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Barriers and prospects for the use of new genetic technologies for food production: Regulatory options in the interests of the Russian economy

T.E. Semenov[1]

[1] Financial University under the Government of the Russian Federation (Moscow, Russia)

Abstract

The discovery of new genetic editing technologies (new genetic technologies, NGT) made it possible to change the genetic material of organisms faster, easier, more accurate and cheaper. Gene modification in the laboratory has become the most promising method of creating new crops. In all developed countries possessing such technologies, including Russia, the question has been raised for a long time whether NGT should be qualified in the legal field in a different way than previously known traditional methods of genetic engineering, which have been in practice since the 1970s.

The Russian and European experience of evaluating technologies in the field of NGT has been studied and summarized in order to overcome the mentioned barriers in the Russian agro-industrial sphere, solve import substitution problems, ensure the sustainable development of domestic breeding and crop production, and realize the competitive advantages available today in Russian legislation for Russian innovative firms and agricultural producers.

The options of modernization of the Russian legislation are considered, which would allow to consolidate and develop the successes of domestic scientists and breeders, to make it more stable and safe to provide Russian consumers (as well as importers of Russian food abroad) with high-quality and inexpensive food products.

For the first time, a comparative analysis of studies of new genetic editing technologies in the context of their industrial implementation and legal regulation, basing on analytics from leading European centers and Russian Federation institutions, was carried out.

Keywords: technology assessment, new genetic technologies, new technologies regulations, genetically modified organism, legislative changes, foreign experience, import substitution.

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Introduction

The higher accuracy and efficiency of new genomic technologies (NGT), commonly referred to as genomic editing technologies, makes them especially promising in breeding activities. The creation of new domestic crop varieties using NGT methods can reduce dependence on seed imports, expand food production, promote export growth and attract investment in Russian companies in the agro-industrial sector and science-intensive start-ups.

At the same time, although the basic Russian law "On Genetic Engineering Activities" does not formally prohibit the circulation of plants and crops whose genome is modified by NGT methods and does not contain foreign DNA, industry legislation de facto prohibits the industrial breeding of plants and animals if they "contain genetically engineered material, the introduction of which cannot be the result of natural processes[1].

[1] Clause. 1, Art. 50 of the Federal Law from 10.01.2002 No. 7-FL "On Environmental Protection". The only exceptions are cases of growing and breeding such plants and animals during examinations, as well as research work. A similar prohibition is contained in Art. 21 of the Federal Law from December 17, 1997 No. 149-FL"On seed production".

Thus, scientific research in this area is allowed, however, the practical application of varieties obtained with the help of NGT is in the "gray zone". An entrepreneur and a scientist who have taken on the development and introduction of a new variety using advanced genetic methods together face a number of legal and organizational barriers. The main one is the task of proving that, firstly, plants (and food products based on them) obtained using genome editing are not GMOs[2], and secondly, that genetically engineered modifications are indistinguishable from those that may be the result of natural processes in nature.

Based on Russian and European experience, the presented article explores options for overcoming the mentioned barriers in order to quickly solve the problems of import substitution in seed and crop production, expand commercial food production, and create competitive advantages for Russian innovative firms and agricultural producers.

1. Description of the current situation in Russia

The discovery of NGT made it possible to change the genetic material of organisms faster, easier, and cheaper[3] [Doudna and Charpentier, 2014]. With the discovery of these "molecular scissors", gene modification in the laboratory has become the most promising method for creating new crops [Chen et al., 2019; Khalil, 2020]. In all developed countries that have such technologies, including Russia, the question has been raised for a long time whether NGT should be qualified in the legal field differently compared to the previously known traditional methods of genetic engineering that have come into practice since the 1970s[4].

In the Russian Federation, the field of genomic technologies is regulated by Federal Law No. 86-FL from July 5, 1996 “On State Regulation in the Field of Genetic Engineering Activities” (86-FL). Since 2016, a law on a virtual moratorium on the widespread use of GMOs has been in force in Russia[5] Cultivation of GM plants (except for laboratory experiments) and breeding of GM animals for food production and other business purposes is illegal.

New genomic technologies are a different tool [Trikoz et al., 2021] compared to the classical methods of genetic engineering, defined in Z86-FL as “a set of methods and technologies, including technologies for obtaining recombinant ribonucleic and deoxyribonucleic acids, for isolating genes from the body, manipulation of genes and their introduction into other organisms. Lawyers and jurists are practically unanimous in the fact that, as a result, NGT are not subject to the regulation of the specified basic law [Tarasov, 2021], that is, they can be used in economic practice.

However, the norms of sectoral legislation adopted several years ago differ in more general and strict, sometimes prohibitive language [Kudelkin, Startsun, 2019]. For example, the cultivation and breeding of plants and animals in our country, "the genetic program of which has been changed using genetic engineering methods and which contain genetically engineered material, the introduction of which cannot be the result of natural processes, is prohibited." The only exceptions are cases of cultivation and breeding of such plants and animals in the course of scientific research or examinations. These prohibitions were included in Art. 21 of the Federal Law from December 17, 1997 No. 149-FL "On seed production" in 2016. Last but not least, one of the main causes became the very resonant publications in the media and public discussions regarding genetically modified food products (up to the denial of genetic technologies in general), which could be summed up as serious public skepticism, and not only in relation to GMOs, but also to the effectiveness of the state regulation of the new technology sector as a whole.

At the same time, the regulation of breeding activities directly related to seed production is actually out of sight of Russian legislation. There is no direct regulatory relationship between genetic engineering and breeding activities, although in fact genomic technologies are a breakthrough tool in breeding work [Vetrova, 2012]. This is another barrier for effective private investment in innovative business to create new breeding achievements by genetic engineering methods, including NGT, since the differences between them are difficult to discern, especially for lawyers in the business community.

We are not talking about direct prohibitions, we are talking about a "gray zone" in legal regulation, the complexity of licensing bureaucratic procedures and, accordingly, high investment risks. Therefore, it is not necessary to count on large-scale private investments in the area under study, as well as on the transition from innovative developments using NGT to the stage of full-fledged pilot introduction of these technologies into the practice of agro-industrial enterprises. But after the pilot implementation stage, there are still many barriers to the transition to widespread implementation and scaling, which is typical for the spread of any new technologies in industry and agriculture [Kuzmin, 2021].

[2] GMOs are genetically modified (GM) organisms, including plants, whose DNA has been intentionally altered using genetic engineering methods. As a rule, these are organisms to which genes have been transferred from another organism, not necessarily related, giving them new characteristics.
[3] Basically, we are talking about technology using short palindromic repeats of DNA or CRISPR/Cas9. Opened in 2012, in 2015 the prestigious Science journal named CRISPR-Cas9 technology the breakthrough of the year. In 2020, the Nobel Prize was awarded for the research in the field of NGT.
[4] It is important that a new gene is transmitted during modification by molecular methods - insertion of a DNA fragment, without the procedure of classical selection - crossing, which also involves the transfer of new genes to new plant varieties or animal breeds, but by other, traditional methods having been used for centuries.
[5] Federal Law No. 358-FL dated July 4, 2016 “On Amendments to Certain Legislative Acts of the Russian Federation in Part of Improving State Regulation in the Field of Genetic Engineering Activities” was developed on behalf of the President of Russia V.V. Putin dated 09/01/2013.

In the absence of public investment in new domestic developments, until recently, a high share of imported seeds in the Russian market has become an economic reality, in particular for such mass and critical for food security crops as sugar beet, potatoes, vegetables, sunflower, corn. When importing them, we depend on foreign seed suppliers, often "contracted" by world leaders in the development of GM crops from the USA, Germany and Switzerland[6].

2. The role of the state in correcting the situation. Overcoming Barriers to the Economic Application of NGT

"Genomic editing, which allows you to change the genome of an organism, is a breakthrough tool that is already being applied in agriculture, industrial biotechnology, medicine and other sectors of the economy in the leading countries of the world." This is one of the key theses of the substantiation of new government approaches in the area under consideration[7].

It was the state, relying on the analysis and legal justifications of the relevant state authorities, that adopted a whole range of programs related to the development of agriculture, import substitution, scientific and technological developments, in which a prominent place is given to the use of NGT in the coming years.

As an example, we will give two subprograms of the Federal Scientific and Technical Program for the Development of Agriculture for 2017-2025 (approved by the Decree of the Government of the Russian Federation dated from August 25, 2017 No. 996) - “The development of selection and seed production of potatoes in the Russian Federation” and “The development of selection and seed production of sugar beet in the Russian federation".

The text of the last subprogram analyzes in detail the issue of critical import dependence in Russian sugar beet seed production. It is indicated that our country, ranking first in the world in terms of the area under sugar beet crops, is "significantly dependent on import supplies of seeds of sugar beet hybrids." At the same time, the volume of the market for these seeds in the Russian Federation is from 5.7 to 5.8 billion rubles.[8]

The high share of seeds of sugar beet hybrids of foreign selection in the Russian market is due to a number of reasons, including the “low level of state support for breeding and seed production of sugar beet and the lack of interest on the part of business in investing in this sector of agricultural production.” The developers of the program specifically point out that when creating new domestic varieties of sugar beet, “the use of modern, but rather costly methods of molecular biology and biotechnology, has practically ceased”, and new methods of “genomic selection and genome editing technology in the breeding process of sugar beet in the Russian Federation today are practically not applied. The conclusion is obvious: the competitiveness of domestically bred sugar beet hybrids is very low.

In the context of this program, it should also be noted that in terms of annual funding, specialized Russian scientific organizations are significantly (20-40 times) inferior to the research structures of foreign seed companies.

Despite increased state funding (mainly in terms of pilot projects), without an influx of corporate and private investment, the situation in this sector is unlikely to change dramatically.

3. Solving the problems to overcome barriers: taking into account foreign experience and analyzing the competitive advantages of Russian market players

Scientific research in the field of application of NGT in crop production in Russia is quite active. In accordance with WTO rules, the import of food products with GMOs is allowed. However, seeds of GM plants are not allowed to be imported. The government has the right to ban the import of GM food into Russia[9].

In all likelihood, the time has come for a substantive analysis of alternatives and making strategic decisions to justify the possibility and necessity of introducing new technologies for genome editing of plants and crops into legal and economic circulation.

The main motivation for the development of Federal Law No. 358-FL of July 4, 2016 “On Amendments to Certain Legislative Acts of the Russian Federation in Part of Improving State Regulation in the Field of Genetic Engineering Activities” (hereinafter referred to as 358-FL) was public concern about the possible harm of GMOs to humans, unpredictable impact on the environment, in particular the hypothetical threat of the transfer of new genes into the wild. What is more, even when growing already available, permitted varieties of GM corn or GM soybeans (dominant on international markets), there is an

[6] With the ban on the import of GM seeds into Russia since 2016, it is difficult to guarantee that with billions of importers, transgenic seeds do not enter domestic fields. For example, according to media reports (see, for example, Regnum on October 5, 2020), Rosselkhoznadzor confirmed the use of rapeseed seeds with an identified gene characteristic of GMOs in only one region of the Russian Federation on a total sown area of 549.76 hectares (https://regnum.ru /news/economy/3081206.html). It should be noted that seeds from foreign suppliers are usually sold on such terms that the buyer cannot leave part of the crop for planting in the next season, otherwise he violates the patent law and is subject to prosecution. The vast majority of GM seeds are developed and marketed by several multinational companies - Monsanto (USA), Syngenta (Switzerland), Dow AgroSciences (USA), Pioneer Hi-Bred (USA), Cargill (USA), Bayer CropScience and BASF (Germany) (according to the AGRO-XXI portal, https://www.agroxxi.ru/gazeta-zaschita-rastenii/zrast/rossii-nuzhny-otechestvennye-gm-kultury.html).

[7] Federal Scientific and Technical Program for the the Development of Genetic Technologies for 2019-2027 (approved by the decree of the Government of the Russian Federation dated from April 22, 2019 No. 479, developed on behalf of the President of the Russian Federation, Decree No. 680 dated from November 28, 2018 "On the Development of Genetic Technologies in the Russian Federation"). http://static.government.ru/media/files/1FErVexYSoVYFduUn1tStWlLkyrkTEmu.pdf.

[8] Id.

[9] This is the norm of Federal Law No. 358-FL of July 4, 2016: “The Government of the Russian Federation has the right to establish a ban on the import into the territory of the Russian Federation of genetically modified organisms intended for release into the environment, and (or) products obtained using such organisms or containing such organisms.

environmental threat: GM plants are resistant to herbicides, and if the cultivation technology is violated, the amount of herbicides used is often exceeded several times[10].

In Russia, as already noted, genetic editing is not within the jurisdiction of FL-358, since organisms obtained using NGT (genome editing) are not formally GMOs and are not subject to the basic Federal Law FL-86[11], which regulates exclusively transgenesis technologies (gene transfer), rather than spot editing.

Due to the absence of a law regulating breeding activities, it can be considered that the use of genomic editing methods for breeding plant varieties, animal breeds and strains of microorganisms for agricultural production purposes are legal and can be used by the breeder in his activities.

It should be noted here that genetic editing techniques can change DNA in a variety of ways: change the pointwise DNA sequence, turn genes on and off without changing the DNA code.[12], etc., however, as a rule, the final product does not contain fragments of foreign DNA (DNA another organism). This is why NGT products are currently not considered GMOs from a legal standpoint. Since foreign genetic information is not introduced, NGT can be conditionally classified as "nature-like" technologies [Kovalchuk et al., 2019; Zhironkin et al., 2019]. However, such a conclusion, made by the "method of exclusion", by analogy with the well-known principle "everything that is not prohibited is allowed", giving Russia a potential competitive advantage in the innovative development of oil and gas pipelines and their economic application, is insufficient. The confidence of academics, legal professionals, and even the adoption of government programs in this area is not sufficient to effectively attract business players. The question arises about the direct mentioning and clear definition of NGT in the legislation.

In the European Union, the situation is reversed: there is a Directive[13] on genetically modified organisms (hereinafter referred to as the Directive), which effectively prohibits the introduction of GM plants on the market without going through an expensive and lengthy risk assessment and monitoring procedure. In July 2018, the European Court of Justice ruled that all crops modified with NGT, including CRISPR-Cas9, are also subject to the GMO Directive. It should be noted that several years ago, after lengthy discussions, the Directive was amended, according to which individual EU Member States were given the right in their national legislation to either prohibit or allow the cultivation of GM crops, based on social, cultural and ethical prerequisites[14]. This significantly expanded the possibilities for including social and ethical factors in the discussion about possible directions for improving the legal regulation of the use of NGT.

Thus, the Russian legislation regarding the regulation of oil and gas wells is not harmonized with the international one. This, on the one hand, makes it possible to borrow experience in the development of new legal acts and procedures for licensing, monitoring and control. On the other hand, when modernizing Russian legislation, it seems expedient to follow our own path, which allows us to achieve competitive advantages for Russian agricultural producers, consolidate and develop the successes of domestic scientists and breeders, and make it more sustainable and safe to provide Russian consumers with high-quality and inexpensive food products.

To implement this approach, it is necessary at least to consider briefly possible scenarios for the legal regulation of NGT, as well as the arguments that are given in public discussions, both in Russia and abroad, on the issues related to regulatory control of biotechnology application.

4. Assessment of technologies in the field of NGT and a general review of scenarios for regulating the sphere of biotechnology according to a study by foreign technology assessment centers

In 2019, the independent Rathenau Institute (Netherlands), which specializes in technology assessment, published the report "Editing the genome of plants and crops: towards a modern biotechnology policy focused on differentiated risk assessment and broader considerations" [Habets et al., 2019] (hereinafter referred to as the report of the Rathenau Institute). The report discusses the main options for maintaining the GMO Directive in relation to NGT, as well as the possibilities for amending the Directive to exclude new genome editing methods from its scope (in cases where the final product is free of foreign DNA).

A hypothetical third option is also being considered, requiring new legislative regulation. Under this option, specific applications of NGT would have to be assessed on a case-by-case basis, based on a graded risk assessment, as well as using an assessment of the product's potential value to society and its ethical acceptability.

[10] Kulikov K.P. (2021). GMOs are illegal in Russia. *Arguments of the week*, 23 Oct.

[11] The concept of "genetic engineering" in accordance with Federal Law-86 ("a set of methods and technologies, including technologies for obtaining recombinant ribonucleic and deoxyribonucleic acids, for isolating genes from the body, manipulating genes and introducing them into other organisms") reduces the use of molecular genetic technologies only to obtain transgenic objects, since the key to the definition of the law is "isolation of genes from the body" and "their introduction into other organisms." This takes the leading direction of genetic engineering activity - genomic editing - beyond the legal framework.

[12] Editing the genome. Overview of KWS breeding methods (2022). https://www.kws.com/.

[13] Directive 2001/18/EC of the European Parliament and of the Council from 12.03.2001, as amended, on the intentional release of modified organisms into the environment. https://pharmadvisor.ru/document/tr3602/. In order to "protect the life and health of people, the health and welfare of animals, the welfare of the environment", the Directive introduced a licensing procedure. In particular, crops covered by the Directive require an environmental risk assessment (ERA) procedure, which implies the risk of direct, indirect and cumulative (immediate and long-term) impacts of GM crops on public health and the environment. In addition, these organisms must be monitored. In accordance with another Directive (No. 1830/2003), traceability and labeling of the relevant products is ensured in order to inform consumers.

[14] Directive 2015/412 of the European Parliament and of the Council was adopted in 2015.

The key points of the Rathenau Institute's report were then developed and supplemented by a wide range of expert judgments in the course of the foresight study carried out by the Council for Science and Technology Assessment (STOA, technology assessment body of the European Parliament), the report of which was published in December 2021 [Woensel et al., 2021] (hereinafter referred to as the STOA Report).

The method of an online survey of interested organizations and experts (stakeholders) was used in preparation of the STOA report. It included two stages and was aimed at exhaustively identifying the pro and contra arguments of the main scenarios for the legal regulation of NGT, which put forward key stakeholders from various fields of activity related to NGT[15].

It should be noted that this methodology for evaluating options and arguments can be largely (albeit with necessary adjustments) used in Russia. This would give a more reliable scientific character to the current and future discussions about the regulation of oil and gas treatment - both in society and in parliamentary and government circles, and would help to avoid excessive politicization and populism in the adoption of legislative and economic decisions.

The analysis of the mentioned reports, as well as the above considerations and conclusions regarding the Russian situation, made it possible to formulate firefly the following main options, pro and contra arguments, as well as scenarios for the legal regulation of new genome editing methods offered to Russian legislators and key economic players in order to make strategic decisions in the field of application of NGT in agricultural business. Under public support and consent solutions would provide: sustainable growth in the production and export of food products; overcoming import dependence; successful development of the innovation process based on domestic achievements in science and bioengineering.

5. Main results of the study: an exhaustive list of scenarios and the main arguments for decision making

The main options for regulating oil and gas wells in the field of their industrial application, taking into account the above considerations, include:

– *strict regulation* - bans, the use of burdensome licensing procedures for business, that is, a scenario similar to the case of GMOs;

– *deregulation* - a permissive policy in relation to NGT, subject to a number of conditions, the main of which is the absence of foreign DNA in the final product;

– *a new regulation* that will potentially combine the advantages of the first and second options and implies a balanced assessment of both each specific NGT product and each specific technology for its production in two key areas - assessment of the potential hazard of the product and assessment of the product and technology, taking into account social and ethical criteria.

When analyzing the main arguments of scientists, experts and groups of influence, possible future scenarios for the regulation of oil and gas, the following general considerations were taken into account (which must be considered a priori, bearing in mind the experience of public discussions in the Russian Federation, the need for a reliable assessment of the socio-economic prospects for the use of oil and gas to launch new domestic food products on the market):

1) significant public skepticism regarding genetically modified products (up to their demonization);
2) objectively existing uncertainties and unknown consequences of the use of NGT, not very long period of their use (about 10 years);
3) an "innate" contradiction when considering the problems of applying genetic (molecular and cellular) engineering methods between taking into account safety issues and stimulating the progress of science and innovation, between the attractiveness of a conservative, protective approach to breeding methods and the need to achieve an innovative breakthrough, competitiveness of domestic science and Russian business[16];
4) genome editing is, in a certain sense, a continuation of the methods of traditional plant breeding, which has made a significant contribution to ensuring food security in Russia;
5) Russia has excellent schools of scientists and breeders who are able to create new domestic varieties using genetic editing methods, subject to strict control conditions and “natural similarity” criteria (absence of foreign DNA, making changes that are possible in wildlife);
6) the resonance of the still not finally resolved problem of labeling products containing GMOs: in the future, NGT products need a different labeling, which, on the one hand, will ensure the freedom of choice for the consumer and the traceability of the product, and on the other hand, will remove social phobias and will contribute to the attractiveness of the product ;
7) the legislator must provide a clear and understandable policy for the public to regulate the market use of NGT products, establish transparent and effective

[15] For this survey, the results of which served as the basis for the subsequent forecasting workshop, STOA invited a core group of 25 participants from six representative groups: agribusiness and science (8 respondents); farmers and environmental NGOs (12 respondents); administrative and state bodies (2 respondents); trade and nutrition science (8 respondents); consumers and lobbying watchdogs (8 respondents); behavioral scientists (2 respondents).

[16] Using the terminology of European law, it can be said that the “precautionary principle and the principle of innovation” may conflict with each other (STOA Report).

Table 1
Strict regulation scenario

Arguments for	Arguments against
Provides a sufficiently high level of environmental protection, health, does not prohibit the use of genetic engineering methods	Правила допуска продуктов на рынок слишком строги, меры почти запретительные, процедуры очень ресурсоемкие для бизнеса
Ensures reliable, evidence-based risk assessment, follow-up monitoring, traceability, transparency when products are released to the market	Limits the state to achieve the goals of sustainable development, competitiveness of the food industry, ensuring food security in the future
Maintains freedom of choice for consumers and farmers thanks to a proven labeling system	Since there are no reliable detection methods, approved control procedures for NGT products, the development and implementation of the latter will cause difficulties and, potentially, discontent in the society.
	The risks of losing the competitiveness of national agriculture, both for Russia and Europe, are growing, since many countries (in particular, the states of South and North America, China, the countries of Southeast Asia) practice opposite approaches - in them, NGT are largely deregulated
	Risks of losing pace in science and innovation in this area, "brain drain" abroad
	GMO labeling will confuse consumers and encourage long-term rejection of NGT products

procedures for assessing risks and benefits with a clear scheme of responsibility for this assessment, based on the simple truth that after the release of new varieties into the open environment, plants can no longer be "returned back";

8) legislation regulating relations in the field of genomic research should, if possible, be proactive in nature, so as not only not to create obstacles to scientific research and innovation, but to serve as their driver, indicating key growth targets in advance and designating deliberate prohibitions and restrictions dangerous to humans and the environment.

Below is an analysis of the main arguments of experts and influence groups, based on the experience and publications of Russian experts, discussions in the legislative and public institutions of the Russian Federation, reports of the Rathenau Institute and STOA on the above scenarios.

1. Scenario of strict regulation - NGT products are equated to GMOs (Table 1). Scenario 1 for the EU implies maintaining the status quo, the GMO Directive does not change. For Russia, scenario 1 implies the introduction of tougher amendments to FL-358 and to the basic Federal Law FL-86.

2. The deregulation scenario (permissive policy for oil and gas) is shown in Table 2. Scenario 2 for the EU implies an amendment to the GMO Directive that removes NGT products from its scope. For Russia, scenario 2 implies at least the maintenance of the status quo, and at the maximum, the "legalization" of NGT in the basic law 86-FL and in industry legislation (provided that there is no foreign DNA in the final product).

3. The new legislative regulation (complex scenario, risk assessment and consideration of social and ethical aspects) is presented in Table 3. regarding social and ethical criteria.

A number of specialists from the Norwegian Advisory Council for Biotechnology (Bioteknologirådet) proposed a model that can be considered one of the options for a new comprehensive legislative regulation[17]. The Norwegian model is based on a balance of methods for assessing risk levels and socio-ethical factors. Unlike the model

[17] Bioteknologirådet (Norwegian Biotechnology Advisory Board). Genteknologiloven – Invitasjon til Offentlig Debatt (The Gene Technology Act – Invitation to Public Debate). 2017. https://www.bioteknologiradet.no/filarkiv/2017/12/Genteknologiloven-uttalelse-invitasjon-til-offentlig-debatt-web.pdf.

Table 2
Deregulation scenario

Arguments for	Arguments against
Simplifies regulation, saves material and human resources	Even small adjustments to the genome can cause big changes in the body. The absence of foreign DNA does not guarantee the safety of genetic editing
Plants produced with NGT are just as safe as those bred in the traditional way by conventional breeding methods, because they do not contain a new combination of genetic material or foreign DNA	Genomic editing technologies are new and there is little experience in safe use. Requires risk assessment and/or monitoring of newly created products
The agricultural production sector remains responsible for ensuring sustainable production and high quality food, traceability is also possible with the new labeling system	Organisms with novel traits derived from NGT can quickly enter environments where they cannot be traced, because in the event of deregulation, it is possible that developers and businesses will not be required to provide methods for detecting NGT plants
Deregulation would allow faster development and innovation, modernizing and stimulating the entire agricultural sector*	The freedom of choice of consumers should be provided with scientifically based information on food production (transparent communication between consumers, developers and manufacturers is key to supporting the development of new technologies, including NGT), the lack of complete information about NGT products is unacceptable
There are numerous examples of developments showing that NGT crops can contribute to the benefits for the agricultural sector, consumers, the environment and the economy as a whole	So far, there is no evidence that NGT will justify its promise to improve the quality and achieve sustainable food production. GMO products, even in countries where their circulation is not regulated, did not live up to the expectations of the 1980s
Stimulation of the seed sector, in which quite a lot of innovative small and medium-sized enterprises can operate	In the case of deregulation, the full-scale risk assessment envisaged for GMOs, as well as long-term monitoring of new products, is not carried out.

* Let us consider the examples of new crop species that are being successfully developed: (1) plants that are resistant to climate change and adverse environmental conditions; (2) plants resistant to new diseases and pathogens; (3) plants that can be cultivated with a sharp reduction in pesticide use; (4) "elite" and niche crops integrated into crop rotation schemes, with high yields and with a reduction in agricultural land, and others.

discussed in the Rathenau Institute report, this approach prioritizes social and ethical criteria in a complex regulatory scenario. Under this scenario, the assessment of the technology and the level of risk of NGT product is carried out mainly according to the criteria of social goals and ethical justification, and the specification of the risk category for the use of a new product occurs at the second stage (Table 4).

Conclusions

Russia will have to change the legislation on the circulation of genetically modified organisms, providing for a differentiated risk assessment depending on the technology used and social aspects, giving, in particular, real opportunities for the widespread use of new genetic technologies in food production.

It is necessary to adopt a new version of the Federal Law dated from July 5, 1996 No. 86-FL “On State Regulation in the Field of Genetic Engineering Activities”, which will clearly spell out the concept of genome editing. It is necessary to develop and adopt a federal law “On Breeding Activities”, which will contain information on selection using bioengineering, as well as the introduction of corresponding changes in the legislation on the environment, on seed production, and in by-laws of the Government of the Russian Federation.

Taking into account the current international experience in the legal regulation of oil and gas in Europe and the United States, the existing risks due to sanction pressure on Russia,

Table 3
New legislative regulation

Arguments for	Arguments against
This option is a compromise between regulation and deregulation, it can be expected to reduce the fears of citizens, preserve the principles of traceability and labeling	Risk assessment criteria (similar to GMOs) are too narrow for a correct assessment of technology, do not take into account the variety of potential consequences of the widespread use of NGT
Risk assessment according to the system of categories (risk levels) would allow for individual adjustment of the assessment procedure in each specific case, including changing, if necessary, the assigned risk category	Combining risk assessment with consideration of social/ethical criteria is not strictly scientific, it can easily become politicized and/or used for populist purposes
The structure and list of risk categories, in accordance with the existing proposals of experts from a number of countries, may be similar to the well-established system of risk categories in the creation of GMOs*	Deregulation of the use of “small” changes in the plant genome (notifying the introduction to the market) will mean that for many crops obtained by NGT methods, risks to humans and the environment will not be assessed
Connecting ethical criteria and predicting social consequences to risk assessment would facilitate the entry into the market of innovations that are beneficial not only from the point of view of business, but also well-being of citizens and the environment	This scenario does not take into account the unintended consequences of genetic editing (CRISPR and similar are still relatively new methods), while it is known that even small changes in the genome can have critical consequences for the whole organism.
Genetic editing introduces only very small changes in DNA that are indistinguishable from the results of conventional plant breeding methods.	At present, it is not possible to convincingly prove that the "small" genetic changes introduced with NGT are completely analogous to those that can be achieved using traditional methods of mutagenesis and selection; it is extremely difficult to make a comparison between them (there are no developed criteria). Thus, it is impossible to reliably verify the "natural similarity" of one or another NGT.
This scenario will facilitate wider adoption of advanced technology assessment methods	Questions that are very complex and unresolved even in the theory: who will be authorized to set the criteria? Who will conduct the proposed risk assessment?

* This takes into account factors such as the method of genetic modification, the type of change made to the sequence, the stability of the changes made, the risks of the modified organism spreading in the environment, and others

Table 4
New legislative regulation with priority of social assessments

Arguments for	Arguments against
Potentially solves social problems (sustainability, ethical justification and economic benefit). This procedure could be considered as obtaining a "social license".	The terms and criteria of social value and ethical acceptability are difficult to unambiguously define, which entails vulnerability to speculation (promises of "pennies from heaven" when introducing a new NGT culture from applicants) in the hope to reduce the requirements for risk assessment in relation to NGT methods
Provides benefits for consumers and enterprises in the production chain, puts environmental protection at the forefront	The scenario requires large public resources, and it is not clear who will bear the brunt of the costs connected with assessing the socio-economic impacts of the new technology. Compliance with social values can be interpreted in a variety of ways and it requires separate consideration, especially taking into account ongoing rapid geopolitical changes.
This incremental approach may be more effective; it would save business resources that are required for risk assessment in the second stage, although at the risk of weeding out promising innovations based on high-quality social and ethical criteria	The scenario does not explain how the risks and potential rewards will be balanced: is it acceptable to admit more risks if the potential product should bring more benefits to society? Who decides which social values are more important than the risks to the safety of the use of certain NGT crops?
The scenario provides more opportunities for the authorities to maintain control over the compliance of the sphere of technology and innovation with the goals of the state policy pursued	Many experts believe that the assessment of product safety should be carried out aside from the assessment of the social value of the product rather than in connection with it.

China's plans for a well-known liberalization of legislation on GMOs[18] Russia needs new domestic crops obtained by the "molecular scissors" methods. Currently, the legislation of the Russian Federation is prohibitive in relation to GMOs and implicitly liberal in relation to products of new genomic technologies. This situation creates a number of competitive advantages that must be preserved and strengthened, implying the need to improve the regulatory framework for genetic engineering activities.

The main scenarios for oil and gas pipeline regulation, pro and contra arguments, comparison of Russian and foreign approaches can be applied in making strategic decisions by both regulatory authorities and economic players. In general, the initial situation is in favor of the fact that the Russian innovation sphere and the food production industry can realize their existing competitive advantages in the coming years.

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[18] In July 2021, the General Reform Commission of the Central Committee of the Communist Party of China approved the "Action Plan for the Revival of the Seed Industry". The document attaches great importance to molecular methods of biological research, including the development of new genetically modified organisms (according to "AgroXXI-agroindustrial portal", 02/17/2022).

About the author

Timur E. Semenov

Candidate of biological sciences, professor-practitioner, Department of Management and Innovation, Financial University under the Government of the Russian Federation, coauthor of the text of the model Innovation Code for the CIS member states (Moscow, Russia).

Research interests: innovation management, technology assessment, strategic management, legal regulation of science and technology.

timur.e.semenov@mail.ru

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