Risks and safety standards for the use of genetically modified organisms in the context of food security

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Abstract. Genetically modified organisms (GMOs) have become the cornerstone of modern agriculture, offering solutions to some of the most pressing issues such as food security, pest control, and climate change. This article discusses the risks and safety standards of using genetically modified organisms (GMOs) in agriculture. Regulatory approaches in Europe, the USA, and Russia are analyzed, as well as the potential environmental and social consequences of GMO use. Both positive and negative aspects of the introduction of GMOs in the agricultural sector are evaluated.

Keywords: Genetically modified organisms (GMOs), safety, risks, agriculture, regulation, ecology, Europe, USA, Russia.

1 Introduction

Understanding today's global food system is not easy. Everyone needs food, and access to adequate food is one of the fundamental human rights. Today, about 1.3 billion people are engaged in agricultural production, and agriculture employs almost half of the world's working population, including 450 million salaried agricultural workers. The majority of the working-age population involved in agricultural production is engaged in food production, first of all, because food determines important physiological processes for maintaining tissue integrity. It regulates the biochemical mechanisms of metabolism and is the main determinant of growth and development.

At the same time, in the world where enough food is produced for every inhabitant of the planet, about 10% of the world's population is constantly hungry. The consequences of constant starvation are terrible: illnesses, blindness, mental retardation in children, and early death. At the same time, overeating and regular overeating are the cause of the most serious diseases among wealthy people in developed countries.

The Rome Declaration of the World Food Security Forum as of November 13–17, 1997 defined the concept of food security as "ensuring that all people have access at all times to food necessary for a healthy and active life". Safe foods are foods that do not pose a risk to human and animal health.

The connection between GMO safety and risks and food safety is vital in modern conditions, where the challenges of feeding a growing population, mitigating climate change, and meeting consumer demands for safe and transparent food are paramount. They are rising global food demand and population growth. With the global population projected to reach nearly 10 billion by 2050, ensuring food safety while increasing agricultural productivity is a major challenge. GMOs offer potential solutions but must be carefully managed to avoid compromising food safety.

Climate change and resilience are urgent concerns. Climate change is influencing agricultural productivity and food safety through extreme weather events, changing pest and disease patterns, and water scarcity. GMOs engineered for drought tolerance or pest resistance can help address these challenges, but their safety must be ensured.

There is also consumer awareness and demand for transparency. Modern consumers are increasingly concerned about the safety and quality of their food. Addressing GMO safety and risks transparently is essential to meet consumer expectations and maintain trust in the food system.

Technological advancements and innovation are rather significant. Advances in genetic engineering, such as CRISPR and gene editing, are expanding the possibilities for GMOs. While these technologies offer exciting opportunities, they also raise new safety concerns that must be addressed to ensure food safety.

Ensuring the safety of GMOs through rigorous scientific evaluation, robust regulatory frameworks, and transparent communication is essential to harness their potential benefits while minimizing risks. By addressing these issues, we can create a sustainable and safe food system that meets the needs of present and future generations. The following legitimate questions arise.

1. Are our food products safe?

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2. What measures and standards should be used, developed and adopted to ensure food safety?

3. How to maintain the competitiveness of the domestic agricultural producer and high food standards?

2 Conditions, materials, and methods

Taking into account global challenges such as climate change, population growth and the need to improve food security, the use of GMOs is becoming increasingly relevant [1]. It is important to understand the risks and safety standards in order to ensure sustainable agricultural development and environmental protection.

The article uses a comparative analysis of approaches to GMO regulations in different countries. Methods of systematic literature review are used, involving data analysis on the effects of GMOs on human health and the environment.

3 Results and Discussion

GMOs are organisms whose genetic material has been modified using genetic engineering techniques. In agriculture, GMOs are mainly used to create crops that are pest-resistant, herbicide-tolerant or have improved nutritional properties. Examples include Bt corn, which produces a toxin harmful to some insects, and golden rice, fortified with vitamin A. However, the use of GMOs is not without controversy, as concerns persist about their potential risks to health, environment, and socio-economic structures.

The use of genetically modified organisms (GMOs) in agriculture has caused serious controversy due to the potential risks they pose to the environment, human health, and socio-economic structures [2–4]. Although GMOs have benefits such as increased crop yields and pest resistance, their risks need to be carefully assessed and managed [5–8]. The following is a detailed description of the risks associated with the use of GMOs in agriculture.

The first is environmental risks, loss of biodiversity, and genetic flow. GMO crops can interbreed with wild relatives or non-GMO crops, resulting in the spread of modified genes. This can reduce genetic diversity and potentially lead to the emergence of "superweeds" or "superbugs" resistant to herbicides or pesticides [9]. In such situation, monoculture can take place. A widespread distribution of several varieties of GMO crops can lead to the emergence of agricultural monocultures, which will reduce the diversity of plant species and make ecosystems more vulnerable to pests, diseases and climate change.

The second is impacts on non-target organisms and harm to beneficial insects. Some GMO crops, such as Bt crops, produce toxins to kill certain pests. However, these toxins can also harm beneficial insects such as bees and butterflies, which are crucial for pollination.

There is also soil health as prolonged use of GMO crops and related herbicides can alter the soil microbiota, potentially reducing soil fertility and destroying ecosystems.

The third is the development of sustainability and pest resistance. Over time, pests can develop resistance to the toxins produced by GMO crops, making the technology ineffective and requiring the use of stronger chemicals.

Herbicide resistance should also be mentioned. The widespread use of GMO herbicide-resistant crops (such as Roundup Ready crops) has led to the emergence of herbicide-resistant weeds, making weed control more difficult and increasing the use of chemicals.

The forth is health risks, allergenicity, and new allergens. Genetic modification can introduce new proteins into crops that can act as allergens. For example, a Brazil nut gene introduced into soybeans has been found to cause allergic reactions in people who are sensitive to nuts.

There are also undesirable effects when the process of genetic engineering can lead to unintended changes in plant biochemistry, potentially leading to the formation of harmful compounds.

It is necessary to note toxicity and markers of antibiotic resistance. Some GMOs are created using antibiotic resistance genes as markers. There is concern that these genes may be transmitted to human pathogens, exacerbating the growing problem of antibiotic resistance.

The long-term health effects of GMO consumption have not been fully understood, and some studies have raised concerns about a possible link to organ damage, immune system problems, and other health problems [10, 11].

There are dietary changes and unintended changes. Genetic modification can inadvertently alter the nutritional profile of crops, potentially reducing their nutritional value or introducing harmful substances.

The fifth is socio-economic risks and monopoly in the market, involving corporate control. The GMO seed market is dominated by several large biotech companies. This raises concerns about monopolistic practices and reduced competition [12], which can lead to higher seed prices and limited choice for farmers.

Patents and intellectual property must be mentioned. GMO seeds are often patented, which prevents farmers from preserving and replanting seeds. This may increase dependence on seed companies and limit farmers' self-reliance.

There are also impacts on small farmers and economic pressures. Small farmers may find it difficult to pay the high costs of GMO seeds and related chemicals, leading to increased debt and financial instability.

Loss of traditional knowledge implies the fact that reliance on GMO technologies can undermine traditional farming practices and knowledge, reducing agricultural diversity and sustainability.

Trade and market access concerns export restrictions. Countries with strict GMO regulations, such as EU countries, may refuse to import GMO crops, limiting market access for GMO-producing countries.

Consumer preferences can be a reason as the growing consumer demand for non-GMO and organic products

may create market problems for GMO producers and exporters.

The sixth is ethical and cultural issues and ethical considerations, playing God. Some critics argue that genetic engineering involves the manipulation of life in ethically questionable ways, which raises concerns about the moral consequences of changing natural organisms [13, 14]. Informed consent implies that consumers may feel that they have not been sufficiently informed about the presence of GMOs in their food, leading to calls for stricter labeling laws.

Cultural impact consists in the fact that there is traditional agriculture. The introduction of GMOs can disrupt traditional farming practices and cultural heritage, especially in developing countries where agriculture is closely intertwined with local customs and identity.

Food sovereignty means that the dominance of several multinational corporations in the field of GMO technologies can undermine local control over food production and agricultural systems.

The next issue is regulatory and scientific issues, inadequate risk assessment, involving short-term focus. Many risk assessments focus on short-term impacts, potentially overlooking long-term environmental and health impacts.

Limited independent research opportunities are understood as follows. Independent research on GMOs is often limited due to restrictive intellectual property laws and corporate control of seed samples. There are gaps in legislation, nonconforming standards. Regulatory standards for GMOs vary greatly from country to country, leading to inconsistencies in safety assessments and approvals.

Enforcement challenges imply that compliance with GMO legislation can be challenging, especially in regions with limited resources for monitoring and enforcement [13, 14].

The architecture of food safety regulation and legal support at the international level is as follows. This is "Vertical" regulation, which is a system of measures focused on products and goods of natural origin. The goods produced from these products form the basis of the human diet and, as a rule, cannot be patented. Therefore, the Directives contain descriptions and identification features that make it possible to distinguish these products from those created artificially (USA and Canada). "Horizontal" regulation is a system of measures (mainly European legislation) that contains requirements for product information, requirements for food production, sanitary requirements, requirements for food additives (dyes, sweeteners, contaminants) and residual amounts of pesticides [15, 16].

Regulation of genetically modified organisms (GMOs) varies significantly in the United States, the European Union (EU), and in Russia. Each region has developed its own regulatory framework based on scientific, economic, and socio-political considerations [17, 18]. Below is a detailed description of how GMOs are regulated in these three regions.

The first region is the GMO regulation in the USA. The regulatory framework in the USA has the coordinated GMO regulatory system involving three major federal agencies [19–23]:

- The United States Department of Agriculture (USDA) that monitors the environmental safety of GMOs, especially their impact on agriculture and ecosystems.
- Food and Drug Administration (FDA) that ensures the safety of products and feeds containing GMOs for human and animal consumption.
- The Environmental Protection Agency (EPA) that regulates the use of GMOs that contain pesticides or have potential environmental impacts.

Key principles are significant equivalence, when GMOs are considered safe unless proven otherwise. They are treated in the same way as their non-GMO counterparts, unless significant differences are identified. The second is product-based regulation, when the focus is on the final product rather than the process used to create it. The third is voluntary Consultation, when GMO developers voluntarily consult with the FDA to ensure safety, although this is not legally required.

The U.S. Department of Agriculture Approval conducts the approval process. The U.S. Department of Agriculture evaluates whether GMOs pose a danger to other plants or agriculture. If approved, the GMO is removed from control and can be cultivated.

FDA Consultation involves the FDA review data on allergenicity, toxicity, and nutritional value. Although it is not mandatory, most companies go through this process to gain the trust of the public. Environmental Protection Agency Assessment is engaged in assessing the amount of pesticides that GMOs produce (for example, Bt crops), the Environmental Protection Agency evaluates their environmental impact and sets recommendations for use. Public opinion and labeling in the United States are generally supportive of GMOs, although there is a vocal minority in favor of stricter regulation.

In 2016, the National Bioengineered Food Disclosure Standard was adopted, requiring mandatory labeling of GMO products by 2022. However, the law allows the use of QR codes or digital information, which are less transparent according to critics.

The case study is Bt Corn, which is widely cultivated in the United States. Bt corn has been approved after extensive testing by the U.S. Department of Agriculture, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). This has significantly reduced the need for chemical pesticides. The regulation of GMOs in the EU has its own regulatory framework. The EU has one of the strictest GMO regulatory systems based on the precautionary principle [24–27]. Key regulatory authorities include the European Food Safety Authority (EFSA) who conducts a scientific risk assessment, European Commission who makes final decisions on GMO approval based on EFSA recommendations and submissions from member States. EU member States may ban or restrict the cultivation of GMOs even after approval at the EU level.

Key principles are a precautionary principle, which states that GMOs are not approved unless proven to be

safe beyond any reasonable doubt. The process-based regulation is focused on the genetic engineering process itself, not just the final product. Mandatory labeling concerns all products and feeds containing GMOs that must be labeled regardless of the presence of GMO material in them.

The approval process involves application submission, when the company submits an application to an EU Member State, which forwards it to EFSA. EFSA evaluates GMOs for environmental, health and safety risks. Consultations with Member States consist in bringing EFSA's findings to the attention of Member States that may have objections. The European Commission makes a final decision, which can be overturned by a majority vote of the Member States. Public perception and labeling are relevant as public opinion in the EU is extremely skeptical about GMOs, fearing long-term effects on health and the environment. Strict labeling laws ensure transparency, and many retailers voluntarily label products as "non-GMO".

The next case study is MON810 corn, which is the only GMO crop that is widely cultivated in the EU, mainly in Spain and Portugal. Several countries, including France and Germany, have banned its cultivation, despite EU approval.

The regulation of GMOs in Russia has its own regulatory framework. Russia adheres to a restrictive approach to GMOs, paying special attention to biosafety and food sovereignty [28–33]. Key regulatory authorities include the Ministry of Agriculture who oversees agricultural policy and regulation in the field of GMOs, Rosselkhoznadzor (Federal Service for Veterinary and Phytosanitary Surveillance) who monitors the safety and quality of agricultural products, including GMOs.

The State Duma has passed a law on GMOs whose basic principle is biosafety. GMOs are considered a potential threat to human health and the environment unless proven otherwise. The next principle is food sovereignty, when Russia prefers self-sufficiency and traditional farming methods to the introduction of GMOs. The restrictive legislation notes that the 2016 law prohibits the cultivation and breeding of GMO plants and animals, with the exception of scientific research. The approval process involves the scientific research stating that GMOs can only be used for controlled research purposes. Risk assessment implies that any GMOs intended for scientific research must undergo a thorough safety assessment.

Commercial cultivation of GMOs is prohibited, and the import of GMO products is strictly limited. Public perception and labeling state that Russia is strongly opposed to GMOs, favoring organic and traditional foods. Labeling laws require a clear definition of the GMO content in food, although the ban on cultivation limits the presence of GMOs on the market.

The next case study is restrictions on GMO imports. Russia has banned the import of a number of GMO products, including soybeans and corn, from countries such as the United States. This policy is consistent with Russia's goal of developing domestic agriculture and reducing dependence on foreign technology, which is summarized in table 1.

Table 1. Comparative table of the GMO regulation in the USA, EU and Russia

Aspect	USA	EU	Russia
Regulatory Approach	Permissive, product-based	Precautionary, process-based	Restrictive, biosafety-focused
Key Principle	Substantial equivalence	Precautionary principle	Food sovereignty
Approval Process	Coordinated framework (USDA, FDA, EPA)	EFSA assessment + member state input	Ban on cultivation, research only
Labeling	Mandatory (with QR codes allowed)	Mandatory (strict)	Mandatory (limited due to ban)
Public Perception	Generally favorable	Highly skeptical	Strongly opposed
Economic Impact	Promotes biotech industry	Limits GMO adoption	Protects domestic agriculture

4 Conclusions

The use of GMOs in agriculture involves a complex set of risks that must be carefully managed to ensure the safety of human health, the environment and socio-economic systems. Although GMOs have significant potential benefits, the risks associated with them underscore the need for a thorough scientific assessment, a transparent regulatory framework, and an open dialogue with the public. A balance between innovation and precautionary measures will be crucial to harness the potential of GMOs while minimizing the risks associated with them.

The regulation of GMOs in the USA, EU and Russia reflects their unique priorities and values. The United States focuses on innovation and economic growth, the EU prioritizes precautionary measures and public trust, and Russia pays special attention to biosafety and food sovereignty. These differences highlight the difficulties of reaching a global consensus on GMO regulation and the need for international cooperation to address the risks and benefits associated with the use of GMOs in agriculture.

The topic of GMO safety and risks is intrinsically linked to food safety, as the introduction of genetically modified organisms into the food supply chain has significant implications for human health, environmental sustainability, and socio-economic systems. In modern conditions, where global food demand is rising, climate change is impacting agriculture, and consumers are increasingly concerned about the quality and safety of their food, understanding this connection is critical.

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