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Legal and regulatory aspects of the genetic materials movement across the customs border

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The functioning of each country's economy involves the export and import of a wide range of goods. To implement state regulation of foreign trade in the field of prohibitions and restrictions, there is a need to streamline goods in some way, which is extremely difficult to do without the existence of a certain structured list. Thus, important administrative levers of state regulation and integral elements of customs policy are measures of non-tariff regulation and the Unified List of Goods created in accordance with them, to which prohibitions and restrictions are applied. [2]

The relevance of the work lies in the fact that the issues of moving organs and tissues of a human, blood and its components have always been and remain one of the most pressing in the field of customs non-tariff regulation. It is a special and specific product that requires the application of a huge number of rules when moving across the customs border of the EAEU. It should also be noted that in the modern world the issue of the movement of human biological materials is increasingly raised at the international and state level, since biomaterials exported to Russia and from Russia can be used to make biological weapons.

In recent years, the transplantation of human organs and tissues has been the object of close attention not only to specialists in the field of medicine, but also to society as a whole. The emergence of a new, largely controversial method of saving the lives of patients could not remain outside the sphere of the legal regulation.

A number of issues in this area are regulated by the Law of the Russian Federation of December 22, 1992 No. 4180-1 "On Transplantation of Human Organs and (or) Tissues". In addition, there are number of bylaws defining the mechanisms for implementing the provisions of the Law, unfortunately, not always exhaustively.

The Federal Law of 20.07.2012 No. 125 "On blood donation and its components" establishes the legal, economic and social bases for the development of blood donation and its components in the Russian Federation in order to organize the procurement, storage, transportation of donor blood and its components, ensuring its safety and clinical use, as well as protecting the health of blood donors and its components, recipients and protecting their rights. [3]

In accordance with the Article 4 of the Law of December 22, 1992 No. 4180-1, the collection and harvesting of human organs and (or) tissues, as well as their transplantation, are carried out in the state and municipal health care institutions. [4]

Taking into account the guidelines of the World Health Organization on the transplantation of human, tissues and organs, as well as in accordance with the aforementioned laws, human organs and tissues cannot be the subject of purchase, sale and other compensated transactions.

It is necessary to pay attention to the fact that samples of human biological materials not intended for medical and diagnostic purposes, including blood transfusion or transplantation, are exported from the customs territory of the Eurasian Economic Union in accordance with the legislation of the Member State in the field of export control.

In the Russian Federation, samples of human biological materials are included in section 4 "Goods and technologies whose export from the territory of the Russian Federation is

controlled for reasons of national security" of the List of dual-use goods and technologies that can be used to create weapons and military equipment in relation to which export control is exercised. [5]

The fact is that licensing for the EAEU countries is regulated mainly by the Instruction on the execution of an application for issuing a license for export and / or import of certain types of goods and the registration of such a license and the Instruction on registration of an export and (or) import of certain types of goods from 06.11.2014, in each Member State of the Union there are departmental acts regulating the issuance of licenses for the importation and (or) export of human organs and tissues, blood and its components. [1]

The main difference is that the regulatory framework at the national level is completely different. In the Russian Federation, as such, there is no Standard for the provision of licensing services for this category of goods, and in Kazakhstan there is the Standard of State services "Issuing a license to import human organs and tissues, blood and its components from the territory of the Republic of Kazakhstan". [6]

As part of the creation of a single market of the Eurasian Economic Union, the system of foreign economic activity associated with the movement of human organs and tissues, blood and its components is a rather complicated process in organizational and legal terms.

Investigation of the problems of human biological materials import and export has shown that these issues acquire a predominant character in the system of biological safety of the Russian citizens and require some solutions in the field of the improvement of legislation.

Источники и литература

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