

LEGAL SUPPORT OF THE SAFE USE OF MICROORGANISMS IN PRODUCTION

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Abstract: The development of effective legal instruments, ensuring the safe use of microorganisms in production, is becoming the top priority task of the state for human development and well-being. The types of risks, associated with the use of microorganisms in production, as well as the factors, causing their occurrence, are analyzed in the article. It was assessed the sanctions for genetic manipulations at the molecular and cellular levels, with the purpose of creation of genetically modified organisms, carried out with gross violation of the conditions, provided for by a special permission (license). It is emphasized, that in order to implement the safety requirements, binding in the customs territory of the Customs Union, to food products, manufacturing in the customs territory of the Customs Union, and to the processes of their production and storage, it is necessary to unify the legislation on the safe use of microorganisms in production, in particular, to develop the Code for the safe use of microorganisms in production.

Key words: microorganisms, food production, technical regulations, licensing, gross violations.

1 Introduction

Currently, the problem of the safe use of microorganisms in production is of particular importance. Blind implementation of the “inertial” scenario in this sphere, which does not involve decisive actions for destroying “super microbes”, resistant to one or several antibiotics, leads to the large-scale negative consequences for human development and well-being. “Super microbes” are easily spread between continents and their movement is usually very difficult to track.

Unfortunately, modern science is aimed at studying only one type of bacteria, and that does not provide a deeper understanding of the resistance of microbial communities, present in the environment.

For example, today in the world there are over 2500 species of salmonella, comprising its new subspecies, resistant to the “drugs of last resort”.

According to foreign scientists, the resistance of microorganisms to antibiotics, including those, which are used in modern medicine, has existed for millions of years. This suggests that antibiotic resistance is an ancient natural phenomenon, firmly built into the general genome of microorganisms (Bhullar et al, 2012).

In addition, there is an opinion, that this problem is so immense that it is impossible to comprehend, taking into account the likelihood of interactions between an unimaginable number of bacteria with, at first glance, unlimited potential for gene transfer, as well as the complex nature of mixtures of chemical compounds, promoting the selection and diversity of mechanisms of resistance formation (Smith et al, 2005).

Currently, most experts agree that wastewater treatment plants are the dangerous hotbeds of horizontal gene transfer, due to the high density of bacteria and the rich content of nutrients (Stalder et al, 2012; Tennstedt et al, 2003). One of such examples is the United Kingdom - the country with a high level of investment in wastewater treatment. Nevertheless, up to 6 million cases, caused by the antibiotic-resistant coliform bacillus *E. Coli*, occur annually, in the coastal waters of this country (Leonard et al, 2015).

2 Methods

Microorganisms and viruses, capable of causing the disease, poisoning and death of humans and animals, are classified by domestic scientists as microbiological agents (Korma, 2018). The change in the virulence of microorganisms and the adaptation of many of them to the used antibacterial agents are

considered as the main reasons for the blurring of clinical picture of diseases in modern conditions (Bozhchenko, 2019).

According to P.S. Oparin, the serious danger in the epidemiological, environmental and hygienic respect is constituted by the waste of medical institutions, since the content of microorganisms in them, including pathogens, is 1,000 times higher than in solid municipal waste (Oparin, 2001). V.G. Akimkina notes that more than 30% of medical wastes are epidemiologically hazardous (Akimkin & Bormashov, 2015).

However, according to the World Health Organization, only 15% of clinical wastes are considered as extremely hazardous materials. The rest, approximately 85%, are ordinary non-hazardous wastes (Pogodina & Baranova, 2018).

According to T.V. Petrova, the main reason for the above discrepancies is the existence of several overlapping lists of pollutants, which are the subjects to regulation for various purposes: protection of human health (sanitary and hygienic regulation); environmental protection (environmental regulation); protection of aquatic biological resources (fishery regulation); protection of ecological systems (for example, protection of Lake Baikal) (Petrova, 2018).

The most relevant and significant area of state policy of many countries in the field of ensuring the quality of products, goods and their safety for human health is the development of legal instruments, which regulate the turnover of food, medicine, cosmetic products, personal care products, and many others, with the complete removal of resistant bacteria, penetrating into environment. Due to this, the legislative framework is formed on the basis of understanding the risks, resulting from the microbial resistance in the environment, and the rational implementation of environmentally sound technologies.

Currently, the Russian Federation has the Comprehensive Program for Development of Biotechnology through 2020. According to this document, an increase in the consumption of biotechnological products from 120 billion rubles in 2010 to 1000 billion rubles in 2020 is envisaged. The volume of output of biotechnological products for the specified period should be increased by more than 33 times - from 24 to 800 billion rubles, with a decrease in the share of imports in consumption from 80 to 40%.

It should be noted, that back in 1980, the USSR ratified the Budapest Treaty Notification No. 63 of July 28, 1987, in which three collections are indicated as International Organism Depositories: the All-Union Collection of Microorganisms, the All-Union Collection of Industrial Microorganisms, and the Collection of Microorganisms of the All-Union Scientific Research Institute of Antibiotics.

Many countries have tough requirements for the work environment through the implementation of the system HACCP (Hazard Analysis and Critical Control Points), which takes into account all types of risks, associated with the use of poor-quality food. Today, this system is a reliable mean for the protection of consumer rights. On the contrary, in Russia, there are only rare organizations with such a system.

On the territory of the Russian Federation, the protection of consumer rights is ensured by a number of regulatory legal acts, including the Law of the Russian Federation of February 07, 1992 No. 2300-1 “On Protection of Consumer Rights”. So, by virtue of Articles 4, 7 of the said Law, the manufacturer (contractor) is obliged to ensure the safety of goods (work) during the specified service life or shelf life of goods (work).

The provisions of the Federal Law of January 02, 2000 No. 29-FZ “On the Food Quality and Safety” (hereinafter - the Law of January 02, 2000 No. 29-FZ) regulate the issues in the field of

ensuring the quality of food products and their safety for human health. The manufacturing of food products, materials and goods, by virtue of the said Law, should be carried out in accordance with technical documents, while meeting the requirements of regulatory documents (Article 17, Part 1).

Basic requirements for the turnover of food products (including those of animal origin) are enshrined in the Technical Regulation of the Customs Union "On Food Safety" TR CU 021/2011, approved by the Decision of the Customs Union Commission of December 09, 2011 No. 880 (hereinafter - TR CU 021/2011).

By virtue of the part 1 of Article 5 of TR CU 021/2011, food products are put on the market in accordance with the technical regulation, as well as the other technical regulations of the Customs Union, applicable for these products. As an example, we use the technical regulation "On the Safety of Milk and Dairy Products" (TR CU 033/2013), adopted by the Eurasian Economic Commission Council Resolution, dated October 09, 2013 No. 67. It establishes the safety requirements for milk and dairy products, binding in the customs territory of the Customs Union.

The production of goods, which do not meet the requirements of the legislation on technical regulation, constitutes an administrative offense under Article 14.43 of the Administrative Offences Code of the Russian Federation.

Such violations include the non-conformity of labeling (in terms of specifying the information about the manufacturer, net weight of the product, etc.), non-compliance with quality requirements (detection of non-dairy fat), reveal of pathogenic microorganisms in finished products (butter and sour cream) in the amount, exceeding the permissible limits of safety indicators. At the same time, according to the apt remark of S.A. Bogolyubov, the optimal functioning of legal liability is sometimes hindered by impracticable prescriptions, which, in fact, cannot be implemented, are untrue, are aimed rather at declaring, imitation, but not at regulation of public relations (Bogolyubov, 2019).

According to Part 2 of Article 24 of the Federal Law of March 30, 1999 No. 52-FZ "On the Sanitary and Epidemiological Well-Being of the Population" (hereinafter referred to as the Law "On the Sanitary and Epidemiological Well-Being of the Population", the persons, who carry out their work and perform services with violation of sanitary rules, must suspend or terminate their activities.

Part 11 of Article 19 of the Federal law "On Licensing of Certain Types of Activities" establishes an exhaustive list of gross violations of license requirements.

3 Results And Discussion

Thus, the failure to comply with the requirements by the individual entrepreneurs or legal entities, as a result of negligence of these persons to the performance of public law obligations, constitutes a significant threat to protected public relations, and does not ensure the maintenance of the necessary level of population protection.

Part 4 of Article 14.1 of the Administrative Offences Code of the Russian Federation provides for administrative responsibility for carrying out the entrepreneurial activities with gross violations of the conditions, envisaged by a special permission (license).

However, the note to this article of the Administrative Offences Code of the Russian Federation indicates, that the concept of "gross violation" is established by the Government of the Russian Federation in relation to a particular licensed type of activity.

At the same time, any documents (materials), obtained in accordance with the current legislation, and on the basis of which the circumstances can be established, stipulated in Article

26.1 of the Administrative Offences Code of the Russian Federation, can serve as the evidence of an offense (for example, protocol of the laboratory tests; conclusion on the results of laboratory tests; expert opinion on the results of laboratory test reports; inspection report; protocol on an administrative offense; explanations of the person, in respect of whom the proceedings are being conducted on administrative offense; testimony of the victim, witnesses, other documents, as well as the testimonies of special technical facilities, material evidence, etc.).

Due to the requirements of Part 1 of Article 28.5 of the Administrative Offences Code of the Russian Federation, the protocol on an administrative offense is drawn up immediately after the identification of administrative offense, and is submitted to a judge, to the body, to an official, authorized to consider the case of administrative offense (Part 4 of Article 28.8 of the Administrative Offences Code of the Russian Federation). Meanwhile, in practice, contrary to the requirements of the Administrative Offences Code of the Russian Federation, the protocol on the administrative offense and the protocol on the temporary prohibition of activities are drawn up much later, after the day the audit has been completed and the inspection report has been drawn up and the order on elimination of violations has been completed. Although the position of the legislator indicates the need to draw up a protocol, entailing the suspension of activities before drawing up an act, based on the results of the audit.

4 Summary

Thus, the failure to take immediate measures, aimed at suspension of the activities, as required by the Administrative Offences Code of the Russian Federation, indicates the absence of a direct threat of damage to the life and health of citizens, from the corresponding economic activity.

The above analysis of existing problems allows us to conclude, that in order to use the microorganisms in production safely, it is necessary to take into account the risks, caused by the following factors:

- 1) evolutionary resistance of microorganisms to antibiotics;
- 2) compliance with foreign legislation in the field of safe food production;
- 3) summation of the types of harmful substances and microorganisms;
- 4) summation of the volume of harmful substances and microorganisms, involved in production of food products;
- 5) the lack of a common information network on the use of microorganisms for peaceful purposes.

5 Conclusions

In conclusion we emphasize, that the proposals, put forward by us, can be used in the process of development of legislative acts, and further unification of legislation on the safe use of microorganisms in production, in particular, when developing the Code for the safe use of microorganisms in production.

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