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LEGAL AND ETHICAL ISSUES OF BIOTECHNOLOGY

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Abstract
The article addresses the legal and ethical issues of biotechnology, regulation of genetic engineering and GMOs, protection of intellectual property and patenting of biotechnological inventions, as well as key bioethical challenges in biomedicine and pharmaceuticals. The impact of biotechnology on human health and the environment is analyzed from the perspective of bioethics and sustainable development.

Keywords: Biotechnology, legal regulation, bioethics, GMO, genetic engineering

Annotatsiya
Ushbu maqolada biotexnologiya sohasining huquqiy-me’yoriy asoslari, gen muhandisligi va GMO mahsulotlarini tartibga solish, intellektual mulk va biotexnologik ixtirolarni patentlash masalalari, shuningdek biotibbiyot va farmatsevtika sohasida yuzaga keladigan asosiy etika muammolari yoritilgan. Biotexnologiyaning inson salomatligi va ekologiyaga ta’siri bioetika tamoyillari

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asosida tahlil qilinib, huquqiy va axloqiy tartibotlarning istiqbollari ko‘rsatib berilgan.

Kalit so‘zlar: biotexnologiya, huquqiy tartibot, bioetika, GMO, gen muhandisligi, patent, ekologik xavfsizlik.

Аннотация

В статье рассматриваются правовые и этические вопросы биотехнологии, регулирование генной инженерии и ГМО, защита интеллектуальной собственности и патентование биотехнологических изобретений, а также основные биоэтические проблемы в биомедицине и фармацевтике. Проанализировано влияние биотехнологий на здоровье человека и окружающую среду с позиции биоэтики и устойчивого развития.

Ключевые слова: биотехнология, правовое регулирование, биоэтика, ГМО, генная инженерия.

Introduction

Biotechnology is one of the fastest-growing fields of modern science and technology, widely applied in medicine, pharmaceuticals, agriculture, the food industry, and environmental protection. According to the World Economic Forum, the global biotechnology market exceeded USD 1.3 trillion in 2023. At the same time, the rapid development of biotechnology raises several issues related to human health, environmental safety, and ethical standards. This situation emphasizes the need for legal and ethical regulation in the field of biotechnology.

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Relevance of the Topic

In the current context of globalization and scientific-technological advancement, biotechnology has become a key factor in the development of medicine, pharmaceuticals, agriculture, food safety, and environmental protection. The widespread implementation of genetic engineering, cell technologies, recombinant DNA, gene therapy, and genetically modified organisms (GMOs) has significant impacts on human health and the environment. Therefore, a thorough study of the legal and ethical issues of biotechnology is highly relevant for contemporary science and society.

The rapid expansion of the global biotechnology market and the practical application of new biomedical products and technologies underscore the necessity for legal regulation. International experience shows that if biotechnological activities are not adequately governed by legal frameworks and bioethical standards, human rights violations, environmental risks, and social conflicts may arise.

Additionally, issues related to gene therapy, the use of embryonic cells, clinical trials, and GMO products provoke extensive societal discussions, requiring a balance between scientific progress and ethical norms. Biological safety, protection of future generations, and sustainable development have become priority areas within bioethics. Thus, a systematic analysis of the legal and ethical aspects of biotechnology, assessment of current regulatory frameworks, and development of improvement strategies based on international experience are of significant scientific and practical importance.

Legal Foundations of Biotechnology

Legal regulation in biotechnology aims to protect human life and health, as well as ensure biological and environmental safety. Governance in this area is implemented through international legal instruments, national legislation, and sanitary and biosafety standards. The 1992 Convention on Biological Diversity

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established the principles of sustainable use of biological resources and the sovereign rights of states over genetic materials.

Regulation of Genetic Engineering and GMOs

Safety issues related to genetic engineering products, particularly GMOs, are governed internationally by the Cartagena Protocol on Biosafety. According to the protocol, GMO products must be scientifically assessed to ensure they do not pose risks to the environment or human health. In the European Union, products containing more than 0.9% GMO content must be mandatorily labeled, whereas in the United States, assessment is primarily based on scientific expertise.

Intellectual Property and Patenting in Biotechnology

Protecting intellectual property in biotechnology is crucial for fostering innovation. According to the World Intellectual Property Organization (WIPO), over 50,000 biotechnology-related patent applications are filed annually. Patentable objects include microbial strains, recombinant DNA technologies, biologically active substances, and diagnostic methods. However, patenting natural sequences of the human genome is restricted in many countries.

Ethical Issues in Biomedicine and Pharmaceuticals

Ethical considerations are particularly important in clinical research. According to the World Health Organization, informed consent is mandatory for all participants in clinical trials. Gene therapy, the use of embryonic cells, and cloning technologies provoke global bioethical debates. In 2005, the United Nations adopted a declaration prohibiting human cloning.

Ethics in Biotechnology Related to Human Health and the Environment

Biotechnological activities can have long-term impacts on ecological balance. Some studies indicate that widespread implementation of transgenic plants may

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reduce biodiversity. Therefore, non-maleficence, responsibility, and sustainable development are considered core ethical principles in biotechnology.

Key International Legal Documents Regulating Biotechnology

No	Document	Year	Regulatory Focus
1	Convention on Biological Diversity	1992	Genetic resources and environmental safety
2	Cartagena Protocol on Biosafety	2000	GMO product safety
3	WHO Bioethics Guidelines	2016	Ethics of clinical research
4	UN Declaration on Cloning	2005	Prohibition of human cloning
5	WIPO Patent Standards	2018	Protection of biotechnological inventions

Conclusion

Biotechnology plays a crucial role in modern societal development. However, its progress must be aligned with strict legal and ethical standards. Legal frameworks and bioethical principles ensure that biotechnology serves human health and environmental safety while providing a solid foundation for sustainable development.

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