ECONOMIC CHALLENGES FOR MODERN LEGAL REGULATION

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Legal Framework for the Development of Bioeconomy: Experience of International Integration Associations

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Abstract: The author examines the basics of legal regulation of the development of the newest direction of economic knowledge — bioeconomy, which is understood by modern science as economy based on the application of biotechnologies using renewable biological raw materials. Bioeconomy is closely related to environmental issues, including the implementation of the concept of sustainable development that provides for the functioning of the national economic complex of the State, when simultaneously ensuring: satisfaction of the growing material and spiritual needs of the population; rational and environmentally friendly management and highly efficient use of natural resources; maintaining favorable natural and environmental conditions for human health, preserving, reproducing and enhancing the quality of the environment and the natural resource potential of social production. The purpose of this research is to study the key regulatory documents adopted at the global and regional levels to ensure the progressive development of the bioeconomy, and the features of the implementation of the fundamental provisions of these documents into national law. In conclusion, approaches that can be borrowed into the legal system of the Russian Federation are considered.

***Keywords*:** bioeconomy; sustainable development; legal regulation; global regulation; regional regulation; law of international integration associations; genetic research; biotechnology; legislation; judicial practice

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1. Introduction

Modernity is characterized by maintaining close attention of society and states to the development of biotechnological, microbiological, molecular genetics and other research, which has become priority of economic progress (Mateescu et al., 2011, p. 451). The rapid advancement of these types of research, their integration into global and national economic systems, has given rise to a new term — *bioeconomy*, which currently means an economy based on the application of biotechnologies using renewable biological raw materials.[1] Bioeconomy is closely related to environmental issues, including the implementation of the concept of sustainable development, which provides for the functioning

[1] Bioeconomics and economics of biotechnology. Available at: https://www.econ.msu.ru/science/bioeco/about/bioeco/ [Accessed 22.04.2024].

of the national economic complex of the state, when simultaneously ensuring satisfaction of the growing material and spiritual needs of the population; rational and environmentally friendly management and highly efficient use of natural resources; maintaining natural and ecological living conditions favorable to human health, preserving, reproducing and enhancing the quality of the environment and the natural resource potential of social production (Makedon and Talavyrya, 2017, p. 31). The concept of "bioeconomics" is being actively elaborated in foreign law, including in European research on this issue (Borgström and Mauerhofer, 2016, p. 373).

In Europe and the USA significant funds and subsidies are allocated for the development of the bioeconomy. Thus, in the member states of the European Union in 2010, the volume of innovative bioeconomy exceeded 2 trillion euros, and the forecast level of its development by 2030 will be about 3 % of GDP in developed countries and somewhat more in developing countries (Rassokhina et al., 2019, p. 152). In the Russian Federation there is also a tendency to apply biological knowledge in various spheres of public life (Zhavoronkova and Agafonov, 2019, p. 100).

A key feature of the development of modern world science and production is the "biologization" of knowledge and processes (Bobyleva et al., 2019, p. 120). Nevertheless, this characteristic attributes to the global science at the turn of the 20th–21st centuries. It was at this time that a number of new interdisciplinary directions emerged, to which "bioeconomy" belongs. With a broad approach to the definition of the concept of "bioeconomy", it is considered as "a discipline that integrates economic and biological knowledge in the field of widespread application of biotechnologies to create a qualitatively new economy and achieve sustainable development of the region" (Makarchuk, 2013, p. 196). At the same time, the terms "green economy", "low-carbon economy" and "bioeconomy" are close in meaning, but not synonymous.[2]

The concept of "bioeconomy", despite its popularity, is practically not used in Russian legislation (Boyarov et al., 2021, p. 36). An exception is the Decree of the Government of the Russian Federation of 15 April 2014 No. 328 "On the approval of the state program of

[2] Bioeconomics and economics of biotechnology.

the Russian Federation 'Development of industry and increasing its competitiveness'" [3] (hereinafter referred to as the Program), where Part I of the Program states that the Russian Federation requires the elaboration of a globally competitive sector of bioeconomy, which along with nanoindustry and information technology should become the basis for modernization and building a post-industrial economy. The Program also notes that in order to solve problems in the field of modernization and innovative development, it is planned to implement measures to advance the national innovation system, including the creation of a full-fledged bioeconomy structure in the Russian Federation. Bioeconomy is also mentioned in the Comprehensive Program for the Development of Biotechnology in the Russian Federation for the period until 2020,[4] approved by the Chairman of the Government of the Russian Federation on 24 April 2012 No. 18653p-P8. However, there is no legally defined concept of "bioeconomy" in the Russian Federation. Taking into account the definitions elaborated in the doctrine, this term is given a broad interpretation (Titova et al., 2023, p. 56).

Despite the fragmentary mention of bioeconomy in legal acts, specialized educational programs are being implemented in the Russian Federation. In particular, St. Petersburg Polytechnic University is recruiting for the Master program "Bioeconomy", the purpose of which is to train highly qualified personnel with comprehensive economic, technological, and managerial competencies for the introduction of innovative biotechnologies in various spheres of production and life.[5]

[3] Collection of legislation of the Russian Federation, 05.05.2014, No. 18 (Part IV), Art. 2173.

[4] Kompleksnaya Programma razvitiya biotekhnologiy v Rossiyskoy Federatsii na period do 2020 goda [Comprehensive Program for the Development of Biotechnology in the Russian Federation for the period until 2020] (2012). Available at: https://fbras.ru/wp-content/uploads/2015/03/bio_2020_programme.pdf [Accessed 12.04.2024]. It should be noted that after 2020, the term "bioeconomics" appears in the Decree of the President of the Russian Federation dated 07.05.2024 No. 309 "On the national development goals of the Russian Federation for the period up to 2030 and for the future up to 2036" as a direction for the formation of a new market and ensuring technological leadership.

[5] What to become: a bioeconomy specialist (2020). Available at: https://www.spbstu.ru/media/news/education/who-become-specialist-bioeconomics/ [Accessed 12.04.2024].

The program of the same name is also being implemented on the basis of the Russian State Agrarian University — Moscow Agricultural Academy named after K.A. Timiryazev.[6] A number of specialized universities and biology departments include the discipline "Bioeconomy" in their curricula, the mastery of which will help future specialists acquire the necessary competencies in the field of industrial biotechnology and biotechnological production.

The emergence of relevant educational programs and training courses eloquently demonstrates the shortage of qualified specialists in this area, which is currently rapidly developing and requires the advancement of appropriate legal regulation. To improve national legal regulation in the field of bioeconomy, it is necessary to focus on approaches formulated at the global and regional levels.

II. International Legal Regulation of Bioeconomy at the Global and Regional Level

II.1. International Legal Framework for the Development of Bioeconomy

The formation of the international legal framework for the development of the bioeconomy occurs in two directions: the greening of agricultural production and industry, as well as the development of medical technologies. The first area is covered by the activities of the Food and Agriculture Organization of the United Nations (FAO). FAO is the first UN agency to formulate a bioeconomy program as one of the priority areas for the implementation of the Strategic Framework, which concentrates the efforts of all states to elaborate conditions for the implementation of innovative solutions to improve the efficiency, equity, resilience and sustainability of agricultural systems. FAO is currently involved in approximately 150 projects related to the bioeconomy, totaling over US $ 330 million, representing about 15 percent of the value of its entire portfolio.[7]

[6] Preparation of the Master program "Bioeconomics." Available at: http://inter.timacad.ru/article/?ELEMENT_ID=2243 [Accessed 12.04.2024].

[7] Bioeconomy as a catalyst for transforming agri-food systems and increasing their sustainability. Available at: https://www.fao.org/newsroom/detail/FAO-bioeconomy-agrifood-systems-science-innovation-forum-2023/ru [Accessed 12.04.2024].

In 2020, FAO hosted the Global Bioeconomy Summit. As a result of this event, a Communiqué was prepared.[8] In it for the first time at the international level a definition of the concept of "bioeconomy" was presented as "the production, use, conservation and restoration of biological resources, including relevant knowledge, scientific disciplines, technologies and innovations that provide sustainable solutions (information, products, processes and services) both within all sectors of the economy and at the level of their interaction, and contributing to the transition to a sustainable economy".[9] Also during the Summit, it was emphasized that in the future the bioeconomy will become a tool, the use of which will help rid the growing population of the planet of poor-quality food products, replacing them with nutritious and environmentally friendly ones; it will ensure sustainable development, reduce environmental damage and significantly reduce waste. At the same time, the FAO emphasizes that the bioeconomy is not limited to the introduction of innovative, "green" solutions in agricultural and industrial production, but involves scaling the experience of "green" development to other areas (for example, medicine).

Sustainable development is becoming the fundamental concept for the functioning of global human society. However, FAO recognizes that not everything related to the bioeconomy is sustainable. Thus, obtaining bioenergy, the most important component of the bioeconomy, can negatively affect the progress of national economies, traditionally focused on the extraction and export of non-renewable energy sources, and pose a threat to food security. It is assumed that at the national level, states must ensure a balance between the "environmental friendliness" of the bioeconomy and the potential threats associated with the reorientation of the domestic energy market towards a "green" course.[10]

[8] Expanding the Sustainable Bioeconomy — Vision and Way Forward. Communiqué of the Global Bioeconomy Summit 2020 (2020). Available at: https://gbs2020.net/wp-content/uploads/2020/11/GBS2020_IACGB-Communique.pdf [Accessed 12.04.2024].

[9] Expanding the Sustainable Bioeconomy — Vision and Way Forward.

[10] Bioeconomy as a catalyst for transforming agri-food systems and increasing their sustainability.

In 2023, under the auspices of FAO, the World Food Forum was held, within which the meeting "Bioeconomy: a catalyst for the transformation of agri-food systems" was held.[11] This event served as a platform for the exchange of views between ministers of national states on the issues of reorienting investments in the bioeconomy and preserving biodiversity as a priority. It is noteworthy that state representatives noted the expansion of the concept of "bioeconomy" beyond agricultural production to include building materials, pharmaceuticals and even vaccines.[12] The continuation of the discussion of the problems of bioeconomy advancement, which started at the 2020 Global Summit, finds its logical continuation in the designated event, as well as the formation of national strategies for promoting the "bioeconomic agenda".

Documents adopted as part of FAO events cannot be considered as legally binding. These documents are the so-called acts of "soft law" and are advisory in nature. The obvious benefit of adopting such documents is to help elaborate unified conceptual approaches to the development of relevant national legislation. However, it is not entirely fair to say that there are no legally binding mechanisms in place for the bioeconomy at the global level. Within the framework of the United Nations, the Convention on Biological Diversity of 1992 was adopted. It formulates the principles of bioeconomy arising from Art. 1 of the Convention: conservation of biological diversity, sustainable use of its components and fair and equitable sharing of benefits associated with the use of genetic resources.[13] Also the foundations of the bioeconomy

[11] Science, Technology and Innovation. Available at: https://www.fao.org/science-technology-and-innovation/science-innovation-forum-2023/programme/bioeconomy--the-catalyst-for-agrifood-systems-transformation/en#:~:text=Carina%20Pimenta%20was%20nominated%20National,from%20the%20University%20of%20Sussex [Accessed 13.04.2024].

[12] Science, Technology and Innovation.

[13] Convention on Biological Diversity, 1992. Available at: https://treaties.un.org/doc/treaties/1992/06/19920605%2008-44%20pm/ch_xxvii_08p.pdf [Accessed 14.04.2024].

are complemented by the provisions of the Cartagena[14] and Nagoya Protocols[15] to the Convention on Biological Diversity.

The concept of "bioeconomy" covers the field of medical research, including research in the field of genetics and human genomics. From the point of view of the formation of a global legal framework in this area, the experience of the United Nations Educational, Scientific, Cultural, Communication and Information Organization (UNESCO) is significant, within the framework of which a number of acts of a recommendatory nature were also adopted: the Universal Declaration on the Human Genome and Human Rights of 1997,[16] International Declaration on Human Genetic Data of 2003,[17] Universal Declaration on Bioethics and Human Rights of 2007.[18] These documents are intended to ensure a balance between the principle of protecting human rights and the principle of freedom of scientific research in the field of genomics and genetics. In the context of the development of the "bioeconomy". balancing these principles at the global (as well as national) level becomes particularly relevant.

Currently, within the framework of international law, the legal regulation of relations in the field of bioeconomy is fragmented and sporadic. Conceptual legal framework is formed at the level of recommendatory acts of "soft law"; legally binding mechanisms affect the issues of bioeconomy indirectly. At the same time, large-scale events

[14] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 2000. Available at: https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf [Accessed 14.04.2024].

[15] Nagoya Protocol on Regulating Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, 2010. Available at: https://www.cbd.int/abs/doc/protocol/nagoya-protocol-ru.pdf [Accessed 14.04.2024].

[16] Universal Declaration on the Human Genome and Human Rights, 1997. Available at: https://www.ohchr.org/en/instruments-mechanisms/instruments/universal-declaration-human-genome-and-human-rights [Accessed 14.04.2024].

[17] International Declaration on Human Genetic Data, 2003. Available at: https://www.unesco.org/en/ethics-science-technology/human-genetic-data [Accessed 14.04.2024].

[18] Universal Declaration on Bioethics and Human Rights, 2005. Available at: https://www.unesco.org/en/ethics-science-technology/bioethics-and-human-rights [Accessed 14.04.2024].

carried out within the framework of FAO over the past 5 years indicate the intention of the global community to form a regulatory framework for the bioeconomy. This intention is reflected in numerous initiatives implemented at the level of international integration associations.

II.2. Bioeconomy and European Union Law

Currently, the European Union is a leader in the global bioeconomy sector (Staffas et al., 2013, p. 2751). The adoption of policy documents in the field of bioeconomy at the EU level was anticipated in the document of the Organization for Economic Cooperation and Development (OECD), adopted in 2009 — "Bioeconomy until 2030: developing a political agenda".[19] This document emphasized the importance of the advancement of biological sciences in the period 1990–2010, since such progress made it possible to apply new knowledge and biotechnologies to ensure sustainable economic development. The growth of biotechnological knowledge and the integration of biotechnologies into industrial production are becoming a condition for the development of the bioeconomy as a special economic system. The program names the following key factors for the development of the bioeconomy: an increase in energy demand combined with the need to reduce greenhouse gas emissions, the creation of platform biotechnologies, the development of research in the field of genetic modification and DNA sequencing, the presence of relevant government programs and macroeconomic incentive mechanisms. These factors and conditions should be taken into account by the OECD member states when elaborating national and supranational approaches to the development of biotechnologies. Since the majority of the EU member states are members of the OECD, the approaches of this organization could not but be accepted at the Union level (Kiryushkin et al., 2019, p. 60).

In 2012, the EU adopted a bioeconomy development strategy called "Innovation for sustainable growth: a bioeconomy for Europe"

[19] The Bioeconomy to 2030: Designing a Policy Agenda. Available at: https://www.oecd.org/sti/futures/longtermtechnologicalsocietalchallenges/thebioeconomyto2030designingapolicyagenda.htm [Accessed 13.04.2024].

(updated in 2018).[20] This document presents the main characteristics of the bioeconomy, namely

A) focusing on the future by attracting additional investments and creating new markets, including by launching investment platforms;

B) attracting public attention to environmental issues, since it is the bioeconomy that is an effective tool for solving environmental problems through following the paradigm of low-carbon and sustainable development;

C) contributing significantly to ensuring energy security and self-sufficiency in resources, including agricultural resources (a positive example in this context is the reduction in the dependence of the EU member states on hydrocarbon energy, its replacement with "green" energy, including through increased collection of biomass and its utilization) ;

D) being an effective tool for European integration and the implementation of pan-European tasks by each member state of the Union (EU institutions and bodies are working on the formation of an appropriate regulatory framework in the field of bioeconomy, including the preparation of recommendations that form the basis of national strategies and road maps).

These characteristics of the bioeconomy for the EU reflect the policy approaches formulated at the OECD level. The fundamental provisions of the OECD documents are set out in the EU program documents, including strategic planning documents. The role of these documents is to equip member states with approaches that they can use to develop a relevant regulatory framework (McCormick and Kautto, 2013, p. 2589). Program documents are quite often revised and supplemented, which is largely dictated by the rapid development of scientific knowledge and industrial production in the field of biotechnology. Thus, the updated 2018 Bioeconomy Strategy provides for 14 specific measures for the development of the bioeconomy, including strengthening and expanding the biotechnology sectors; development of national bioeconomies through the implementation of supranational program

[20] Innovating for Sustainable Growth: A Bioeconomy for Europe. Available at: https://op.europa.eu/en/publication-detail/-/publication/1f0d8515-8dc0-4435-ba53-9570e47dbd51 [Accessed 13.04.2024].

provisions into the legislation of each member state; awareness of the ecological boundaries of the bioeconomy.

In 2022, the European Commission presented a report on the implementation of the provisions of this Strategy.[21] It singled out a number of important trends in it, namely promotion at the national level of the concept of intersectoral cooperation and principles of sustainability for the development of the bioeconomy; progress in the development of the bioeconomy in the EU member states located in Central and Eastern Europe, which is associated with the formation of a favorable investment climate and financial assistance from the EU; attraction of private investment in startups in the field of biotechnology. The report demonstrated that in the decade since the adoption of the first "bioeconomy" strategy, much has been done to ensure that pan-European approaches to creating a sustainable "green" economy are reflected in the policies and programs of individual states. At the same time, at present there are still gaps in the implementation of the Action Plan in the field of bioeconomy, because not all states take a comprehensive approach to solving the problem of developing this economic system. Also, national jurisdictions have not fully resolved the issue of how to manage biomass needs to meet the best way the environmental and economic needs of a climate-neutral Europe. In addition, the problem of developing more sustainable consumption patterns needs to be addressed.

Despite the abundance of program documents, including strategic planning documents, specialized legislation in the field of bioeconomy has not yet been formed in the EU. However, a number of legally binding documents that form the sources of secondary law of the Union address the issue of bioeconomy. Among such documents it is worth mentioning acts in the field of environmental protection and acts in the field of energy policy:

a) Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving

[21] Report COM/2022/283: EU Bioeconomy Strategy Progress Report — European Bioeconomy policy: stocktaking and future developments, 2022. Available at: https://knowledge4policy.ec.europa.eu/publication/report-com2022283-eu-bioeconomy-strategy-progress-report-european-bioeconomy-policy_en [Accessed 13.04.2024].

climate neutrality and amending Regulations (EC) No. 401/2009 and (EU) 2018/1999 ("European Climate Law");[22]

b) Regulation (EU) 2018/1999 of the European Parliament and of the Council of 11 December 2018 on the Governance of the Energy Union and Climate Action, amending Regulations (EC) No. 663/2009 and (EC) No. 715/2009 of the European Parliament and of the Council, Directives 94/22/EC, 98/70/EC, 2009/31/EC, 2009/73/EC, 2010/31/EU, 2012/27/EU and 2013/30/EU of the European Parliament and of the Council, Council Directives 2009/119/EC and (EU) 2015/652 and repealing Regulation (EU) No. 525/2013 of the European Parliament and of the Council;[23]

c) Regulation (EU) No. 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species;[24]

d) Directive (EU) 2019/944 of the European Parliament and of the Council of 5 June 2019 on common rules for the internal market for electricity and amending Directive 2012/27/EU (recast);[25]

[22] Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No. 401/2009 and (EU) 2018/1999 (European Climate Law). Available at: https://eur-lex.europa.eu/eli/reg/2021/1119/oj/eng [Accessed 13.04.2024].

[23] Regulation (EU) 2018/1999 of the European Parliament and of the Council of 11 December 2018 on the Governance of the Energy Union and Climate Action, amending Regulations (EC) No. 663/2009 and (EC) No. 715/2009 of the European Parliament and of the Council, Directives 94/22/EC, 98/70/EC, 2009/31/EC, 2009/73/EC, 2010/31/EU, 2012/27/EU and 2013/30/EU of the European Parliament and of the Council, Council Directives 2009/119/EC and (EU) 2015/652 and repealing Regulation (EU) No. 525/2013 of the European Parliament and of the Council (Text with EEA relevance.). Available at: https://eur-lex.europa.eu/eli/reg/2018/1999/oj/eng [Accessed 13.04.2024].

[24] Regulation (EU) No. 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species. Available at: https://eur-lex.europa.eu/eli/reg/2014/1143/oj/eng [Accessed 13.04.2024].

[25] Directive (EU) 2019/944 of the European Parliament and of the Council of 5 June 2019 on common rules for the internal market for electricity and amending Directive 2012/27/EU (recast) (Text with EEA relevance.). Available at: https://eur-lex.europa.eu/eli/dir/2019/944/oj/eng [Accessed 13.04.2024].

e) Directive (EU) 2023/2413 of the European Parliament and of the Council of 18 October 2023 amending Directive (EU) 2018/2001, Regulation (EU) 2018/1999 and Directive 98/70/EC as regards the promotion of energy from renewable sources, and repealing Council Directive (EU) 2015/652.[26]

Among the documents directly related to the problems of bioeconomy development, there are also acts in the field of scientific research and innovation, in particular:

a) Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed;[27]

b) Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC;[28]

c) Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions;[29]

[26] Directive (EU) 2023/2413 of the European Parliament and of the Council of 18 October 2023 amending Directive (EU) 2018/2001, Regulation (EU) 2018/1999 and Directive 98/70/EC as regards the promotion of energy from renewable sources, and repealing Council Directive (EU) 2015/652. Available at: https://eur-lex.europa.eu/eli/dir/2023/2413/oj/eng [Accessed 13.04.2024].

[27] Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance). Available at: https://eur-lex.europa.eu/eli/reg/2003/1829/oj/eng [Accessed 13.04.2024].

[28] Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. Available at: https://eur-lex.europa.eu/eli/reg/2003/1830/oj/eng [Accessed 13.04.2024].

[29] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. Available at: https://eur-lex.europa.eu/eli/dir/1998/44/oj/eng [Accessed 13.04.2024].

d) Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified microorganisms (recast).[30]

The presented list of acts is not exhaustive. The years of adoption of documents indicate that "bioeconomy issues" have worried European legislators since the late 90s of the twentieth century. At the same time, the term "bioeconomy" has not yet become a full-fledged legal category in European law. Since the process of systematization of supranational legislation in the field of biotechnology at the level of the European Union is currently ongoing,[31] the possibility of this term gaining regulatory recognition, as well as the formation of basic principles of legal regulation in this area, is increasing.

II.3. Bioeconomy and International Integration Associations of South America and Africa

The "bioeconomy" agenda is also reflected in the documents of international integration associations in South America and Africa. Taking into account the large number of integration associations, we will focus on two organizations that carry out active rule-making work in areas directly or indirectly related to the bioeconomy.

The experience of the South American Common Market (MERCOSUR), within which a strategy is also elaborated to promote the bioeconomy as a key component of competitive development is quite notable. At the same time, MERCOSUR regulation in the field of bioeconomy is advancing under the influence of the EU, which is dictated by the successful bilateral interaction of these international

[30] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast) (Text with EEA relevance). Available at: https://eur-lex.europa.eu/eli/dir/2009/41/oj/eng [Accessed 13.04.2024].

[31] In particular, in 2023, the European Commission presented a draft Proposal to simplify the research and commercialization of gene-edited plants. The goal of this document is to create an enabling environment for scaling up research that improves the resilience of crops to climate change, pests and diseases, and to create plants that require less fertilizer. This proposal is consistent with the targets of the supranational Bioeconomy Strategy.

organizations. The legal form of such interaction was the conclusion of the EU-MERCOSUR Trade Agreement,[32] which stipulates that the parties undertake to share such goals and values as sustainable development, environmental protection, combating climate change, encouraging companies of the parties to act responsibly and maintaining high food safety standards. These targets are consistent with the key provisions of the EU strategic documents in the field of bioeconomy. At the same time, MERCOSUR pursues an independent policy in the field of biotechnology, focusing on the universal and regional agenda. The MERCOSUR member states (Brazil, Argentina, Uruguay, Paraguay) adopted the terminology of the UN Convention on Biodiversity, including the provisions of the Nagoya and Cartagena Protocols, implementing it into program documents for the development of biotechnologies, nanotechnologies and the bioeconomy.[33]

At the MERCOSUR level, Resolution Mercosur/GMC/RES No. 13/04[34] was adopted. It emphasizes the importance of the use of biotechnology in agricultural production. This Resolution established the Special Group on Agricultural Biotechnology that later transformed into the Commission on Agricultural Biotechnology. The Commission's tasks include harmonizing the regulatory framework in the field of biosafety and coordinating the actions of member states in relation to genetically modified organisms. The document provides an important rule according to which, if a MERCOSUR member state authorizes the use of a genetically modified organism for the production of food for humans or animals at the national level, such state must notify the Commission on Agricultural Biotechnology. Thus, the Commission exercises control over the circulation of genetically modified organisms

[32] EU-Mercosur trade agreement: the agreement in principle, 2019. Available at: https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/countries-and-regions/mercosur/eu-mercosur-agreement/text-agreement_en [Accessed 13.04.2024].

[33] In particular, in Argentina the Federal Program for the Promotion of Biotechnologies and Nanotechnologies is being implemented, in Paraguay — the National Policy and Program in the Field of Agriculture and Forestry.

[34] Resolution Mercosur/GMC/RES No. 13/04. Available at: https://servicios.infoleg.gob.ar/infolegInternet/anexos/105000-109999/108789/norma.htm [Accessed 13.04.2024].

within the framework of the above-mentioned international integration association.

To finance activities in the field of biotechnology at the MERCOSUR level, the Structural Convergence Fund operates, implementing the project "Research, education and biotechnologies applied in health care". This project provides funding for effective solutions to combat chronic and infectious diseases.[35] Another financial instrument for supporting programs in the field of bioeconomy and biotechnology is joint financing of projects with the involvement of the state or an integration association. Thus, GMC resolutions No. 58 of 2005 and No. 01/14 of 2014 approved the signing of the Biotechnological Project Financing Agreement between MERCOSUR and the European Union, BIOTECH I and II. The agreements, also known as BIOTECSUR,[36] aim to promote the development and application of biotechnology in MERCOSUR. At the same time, the coverage of the areas of use of biotechnologies is expected to be as wide as possible: agriculture, healthcare, scientific research, etc.

As for the experience of international integration associations in Africa, in this case, unlike South America, it is not representative in terms of the formation of specialized strategies for the development of the bioeconomy. African integration associations demonstrate an example of fragmented regulation in this area. At the same time, some integration associations have adopted program documents covering certain aspects of "bioeconomy" issues (Poku et al., 2018, p. 134). Thus, the African Union has had a Policy and Guidelines for Bioenergy Development in Africa since 2013,[37] which aims to improve energy security and access, as well as rural development in Africa. As goals for the advancement of the bioenergy sector, the document enumerates: integration of bioenergy into energy balance strategies and national

[35] The MERCOSUR Fund for Structural Convergence (FOCEM).

[36] BIOTECSUR, 2023. Available at: https://www.recyt.mercosur.int/biotecsur/po/biotecsur.php [Accessed 13.04.2024].

[37] Africa Bioenergy Policy Framework and Guidelines Towards Harmonizing Sustainable Bioenergy Development in Africa, 2013. Available at: https://au.int/sites/default/files/documents/32183-doc-africa_bioenergy_policy-e.pdf [Accessed 13.04.2024].

development strategies that improve access to energy; integration of policies, measures and actions (e.g standards) with regional initiatives; developing cooperation with industrialized countries to benefit from knowledge and technology transfer; adaptation of sustainability criteria adopted in other states and (or) integration associations or proposed at the international level. At the same time, it must be stated that bioenergy is only a part of the bioeconomy, and a significant number of areas of development of the bioeconomy have not been covered by specialists in the field of African integration. Currently, even at the level of such a large-scale integration organization as the African Union, an integrated approach to promoting the bioeconomy on the African continent is not being implemented.

II.4. Bioeconomy in the Post-Soviet Jurisdictions: theCommonwealth of Independent States and the Eurasian Economic Union

Among international organizations, including international integration associations operating in the post-Soviet space, let us turn to the relevant experience of the Commonwealth of Independent States (CIS) and the Eurasian Economic Union (EAEU). It should be noted that neither in the first nor in the second case is it possible to talk about the presence of program documents, including strategic planning documents, in the field of bioeconomy. At the same time, it would also be unfair to say that the documents of the CIS and the EAEU do not at all cover the issues of promoting the bioeconomy in their member states. We are talking here about the initial stage of the formation of legal regulation, when the key term "bioeconomy" is not reflected in official documents, but individual aspects and characteristics of the bioeconomy penetrate into supranational regulation (Titova et al., 2023, pp. 56–79).

Within the CIS there are a number of documents that can be meaningfully attributed to "bioeconomy" issues. In particular, in 2013, by decision of the Council of Heads of Government of the CIS, the Concept of cooperation of the CIS member states in the field of use of renewable energy sources and the Plan of priority measures for its

implementation were approved.[38] This Concept is aimed at expanding interstate cooperation in the field of use of renewable energy sources (RES) and further development of their application. It is based on the priority of the economic interests of the CIS member states and is aimed at creating conditions conducive to ensuring their energy security and sustainable development, which also characterizes the bioeconomy.

In addition to the "energy" component, CIS documents also cover the environmental agenda. Thus, the Model Law "On environmental responsibility in relation to the prevention and elimination of harm to the environment" (adopted at the thirty-third plenary meeting of the Interparliamentary Assembly of the CIS Member States by Resolution No. 33-10 of 3 December 2009)[39] provides for a system of environmental responsibility for the prevention and elimination of harm environment by shifting the burden of compensation for environmental damage from society as a whole to economic entities whose activities caused harm, including a definition of the concept of "sustainable state of the environment" and enshrining the principle of international environmental law "the polluter pays".

In addition, another document contributes to the formation of a "bioeconomy" paradigm in the CIS — the Model Law on the Protection of Human Rights and Dignity in Biomedical Research in the CIS Member States (adopted in St. Petersburg on 18 November 2005 by Resolution 26-10 on 26th plenary meeting of the Interparliamentary Assembly of the CIS Member States).[40] This document proposes unified approaches to the formulation of state guarantees for the protection of human

[38] Concept of cooperation of the CIS member states in the field of use of renewable energy sources and the Plan of priority measures for its implementation, 2013. Available at: https://mpei.ru/Structure/Universe/IHRE/structure/reee/Documents/consept-plan-2013.pdf [Accessed 13.04.2024].

[39] Model Law "On environmental responsibility in relation to the prevention and elimination of harm to the environment" (adopted at the thirty-third plenary meeting of the Interparliamentary Assembly of the CIS Member States by Resolution No. 33-10 of 3 December 2009). Available at: https://base.spinform.ru/show_doc.fwx?rgn=29907 [Accessed 13.04.2024].

[40] News Bulletin. Interparliamentary Assembly of States Parties of the Commonwealth of Independent States (2006). Vol. 37. P. 312–326.

rights, dignity, autonomy and integrity when conducting biomedical research, based on the provisions of the state constitution, and taking into account the need to implement the principles proclaimed in key international documents.[41] However, model legislation is not legally binding; in fact, it only helps to harmonize national legal regulation within the framework of an international organization. In this area, this helps the participating states to develop common approaches and level out emerging legislative contradictions.

Unlike the CIS, in the acts of the Eurasian Economic Union one can find mention of the term "bioeconomy". In particular, Order of the Council of the Eurasian Economic Commission dated 18 October 2016 No. 32 "On the formation of priority Eurasian technological platforms"[42] mentions development in the field of biotechnology and bioeconomy as the goal of creating the Eurasian technological platform "EURASIABIO" (Yakovets and Rastvortsev, 2016, pp. 6–21). Also, certain aspects of the bioeconomy (including innovative pharmaceuticals in terms of the production of high-tech medicines) are reflected in such EAEU documents as Decision of the Council of the Eurasian Economic Commission dated 3 November 2016 No. 78 "On the rules for registration and examination of medicines for medical use",[43] Decision of the Council of the Eurasian Economic Commission dated 3 November 2016 No. 76 "On the approval of the requirements for labeling of medicinal products for medical use

[41] Such documents include the Nuremberg Code, the International Code of Medical Ethics of the World Medical Association (WMA), the WMA Declaration of Helsinki, the Council of Europe Convention on Human Rights in Biomedicine, the International Guidelines for Biomedical Research Involving Human Subjects (CIOMS), the Qualitative Guidelines clinical practice of the World Health Organization and recommendations of the WHO ethics committee conducting the examination of biomedical research.

[42] Order of the Council of the Eurasian Economic Commission dated 18 October 2016 No. 32 "On the formation of priority Eurasian technological platforms". Available at: https://docs.cntd.ru/document/456047406 [Accessed 13.04.2024].

[43] Decision of the Council of the Eurasian Economic Commission dated 3 November 2016 No. 78 "On the Rules for registration and examination of medicines for medical use". Available at: https://docs.cntd.ru/document/456026097 [Accessed 13.04.2024].

and veterinary medicinal products".[44] At the same time, within the framework of this integration association, a unified concept for the development of the bioeconomy has not yet been formed.

III. Conclusion

To summarize this research, it should be noted that at the global and regional levels an attempt has been made to create unified approaches to the development of the bioeconomy, which need to be adapted to national legal orders. Such approaches include transition to a sustainable economy; introduction of "ecologically friendly" food production using high-tech innovative technologies (biotechnologies); environmental protection and reduction of production waste; scaling the experience of "green" production to the field of medicine and pharmaceuticals and other environmental issues and will significantly reduce waste. Moreover, such approaches are formulated mainly in program documents and strategic planning documents, which at the global level are advisory in nature, so their implementation depends entirely on the political will of states. Legally binding international treaties and agreements also reflect the "bioeconomy" agenda, but such reflection is fragmented and sporadic. A positive example of consolidating the principles of legal regulation of relations in the field of bioeconomy is the European Union, within which not only relevant policy documents are in force, but also legally binding acts (regulations, directives and decisions) have been adopted that take into account trends in legal regulation at the global level. As for integration associations with the participation of the Russian Federation, at present neither the CIS nor the EAEU have adopted regulatory documents that would formulate the legal framework for the development of the bioeconomy. At the same time, taking into account the formation of a common market of the EAEU, including in the field of agricultural

[44] Decision of the Council of the Eurasian Economic Commission dated 3 November 2016 No. 76 "On approval of the Requirements for labeling of medicinal products for medical use and veterinary medicinal products". Available at: https://docs.cntd.ru/document/456026094 [Accessed 13.04.2024].

products, industrial products, as well as medicines, it seems necessary to develop a framework for regulating the bioeconomy on the part of the institutional structures of the Eurasian Economic Union.

References

Bobyleva, S.N., Kiryushina, P.A. and Kudryavtseva, O.V., (2019). *Green Economy and Sustainable Development Goals for Russia*. Moscow: MSU Faculty of Economics Publ. (In Russ.).

Borgström, S. and Mauerhofer, V., (2016). Developing law for the bioeconomy. *Journal of Energy & Natural Resources Law*, 34(4), pp. 373–406, doi: 10.1080/02646811.2016.1200349.

Boyarov, A., Osmakova, A. and Popov, V., (2021). Bioeconomy in Russia: Today and Tomorrow. *New Biotechnology*, 60, pp. 36–43, doi: 10.1016/j.nbt.2020.08.003. (In Russ.).

Kiryushkin, P.A., Yakovleva, E.Yu., Astapkovich, M. and Solodova, M.A., (2019). Bioeconomics: experience of the European Union and opportunities for Russia. *Bulletin of Moscow University. Series 6: Economics*, 4, pp. 60–77, doi: 10.38050/01300105201945. (In Russ.).

Makarchuk, O.G., (2013). Fundamentals of the development of bioeconomy. *Current problems of the humanities and natural sciences*, 4, pp. 196–200. (In Russ.).

Makedon, G.M. and Talavyrya, N.P., (2013). Bioeconomy as one of the foundations of sustainable development of society. *News of the Velikolukskaya State Agricultural Academy*, 1, pp. 31–35. (In Russ.).

Mateescu, I., Popescu, S., Paun, L., Roata, G., Bancila, A. and Oancea, A., (2011). Bioeconomy. What is bioeconomy? How will bioeconomy develop the next two decades. *Studia Universitatis "Vasile Goldi"*, 17.21(2), pp. 451–456.

McCormick, K. and Kautto, N., (2013). The Bioeconomy in Europe: An Overview. *Sustainability*, 5, pp. 2589–2608, doi: 10.3390/su5062589.

Poku, A.G., Birner, R. and Gupta, S., (2018). Is Africa ready to develop a competitive bioeconomy? The case of the cassava value web in Ghana. *Journal of Cleaner Production*, 200, pp. 134–147, doi: 10.1016/j.jclepro.2018.07.290.

Rassokhina, I.I., Kotkova, D.N. and Platonov, A.V., (2019). Analysis of global publication activity in the field of "bioeconomy". *Problems of territory development*, 3(101), pp. 152–165, doi: 10.15838/ptd.2019.3.101.10. (In Russ.).

Staffas, L., Gustavsson, M. and McCormick, K., (2013). Strategies and Policies for the Bioeconomy and Bio-Based Economy: An Analysis of Official National Approaches. *Sustainability*, 5, pp. 2751–2769, doi: 10.3390/su5062751.

Titova, E.S., Shishkin, S.S. and Shtykhno, D.A., (2023). Bioeconomy is one of the ways to sustainable development of Russian regions. *Federalism*, 1(109), pp. 56–79, doi: 10.21686/2073-1051-2023-1-56-79.

Yakovets, Yu.V. and Rastvortsev, E.E., (2016). On the system of goals and strategies for sustainable development of the Eurasian Economic Union. *Economic strategies*, 7(141), pp. 6–21. (In Russ.).

Zhavoronkova, N.G. and Agafonov, V.B., (2019). Theoretical and methodological problems of legal support of environmental, biosphere and genetic security in the national security system of the Russian Federation. *Lex Russica*, 9, pp. 96–108, doi: 10.17803/1729-5920.2019.154.9.096-108.

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