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Bioethics and Biolaw as Bioeconomy Regulators

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Abstract: The paper deals with the ethical and legal principles (foundations) of economy that have been important and required to a various extent at different stages in history. Advances in science and technology, emergence of modern biotechnologies, including the genetic ones, as well as shifts to new technological paradigms, on the one hand, make the emerging economy drift towards bioeconomy, and, on the other hand, increase the need for legal and ethical regulators. In view of the above, bioethics and biolaw begin to play an increasingly active role at the new stage of human civilization development. In Russia, the phenomena of bioethics and bio-law are at the initial stage of their institutionalization, they become more and more appealing due to the intensification of public debates, as well as due to an increase in the number of conflicts caused by the attempts to implement and broadly apply the achievements of biology, medicine and other sciences about life in daily practice.

Keywords: Economy, bioeconomy, ethics, bioethics, law, biolaw, technologies, conflicts, the concept of four "BIOs", regulation, biopolitics

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I. Introduction

Throughout almost the entire history of human civilization development — at least since the emergence of states — economy, to various extents, has been exposed to some influence, attempts to regulate the social relations most significant for the political and (or) economic elites. Imposition of taxes, fees, and other charges, as well as the economic relations between the state and the church, or the state and the neighboring countries, have been inevitably fixed in certain rules, laws and other regulations. At the same time, most of the routine economic issues have been left to the discretion of such regulators as morality, religion, and ethics due to their significant role in traditional societies. Economy has been "included" in daily life (Ivashkovsky, 2011), rather than opposed to it.

The relative gap between society, the institutions thereof, and economy began to emerge in the Middle Ages and reached its climax by the 20th century. Private interest became the key driver, and economic resources (land, labor, capital) became the limiter. To a certain extent, the state could act as a regulator, catering to the most significant public interests, and limiting certain types of economic activity (with evidently negative social consequences). However, overall, the achievement of the nearest economic goal was generally no longer associated with an ethical choice. This issue was left to the discretion of the authorities, the legislators.

However, the processes and the events negative for human civilization (the struggle of workers for their social rights, revolutions,

world wars, economic downturns, and sometimes even economic depressions, etc.) forced scientists to once again pay attention to the ethical and legal aspects of supporting economic activity, as well as to the need for a balanced policy in the state (not only in terms of economy, but also in terms of other aspects such as demography, family, migration, etc.).

An individual is not only a subject of certain economic relations (labor, management, or property ones), but also an active participant in non-economic relations. By mid-20th century, technologies had already provided the opportunity to significantly reduce the working day duration, and to form the sphere of consumption and leisure. Various service markets have begun to grow fast, and employment has been rapidly changing. An individual has been increasingly pushed out of the economic turnover, becoming an active consumer of services, rather than a producer of goods.

In the second half of the 20th century, bioethics and medical law began to stand apart as responses to biotechnological challenges, as well as due to the evident need for social control over medical professionals, and (later) biologists. Unless decisive measures are taken, the primacy of economic interests over any others (social, environmental, etc.) can lead to irreversible consequences for certain states, regions, and even humanity as a whole, within the next few years.

II. Bioeconomy as a Phenomenon

Much has been written about bioeconomy and its "sprouts". Currently, there are different approaches to understanding bioeconomy.

Bioeconomy is the sustainable controlled conversion of biomass into a range of food, health, and industrial products, as well as energy (BECOTEPS. The European Bioeconomy in 2030 — Delivering Sustainable Growth by addressing the Grand Societal Challenges, n.d.).

Bioeconomy is a biobased, renewables-based, sustainable economy (Brunori, 2013).

Bioeconomy is a branch of social science that integrates the disciplines (and knowledge) of economics and biology in order to solve its own problems and to create a coherent theory explaining the events and processes occurring in connection with the development of new biotechnologies (Mateescu et al., 2011).

Despite some differences in approaches to understanding bioeconomy, it is based on an emerging biotechnological platform which is unique for the current time in history and allows, along with other modern (digital, management, etc.) technologies, both creating absolutely new products (goods, works, services), and significantly influencing the existing ones. Biotechnologies stimulate development of new segments and/or sectors of economy, have a significant impact on the processes and the speed of modernization of the existing ones (especially in high-tech sectors/segments) (Schwab, 2016), and are capable of boosting business activity in the traditional industries and sectors of economy, i.e., have serious innovative, multiplier and other effects.

Biomedicine and biopharmaceutics, agriculture, food industry, as well as bioenergy sector have the highest potential for development. A good potential for development exists in the IT sector facilitating the exchange of bio-data, and genetic or other information about humans, plants, animals. There are also some prospects for the introduction of certain biotechnologies in the environmental sector.

The main driver of the emerging bioeconomy as a whole, as well as its individual industries and sectors, are biotechnologies and other technologies (medical, digital, etc.) generating a synergistic effect when used together. The already existing, as well as the potential capabilities thereof evidence the emergence of not only breakthrough, but also disruptive innovations, that allow not only significantly improving the products circulating in the market, but also changing the production, technological and even some social processes.

Bioeconomy is a slowly emerging economy of a new type, characterized not only by active exploitation of biotechnologies and bioresources (which is typical for any economy), but also by the use of such technologies and resources following scientifically sound principles which ensure the rational use thereof, the "closed-loop" lifecycles of biotechnologies and other technologies, therefore allowing minimization of the negative impact of various factors on the environment, the biosphere.

So far, it looks like an experimental economy with unclear actual long-term prospects, and sometimes even like science fiction (in terms of closed-loop cycles, full reproduction, effective management of environmental and other risks). However, the objective laws of nature will sooner or later force the human civilization to follow the path of practical implementation of the concept of three (biotechnology — biosafety — bioeconomy) or even four (biotechnology — biosafety — bioeconomy — biopolitics) "BIOs" (Mokhov, 2020), and bioethics and bio-law, most likely, will soon become the regulatory basis therefor and remain so for decades. In this instance, it is important not to waste time in order to prevent serious mistakes that can discredit the really useful technologies, by timely drawing a line of demarcation between the useful technologies and the harmful or "questionable" ones (including the products obtained through the use thereof).

Some countries (UK, USA, etc.) (BBSRC, Biotech Britain, 2015) expect a rapid growth of bioeconomy over the next decade, along with weakening of the role and importance of the traditional industries and sectors both in economy and in politics.

Due to the novelty of the phenomenon under consideration, the word "bioeconomy" is not often mentioned in laws, regulations and other national documents. Resolution of the Government of the Russian Federation No 316 of 15 April 2014 entitled *Approval of the "Economic Development and Innovative Economy" State Program of the Russian Federation* pointed out the need for a transition from individual measures in support of the sphere to formation of an integral system for the development of bioeconomy in Russia. The term "bioeconomy" was also mentioned in other documents that are no longer valid.¹

While some time ago the economic policy was determined by landowners, then by industrialists, and now — almost everywhere — by bankers, they may soon start to be squeezed out by the proteges of biotech

¹ Rasporyazheniye Pravitel'stva RF ot 27.12.2012 № 2539-r "O gosudarstvennoy programme RF'Razvitiye promyshlennosti i povysheniye yeye konkurentosposobnosti" [Order of the Government of the Russian Federation No 2539-r dated 27 December 2012 On "Industry Development and Competitiveness Increase" State Program of the Russian Federation]. Collection of Legislation of the Russian Federation, 2012, No 53 (Part II), Art. 8043.

companies. On the one hand, this is a natural process for innovative technologies development (intellectual work and innovation are being actively supported at the official level in many countries, while "money bags" — under various pretexts, although not always successfully — are being pushed away from making key political decisions due to the obvious contradictions between the capital and the labor), however, on the other hand, a rapid expansion of new entities into the economic and (or) political elites may lead to imposition of wrong priorities on the society through laws and administrative procedures, which will manifest itself in a biased, unbalanced biopolitics, and cause a serious social conflict.

It is not a mere coincidence that — despite the innovative, experimental nature of certain technologies and solutions — scientists, experts, and policymakers are already raising and discussing the issues of ensuring biological and other kinds of safety/security. Decoding of the human genome, as well as the genomes of many animals and plants, digitalization of considerable amounts of genetic information, the possibilities opened up by the actively developing synthetic biology and other directions of science and technology advancement allow extensive intervention into the human and/or animal genome, creation of chimeras, biological objects with predetermined programmable properties, as well as a "synthetic genome" or fragments thereof which can be introduced into a biological object and make possible its subsequent reprogramming, or transformation. Such technologies open up vast prospects for agriculture, industry, medicine (including veterinary), and pharmaceutics. However, haphazard, not properly thought through, decisions, the "race for the genome", for scientific (research) and other kinds of success at any cost may entail serious problems of a biological, social and economic nature. Besides, we must not forget about the existence of formal and non-formal groups trying to achieve their political, military and other goals using technological advances and advantages.

Knowing the ethnic and other collective characteristics of [geographically] concentrated communities, one can try creating a "selective" weapon. Such attempts are being made in the USA, China, Japan, and some other countries. The corresponding research and

development may be financed by both NGOs and individuals. The research is taking place in the following areas: modifications of highly dangerous infectants; production of latent viruses, genetic elements (introduced on viruses); production of new toxins (with higher resistance and virulence); synthesis of new biological compounds (bio-poisons).

The control over military biorobots, as well as artificial intelligence systems aimed at causing harm to human health or life, and the environment, are becoming a separate problem.

In view of the above, the countries all over the world are facing the need to promptly resolve the issues of ensuring biosafety, creating biological risk management systems, performing comprehensive assessment of biotechnologies, monitoring new technologies and biological objects.

The principle of precaution known in international, medical, and environmental law acquires a new perspective, requiring development of a set of measures in order to ensure its implementation and application in practice.

A number of fundamental challenges also exist in the development of bioeconomy as a whole (from modernization or disruption of the prevailing global and national economic models, to the shift of the macroeconomic and social processes management paradigm). The existing challenges and threats to civilization are becoming so obvious that they must not be ignored, although the current daily problems facing the policymakers and governments focused on solving short-term national issues make them actively resort to the "avoidance" technique. This results in decades of unproductive work of experts consisting in development of recommendations, "roadmaps", and similar documents, which, as a rule, are neither universally binding, nor supported by the necessary enforcement or other efficient mechanisms. Consequently, governmental and nongovernmental entities and institutions fail to respond even to insignificant new or unconventional challenges and threats.

Along with the old (and still outstanding) problems related to the functioning of economic entities, businesses, and their harmful activities (at least from the standpoint of ecology, environmental pollution), new ones are coming up. The power resource of science and technology is

steadily increasing; the opportunities for managing the conception of life (birth), as well as the lifecycle of living systems (including dying and death) are emerging. Importantly, such living systems include not only the simplest organisms, but also higher ones, and even humans.

It is impossible to stop the progress of science/research and technology, as this is a natural process. However, technologies are not alike: some of them have evidently positive social, economic and other effects, while others do not. Most frequently, a new technology has a certain set of positive and negative (undesirable) properties, qualities, and characteristics, which complicates and renders difficult the decision on whether its use and application should be broad or limited. The issue of value-related priorities, of a hierarchy of values for a particular society or state, is becoming increasingly relevant.

Some technologies are intended primarily for specific individual purposes (e.g., medical abortion, surrogacy), some others — for state purposes (e.g., missile, space and other military technologies), and still others — for public, social, purposes (e.g., healthcare or waste disposal technologies).

In our opinion, the cutting-edge technologies should, mostly and primarily, serve not an abstract economy focused on making a profit "at any cost" (to the detriment of public interests, ecology, etc.), but the implementation of such fundamental human values as preserving and maintaining people's health, as well as increasing the duration of their active and healthy life. A high quality of life is possible only if there is affordable and healthy food, clean water and air, comfortable housing, and favorable environment. At the same time, we cannot forget about the limits of economic growth and unequal distribution of wealth, which, on the one hand, require imposing certain restrictions on the traditional (extensively developing) industries and sectors of the economy, and, on the other hand, require stimulating the development of technologies which can ensure the transition from the extensive path of economic development to the intensive one. The issue of environmental sustainability of biosystems is becoming more and more pressing, and a timely settlement thereof is a prerequisite for resolving the accumulated problems of both the functioning economy, and the

emerging bioeconomy fraught with environmental risks incomparably higher than those well known to us.

Advances in technologies require determining the key vectors of development thereof, as well as understanding (at various levels, from researchers in labs and innovative businesspeople to policymakers) the logic of the development of society in the context of a new biological and digital reality.

In this connection, the issues of strategic planning and comprehensive technology assessment come to the fore. It is not a mere coincidence that assessment of cutting-edge biological and other technologies increasingly includes not only the assessment of their effectiveness (by type: economic, medical, social, energy-related, etc.) and safety (social, biological, etc.), but also the ethical and legal assessment, which, in turn, drives further development and institutionalization of bioethics and biolaw as a science, a sphere of applied research, expert practice, emerging regulators of an increasing number of social relations in bioeconomy.

III. Bioethics as a Phenomenon and Its Significance in Regulating the Emerging Bioeconomy

One of the founders of bioethics, Van Rensselaer Potter (2002), outlined the goal of this science: to learn to survive in new conditions, which requires taking into account both the biological knowledge and the universal human values when making the most important decisions.

The subject of bioethics is undergoing the process of crystallization. In simplified terms, bioethics is understood as the science dealing with moral/ethical behavior with regard to life, health, and the attitude of an individual to living things (humans, animals, plants, the environment, the biosphere).

Irina Siluyanova (2008, p. 256) looks at bioethics from the standpoint of its overarching ultimate task — that of preserving the human life.

Natalya Sedova (2005) speaks about the non-formal regulation of relations in medicine and other spheres, distinguishing the theoretical (science and research), practical and applied spheres in it.

Igor Ponkin and Alexandra Ponkina (2014) suggest considering bioethics as a science (studying moral, ethical, legal, and anthropological issues) and a system of regulations (a set of deontological imperatives

Noteworthily, the reference to the system of regulations is positive in some definitions, and significant for us.

in medicine, pharmaceutics, etc.).

In Russian science/research and specialist publications, bioethics is closely associated with medical ethics and medical deontology (Semina, 2021). This is due to the developed state of medical ethics, and the legitimization of ethical principles specifically in relation to medicine and healthcare. Ethics-related regulation is also common in the sphere of circulation of pharmaceuticals and medical devices. The Russian legislation contains provisions directly stipulating the activities of ethics boards, councils or committees, and the procedures for ethics reviews with regard to certain medical products requiring official registration before going to market.

In science and research as a whole, as well as in biology, psychology and some other spheres of activity sensitive in terms of ethics, the situation is much worse. These spheres lack not only ethics-related standards and (or) institutions, but sometimes even special industry-specific (or sector-specific) laws which could stipulate and formalize the ethics-related issues.

Bioethics is not a purely corporate entity (like medical ethics, or the ethics of a lawyer, notary, etc.), but functions as a multidisciplinary field of knowledge that establishes, develops and upholds — using its own resources and capabilities — the basic ethical principles regarding its subject matter and area.

A number of countries not only allow for certain elements of institutionalization of bioethics, but have bioethics centers actively functioning on a permanent basis (e.g., Center for Bioethics at the Catholic University of the Sacred Heart (Italy); Institute for Bioethics (Netherlands); Centre for Biomedical Ethics and Law at the University of Louvain (Belgium)).

In Russia, there are ethics (bioethics) boards/councils (committees) affiliated with the Ministry of Health of the Russian Federation, as well as local ethics boards/councils (committees) affiliated with medical

and some research organizations. However, a clear understanding of their structure, principles, subject matter, operational boundaries, and hierarchy, has not formed yet. In recent years, due to the development of genetic, information and other technologies, the interest in bioethics, as well as in bioethics boards/councils (committees) and other institutions, has increased. There are proposals to create a developed network of such institutions, and to ensure implementation of a single national policy in this area, in the way similar to some other countries (Mokhov, 2020).

Despite the differences in approaches to defining the subject matter of bioethics, as well as its boundaries, the correlation of spheres, and the importance of science/research and practice in bioethics, most authors point out that one of the tasks of bioethics is to establish some standards and guidelines. At the same time, the authors' positions may differ: from complete absorption of law by bioethics to an almost complete or partial demarcation between the norms of ethics and law, the ethical and the legal regulation of the most important kinds of relations (from conception of life to death and even further).

In our opinion, the truth is between the two extremes. The norms (standards) of professional ethics and ethics in general have existed and, apparently, will continue to exist for a long time. As a rule, with the development of the state, law and legislation, they tend to increasingly play not a decisive, but an important auxiliary role in the regulation of certain kinds of social relations (professional, employment, etc.) in the boundary zones where, on the one hand, regulation is necessary, and, on the other hand, "non-legislative" regulation is considered to be acceptable and sufficient at a certain stage of the state, law, and society development. All of the known legal norms were once moral, ethical, or religious norms, but not all of the known social norms for various reasons (from insufficient significance, or the limits to which law can intervene in certain relations, to the impossibility of an accurate description) — become legal norms. Moreover, a direct conflict is possible between some of them, which is resolved in favor of the legal norm as a definite and formalized gauge of what is considered to be right.

At the same time, ethics and the norms thereof, although conventionally considered to be auxiliary regulators, to be standard, generally accepted, non-legislative rules, are no less important, and sometimes — at a certain stage of society, law and legislation development — are the only regulators of social relations. Nowadays, they even might be considered a "new religion" during formation and development of biotechnological and digital reality, in a rapidly changing global landscape. They reflect the foundations, the bonds of society, based on the norms of morality, religion, traditional culture, and the experience of past generations.

The existing differences between law and ethics (bioethics) allow bringing up and discussing the issue of biolaw as another regulator of bioeconomy.

IV. Biolaw as a Phenomenon and Its Significance in Regulating the Emerging Bioeconomy

The debate about the place of ethical norms in the system of social regulators, the existence of similarities with and some fundamental differences from the norms of law, including a common subject-matter domain and non-coinciding areas, the correlation and the boundaries between governmental regulation and self-regulation, as well as "hard" and "soft" regulation, allow speaking about biolaw along with the phenomenon of bioethics.

In specialist publications, the following common features of ethical and legal regulators are usually mentioned: they are social norms; they are obligatory for those to whom they apply; there are sanctions for their violation (Valiev, 2016); the norms are of a practical, applied nature (Bakshtanovskii and Sogomonov, 2007).

The main differences between ethical and legal norms are as follows: wider boundaries of ethics in comparison with law (law is a minimum of ethics (Gutnik, 2017)); a legal norm comes from the government, while an ethical norm comes from the professional community; the procedure, the process for adopting and communicating a legal norm is strictly defined by law, which is not the case with ethical norms (they are adopted based on the established rules, and customs; although adoption of some ethical norms is sanctioned by law or in accordance with the procedure established by law); a norm of law is a form of governmental

regulation, while the norm of ethics is a form of self-regulation, selforganization of the type or the sphere of professional activity; the subsidiary role of ethical norms in regulation of certain social relations.

As Sergey Alekseev (1966) point out, law is the main instrument of the state through which social relations are influenced in order to organize them. In certain instances, the borderline between a norm of bioethics and a norm of law (legislation) becomes completely or partially erased (from "soft law" to direct implementation of an ethical norm into a norm of law).

For example, in Russia, the ethical principle of confidentiality, medical (health) privacy, is also a legal principle formalized in Article 4 and some other articles of Federal Law No 323-FZ [in Russian: N^0 323- Φ 3] of 21 November 2011 entitled *Fundamentals of Public Healthcare* in the Russian Federation.²

The need to protect vulnerable people has been reflected both in Federal Law No 323-FZ of 21 November 2011 (Fundamentals of Public Healthcare in the Russian Federation), and in Federal Law No 61-FZ [in Russian: N^0 61- Φ 3] of 12 April 2010 (Circulation of Pharmaceuticals),³ as well as in other federal laws and regulations.

Of interest is the experience of other countries with a practice of formalizing ethical norms in legislation through which many ethical norms become legal norms. However, in such instances, ethical regulation remains in place, and the work of ethics boards/councils (committees) acquires a new ethical and legal meaning, despite the significant differences in assessing the issues of bioethics in different countries (Zakharova, 2020).

For example, in France, the Bioethics Law has been adopted and — with some amendments — has been in effect for more than two decades.⁴ South Korea has the Bioethics and Safety Act⁵ in place. The Chinese

² Collection of Legislation of the Russian Federation, 2011, No 48, Art. 6724.

³ Collection of Legislation of the Russian Federation, 2010, No 16, Art. 1815.

 $^{^4}$ Projet de Loi relatif à la bioéthique. Available at: https://www.assembleenationale.fr/dyn/15/textes/l15t0474_texte-adopte-seance.pdf [Accessed 24.12.2020]. (In Fr.).

⁵ Bioethics and Safety Act. Available at: https://mbbnet.ahc.umn.edu/scmap/KoreanBioethics.pdf [Accessed 24.12.2020]. (In Eng.).

Biosecurity Law⁶ includes the norms regulating research in the sphere of biotechnologies in order to prevent any kind of misuse thereof.

Biolaw is usually mentioned in Russian research papers and publications without an analysis of its essence, subject matter, or other features. In its most general form, biolaw makes it possible, with sufficient degree of completeness and certainty, to perform systemic regulation of the key social relations arising in various spheres of economy (medicine, pharmaceutics, industry, agriculture, energy sector, etc.) in connection with development, creation, implementation, and application of cutting-edge biotechnologies.

Biolaw is a phenomenon that has not gained sufficient attention in the Russian science of law yet. It emerged at the junction and almost simultaneously with bioethics, but it cannot be reduced to bioethics only, since legal norms — unlike ethical, moral, or other kinds of norms — are obligatory for everyone and formally defined. A thing that bioethics and biolaw have in common is the platform: the human activities involving the use of living matter (Luk'yanov, 2008) to accomplish a fairly wide range of tasks. Partially, the range of tasks facing biolaw is accomplished within the framework of the science of medical, environmental and some other branches of law, the subject matter of which is narrower as compared to bio-law (the sector-based, or the activity-based approach).

In our opinion, biolaw can be understood as a totality of various kinds of social relations (from use and preservation of the animal world to biomedical, biopharmaceutical, bioenergetic and other types of activities), where biotechnologies, biosystems, cells, tissues, or organs of plants, animals and humans are used.

Biolaw is not a separate branch of law either in terms of the scale of the tasks to be accomplished, or in terms of the area of application, or in terms of the range of entities the activities of which are subject to legal regulation. We are talking about supra-sectoral regulation of social relations that have a common technological platform, as well as common foundations and principles.

⁶ Biosecurity Law of the P.R.C. (中华人民共和国生物安全法). Available at: https://www.chinalawtranslate.com/en/biosecurity-law/ [Accessed 24.12.2020]. (In Eng.).

In connection with the above, biolaw has a complex structure of internal (within the boundaries of law) and external relations (with other spheres of practice, and areas of human knowledge). It actively uses the experience/practices of the theory of law and state, administrative and civil law, as well as medical, pharmaceutical, sports, environmental, energy and other branches of law (legislation).

The development of bioeconomy and the individual spheres thereof requires prompt development of this branch of science, at least for the sake of ensuring efficient law-making and expert work. In the absence of such development, noticeable difficulties are already arising in practice with the development and implementation of genetic and other technologies, biomedicine and biopharmaceutics, biobanking, etc.

V. Conclusion

Advances in technologies require determining the main vectors of their development, as well as understanding — at various levels — of the inner logic of their development, which, in the present-day law-governed and welfare states, is unthinkable without an ethical and legal base.

In practical terms, bioethics is a system of standard, generally accepted, non-legislative rules. In certain individual instances, the borderline between a norm of bioethics and a norm of law (legislation) becomes completely or partially erased (from "soft law" to the direct implementation of an ethical norm into a norm of law).

Biolaw emerged at the junction with bioethics, but cannot be reduced to bioethics only, since most of the legal norms are obligatory for everyone and formally defined. It has complex connections and correlations with bioethics, having a common subject-matter domain with bioethics, but not absorbed by the latter.

Bioethics and biolaw provide an ethical and legal framework for relevant (legitimate) activities aimed at the development of bioeconomy as a whole, as well as individual spheres and sectors thereof.

Bioethics and biolaw are making their first steps in Russia. The development of legislation in this area, building on the existing experience and practices of law, ethics and other sciences, will become one of the drivers of bioeconomy development in Russia.

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