



REGULATORY CHANGES FOR TRADE IN PRODUCTS CONTAINING GMOS

FAO food manufacturers, biotech sector, agriculture companies and other producers of goods manufactured with the use of genetically modified organisms (GMOs)

Pepeliaev Group advises that, on 3 July, the Russian President signed Federal Law No. 358-FZ “On amending certain items of the legislation of the Russian Federation to enhance the state regulation of genetic engineering” (the “Law”)¹.

The purpose behind the Law was to set control over the breeding and growing of any animals and plants whose genetic programming has been modified and to streamline the regulation process in this area.

Before the Law was adopted, the main instrument regulating genetic engineering was Federal Law No. 86-FZ “On the state regulation of genetic engineering” dated 5 July 1996 (“Law No. 86-FZ”). Further, federal executive bodies adopted a number of regulations regarding the registration of genetically modified organisms (we list these below). Therefore, the current statutory framework regulating genetic engineering is rather piecemeal and it deals with only certain aspects of the sector.

Current regulation

- The Russian Government’s Resolution No. 26 “On the state registration of feed manufactured from genetically modified organisms” dated 18 January 2002
- The Russian Government’s Resolution No. 120 “On the state registration of genetically modified organisms” dated 16 February 2001 (in effect until 1 July 2017)
- The Russian Government’s Resolution No. 839 “On the state registration of genetically modified organisms intended to be released into the environment and products manufactured with the use of such organisms or containing them” dated 23 September 2013 (to be applied from 1 July 2017)
- Order No. 489 of consumer regulator Rospotrebnadzor “On approving the Administrative Regulations to be followed by the Federal Service for Supervision over Consumer Rights Protection and Human Welfare when performing the state function of regulating and overseeing the licensing of activities that involve the use of human and animal infectious agents (except when used for medical purposes) and genetically modified organisms of potential hazard levels III and IV in closed-loop systems” dated 18 June 2014
- Order No. 466 of the Russian Ministry of Agriculture “On approving the Administrative Regulations to be followed by the Federal Service for Veterinary and Phytosanitary Supervision when performing the state function of state registration of feed derived from genetically modified organisms” dated 6 October 2009.

Contents of the Law

Bans on seeding, growing and breeding genetically modified plants and animals in Russia

It is prohibited to use seeds to be planted (sown) from plants produced with the use of genetic engineering methods, and to grow or breed plants and animals whose genetic programming has been modified with the use of genetic engineering methods.



The ban on seeding genetically modified organisms may result in transgenic forms being used less in the manufacturing of products in Russia, which in the mid- and long-term may result in both the Russian agriculture sector and the biotechnology sector becoming uncompetitive.

¹ The Law came into force on 4 July 2016, except for the provisions regarding the administrative offence, which will come into effect from 1 July 2017.

New powers of the Russian Government

The Government may impose a ban on the import into Russia of genetically modified organisms and products containing same based on the results of monitoring. The monitoring of the influence, on a human being and the environment, of genetically modified organisms and products manufactured with the use of such organisms or containing same means, in the case at hand, a set of measures to collect, process, analyse and publish information regarding the influence of GMOs on human health and the environment.



This legal provision does not introduce an express ban on importing GMOs, but only creates mechanisms for potentially restricting such imports and vests the right in question with the Government. Nevertheless, it should be noted that the availability of such mechanisms potentially allows them to be deployed, including when foreign policy and the economic situation changes. By introducing such restrictions, the state is reinforcing its role in the sphere, which is also evidenced by new trends in the state regulation of genetic engineering, such as: monitoring of the influence on a human being and the environment of genetically modified organisms and products manufactured with the use of such organisms or containing same and regulation of the release of genetically modified organisms into the environment.

New requirements for importers of GMOs

The Law stipulates that importers have an obligation to undergo statutory procedures to register products imported into Russia (previously, only GMOs themselves had to be registered).



The previous version of Law No. 86-FZ did not contain any such specification. In accordance with the Russian Government's Resolution No. 120 dated 16 February 2001, at present only GMOs themselves currently need to be registered. With the Russian Government's Resolution No. 839 dated 23 September 2013 coming into force from 1 July 2017, products will also be subject to registration.

Administrative liability for breaking the rules for using GMOs

The Law has amended the Russian Code of Administrative Offences.

A breach of legislation relating to genetic engineering will form a separate body of an administrative offence. Sanctions will be imposed if the offence manifested itself in GMOs being used other than in compliance with the permitted or intended types of use or in violation of specific conditions for using the modified organisms, including the manufacturing of a certain type of product, using modified organisms and/or products that have not been registered in manner required by statute. For such offences, the Law sets liability in the form of an administrative fine for a company's officers (up to RUB 50,000) and for a company itself (up to RUB 500,000).

Cases regarding such offences will be considered by the regulatory bodies that oversee the release of genetically modified organisms into the environment.

In accordance with clause 3 of Russian Government's Resolution No. 839 dated 23 September 2013, such bodies include the following:

- the Russian Ministry of Healthcare - with respect to modified organisms used to manufacture medicines for humans, as well as medicines for humans obtained from the use of modified organisms or containing same
- the Federal Service for Supervision in Healthcare - with respect to modified organisms used to manufacture medicines for humans, as well as medicines for humans obtained from the use of modified organisms or containing same
- the Federal Service for Supervision over Consumer Rights Protection and Human Welfare - with respect to modified organisms used to manufacture food ingredients and foodstuffs, as well as food ingredients and foodstuffs obtained from the use of modified organisms or containing same
- the Federal Service for Veterinary and Phytosanitary Supervision - with respect to modified plants and animals intended to be bred and planted in Russia; modified micro-organisms for agricultural purposes; modified organisms used to manufacture feed and feed additives for animals; modified organisms used to produce veterinary medicines, as well as feed and feed additives for animals; and veterinary medicines obtained from the use of modified organisms or containing same.

It should be recalled that the intended use was established in the Russian Government's Resolution No. 839 dated 23 September 2013 and covers the following:

- a) the production of medicines for humans
- b) the production of medical devices
- c) the production of food ingredients and foodstuffs
- d) the production of feed and feed additives for animals
- e) the production of medicines for veterinary purposes
- f) the breeding and/or growing in Russia of modified plants and animals and micro-organisms for agricultural purposes.



How the above new provisions will affect the development of the industry in the long run will depend on whether GMOs are products that require oversight and whether measures stipulated by the new Law will be used for the purposes stated.

Exceptions

The new requirements of the Law concerning the ban on the use of seeds as well as growing and breeding of plants and animals whose genetic programming was modified by the use of genetic engineering methods do not apply to seeding, planting and breeding such plants and animals in the context of expert review and research and development projects.



The introduction of the above exception points to the conclusion that the general ban on breeding and planting genetically modified organisms in Russia does not mean that genetic engineering is becoming irrelevant as a science. Quite to the contrary, the amendment is evidence that the state has a positive intention to develop the highly promising scientific sector and subsequently to use it in practical areas. Such research and expert examinations will help to demonstrate that GMOs can be used safely and effectively.

What to think about

Producers and distributors of products manufactured with the use of genetically modified organisms or containing same should study the text of the Law. They should also take into account that the adoption of the Law means that there is a new body of an administrative offence in genetic engineering. Moreover, it is essential to keep in mind the new requirements for importing genetically modified organisms and products manufactured with the use of same.

Market players should now monitor the practical implementation of the Law as well as whether subordinate legislation is adopted and whether official executive bodies issue any clarifications on the matter.

Help from your adviser.

Pepeliaev Group lawyers have extensive experience in the regulation of the FMCG, agriculture and biotechnology sectors and they are ready to provide comprehensive legal support on issues relating to GMOs. This includes preparing legal opinions, drafting documents, and representing companies before regulatory authorities and in court.

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