INTRODUCTION

The volume of agricultural crops cultivated via modern genetic technologies is increasing every year worldwide, suggesting that genetic technologies are the most rapidly introduced in the history of contemporary agriculture. The first genetically modified (GM) plants were used in practice in 1996 [1]. In 2018, the cultivated area of agricultural GM crops increased to 192 million hectares, and the scope of their use over the past 22 years has increased by about 113 times [2].

Since 2013, a new gene editing (changing) method called Clustered Regulatory Interspaced Short Palindromic Repeats (CRISPR)/Cas9 has been developed as one of genetic engineering methods. It is characterized by the relative simplicity of genetic engineering, high accuracy, and efficiency of work in human, animal, and plant cells.

The application of CRISPR/Cas9 has a potentially positive effect on the agricultural economy and the reduced risks compared with technologies for GM plant production. This positive effect has been widely discussed in terms of regulatory rules applicable to genome-edited (GE) plants and their relationship with regulatory rules regarding technologies on the production of genetically modified organisms (GMOs).

In Russia, and other countries, where the cultivation of GM plants is still banned, these issues are most urgent. As such, studies should determine whether GE plants are recognized as GM plants. Once these plants are clearly defined, they may be grown in Russia for economic purposes to obtain food and fodder.

Appropriate regulations related to GE plants should be established for the state management of the development of genetic technologies, which are noted in the federal scientific and technical program for the development of genetic technologies in 2019–2027.[1]

In international regulatory practice, diametrically opposing approaches to GE plants are available [3]. This issue was urgent in Russia after the European Court of Justice adopted a decision to extend the European legal regulation associated with GM plants to GE plants in 2018 [4].

However, none of the foreign legal systems have formed an ideal mechanism for regulating plant cultivation through genomic technologies; these plants can be considered as a model [5]. In this regard, this study analyzed the experience of legislative regulation and its interpretation by law enforcement officers associated with GE plants in various legal systems.

In formulating proposals for improving the Russian legislation on GE plants, the norms of European and North American legislation should be primarily considered. The regulation of GM plant cultivation in these legal systems is based on fundamentally different approaches, but Russia is yet repeating the experience of the legal regulation of the European Union (EU). Approaches proposed by European regulators are often criticized in the scientific community [6]. In our article, issues related to the determination of the legal status of GE plants under the Russian statutory regulations and the admissibility of their cultivation in Russian territories is discussed.

[1] Resolution of the Government of the Russian Federation No. 479 of April 22, 2019 “On approval of the Federal Scientific and Technical Program for the Development of Genetic Technologies for 2019–2027.” http://pravo.gov.ru/proxy/ips/?docbody=&nd=102543863.

BODY

Essence of CRISPR/Cas9

During bacterial evolution, the CRISPR/Cas system developed as a resistance mechanism to phage DNA, that is, as acquired immunity [7]. The elements of this system can be used to edit genomes of higher eukaryotes. CRISPR/Cas is essential because of the following (stages):

1. In laboratories, a transformation vector is constructed. It is composed of the following: (1) the nuclease protein gene and (2) the nucleotide sequences of gRNA with a region having 20–23 nucleotides complementary to the target plant gene, whose sequence is supposed to be changed. Nuclease is isolated from *Streptococcus pyogene* (SpCas9 or Cas9), which does not require additional cofactor proteins for binding to DNA and cutting; this enzyme is most actively used in genetic studies [8].

2. As a result of plant transformation, a genetic construct with a gRNA and a nuclease encoding gene enters the target cell and becomes incorporated into the cell chromosome. During the subsequent expression, gRNA combines with a nuclease protein and forms a CRISPR/Cas complex.

3. The CRISPR/Cas complex approaches the target gene via Brownian movement. Then, gRNA recognizes the complementary region of the host's DNA, and nuclease cuts the recognized DNA region into two strands outside the recognized region. Afterward, cellular enzymes repair (restore) the resulting breakage. However, gene mutations occur as small insertions or deletions (indel-mutations). They also manifest as single-nucleotide substitutions.

Efforts have been devoted to editing genes by using the CRISPR/Cas system without introducing a genetic construct into a plant genome. For example, ribonucleoprotein complexes consisting of nuclease and gRNA are assembled *in vitro* and transferred into protoplasts or plant zygotes [9–13]. This variant of genomic editing can be described as "traceless" because it is performed without embedding a foreign DNA (DNA-free).

In addition to the CRISPR/Cas construct (gRNA and nuclease gene), marker genes are introduced to numerous transformation methods. These genes are necessary to select transformed plants, but they are removed during crossing and selection in subsequent generations while retaining mutation in the target gene. However, attributing such plants to GM plants is controversial. Therefore, GE plants do not have foreign information in their genome. In this sense, GE plants do not differ from plants obtained by crossing and selecting individual plants with emerging spontaneous beneficial mutations.

Prospects for the application of CRISPR/Cas9 in crop production and criticism of this technology

The CRISPR/Cas9 system has been successfully applied to model plants (e.g., *Nicotiana benthamiana*, *N. tabacum*, and *Arabidopsis*) and major agricultural plants, such as wheat, corn, rice, barley, cabbage, sorghum, and tomatoes. Our search for publications with the keywords "Crispr Cas9, plant" in the PubMed database (https://www.ncbi.nlm.nih.gov/pubmed) showed 5 articles in 2013, 556 articles in 2019, and 300 articles in the first half of 2020. The detailed protocols of targeted mutagenesis using the CRISPR/Cas9 system for many plants have been established [14].

Studies have demonstrated the high potential of CRISPR/Cas9 for the intensification of agriculture [15, 16]. For instance, this technology can be utilized to produce GE plants adapted to global climate changes [16]. In Russia, CRISPR/Cas9 can be applied to obtain scientific research results as a basis for ensuring food independence from international technologies.

However, criticisms against CRISPR/Cas9 should be considered; for example, various factors that may limit its widespread use should be explored to improve the genome of agricultural crops [17]:

- possibility of off-target mutations
- low efficiency of mutagenesis and persistent CRISPR activity in subsequent generations
- possibility of transferring mutations to wild-type populations
- risk of the revised version returning to its original phenotype, especially in cross-pollinated plant species during their release into the environment

Scientific data have yet to be obtained to clearly describe the increased risk of GE-plant varieties compared with that of plants obtained via traditional breeding methods.

Genetic changes caused by contemporary methods of genome editing do not pose a threat that likely exceeds the risk arising in nature and traditional breeding because genetic changes in nature occur even before the emergence of humans as a species; furthermore, traditional breeding has significantly increased the quantity and quality of agricultural products without obvious risks [18].

Mutations arise through traditional breeding. In such mutations, breeders aim to obtain plant forms with improved economically useful attributes through multiple crosses. Many attributes of plants are controlled by several genes, but their regulatory mechanism has yet to be determined. This problem seems simple if a given attribute is controlled by one gene that has been fully described. For example, more than 60 years ago, American breeders obtained a form of corn (Stock 6 line) through multiple crosses; when Stock 6 line is used to pollinate other lines, the number of matroclinal haploids in the offspring increases, so they can serve as the initial material to produce isogenic lines in modern breeding [19, 20]. However, studies have yet to identify the factor that determines the ability of Stock 6 line to induce haploid formation at the genetic level. In February–March 2017, three independent groups of scientists from France, America, and China published data on decoding a spontaneous mutation, which involves insertion in four nucleic bases, leading to a shift in the reading frame in the fourth exon and changing 20 amino acids; this mutation occurs during traditional breeding via crossing and selection [21–23]. With CRISPR/Cas, the same mutation in *ZmPLA1* can be obtained, resulting in a phenotype similar to that of Stock 6 line [23]. Therefore, the same mutation as the one induced via traditional breeding may be achieved through genetic engineering. However, plants produced through traditional breeding are not classified as GM plants.

Regulation of the cultivation of GM plants in different countries

Legal regulation in relation to GM plant cultivation is formed on the basis of an established approach in a particular state. Legislation on GMOs has been developed in the world since the 1980s. However, universal rules on the possibility and procedure of growing GM plants have yet to be established. Conventionally, the legal regulation of GM plants is divided into two approaches, namely, process- and product-based approaches. In process-based approaches, the risk of using a particular product is likely due to its production process; in product-based approaches, this risk is attributed to product characteristics, which may not be related to production processes [24–26].

In the EU, the regulation of GMOs is based on a process-based approach. When the risks associated with genomic modification are considered special and caused by artificial human intervention in natural processes, the obtained organisms should be under special and stricter regulations compared with analogs obtained via traditional selection and undirected mutagenesis.

According to the EU Directive 2001/18/EC, a GMO is defined as any organism (except humans) whose genetic material has been altered in a different way that it occurs naturally during mating or natural recombination [27]. Traditional random mutagenesis methods (crossing and breeding) are removed from the regulation of the Directive because they do not require further regulation.

Product-based regulation is established on the basis of an assessment of the safety of a specific final GMO product. It considers the fact that the risk to human health and the environment is not predetermined by the process of obtaining a product. A new cultivar of agricultural plants obtained through traditional breeding and mutagenesis, transgenesis, or genomic editing can be hazardous. However, this approach is dominant in the USA, Canada, and several South American countries where GM plants are commercially cultivated.

Product-based approaches are likely more justified from a scientific point of view. In process-based approaches, social and economic prerequisites associated with the concerns of traditionally minded segments of society regarding the latest technologies are considered.

The EU directly recognized the lack of a direct relationship between the introduction of regulatory restrictions on GMOs and the scientifically based risks of their economic use. In 2015, significant changes were made in the legislation on the legal regulation of GM plant cultivation in the EU; as such, the Directive 2001/18/EC [27] covered the right of EU members to restrict or prohibit the cultivation of GM plants approved in the EU in their territory because of socio-economic concerns, not their hazard to humans or the environment. Agricultural policy is identified as one of these goals, which can include protectionism related to organic farming. In Russia, a process-based approach associated with the determination of the rules is applied to cultivate GM plants [28]. Therefore, regulatory practices in the EU have been widely explored.

Approaches to regulating the cultivation of GE plants

A unified approach has yet to be developed to determine the legal status of GE and GM plants at an international level; therefore, each country or supranational entity with the right to implement statutory regulation resolves this issue at its own discretion.

In 2018, the United States Department of Agriculture decided against regulating GE-plant cultivation because they are indistinguishable from those obtained via traditional breeding methods. With the newest of these methods, including CRISPR/Cas editing of the genome, the use of traditional tools can be expanded to plant breeding because they can be utilized to obtain new plant attributes faster and more accurately than using other breeding methods [29].

In countries where a product-based approach has been adopted, no special restrictive legal regulation related to GE plants has yet to be created. However, such regulations are likely unnecessary because the principle involving the production of new plant varieties through modern technologies is either approved or disregarded for economic purposes based on their final characteristics, not their production methods [25].

In the analysis of the types of changes during CRISPR/Cas editing of the genome, the obtained GE organisms should not be subject to special regulations on biosafety because the resulting genetic combination cannot be considered new [30].

In countries where a process-based approach is adopted, the attitude toward GE plants is the same as that toward GM plants. Thus, in 2018, the European Court of Justice officially interpreted the Directive 2001/18/EC; in accordance with this directive, GE plants are categorized under the legal regime for GM plants [4]. Although genomic editing can be applied to obtain plants that do not meet the definition of GMOs under this directive, the court decided that the special legal regulation should be extended to GE plants.

This conclusion of the European Court was based on scientific research conducted within the EU, as well as other factors. In 2015, after the first articles on the possibility of using CRISPR/Cas on plants were published in 2013, the applicability of Directive 2001/18/EC to genome editing technologies was analyzed in accordance with the order of the German Federal Office for Nature Conservation [31]. This directive was expansively interpreted on the basis of systemic and teleological interpretation; therefore, directed genome editing refers to the methods regulated under Directive 2001/18/EC [31]. This position is based on the concept that the implementation of the precautionary principle implies the need for stricter regulation related to GE organisms that differ from traditional breeding. The following arguments were made by the European Court in its decision:

• The risks associated with the use of new methods may be similar to those related to the production and release of transgenic organisms.

• New methods can be utilized to produce GM varieties much faster and in a much larger amount than those obtained using traditional methods of random mutagenesis [4].

However, the decision of the European Court of Justice has been criticized by the European scientific community. The following counterarguments were presented by the Group of Chief Scientific Advisers of the Scientific Advisory Mechanism of the European Commission [32]:

• Changes in the genome of an organism as a result of using traditional methods of mutagenesis are more radical and less predictable than those obtained via genomic editing.

• The accuracy and direction of making changes in genomic editing is more important than the rate of obtaining new varieties in safety assessment.

• Fewer intermediate and undesirable varieties are obtained via genomic editing methods than those produced via traditional random mutagenesis [32].

In response to the 2018 European Court of Justice decision, the need for plausible and differentiated regulation in the EU for GM and GE plants is indicated in a joint statement by the German National Academy of Sciences Leopoldina, the Union of German Academies of Sciences, and the German Research Foundation [33]. This position was supported by the European Academies Science Advisory Council (EASAC) [34]. According to the EASAC, the reform should be performed immediately; if an organism obtained by genome editing does not contain foreign DNA, it should not be classified by the EU legislation as a GMO.

With the emergence of GE plants, existing process-based approaches have shown disadvantages; in some instances, when two plants modified through traditional breeding and genomic editing are identical, they will be subject to completely different regulatory requirements because they are obtained through different methods (e.g., mutation in *ZmPLA1* in maize [23]).

As such, numerous researchers suggested the need to revise the concept of regulation adopted in the EU and other countries where a process-based approach is adopted to regulation; therefore, GE plants without transgenic insertions should be classified as equivalent to those obtained through traditional breeding [18, 26].

In a product-based approach, the safety of each new product must be assessed regardless of the way it is produced, but its effects on humans and animals should be considered [35].

The European legislation proposes to avoid using the term "GMO" because it cannot be easily defined and is used mainly in a negative socio-political context; instead, "new agri-food products" should be used as an object of legal regulation [36].

Other models of regulation related to GE plants have also been proposed [18, 37]. For example, a flexible model should provide four levels of regulatory rigor depending on the type of genetic changes, including insignificant (zero mutations) and significant (transgenesis) alterations. This model will allow countries implementing process-based regulation to shift gradually to product-based regulation [38].

Therefore, this approach can be applied to the Russian Federation. However, the current state of legal regulation associated with GM and GE plants is determined in accordance with not only scientific criteria but also socio-economic considerations.

Regulation of GM and GE plants by the statutes of the Russian legislation

Since 1996, the cultivation of transgenic plants for economic purposes has been completely banned in Russia. [2] However, the cultivation of GM plants has been allowed for research purposes and expert examinations since 2016. Furthermore, importing from foreign manufacturers of GM plants and products derived from them is allowed in Russian territories. The procedures for importing such products have been simplified; in April 2020 a decision was made to import transgenic soybeans and meal into Russia by the end of 2021 despite the absence of state registration procedures according to the current rules. A permit issued earlier was sufficient in accordance with the rules in force until July 2017.[3]

The turnover of products obtained from or composed of GMOs is not limited to Russia, but only the requirement for its state registration is in effect. Special rules that aim to regulate the production and

[2] Federal Law No. 358-FZ of July 3, 2016 "On Amendments to Certain Legislative Acts of the Russian Federation in terms of improving state regulation in the field of genetic engineering." http://pravo.gov.ru/proxy/ips/?docbody=&nd=102404554.

[3] Resolution of the Government of the Russian Federation No. 520 dated April 16, 2020. http://publication.pravo.gov.ru/Document/View/0001202004200028.

cultivation of GE plants and the distribution of products obtained from them in the Russian Federation have yet to be established. However, studies have yet to confirm whether prohibitions on GM plants established by Russian legislation refer to them or not.

GMOs in Russia were defined in the Federal Law of July 5, 1996, No. 86-FZ "On State Regulation in the Field of Genetic Engineering"[4] (hereinafter referred to as the Law on Genetic Engineering): "GMO is an organism or several organisms, any noncellular, unicellular, or multicellular formation, capable of reproduction or transmission of hereditary genetic materials, different from natural organisms, obtained using genetic engineering methods and containing genetically engineered material, including genes, their fragments or combinations of genes."

From a legal point of view and ease of enforcement, this definition is poorly presented because it contains redundant characteristics and prevents the unambiguous classification of one or another organism as GMO in each specific case. Even though the systemic interpretation of the norms of the Law on Genetic Engineering is considered, understanding the differences, between GMOs and a natural organism and how this difference should be established is impossible in the opinion of a legislator. No special bylaws that would specify this procedure have also been developed.

According to the Law on Genetic Engineering, the definition of GMO can be called a legal atavism because it has been in effect since 1996. In formulating this definition, the legislator did not anticipate the subsequent development of biotechnology and did not foresee the possibility of the emergence of plants and animals obtained via genetic engineering methods. However, genetically engineered plants and animals do not differ from their natural counterparts.

The ban on the cultivation of GM plants is implemented in another normative act, namely, the Federal Law of January 10, 2002, No. 7-FZ "On Environmental Protection"[5] (hereinafter referred to as the Law on Environmental Protection). According to this law, the term "GMO" should no longer be used; instead, such organisms refer to plants and animals whose genetic program has been modified using genetic engineering methods and that contain genetically engineered material. However, the introduction of which cannot be the result of natural processes. In fact, this description was an attempt by the legislator to provide an alternative definition of a GMO or a transgenic organism despite the existence of a special law stating the appropriate terminology. However, this act is a clear violation of the technique of developing legal acts.

All these definitions focus on the fact that special regulations are established for artificially obtained organisms that differ from natural ones. Therefore, plants whose genome does not acquire a foreign DNA as a result of genomic editing should not be classified as GMOs. T.V. Matveeva and M. Azarakhsh [39] arrived at this conclusion after they analyzed the aspects of CRISPR/Cas. They pointed out that the prohibitions established by the legislation should not apply to GE organisms. In Russia, softer requirements will be applied to them.

In our opinion, this conclusion is absolutely correct from legal and scientific points of view. However, we are concerned about the prospects of law enforcement practice in Russia because courts and other bodies

[4] http://pravo.gov.ru/proxy/ips/?docbody=&nd=102042295.
[5] http://pravo.gov.ru/proxy/ips/?docbody=&nd=102074303.

applying the law will abandon the literal interpretation of the definition given in the law and proceed to an expansive one. This practice is demonstrated by the experience of the EU regulation, where the European Court disregarded the literal interpretation of Directive 2001/18/EC and extended the legal status of GM plants to GE plants [4].

Despite different legal systems, such a legal scenario in the Russian Federation may be implemented. Prerequisites are related to the fact that legislation on genetic engineering in Russia was initially formed on the basis of the European regulatory experience, and the European legislation was mainly applied to the development of the Law on the State Regulation of Genetic Engineering [40]. In addition, the continuation of the ban on the commercial cultivation of GM plants[6] was introduced in 2016 in the new law. It confirmed the focus of the Russian legislator on the protection of organic farming and the maximum limitation of the introduction of genomic technologies into agriculture. Therefore, the legal status of GE plants in the Russian Federation is ambiguous and should be defined more clearly.

Legal risk of the lack of certainty in the legislation of the Russian Federation regarding the status of GE plants

The legal status of GE plants is poorly defined. This unclear definition is a legal risk that must be considered in activities by scientific organizations and teams involved in obtaining new plant varieties via genome editing technology, agricultural corporations, and private farmers who plan to launch the economic cultivation of such varieties.

Further studies should be performed to clarify whether GE plants are unambiguously released from the special regulation implemented in Russia in relation to GMOs. A statutory instrument or clarification should also be provided by a competent Russian authority, which has the nature of an official interpretation of the law. For example, a statement by the State Duma or a decision of the Constitutional Court should be presented.

In a case of legal uncertainty regarding the status of GE plants, the law enforcement practice of executive authorities can change at any time. Works and products currently beyond the control of state bodies may be prohibited. Accordingly, economic entities, which likely interpret the legislation based on their own discretion, are exposed to the risk of receiving instructions from control and supervisory authorities in terms of the need to prevent law violations.

This situation has a negative impact on the development of Russian science and agriculture associated with various applications of modern genomic technologies, particularly medicine [41].

As a result, Russian innovations cannot be implemented in Russian territories. This situation limits the development of new varieties of GE plants in Russia. The presence of a legal risk of the recognition of GE plants in Russian territories reduces the interest of investors in their work and the possibility of their practical implementation. In addition, it threatens the food security of the Russian Federation because it is dependent on the supply of foreign GMO raw materials.

[6] Federal Law No. 358-FZ of July 3, 2016 “On Amendments to Certain Legislative Acts of the Russian Federation in Terms of Improving State Regulation in the Field of Genetic Engineering.” http://pravo.gov.ru/proxy/ips/?docbody=&nd=102404554.

As a consequence of legal uncertainty related to GE plants, a defect in legal drafting methodology is a legal risk; a legislator must consistently apply relevant concepts to construct a legal norm, and their arbitrary interpretation is not allowed [42–44]. A statutory instrument cannot be considered a law if the constated rules of conduct are not formulated clearly and not precise enough to be understood and applied [45].

Therefore, corrective amendments should be introduced to Russian legislation to prevent unambiguously the expansion of the restrictive regulation provided for GM plants to GE plants.

Proposals for the development of Russian legislation on the cultivation of GE plants

In Russia, a process-based approach to the regulation of crop production via genomic technologies is currently being implemented in its most stringent version, namely, a complete prohibition on GM plant cultivation, which is typical for most EU countries except Spain and Portugal.

In our opinion, this approach, which does not meet the requirements of scientifically grounded regulation, has become a negative factor of the development of legal regulation related to innovative technologies. The assessment and regulation of the use of modern genomic technologies should be based on evidence, and probable benefits and any hypothetical risks should be considered; they should be proportionate and flexible enough to cover not only current technologies but also possible future scientific breakthroughs [46].

The prohibition on GM plant cultivation is a legal and political reality; therefore, it cannot be ignored in formulating proposals for the improvement of the Russian legislation. In this regard, the changes proposed should consider this prohibition and correlate with it; otherwise, they cannot be implemented.

Under such conditions, the Russian legislation on GMOs in general and GE plants in particular should be improved gradually:

1) A differentiated regulation was established for the assessment of the risk level in terms of releasing GE plants into the environment, where GM plants will have the highest risk, and GE plants free from foreign genetic materials will have the lowest risk.

2) The transition to product-based regulation when the risk in relation to a new plant variety obtained using genomic technologies is assessed individually before registering them as a result of breeding achievements.

In any case, this should be accompanied by the development of rules for the joint cultivation of plants obtained through genomic technologies and traditional plant varieties. It aims to prevent the uncontrolled spread of GM and GE plants and cross-pollination with crops of traditional varieties. This task is a priority because GE-plant cultivation for scientific purposes in Russia is specifically permitted but not regulated by any rules. At stage 1, the definitions used in Russian legislation should be amended to unify them.

In the Law on the State Regulation of Genetic Engineering (Art. 2), one term should be used: “transgenic organism as an organism whose genome has been artificially altered by introducing inherited foreign genetic material” instead of the two terms “GMO” and “transgenic organism.” This definition should also be supplemented with a proviso that “organisms obtained using genomic editing methods are not considered as transgenic.”

This regulation seems justified because GE plants can be obtained without inserting a foreign DNA, and the construct introduced during genome editing can be removed during crossing and selection in future generations. Thus, in subsequent generations, no foreign genetic information is present.

Accordingly, in the Law on Environmental Protection (Art. 50), the current prohibition on commercial GM plant cultivation can be supplemented as follows: “Commercial GM plant cultivation is allowed in Russian territories if they are obtained without introducing a foreign DNA.”

The rules for growing nontransgenic GE plants in Russian territories should be established by the Government of the Russian Federation based on scientific experiments to determine the safe distances for the joint cultivation of different species of GE and non-GE plants. Detailed rules should be prepared by the Russian Government within a period specified by law. Thus, requirements should be established on the basis of the results of risk assessment at various levels of rigor in relation to the cultivation of plants obtained using genomic technologies.

In our opinion, the most general framework norms should be established at the government level by transferring the main regulation on individual agricultural crops to the level of the constituent entities of the Russian Federation. Scientific studies have evaluated and described the possibilities of hybridizing GM and GE-agricultural plants with related nontransgenic plants in a local ecosystem [47].

In the next step, a decision on the possibility of recognizing GE-agricultural plants as breeding achievements may be adopted at the state level, and their inclusion in the State Register of breeding achievements permitted for use with a special note. Therefore, an organism is a GE-plant variety and in the presence of results of a special assessment of safety for humans and the environment. This step will allow for the controlled cultivation of the varieties of GE-agricultural plants in the territory of the Russian Federation.

Organizational and managerial issues must be resolved because no proposals for legal regulation in genomic technologies can be implemented without them. In Russia, a mechanism has yet to be developed to ensure decision-making in the regulation of biotechnology and genomic technologies strictly on a scientific basis. As such, an imbalance exists in legal regulation. Therefore, a risk assessment should be performed to establish requirements for the cultivation of plants obtained using genomic technologies. A new variety should be subsequently approved by a special interdepartmental body. This body should represent the interests of various government bodies, the scientific community, and agricultural producers.

The creation of such regulations is a common activity. For example, in Brazil, the National Technical Commission for Biosafety (CTNBio) performs risk assessments for GM plants. CTNBio is composed of officials from nine federal ministries and experts in the fields of consumer rights and farming. The commission issues field trial permits. GM plants can be released into the environment only after a biosafety quality certificate is obtained from the national technical commission [48]. Similar bodies exist in other countries, including European countries, whether GMOs are grown in them [49] or not [50].

In Russia, a similar body was established in the past. The Interdepartmental Commission on Genetic Engineering was initially the main organizational element of regulation in genetic engineering in Russia, but it was disbanded. Therefore, the implementation of proposals will enable the creation of a legislative framework that ensures the safe commercial use of GM and GE plants in Russia.[7]

CONCLUSION

Since 2013, a new gene editing method called CRISPR/Cas9 has been widely used as a genetic engineering method. In 2020, CRISPR/Cas9 was awarded the Nobel Prize for its development. It is utilized to obtain targeted mutations in the genomes of agricultural plants. In international regulatory practice, different process- and product-based approaches related to GE plants were previously applied to GM plants.

Product-based regulation is prevalent in the USA, Canada, and several South American countries involved in the cultivation of commercial GM crops. In the EU, whose legislation is closer to that of Russia, GMO cultivation is regulated via a process-based approach. Consequently, the volume of cultivated GM plants has significantly decreased, or their cultivation has been completely banned because public concern about new technologies and protectionism associated with organic farming is considered.

The status of GE plants has yet to be defined in the Russian legislation. Based on the results of the analysis of related literature on the biosafety of GE plants, our proposal is that amendments on the Russian legislation should be made to prevent including GE plants in the restrictive regulation for GM plants. Furthermore, scientifically grounded rules for the joint cultivation of GE plants and traditional plant varieties in Russia should be developed and introduced to prevent the uncontrolled spread of GM and GE plants and restore state control in genetic engineering. With the active use of CRISPR/Cas9 in Russia to create new plants varieties, a faster selection process can be implemented, and food security and independence from foreign technologies can be ensured.

ADDITIONAL INFORMATION

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[7] Resolution of the Government of the Russian Federation No. 464 of April 22, 1997 “On the Interdepartmental Commission on the Problems of Genetic Engineering.” http://pravo.gov.ru/proxy/ips/?docbody=&nd=102046767.