

client alert

REGULATORY | RUSSIA |

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RESTRICTIONS IMPOSED ON THE APPLICATION AND IMPORT OF GENETICALLY MODIFIED ORGANISMS

A major change to Russian regulations affecting the development of genetically modified organisms and plants in Russia, and their import, came into effect on 4 July 2016.

The change results in a considerably more restrictive regulatory regime for the use (including breeding and cultivation) and import of genetically modified organisms (“**GMOs**”), genetically modified plants and products developed with the use of or containing GMOs (“**Derived Products**”) in Russia. The legal basis for implementing the regulatory change is Federal Law No. 358-FZ dated 3 July 2016 “On Amendments to Certain Legislative Acts of the Russian Federation for the Improvement of the State Regulation of Genetic Engineering Activities” (the “**Law**”).

Despite strengthening the regulatory regime for GMOs and Derived Products, the period since 4 July 2016 has not seen the regulatory authorities actively bringing the restrictions of the Law into effect, as summarised below.

The Law introduced the following measures:

- a prohibition on breeding genetically modified plants and animals in Russia (subject to limited exceptions);
- potential import bans on specific GMOs and Derived Products; and
- a prohibition on the import and use of genetically modified plant seeds.

PROHIBITION ON BREEDING GENETICALLY MODIFIED PLANTS AND ANIMALS

The Law bans cultivating and breeding plants and animals in Russia that:

- have had their genetic programme modified through genetic engineering; and
- contain genetic engineering material (including genes, gene fragments or combinations) that is unable to appear in a plant or an animal as a result of natural processes.

The only exception to the prohibition includes the breeding of such plants and animals in the course of examinations (expertise) and scientific research.

POTENTIAL IMPORT BAN ON GENETICALLY MODIFIED ORGANISMS AND DERIVED PRODUCTS

The Government of the Russian Federation (the “**Government**”) is now authorised to ban the import of GMOs intended for release into the environment, as well as Derived Products, provided that:

- the impact of such GMOs and Derived Products on humans and environment has been duly monitored prior to the ban; and
- the results of such monitoring are negative.

PROHIBITION ON THE IMPORT AND USE OF GENETICALLY MODIFIED PLANT SEEDS

An additional restriction affects plant seeds that have had their genetic programme modified and which contain genetic engineering material that is unable to appear in plant seeds as a result of natural processes (“**GMO Plant Seeds**”): it is now prohibited to:

- use GMO Plant Seeds for sowing; and
- import GMO Plant Seeds into the Russian Federation.

The sowing of GMO Plant Seeds is, however, allowed in the course of examinations (expertise) and scientific research.

ADMINISTRATIVE LIABILITY

Along with the rules banning or otherwise restricting the use, cultivation and import of GMOs and Derived Products, the Law establishes administrative liability for the breach of those rules, although such liability may only be imposed from 1 July 2017.

After 1 July 2017, a legal entity will be subject to RUR 100,000 to 500,000 fines for:

- the use of unregistered GMOs or Derived Products (including any use after the expiry of the registration certificate);
- the use of GMOs contrary to the aims they have been registered for;
- the use of GMOs in breach of specific use conditions set out therefor in their registration documents (including the manufacture of a certain type of Derived Product).

Along with the legal entity violating the GMO regulation, its officials may also be held liable for the breach as well – a separate fine of RUR 10,000 to 50,000 may be imposed on the CEO or other competent staff of a violating company.

APPLICATION OF THE LAW IN PRACTICE AND OPEN ISSUES

- No significant change in the procedural aspects of the GMO state registration has happened yet following the enactment of the Law. Although the Government approved new procedures for the state registration of GMOs and Derived Products¹ as a part of the global regulatory reform affecting the GMOs in 2013, respective updated registration procedures will only come into force on 1 July 2017.
- The Government has not yet enacted any regulation for the procedures of monitoring GMOs or Derived Products that may result in a ban on their import into Russia. For that reason, the Government has not yet banned any specific GMO or Derived Product for its import or use in Russia due to negative monitoring results.
- The regulations available to date do not yet provide for a clear legal definition of “scientific research” and “examinations (expertise)” to determine the possible purposes of allowed forms for cultivation (breeding) of GMOs or genetically modified plants, as well as for import or use of GMOs, Derived Products and GMO Plant Seeds in Russia.
- Following the enactment of the Law, the procedure for exchanging information on the registered GMOs and Derived Products for the key regulatory bodies entrusted with supervisory functions in the regulated sphere² has been simplified, and each such body would now be entitled to update the unified state register of GMOs and Derived Products (the “Register”)³. The Register is supposed to be available to the public at <http://www.gmo.rosminzdrav.ru>, but it has not been put in place yet (according to the Ministry of Healthcare, the website incorporating the Register is expected to be available by 1 January 2017).
- Although the competent state bodies have not yet developed a consistent practice of examinations and import banning of the GMO Plant Seeds, it should be noted that the competent state authorities are generally authorised to conduct inspections and supervision over the plant seeds and derived food products (e.g., Rosselkhoznadzor may undertake examinations of agriculture, in particular plant seeds, and Rospotrebnadzor may test food products and their proper labelling).
- Consequently, the risk of being held liable for imports of the GMO Plant Seeds should be taken into account.

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¹ Regulation of the Government of the Russian Federation No. 839 dated 23 September 2013.

² The Ministry of Healthcare of the Russian Federation, the Federal Service for Surveillance in Healthcare (Roszdravnadzor), the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor) and the Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor).

³ Order of the Ministry of Healthcare of the Russian Federation No. 476n dated 5 July 2016.

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