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THE CONCEPT OF HUMAN ORGANS AND TISSUES WITH REFERENCE TO TRANSPLANTATION: LESSONS FROM INTERNATIONAL LAW

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The definition of the term “human organs and tissues” is considered with reference to the transplantation of organs and tissues. We review the doctrinal approaches, provisions of international legal acts, international instruments, and national legal frameworks related to the transplantation of human organs and tissues. We conclude by proposing a definition of the terms “human organ” and “human tissue” with emphasis on the substantive aspects inherent in them.

Keywords: human organ; human tissue; transplantation; Oviedo convention; World Health Organisation; Council of Europe; European Union; Commonwealth of Independent States; Eurasian Economic Union.

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ПОНЯТИЕ «ОРГАНЫ И ТКАНИ ЧЕЛОВЕКА» В СФЕРЕ ТРАНСПЛАНТАЦИИ: МЕЖДУНАРОДНО–ПРАВОВОЙ АСПЕКТ

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Рассматривается термин «органы и ткани человека» в сфере трансплантации. Анализируются доктринальные подходы, положения международно-правовых актов, актов международных организаций, национальное законодательство государств, регламентирующих вопросы, связанные с трансплантацией органов и тканей человека. В заключении предлагается определение терминов «орган человека», «ткань человека», выделяются характерные признаки, присущие данным терминам.

Ключевые слова: орган человека; ткани человека; трансплантация; Конвенция Овьедо; Всемирная организация здравоохранения; Совет Европы; Европейский союз; Содружество Независимых Государств; Евразийский экономический союз.

Introduction

There is growing awareness in society about human organ and tissue transplantation and its potential for saving lives. However, there is also no uniform legal instrument governing the transplantation of human organs and tissues.

“Globally, 139,024 organ and tissue transplants were carried out in 2017 which represents only 10 % of the need for transplants”¹. Multiple non-profit international organisations facilitate the allocation and cross-border exchange of organs and tissues: Eurotransplant, Scandiatransplant, the South Alliance for Transplants, Balttransplant and Facilitating Exchange of Organs Donated in European Union Member States (FOEDUS) among others. Belarus has collaborated with FOEDUS since 2017².

In 2021 6,398 organs were transplanted through Eurotransplant³. Around 21.4 % of these organs were exchanged cross-border, as compared to 21.3 % in 2019⁴. The South Alliance for Transplants was responsible for more than half of all organ donors and nearly a half of all recipients of transplants in the European Union⁵. Each year, around 7,000 kidney transplant procedures (10 % of the total) were performed in transplant tourists⁶.

A uniform definition of the term “human organs and tissues” as objects of cross-border exchange could facilitate international cooperation in transplantation. The absence of uniform terminology and definitions could facilitate the trafficking of organs or tissues and illegal transplantation thereof. The lack of a uniform concept of human tissue or organ, or where their definitions are too narrow (e. g. an organ is equated to a kidney, and not other human organs) can create openings for shadow transplantation because the object of transplantation is not clearly defined in law. At present, the practice of cross-border organ exchange supersedes the legal regulation of these terms.

The objects of transplantation are human organs and human tissues. National legal frameworks establish lists⁷ of human organs and tissues that may constitute objects of transplantation. However, national legal frameworks do not necessarily use legal definitions of the terms. Multiple interpretations call for deeper analysis. Current research covers the following relevant topics: status of donors and transplant recipients [1], transplantation of human organs and tissues [2; 3], human rights

¹Status of human organ and tissue donation and transplantation in the WHO African region [Electronic resource]. URL: <https://www.afro.who.int/sites/default/files/2021-02/AFR-RC70-12%20Status%20of%20human%20organ%20and%20tissue%20donation%20and%20transplantation.pdf> (date of access: 02.02.2022).

²Беларусь в топе-50 по количеству трансплантаций [Электронный ресурс]. URL: <http://minzdrav.gov.by/ru/sobytiya/belarus-v-tope-50-po-kolichestvu-transplantatsiy/> (дата обращения: 02.02.2022).

³Preliminary Eurotransplant annual figures 2021 online [Electronic resource]. URL: <https://www.eurotransplant.org/2022/01/20/preliminary-eurotransplant-annual-figures-2021-online/> (date of access: 02.02.2022).

⁴Ibid.

⁵Organ donation and transplantation. Facts, figures and European Union action [Electronic resource]. URL: [https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/649363/EPRS_BRI\(2020\)649363_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/649363/EPRS_BRI(2020)649363_EN.pdf) (date of access: 02.02.2022).

⁶Flaherty G. T., Nizrull Nasir, Gormley C. M., Suyash Pandey. Transplant tourism and organ trafficking: current practices, controversies and solutions [Electronic resource]. URL: http://www.ijtmgh.com/article_132577_6f0fdaa85cfc4799ece63a1ff8b68c5b.pdf (date of access: 02.02.2022).

⁷Приказ Минздрава России № 306н, РАН № 3 от 04 июня 2015 г. «Об утверждении перечня объектов трансплантации» [Электронный ресурс]. URL: http://www.consultant.ru/document/cons_doc_LAW_181448/2db977b788fafa4516ee74983ed18c0e-c50f102/ (дата обращения: 02.02.2022) ; Постановление Министерства здравоохранения Республики Беларусь от 29 августа 2012 г. № 134 «О некоторых вопросах трансплантации органов и тканей человека» [Электронный ресурс]. URL: http://minzdrav.gov.by/upload/lcfiles/000127_64755_PostMZ_N134_2012.doc?ysclid=kz6md1uy2x (дата обращения: 02.02.2022).

in transplantation⁸ [4–7], ethical problems⁹ [8], legal aspects of organ harvesting [9–12]), trafficking in organs and tissues [13], illegal transplantation [14].

The definition of the concept of human organs and tissues has received little attention in legal scholarship.

Results and discussion

There is a large amount of ambiguity in the treatment of organs and tissues in scholarly literature. E. S. Kayasseh [15, p. 7] defines an organ as a part of the human body or an organism. Other scholars supplement this general definition with further characteristics, e. g. “being formed as a result of a natural biological process” [16, p. 216], “a collection of several tissues fulfilling a common function in a structural unit [of the human body]”¹⁰, “part of an animal or plant organism that has a specific structure and performs specific functions”¹¹ (hereinafter translated by us. – V. K.).

Some scholars define an organ as an object in limited circulation [17, p. 157; 18; 19, p. 84; 20, p. 109]). Others refute this approach [21; 22, p. 216]).

Still, A. G. Bezverkhov defines organs and tissues as “objects in limited civil circulation as provided by the special legislation on transplantation” [23, p. 193]. In general, there is no uniform approach in legal scholarship to the definition of an organ or tissue. For example, E. Bibeyz defines tissue as a “cellular organisational level intermediate between cells and the complete organ”¹². In turn, D. U. Balgimbekov, B. U. Seitkhodzhin, A. S. Koszhanov view human tissue as “an ensemble of similar cells of identical origin that form a unity and perform a specific function”¹³.

Internationally limited attempts have been made to overcome this diversity. Many legal instruments do not define the terms altogether, relying on context and practice. For example, the Guiding principles on human cell, tissue and organ transplantation of World Health Organisation (WHO) of 2010 (hereinafter the “Principles of WHO”), the Declaration of Helsinki of World Medical Association of 1964 (hereinafter – the Declaration of WMA), the Convention for the protection of human rights and dignity of the human being concerning

We review a body of international, regional and national legal instruments and doctrinal sources to identify the essential attributes of human organs and tissues to be covered in a legal definition for the purposes of transplantation.

the application of biology and medicine of Council of Europe of 1997 (hereinafter – the Oviedo convention), the Additional protocol to the Oviedo convention of 2002 (hereinafter – the Additional protocol), the United Nations Convention against transnational organised crime, the Protocol to prevent, suppress and punish trafficking in persons, especially women and children, the Council of Europe Convention on action against trafficking in human beings provide no definitions of these legal concepts.

Some international treaties, documents of international organisations, and national legal frameworks on transplantation define organ as a part of the human body, subject to several qualifications. For example, the Global glossary of terms and definitions on donation and transplantation of WHO¹⁴, art. 3 of the 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 (hereinafter – the Directive of 2004), art. 2 of the Convention against trafficking in human organs of the Council of Europe of 25 March 2015 No. 216 (hereinafter – the Convention No. 216), art. 3 of the 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 (hereinafter – the Directive of 2010) define the human organ as a differentiated and vital, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with an important level of autonomy. Para 28 of the Explanatory report to the Additional protocol provides that a human organ consists “of a structured arrangement of tissues which, if wholly removed,

⁸Жарова М. Этические проблемы трансплантации органов и тканей [Электронный ресурс]. URL: <http://www.relga.ru/Environ/WebObjects/tgu-www.woa/wa/Main?textid=2726&level1=main&level2=articles> (дата обращения: 02.02.2022) ; Коржик А. Этические проблемы трансплантации органов и тканей [Электронный ресурс]. URL: <https://bioethics.belmapo.by/article/ethical-problems-of-transplantation-of-organs-and-tissues> (дата обращения: 02.02.2022).

⁹Ивентьев С. И. Четвертое и пятое поколения прав человека как основа духовного и нравственного возрождения человечества [Электронный ресурс]. URL: <http://econfr.uae.ru/pdf/2013/11/2935.pdf> (дата обращения: 02.02.2022).

¹⁰Balgimbekov D. U., Seitkhodzhin B. U., Koszhanov A. S. Criminal and legal characteristics of forced and/or the unlawful removal of human organs and tissues for transplants under the legislation of the Republic of Kazakhstan [Electronic resource]. URL: <https://articlekz.com/en/article/15738> (date of access: 02.02.2022).

¹¹Толковый словарь Ефремовой [Электронный ресурс]. URL: <https://gufo.me/dict/efremova/%D0%BE%D1%80%D0%B3%D0%B0%D0%BD> (дата обращения: 02.02.2022).

¹²Bibeyz E. Tissue is a cellular organisational level intermediate between cells and a complete organism [Electronic resource]. URL: <https://ru.scribd.com/document/73826397/Tissue-is-a-Cellular-Organizational-Level-Intermediate-Between-Cells-and-a-Complete-Organism> (date of access: 02.02.2022).

¹³Balgimbekov D. U., Seitkhodzhin B. U., Koszhanov A. S. Criminal and legal characteristics...

¹⁴The global glossary of terms and definitions on donation and transplantation of WHO [Electronic resource]. URL: <https://www.who.int/transplantation/activities/GlobalGlossaryonDonationTransplantation.pdf?ua=1> (date of access: 02.02.2022).

cannot be replicated by the body”¹⁵. Art. 1 of the Agreement on cooperation among the member states of the Commonwealth of Independent States in the fight against trafficking in human beings, human organs and tissues of 2005 (hereinafter – the Agreement of the CIS), art. 1 of the Law of the Kyrgyz Republic of 13 January 2000 No. 2 “On transplantation of human organs and (or) tissues” state that a human organ is a collection of tissues formed by evolution, and united by a common function, structural organisation and development¹⁶. The Declaration of Istanbul on organ trafficking and transplant tourism of 2008 defines organ in the context of transplant tourism as a commodity, including by being bought or sold or used for material gain.

Furthermore, definitions of the human organ are also found in national legal frameworks. Some states have no legal definitions of organs (UK¹⁷, Latvia¹⁸, USA¹⁹, Israel²⁰, China²¹, Australia²²).

Some states use the definitions of the Convention No. 216 and the EU directives of 2004 and 2010, as in Spain²³, Finland²⁴, Poland²⁵, Moldova²⁶, and Ukraine²⁷.

In general national legal frameworks on transplantation define organs and tissues as a part of the body or a part of an organism, albeit with certain variations.

In Lithuania²⁸, Germany²⁹, Czech Republic³⁰ human organs are defined as heterogeneous tissues that maintain a structure, blood supply, perform physiological functions.

A different definition is contained in art. 3 of the Swiss federal act on the transplantation of organs, tissues and cells of 8 October 2004 (hereinafter – Swiss federal act): “Any part of the body whose cells and tissues together comprise a unit with a specific function”.

According to art. 1 of the Law of the Republic of Armenia of 11 May 2002 No. 3P-324 “On transplantation of human organs and (or) tissues” a human organ consists of various tissues, one of which is predominant, and maintains a particular shape, and a distinctive structure, occupies by a place in the body and performs vital activity”.

Art. 1 of the Health Code of the Republic of Tajikistan of 30 May 2017 No. 1413 refers to an organ as a part of an organism with a distinct structure and purpose.

Furthermore, the laws on transplantation of Belarus³¹, Turkmenistan³² and Uzbekistan³³ (not in force) define human organs and tissues as anatomical formations that do not determine personality traits.

¹⁵The explanatory report to the additional protocol to the Oviedo convention [Electronic resource]. URL: https://www.ejprarediseases.org/wp-content/uploads/2021/10/Explanatory-Report-to-the-Oviedo-Convention_1997.pdf (date of access: 02.02.2022).

¹⁶Соглашение о сотрудничестве государств – участников Содружества Независимых Государств в борьбе с торговлей людьми, органами и тканями человека [Электронный ресурс]. URL: <http://www.cis.minsk.by/reestr/ru/index.html#reestr/view/text?doc=1901> (дата обращения: 02.02.2022).

¹⁷Human tissue act 2004 [Electronic resource]. URL: http://www.legislation.gov.uk/ukpga/2004/30/pdfs/ukpga_20040030_en.pdf (date of access: 02.02.2022).

¹⁸On the protection of the body of deceased human beings and the use of human tissues and organs in medicine [Electronic resource]. URL: <https://likumi.lv/ta/id/62843-par-mirusa-cilveka-kermenai-aizsardzibu-un-cilveka-audu-un-organu-izmantosanu-medicina> (date of access: 02.02.2022).

¹⁹Anatomical gift act [Electronic resource]. URL: <https://uniformlaws.org/committees/community-home?CommunityKey=015e18ad-4806-4dff-b011-8e1ebc0d1d0f> (date of access: 02.02.2022).

²⁰Israel organ transplant act law [Electronic resource]. URL: <https://sections.tts.org/DOI/Israel%20Transplant%20Law.pdf> (date of access: 02.02.2022).

²¹China human organ transplant act [Electronic resource]. URL: <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020024> (date of access: 02.02.2022).

²²Australian organ and tissue donation and transplantation authority act [Electronic resource]. URL: <https://www.legislation.gov.au/Details/C2017C00206> (date of access: 02.02.2022).

²³Real Decreto 1723/2012, de 28 de diciembre, por el que se regulan las actividades de obtención, utilización clínica y coordinación territorial de los órganos humanos destinados al trasplante y se establecen requisitos de calidad y seguridad [Electronic resource]. URL: <https://www.boe.es/buscar/pdf/2012/BOE-A-2012-15715-consolidado.pdf> (date of access: 02.02.2022).

²⁴Act on the medical use of human organs, tissues and cells [Electronic resource]. URL: <https://www.finlex.fi/en/laki/kaannokset/2001/en20010101.pdf> (date of access: 02.02.2022).

²⁵Act on the collection, storage and transplantation of cells, tissues and organs [Electronic resource]. URL: http://www.poltransplant.pl/Download/transplantation_act.pdf (date of access: 02.02.2022).

²⁶Закон Республики Молдова от 6 марта 2008 г. № 42-XVI «О трансплантации органов, тканей и клеток человека» [Электронный ресурс]. URL: http://base.spininform.ru/show_doc.fwx?rgn=22702 (дата обращения: 02.02.2022).

²⁷Закон України «Про застосування трансплантації анатомічних матеріалів людині» [Електронний ресурс]. URL: http://search.ligazakon.ua/1_doc2.nsf/link1/T182427.html (дата звернення: 02.02.2022).

²⁸Lietuvos Respublikos žmogaus audinių, ląstelių, organų donorystės ir transplantacijos įstatymas 1996 m. lapkričio 19 d. Nr. I-1626 [Electronic resource]. URL: <https://www.e-tar.lt/portal/ru/legalAct/TAR.D00D08A48D5D/ICAzJHUonx> (date of access: 02.02.2022).

²⁹Gesetz über die Spende, Entnahme und Übertragung von Organen und Geweben [Electronic resource]. URL: <https://www.gesetze-im-internet.de/tpg/TPG.pdf> (date of access: 02.02.2022).

³⁰Act on donation, collection and transplantation of tissues and organs and on amendments to certain acts [Electronic resource]. URL: <https://www.zakonyprolidi.cz/cs/2002-285> (date of access: 02.02.2022).

³¹Закон Республики Беларусь от 4 марта 1997 г. № 28-З «О трансплантации органов и тканей человека» [Электронный ресурс]. URL: <https://etalonline.by/document/?regnum=H19700028> (дата обращения: 02.02.2022).

³²Закон Туркменистана от 29 августа 2013 г. № 425-IV «О трансплантации органов и (или) тканей человека» [Электронный ресурс]. URL: http://base.spininform.ru/show_doc.fwx?rgn=62447 (дата обращения: 02.02.2022).

³³Закон Республики Узбекистан «О трансплантации органов, тканей и (или) клеток человека» [Электронный ресурс]. URL: <http://old.regulation.gov.uz/ru/documents/1597> (дата обращения: 02.02.2022).

Conversely, the law on transplantation in Pakistan³⁴ defines an organ as any part of a human body, organ or tissue.

In Indian law³⁵ a human organ is any part of a human body consisting of a structured arrangement of tissues which, if wholly, removed, cannot be replicated by the body.

While the conventional approach is to view an organ as a part of the body, the legal frameworks of some countries (e. g. Lithuania, the Czech Republic, or Moldova) also applies the term to a part of an organ, subject to several conditions. The Convention No. 216 and Directive of 2010, also take the same approach, treating as an organ a part thereof, if it performs the same function as the whole organ in the human body, supports its structural integrity and vascularisation.

The function of a part of an organ must be similar to that of the whole organ and or a part of the body; it must consist of different types of tissue, fulfil a distinct function and otherwise be equivalent to an organ, as laid down in art. 3 of the Swiss federal act.

In summary most states define the following distinctive characteristics of a human organ in their national legal frameworks:

- part of the body or organism, with some degree of separateness or autonomy;
- a complex arrangement of cells;
- a part of the body which is made up of different types of tissue.

In this case the part of the body or the arrangement of cells must have a distinctive structure, function, organisation or development, maintain the structure and vascularisation (blood supply), perform a physiological function with a significant degree of autonomy.

Human tissue is defined along similar lines.

Legal definitions of the term “tissue” are found in the laws of the UK, Latvia, Belarus, Turkmenistan, Uzbekistan, the Czech Republic, India, the USA, Israel, and China.

The Global glossary of terms and definitions on donation and transplantation of WHO and art. 3 of the Directive of 2004 indicate that the human tissue is any constituent part of the human body formed by cells.

National, regional, and international instruments of law also define the human tissue as all constituent parts of the human body.

Nevertheless, these definitions emphasise different aspects of the term.

Art. 3 of the Directive of 2004 and the national laws of transplantation of Finland, Poland stress that human tissue is formed by cells.

The Cabinet of Ministers of the Council of Europe adopted the definition that “includes surgical residues but excluding organs, blood and blood products as well as reproductive tissue, such as sperm, ovum, and embryos. Hair, nails, placentas, and body waste products are excluded”³⁶.

Art.1 of the Agreement of the CIS conceptualises tissue as an arrangement of cells and non-cellular structures united by a common function, structure and (or) origin³⁷.

With reference to transplantation, most countries define tissue differently. For example, art. 2 of the Law of the Republic of Lithuania of donation and transplantation of human tissues, cells, and organs of 19 November 1996 No. I-1626 prescribes that human tissue is a component of the human body that is made up of cells.

Under art. 4 of the Australian law of donation and transplantation, human tissue is “a part of a human body (other than an organ); a part of an organ; or a substance extracted from, or from a part of an organ; any other part of a human body; but does not include a substance or thing specified in the regulations”³⁸.

Similarly, art. 3 of the Federal act of 8 October 2004 on the transplantation of organs, tissues and cells states: “Human tissue is a structured association of cells, consisting of the same or different types of cells, that has a common function in the body”.

In the Law of the Republic of Armenia of 29 August 2013 No. 425-IV “On transplantation of human organs and (or) tissues”, tissue is “a community of formed cells and extracellular material”.

The Law of the Kyrgyz Republic 13 January 2000 No. 2 “On transplantation of human organs and (or) tissues” provides that organs and tissues are systems of cells and non-cellular structures or in the art. 1 of the Health Code of the Republic of Tajikistan of 30 May 2017 No. 1413 tissue is defined as cell compounds and derivatives thereof (intercellular substances).

While the legal framework of Tajikistan also determines that cells must be united by a common origin, it also provides specific examples of tissues – bone

³⁴The Pakistan law of the transplantation of human organs and tissues act 2010 [Electronic resource]. URL: http://punjablaws.gov.pk/laws/2428a.html#_ftn1 (date of access: 02.02.2022).

³⁵The transplantation of human organs and tissues act [Electronic resource]. URL: <https://www.indiacode.nic.in/handle/123456789/1962?locale=en> (date of access: 02.02.2022).

³⁶Texts of the Council of Europe on bioethical matters [Electronic resource]. URL: [https://www.coe.int/t/dg3/healthbioethic/Texts_and_documents/INF_2014_5_vol_I_textes_%20CoE_%20bio%C3%A9thique_E%20\(2\).pdf](https://www.coe.int/t/dg3/healthbioethic/Texts_and_documents/INF_2014_5_vol_I_textes_%20CoE_%20bio%C3%A9thique_E%20(2).pdf) (date of access: 02.02.2022).

³⁷Соглашение о сотрудничестве государств – участников Содружества Независимых Государств в борьбе с торговлей людьми, органами и тканями человека [Электронный ресурс]. URL: <http://www.cis.minsk.by/reestr/ru/index.html#reestr/view/text?doc=1901> (дата обращения: 02.02.2022).

³⁸Australian organ and tissue donation and transplantation authority act 2008 [Electronic resource]. URL: <https://www.legislation.gov.au/Details/C2017C00206> (date of access: 02.02.2022).

marrow, musculoskeletal, vascular, heart valves, skin, and other tissues.

Remarkably, art. 2 of the Law of the Republic of Moldova of 6 March 2008 No. 42-XVI “On transplantation of human organs, tissues and cells” states that tissues are any parts (anatomical formations) of the human body formed from cells. By comparison, the law of Spain treats as tissue any and “each component of the human body, which consists of cells held together by connective tissue of one type or another”³⁹.

Outside the realm of transplantation, human tissue may also be approached as a commodity. The constituent documents of the Eurasian Economic Union have no references to human tissue or organs. However, art. 2 of the Decision of the board of the Eurasian Economic Commission No. 30 “On measures of non-tariff regulation” refers to samples of human biological materials, defined as tissues obtained in the course of biomedical and (or) clinical research.

Organs and tissues are also mentioned in section 2.21 of the uniform list of goods to which non-tariff regulation measures are applied in trade with third countries, adopted by the Protocol on non-tariff regulation measures concerning third countries. Art. 4 of the said document states that the import and (or) export by individuals of samples of human biological materials as goods for personal requires the possession of a permit. Effectively the rules of the Eurasian Economic Union treat organs and tissues as a commodity intended for personal use, and also for biomedical and clinical research.

The import and export of human tissue are regulated by the Directive of 2004, and the exchange of organs is by the Directive of 2010. Both are allowed not only to the EU member states but also to third countries.

The export of tissue is permissible only if performed by accredited, appointed, authorised or licensed tissue institutions for this activity, only with the sanction of the competent authorities according to art. 9 of the Directive of 2004.

The exchange of human organs among the EU member states is permitted only under the supervision of the competent authorities or other authorities involved in the process from donation to transplantation or disposal of organs according to art. 10 of the Directive of 2004.

However the exchange of organs with third countries requires authorisation from the competent authorities, and also from the European organisations for the exchange of organs with valid agreements with partners in third countries (art. 20 of the Directive of 2004).

Overall, the above analysis allows us to conclude that despite the desirability of a uniform approach to the definition of human tissues and organs, the legal definitions of these terms are still far from being uniform across countries and regions.

In the CIS, a regional agreement refers to organs and tissues, but a uniform approach is lacking.

The supranational and national legal frameworks of the EU member states show a higher degree of harmonisation, provided by the Directive of 2010 and Convention No. 216.

The legislative approaches of the countries not covered by the Agreement of the CIS or the Convention No. 216 show a high degree of variation and share just one common attribute, the treatment of the human organ as a part of the human body consisting of tissue. Some national legal frameworks also views parts of an organ as an organ. Generalisations are problematic, as some legal frameworks do not define tissue separately from an organ, while others provide no definitions altogether.

As provided by the Law of the Republic of Moldova of 6 June 2008 No. 42-XVI “On transplantation of human organs, tissues and cells” and the Convention No. 216, a part of an organ may also be treated as an organ.

Even fewer national laws offer definitions of tissues. Of regional instruments, only the CIS agreement and the Directive of 2004 make references to tissues. Most national legal frameworks contain no references or definitions of tissue.

Some national legal frameworks exclude from the notion of organs and tissues those that define the distinctive features of human personality.

The Declaration of Istanbul on organ trafficking and transplant tourism of 2008, EU directives and decision of the board of the Eurasian Economic Commission of 21 April 2015 No. 30 “On measures of non-tariff regulation” define human organs in the context of commodity trade.

Conclusion

The body of the legal instruments against illegal transplantation of organs and tissues consists of international treaties (the United Nations Convention against transnational organised crime, the Protocol to

prevent, suppress and punish trafficking in persons, especially women and children, the Council of Europe Convention on action against trafficking in human beings, the Agreement of CIS, the Convention No. 216,

³⁹Real Decreto 1723/2012, de 28 de diciembre, por el que se regulan las actividades de obtención, utilización clínica y coordinación territorial de los órganos humanos destinados al trasplante y se establecen requisitos de calidad y seguridad [Electronic resource]. URL: <https://www.boe.es/buscar/pdf/2012/BOE-A-2012-15715-consolidado.pdf> (date of access: 02.02.2022).

the Oviedo convention, the Additional protocol), soft law of international organisations (Principles of WHO, acts of Eurasian Economic Union), supranational law (Directives of 2004 and 2010), acts of an advisory nature (the Declaration of WMA, the Declaration of Istanbul on organ trafficking and transplant tourism of 2008), and national acts or codes of transplantation of human organs and tissues.

However, a uniform definition of human organs and tissues is absent. The definitions found in regional treaties (Convention No. 216, Agreement of the CIS) and Directives of 2004 and 2010 provide that a human organ is a part of the human body. The Agreement of CIS defines a human organ as a part of an organism.

The definition of the Convention No. 216 is used in several other EU instruments that are not binding.

With reference to transplantation, organs and tissues are defined as parts of the body or parts of the organism. The definition depends on the obligations applicable to a party under the Convention No. 216 or the Agreement of the CIS.

However, the parties to these instruments may adopt the definitions provided by these instruments, and provide their own definitions or no definition at all.

In the most general sense, organs and tissues are understood as parts of the human body or the human organism. Other common attributes include a distinctive structure, function, and vascularisation.

Some national acts define a human organ as an arrangement of tissues, a commodity or anatomical formations that do not define personality traits.

In some legal frameworks a part of an organ may be treated as an organ, if it performs the same function as the whole organ of the human body, and supports its structural integrity and vascularisation. The relevant provisions are found in the Convention No. 216, Directive of 2010, and the laws of Lithuania, the Czech Republic and Moldova.

Only one international treaty (Agreement of CIS) provides a definition of tissue. There is also a definition of tissue in EU law (Directive of 2004). With reference to transplantation, most legal frameworks define tissue as being formed by cells, an arrangement of cells, use a different approach or provide no definitions at all. All of this makes generalisations problematic.

The variety of legislative approaches prevails despite the provisions of the Convention No. 216, Agreement of the CIS, and the trend toward harmonisation. We believe that a harmonised definition of human tissue and a human organ could encompass the descriptors and attributes singled out in our analysis.

Organs are complex systems of cells, parts of the body or organism that possess structural integrity, vascularisation and performance of bodily functions with a significant level of autonomy and cannot re-grow after removal; they may also be part of an organ if they perform the functions of the whole organ and maintain structure and vascularisation.

Tissues are systems of cells consisting of one or different cell types, or non-cellular compounds connected with intercellular substances and united by a common function, structure and origin.

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