hybrots as embryos are not used and utilization for merging a neural tissue with a computer chip cannot be considered transplantation as its purpose is not to save another human being.

The European Union adopted several documents that regulate use of human cells and tissues.[20] All of these directives have been implemented into the Czech law.[21] Utilization of human tissues and cells for the purpose of creating a hybrot can be done in several regimes. Tissue and cell collection according to Transplantation Act[22] can only be performed for subsequent transplantation in the recipient. However, hybrots cannot be considered recipients. Any material collected under this act needs to be stored in a tissue bank. On the other hand, the Act on quality and safety of human tissues and cells permits procurement of human cells and tissues for use in products made from human tissues and cells while these products are again presumed to be used in humans. Moreover, the Act permits the procurement of human cells and tissues for use in products covered by

[18] MARKS, P. Robot to be controlled by human brain cells. In: *NewScientist* [online]. 9. 9. 2009 [2019-11-18]. Available at: <https://www.newscientist.com/article/dn17761-robot-to-be-controlled-by-human-brain-cells/>.

[19] Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. In: *Council of Europe* [online]. 4. 4. 1997 [2019-11-18]. Available at: < https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164>.

[20] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (Text with EEA relevance), Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (Text with EEA relevance), and Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.

[21] Act No. 296/2008 Coll., on quality and safety of human tissues and cells intended for human use and on amendments to related acts.

[22] Act No. 285/2002 Coll., on donation, procurement and transplantation of tissues and organs and on amendments to certain acts (Transplantation Act).

other legislation. The problem here is that hybrots are not covered by other legislation. By analogy, provisions of this act, namely conditions set out in §§ 16 – 20a will apply.

The legislation in force permits procurement of human tissue for the purpose of creating a hybrot on the condition that a research project is approved by a respective authority. Special rules apply to stem cells. In special cases of provision of medical services as a part of a neuropsychiatric procedure, neural tissues can be collected directly from the human brain as well.

CONCLUSION

The Czech law allows use of living biological tissues, namely neural tissues for the purposes of constructing hybrots. Both animal and human cells and tissues can be used. Utilization of human neural tissues and cells is in general conditioned by an approval of a research project. The use of animal neural tissues and cells is, however, not so clear. The Czech law allows killing of an animal for the purpose of using products of such an animal. However, in such case scientists do not need to request approval of an experimental design. This might be considered problematic with regard to the principle of minimization of suffering as it is currently unclear whether a living neural tissue embedded in a computer chip and stimulated by electric signals can experience pain.