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SOCIAL AND ETHICS-LEGAL ASPECTS OF BIOECONOMY

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Abstract

The article discusses the ethical and legal problems of regulation of the introduction of modern biotechnology in agriculture. First and foremost is biotechnology and genetic engineering. The main objective of this study was to identify the best practices of social regulation negative effects of modern biotechnology on the basis of a comparative review of European and Russian legal regulations of food safety. The study also focuses on the risks of introduction of biotechnology in agriculture and provides general classification of them namely food, agricultural, environmental, patent, social and ethical. Based on the analysis of the best European practices, the article concludes the necessity of international quality standards on risk assessment of quality and food safety in the Russian Federation. Despite the fact that the risk assessment system is used already for some time, consumers don't always trust the reliability of the results. One explanation of this fact is that a national food safety system in the past had problems with the timely alert about the potential dangers of certain products. In many countries the reason for the rejection of certain products, the manipulation of genetically modified organisms (GMOs) can be social and ethical views. Such conflicts often reflect deeper issues relating to the interaction between human society and nature – issues that must be fully taken into account in any attempt of public communication. Proposed human expertise in the form of agrobioethics similar to bioethics in biomedical technology is understood as a mechanism of social control and regulation of the new «life systems" in the Bioeconomy.

Keywords: *bioeconomy, biotechnology, genetic engineering, risk, law, bioethics, agrobioethics.*

JEL Classification: *O13,O33, Q16*

1 Introduction

Global challenges and strategic socio-economic priorities for the future of Russia and its regions, has led to the need to expedite the study, forecasting and design tools that should contribute to the sustainable development of rural areas, to ensure the safety and quality of life, protect the environment and improve environmental management. The Rome Declaration of the world forum for food security from 13 — 17 November 1997 defined the concept of food security as "access of all people at all times to the food needed for a healthy and active life".

The agriculture in the 21st century faces multiple challenges: it has to produce more food, feed and fiber for a growing population with a smaller rural labour force, more feedstock for a potentially larger market of bioenergy, it should contribute to the overall development in dependent on agriculture for developing countries should apply more efficient and sustainable production methods and adapt to climate change (Ron Johnston, 2011). Food security from the point of view of any state is the ability of the state regardless of external and internal threats to the population's needs in food in quantities, quality and the assortment corresponding to accepted standards and safety regulations.

Key issue:
1. Whether our food is safe in terms of application of new biotechnologies?
2. What measures should be taken in the convergence of the global food market for the standardization, regulation and security of the consumer?

The main problems of food safety:
1. Low-income citizens are forced to give preference to cheap (and often falsified) and substandard food.
2. The trend of a General decline in quality of food and the increase of anxiety to the production of food using genetic engineering.
3. The increase in revenues of genetically modified foods (GMOs) and products thereof: soybeans, corn, canola, rice, potatoes, pumpkin, papaya etc.
4. The proliferation of intellectual property rights on genetically modified seed and breeding material of large transnational corporations (TNCs).
5. Low level of awareness of both the farmers and consumers about the standards of food safety.
6. A large number of legal regulations, international and domestic (more than 300).
7. The complexity of harmonization of the requirements for the competitiveness and high standards of food safety.

The main objective of this study was to identify the best practices of social regulation negative effects of modern biotechnology on the basis of a comparative review of European and Russian legal regulations of food safety.

1.1 International policy and system standards to ensure food safety: brief overview

In 2005, Organization for economic cooperation and development (OECD) in the framework of the International programme for the development of the future launched a project on "Prospects of development of Bioeconomy 2030"(OCED, 2009. The main prerequisites for the development of the Bioeconomy in a global scale are:

- population growth, its per capita income and educational level, primarily in developing countries, where, according to forecasts, in 2030 will accommodate 97% of the 8.3 billion people on the planet;
- increase in energy demand combined with the need for measures to reduce the greenhouse effect;
- population ageing in the EU, BRIC, and the growing demand for food, the production of which will use transgenic plants and animals.

At the international level, the World trade organization (WTO) is responsible for developing regulations concerning the hygiene and safety of food products. The agreement on sanitary and phytosanitary (SPE-agreement), which concluded WTO members, includes a wide range of activities relating to the protection of people and animals from diseases associated with the consumption of food products. The Europe Union (EU) law reflects its obligations to the WTO and meets the requirements of the Commission "Codex Alimentarius", if appropriate (Sadik et al, 2016). In each member state of the EU is responsible to independently monitor the compliance with EU directives. The directives also establish General principles of control, sampling and inspection of food products. Member States are only obliged to inform the European Commission about their activities for control.

European legislation concerning food products can be divided into the following three main components. Legislation concerning food safety, which covers areas such as hygiene, food products, food additives, materials in contact with food products, new food products, and control systems. The second family of laws applies to information for consumers, which mostly seem to be on the labels. The third family of laws establishing quality requirements aimed at protecting the quality and comprises "vertical" directives, i.e. directives for dairy products, dietetic products and specific products produced in certain regions (European Commission Directives, 2000, 2002, 2012, 2014) .

Over the past 15 years developed new approaches and new principles of the international system standards to ensure food safety, namely:

1. The principle of "From farm to table" - a systematic approach, the control parameters of food safety at all stages of production — from receipt of raw materials to product use by the end user. The concept "From farm to table" is an integrated system of quality control of food and feed, traceable at all stages of production and delivery of food products. Safe products are the foods that do not pose a risk to the health of humans and animals.
2. The principle of "Traceability" in the production chain of feed and food. "Traceability" - a systematic approach, the control parameters of food safety at all stages of production — from receipt of raw materials to product use by the end consumers.

   The main mechanisms of quality assurance and food safety in the WTO are the Code of Alimentarius and Hazard Analysis and Critical Control Points (HACCP) (Van der Meulen B., 2010). The Code of Alimentarius (Codex) is an international system of standards, which aims to ensure food safety and the removal of barriers to world trade.

Principle of construction:

- minimum of security requirements that can support the even poorer countries;
- build product groups in accordance with the practice and features of world trade in specific goods; - the principle of reliance on vertical standards;
- the unity of requirements to the construction standards (the unity of form);
- the unity of the rules of standards development (control from one center).

Requirements:

- make up products and raw materials, food hygiene;
- additives, residual pesticides, pollutants;
- packaging requirements, labels, distribution;
- advertising;
- methods of analysis and sampling and other at all stages of the food chain "from farm to fork" for

  Europe and other countries accepting the requirements of Codex Alimentarius.

Russian legislation in the field of food safety has the following structure and quantitative parameters:

1. In the field of veterinary surveillance (39 of which 10 Federal law).
2. In the field of phytosanitary control (36 of them 5 of the Federal law).

3. In the field of safe handling of pesticides, agrochemicals and seed control (25 of them 3 Federal law).
4. In the field of consumer protection and the environment (22 of them 3 Federal law).

Total: 120 major legal documents, not including technical regulations and sanitary rules! (Sadik et al, 2016).

2 Data and Methods

When performing this study, we used the analysis and review of the international and Russian normative legal acts, regulating the standards and norms of food safety in terms of the development of the Bioeconomy (Garcilazo, E., 2014). Following methods were used: system analysis, historical retrospective, comparative.

Aachievements of biology, biochemistry, plant breeding, genetics, microbiology mean a real revolution in agriculture - biotech. Its achievements are the new means of production, innovative technologies as integral elements of the zone systems of agriculture, genetic engineering. Gene or genetic engineering is fundamentally different from the selective breeding involved in methods to create varieties and hybrids of plants, crops and animal breeds. The task of genetic engineering is to obtain the desired qualities of a modified or genetically modified organism. Unlike traditional breeding, in which the genotype is only indirectly altered, genetic engineering allows direct intervention in the genetic apparatus using molecular cloning techniques. When entering into the body (it can be a plant, an animal, a micro-organism and a person) new genes can give it a new desirable characteristic, which he had never before. Organisms that have undergone genetic engineering are called GMO (genetically modified organism).

One of the important tasks of genetic engineering in agriculture is to obtain plants that are resistant to viruses, since currently there are no other ways to combat viral infections of crops. The introduction of the virus shell protein genes into plant cells makes plants resistant to this virus. Currently obtained transgenic plants capable of resisting the effects of more than a doesn't different viral infections. Another important task of genetic engineering relates to the protection of plants from insect pests. The use of genetic engineering in agriculture has reduced the use of insecticides by 40 - 60%. In other words, the production of genetically modified organisms (GMOs) increases the yield of cultivated plants and the productivity of farm animals. All this increases the possibility of solving the problem of food in the world and becomes a way of reducing the price of food.

However, the use of GMOs, despite the wide and rapid spread, is a legitimate concern. Some experts, while not denying the vast potential of agricultural

biotechnology in food production, at the same time, warn that the benefits of biotechnology should not be valued too high, and in determining its role in global agricultural production should not fall out of attention of potential negative consequences. Scientists fear that the use of seeds derived from biotechnology may result in the loss of genetic diversity among crops, as indigenous species can be replaced in the same way as modern hybrids have replaced many traditional varieties or breeds. Movement towards genetic homogeneity can lead to greater plant susceptibility to many pests, diseases or other negative environmental impacts, problems that are the scourge of monoculture farming. There are also ethical problems associated with the transformation and introduction of genes of one species of plants or animals in the genetic apparatus of another species.

European Group on ethics have stressed the need for an integrated perspective and approach to the agrarian technology so that when the ethical impact assessment of the new technology took into account the aspects of production, storage and distribution. The main objectives, such as food security, food safety and long-term use (persistence), in her view should be adopted as the main priorities and principles on which each technology in agriculture should be equal.

Systematizing the GMOs risks, we can suggest their classification. The basis for the classification is the level of possible harm and safety for the key components of the food market: food, environment, agriculture, consumer health, the right to change and the possession of new natural objects. This risk classification can be used to develop measures to prevent the impact of possible threats from the introduction of GMOs in agriculture.

Food risks:

- direct effect of toxic and allergenic proteins in transgenic GMOs.
- risks, indirect pleiotropic effect of transgenic proteins on the metabolism of plants.
- risks, mediated by the accumulation of herbicides and their metabolites in resistant varieties and species of agricultural plants.
- risks of horizontal transfer of transgenic constructs in the first place in the genome for symbiotic human and animal bacteria (E. coli, Lactobacillus (acidophillus, bifidus, bulgaricus, caucasicus), Streptococcus thermophilus, Bifidobacterium, etc.).

Environmental risk:

- reduction in varietal diversity of crops as a result of widespread application of GMO derived from a limited set of parent varieties.
- uncontrolled transfer of structures, especially in determining the different types of resistance to pesticides, pests and plant diseases, due to re pollinate with

related wild and ancestral species. In this regard, reduction of biodiversity of wild ancestral forms of cultivated plants and the formation of "super weeds".
- risks of uncontrolled horizontal transfer of structures in the rhizosphere microflora.
- a negative impact on biodiversity through the defeat of the toxic transgenic proteins non-target insects and soil micro flora and violation of the trophic chains.

Agronomic risks:
- unpredictable changes of non-targeted properties and characteristics of modified varieties, are associated with pleiotropic effect of the gene introduced. Ex.g., reduced resistance to pathogens during storage and resistance to critical temperatures during the growing season in cultivars resistant to insect pests.
- deferred property changes, after a few generations associated with the adaptation of a new gene of the genome and as a new manifestation of pleiotropic properties, and the change is already declared.
- the inefficiency of transgenic pest resistance after a few years of mass use of this variety.
- use by terminal manufacturers to monopolize seed production.
- Social risk:
- growth unequal distribution of income of specific agricultural producer and owner of patents for modern biotechnology.
- decline in food quality and availability.

Ethical risks:
- use of seeds, biotechnology-derived products, can lead to loss of genetic diversity of agricultural crops.
- the movement toward genetic uniformity can lead to higher susceptibility of plants to many pests, diseases or other negative impacts on the environment.
- there are ethical problems associated with the transformation and implementation of genes of one species of plant or animal into the genetic apparatus of a different type.

Patent risks:
- Six years ago, Monsanto sued by 75-year-old farmer from Indiana, Vernon Hugh Bowman for patent infringement for seeds and won. But the farmer did not leave the matter and went to the end of February 2013, the U.S. Supreme court.
- As of January 2013, Monsanto filed 144 law suit against 410 farmers in 27 States. According to the report, released last week by the centre CFS (Center

for food safety), for many years, Monsanto is spending huge resources to "watch" and to sue farmers: 75 employees and a budget in 2003 — $ 10 million per year. The authors of the report also indicate that by the end of 2012, Monsanto had received from farmers and agricultural businesses more than $423,5 million dollars for patent infringement.

3 Results and Discussion

Over the last three years the import of genetically modified products in Russia has grown three times. But in most cases they are issued for products "of natural origin". According to the Institute of nutrition in 1998, cases of use of GMOs in the production of products were isolated. However, currently the Russian market is experiencing a real expansion of genetically modified foods. According to Russian legislation, products containing from 5% components GMOs must be labelled accordingly. But, according to Greenpeace, many manufacturers are considered. One of the main reasons for this is the absence in Russia of a system of control over the use of GMOs in food products. There are no laboratories able to the extent necessary to carry out quantitative estimation of GMO content in food products; there are no approved methods, no means for implementing continuous monitoring. In the end, consumers suffer: they don't have all the necessary information about the foods that you acquire. According to the Institute of Nutrition and Research Institute of the Meat Industry, currently in Russia there are no standardized methods of quantitative determination of GMOs in the finished food. Authorized laboratories of Sanitary-epidemiological services can provide only a qualitative analysis of food (European Commission Directives, 2000, 2002, 2012, 2014).

Given the global nature of the agricultural sector of the Bioeconomy, a special urgency today is the international cooperation in the field of legal and ethical regulation of the development and implementation of biotechnology.

The benefits of adopting international food safety standards are:

- provides consumers with the necessary guarantees for food safety;
- recognition from consumers;
- achieve greater conformity with the international requirements, which is especially important in the conditions of WTO;
- use of world experience in the field of management systems food safety;
- the transition to the new level of production culture, thought, and labour discipline;

- foreknowledge of potential threats to product safety and the use of preventive measures, instead of the late action of rework and recall products; a systematic approach, the control parameters of food safety ("from farm to table»);
- reduce costs associated with production defects;
- the market expansion of products, including its implementation in foreign markets;
- additional competitive advantages in tenders and competitions;
- increase of investment attractiveness;
- the creation of a manufacturer's reputation quality and safe food product;
- to increase the confidence of suppliers and the advantages in getting orders from other companies.

Discoveries made in recent years in the field of Life Sciences, are seen by experts as a convincing proof that the XXI century will be the age of biotechnology, which, in combination with nanotechnology and bioinformatics, will fundamentally change existing approaches to the creation, production and consumption of products, and ultimately, will form the Foundation for sustainable growth on a global scale, for complex changes in the economy, society and politics. However, they give rise to legitimate fears in terms of safety for human health and the environment. First, it refers to genetic engineering, which can bear certain risks (F. Nezhmetdinova, 2014). For Russian consumers the presence of these risks is complicated by the following circumstances:

- In Russia approved documents somewhat later than in the countries of the European Union in the field of legal regulation of the production of GMOs.
- In Russia there is no special Federal law governing GMOs. There are not enough trained specialists for the supervision of GMOs.
- In Russia there are no wide professional discussion in the medical community of the problem of GMOs.
- The existing country documents does not require large-scale and long-term studies on the safety of GMOs, but also the environmental consequences of GMO use
- It should be added that the existing regulatory framework provides a deliberate legal bias in favor of producers of GMOs.

The last quarter of the 20th century and the beginning of the 21st gave rise to a specific phenomenon, which German sociologist Ulrich Beck have termed "the other modern" or "risk society" (Beck U., 1999). However, as noted by P. D. Tishchenko, the specificity of the social context of biotechnology is historically uncertain, when science and society, social phenomena and people are constantly experiencing ourselves in the attempts of self-identification and thus are constantly

changing, becoming other (P. D. Tishchenko,1994). These changes create a "constellation of opportunities" that confronts a man chose a certain line of development of the many possible ways (Nezhmetdinova F., 2013). And here, rightly, in our view, emphasizes the changing meaning and use of the concept of "risk", which, first, from the category, only personal space moves to the global level. Second, if in the previous century, risk was seen as the result of insufficient development of technologies and scientific knowledge, today, the risk arises where there is redundancy of technological and scientific progress (Nezhmetdinova F., 2013).

Understanding these risks brings us closer to awareness of the increasing relevance of humanitarian expertise in the form of bioethics. Currently bioethics on the one hand it recognized the scientific interdisciplinary knowledge, the subject of which is evaluation and selection of the moral criterion of relationship to the living. On the other hand is approved by the world community of social practice of ethical regulation of research and first clinical studies, the introduction of modern NBIC-technologies in economy and production (Nezhmetdinova F., 2013).

It is also needed a work in the direction of more coordinated ethical review of the application of modern food biotechnology and GMO foods. This will help the analyses of risks and benefits to human health and the environment, assessment of socio-economic factors, including intellectual property rights, as well as in the consideration of ethical aspects. As a result it will increase the relevance of the experience of bioethics to increase its social value and new forms. One of these areas of development may be agrobioethics understanding as a mechanism of social control and regulation of the new "financial viability" in the Bioeconomy (F.Nezhmetdinova, 2010).

Agrobioethics is a new approach to resolving ethical dilemmas that may arise in daily practice the application of new technologies in agriculture. It is skills of dispute resolution, emotional intelligence, interpersonal and social communication how to resolve differences between producers and consumers of agricultural products of the state and civil society. The goal is it to reach consensus, based on the health and safety of the consumer, taken by all the defendants, and consistent with the laws and principles of bioethics (F.Nezhmetdinova, 2010).

4 Conclusion

It becomes obvious fact of the need to bring to the analysis and development of standards for the safety assessment of the introduction of modern technology in agriculture additional tools, such as agrobioethics. The main problem of agrobioethics related to GMOs is conflict of rights and interests of producers and consumers of GMOs. In reasoning about positive and negative aspects of GMO

technology is not to yield to emotions and to make unsubstantiated conclusions, accusing the biotech company that they are "cashing in on human misery" or trying to destroy the natural ecosystem and to "turn the earth into a desert." However, it should be remembered that uncontrolled use of such powerful techniques can indeed lead to negative consequences, and necessary, as in any issue, to find some "middle ground". The control over the activities of biotech companies should involve independent experts, scientists and government officials; work on creation and introduction on the market of genetically modified crops should be highlighted in the press, often because of fear of GMOs occurs exclusively due to the low awareness of the population and has no real Foundation.

The practice in modern democratic societies, shows that these discussions are absolutely necessary not only for a more complete understanding of all the "pros" and "cons" of applying the methods of invading privacy rights at the level of genetics. They also allow us to discuss the ethical aspects and to determine long-term effects of applications of biotechnology, which in turn, helps legislators to create an adequate legal base regulating this sphere of activities in favour of the protection of individual rights. It is possible to create the Ethical committees of agrobioethics which similar to ethical committees in the field of medical clinical trials (Nezhmetdinova F.T., 2010).

Given the global nature of bio-economic development, of particular relevance today is international cooperation in the sphere of legal and ethical regulation of the development and implementation of biotechnology. An important place in this cooperation belongs to the bioethics, which has considerable positive experience of interdisciplinary dialogue and practice. Successful development of the Bioeconomy is possible only in conditions of confidence of its safety and usefulness, like the life of a specific person, and for the planet as a whole.

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