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GOR Resolution 770 Amends Rules for Registration of GE Organisms

Report Categories:

Biotechnology - GE Plants and Animals

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Report Highlights:

Government Resolution No. 770 of June 29, 2017 amends Russia's framework of rules for the registration of GE organisms and products derived or containing such organisms. The Resolution conforms to Federal Law No 358 of July 3, 2016, which bans cultivation and breeding of GE plants and animals within the territory of the Russian Federation. The previous framework, based on Government Resolution No. 839 of September 23, 2013, would have allowed the possibility of registering GE crops and animals for cultivation and breeding beginning July 1, 2017.

Background Information

On June 29, 2017, the Government of the Russian Federation issued Resolution No. 770 “On Amending the Resolution of the Government of the Russian Federation No. 839 of September 23, 2013”. Resolution No. 770 amends Russia’s framework of rules for the registration of GE organisms and products derived or containing such organisms. The Resolution conforms to Federal Law No 358 of July 3, 2016, which bans cultivation and breeding of GE plants and animals within the territory of the Russian Federation.

The previous framework, based on Government Resolution No. 839 of September 23, 2013, allowed for the possibility of state registration of GE organisms for release into the environment. This includes cultivation and breeding, setting the framework rules for the state registration of such organisms as well as products derived from or containing such organisms, and distributing the authority for such registration and control among several institutions. The registration should have begun on July 1, 2017¹. Meanwhile, in July 2016, Russia adopted the Federal Law No 358-FZ², which prohibits the cultivation and breeding of plants and animals whose genetic program has been changed using methods of genetic engineering, except for cases of examination and research.

By July 1, 2017, the following authorized institutes should have developed regulatory documents for such registration of GE organisms:

- Federal Service for Surveillance of Consumer Rights Protection and Human Welfare (Rospotrebnadzor) – registration for food;
- The Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoz nadzor or VPSS, English abbreviation) – registration for feeds, feed additives, veterinary drugs.

The regulatory documents for registration of GE organisms for food were developed on time and already used in registration of GE organisms for food, while the regulatory documents for registration of GE organisms for feeds, feed additives and veterinary drugs were not developed by July 1, 2017. The status of this registration is not clear.

Summary of Amendments

Resolution No. 770 of June 29, 2017, amends the text of Resolution 839 and the rules for the State Registration of GE Organisms and Products (hereinafter – the Rules):

- Emphasizes that the rules of registration, monitoring and control set in the Resolution 839 of 2013, apply to all GE organisms and products, including "products imported into the territory of the Russian Federation." The original text did not explicitly emphasize imported products;
- Confirms that Rospotrebnadzor and VPSS shall inform the Ministry of Health of the Russian Federation (Article 5 of the Resolution 839) on the results of monitoring the effect of GE

¹ FAS/Moscow reported on the Resolution 839 in the GAIN reports: [Government Resolution on GMO Registration for Environmental Release_9-25-2013.pdf](#), [GMO Registration for Cultivation Postponed_6-27-2014.pdf](#), and in [Agricultural Biotechnology Annual_4-3-2017.pdf](#).

² FAS/Moscow GAIN report [Russia Bans Cultivation and Breeding of GE Crops and Animals_7-12-2016.pdf](#)

organisms and products on humans and the environment. In addition, they will also send information regarding control over the release of GE organisms into the environment;

- Adds that “modified organisms not intended for release into the environment” are not subject to the state registration (Article 2 of the Rules);
- Sets the validity period for certificates of state registration of GE organisms and GE products for “up to 10 years” (Article 7 of the Rules);
- Amends Article 11 of the Rules in a way that does not allow cultivation and breeding of GE crops and animals:

Previous text	New text
11. There are the following kinds of intended use of modified organisms: a), b), c), d), e), f) The breeding and growing on the territory of the Russian Federation of modified plants and animals as well as of microorganisms for agricultural use;	11. There are the following kinds of intended use of modified organisms: a), b), c), d), e), f) The breeding and growing on the territory of the Russian Federation of modified plants and animals as well as of microorganisms for agricultural use (except for plants and animals containing genetically engineered material, the introduction of which cannot be the result of natural (inherent) processes);

- Adds that documents with the results of molecular genetic research, which are submitted by the applicant, shall contain information, on “the conformity of the genetic modification with natural (natural) processes”;
- Confirms that the registration, monitoring and control over the GE organisms for food and GE food products are the authority of the Federal Service for Surveillance of Consumer Rights Protection and Human Welfare (Rosпотребнадзор). In addition, the registration, monitoring and control of GE organisms used for feeds, feed additives and veterinary pharmaceuticals as well as such products containing GE organisms is the authority of the Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhozнадзор or VPSS, as the English abbreviation) at the Ministry of Agriculture of the Russian Federation (Article 2 of the Resolution 839);
- Adds (to articles 24 and 25 of the Rules) that the state register of modified organisms and products shall contain (g) information on the results of monitoring the effects of modified organisms/products on humans and the environment, which is added by registration authorities as such monitoring is carried out.

Some industry sources have noted that according to Resolution 770 “medical products and medical devices” are currently excluded of the scope of GMO registration (Amendments to Article 7 of the Rules). However, it is not yet clear whether this exclusion would apply to veterinary drugs as well.

Comments

Resolution 770 does not make modify the due date for registration of GE organisms and products containing such organisms, which still remains July 1st, 2017. At the same time, as of July 1st, 2017, VPSS did not have any registration or monitoring documents for GE feeds, feed additives and veterinary drugs. The Russian Ministry of Agriculture has drafted nine regulatory documents with methodological

guidelines (hereinafter – procedures). The Ministry guidelines address safety assessment and testing of GE organisms for production of feeds, feed additives, drugs for veterinary use, GE animals and GE microorganisms. There is also a document that outlines the functions of the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS) at the Ministry of Agriculture. For further information on these draft documents, please refer to GAIN [Draft Regulations for GE Feeds and Other Products 6-29-2017.pdf](#). According to industry sources, the draft documents have raised serious concerns among scientists and experts in the sphere of biotechnology. There are specific concerns that the prescribed procedures for the safety assessment of feeds cannot be implemented. To date, none of the draft documents have been approved. With no finalized regulatory documents for biosafety or for the registration of GE feeds, feed additives and veterinary pharmaceuticals, there is a de facto suspension on new registrations of feeds and feed additives containing GE organisms or products derived from GE organisms. The ongoing uncertainty of situation will continue to have a seriously impact on the trade of these products.

Resolution No. 770 of June 29, 2017

The Russian text of the Resolution No. 770 of June 29, 2017 is on the site:

<http://government.ru/media/files/12ZF6o3Z9m4toLDUehVzzeGLj201gv68.pdf>. The unofficial translation of the Resolution and the Amendments is given below.

Note: All Russian legislative and regulatory documents use the term GMO (genetically modified organisms) or GMM (genetically modified microorganisms) instead of genetically engineered (GE) organisms/microorganisms. Therefore, throughout this report, when referring to language in those documents, we will default to the terms as used in the document.

Begin unofficial translation:

GOVERNMENT OF THE RUSSIAN FEDERATION

Resolution
of June 29, 2017, No. 770,
MOSCOW

On Amending the Resolution of the Government of the Russian Federation
of September 23, 2013, No. 839

The Government of the Russian Federation decrees:

Approve the attached amendments to the Resolution of the Government of the Russian Federation of September 23, 2013 No. 839 "On the State Registration of Genetically Engineered Organisms Intended for Release into the Environment, as well as Products Obtained Using Such Organisms or Containing Such Organisms "(Collection of Legislation of the Russian Federation, 2013, No. 39, Article 4991, 2014, No. 25, Article 3317).

Chairman of the Government
of the Russian Federation

D. Medvedev

APPROVED
By the Resolution of the
Government of the Russian Federation

Amendments
to the Resolution of the Government of the
the Russian Federation of September 23, 2013 No. 839

1. The title shall be supplemented with the words "including the said products imported into the territory of the Russian Federation".

2. Articles 1 and 2 shall be supplemented with the words "including the said products imported into the territory of the Russian Federation".

3. Article 5 shall be reworded as follows:

"5. To establish that the Federal Service for Supervision of Consumer Rights Protection and Human Welfare and the Federal Service for Veterinary and Phytosanitary Surveillance monitor the effects on humans and the environment of genetically engineered organisms and products obtained using such organisms or containing such organisms, as well as control over the release of genetically engineered organisms into the environment, and send information on the results of conducted monitoring and control to the Ministry of Health of the Russian Federation. ".

4. Article 6 is no longer in force.

5. In the "Rules for the State Registration of Genetically Engineered Organisms Intended for Release into the Environment, as well as Products Obtained Using Such Organisms or Containing Such Organisms" approved by the said resolution:

a) The title shall be supplemented with the words, "including the said products imported into the territory of the Russian Federation";

b) Article 1, after the words "such organisms", shall be supplemented with the words, "including said products imported into the territory of the Russian Federation";

c) Article 2, after the second paragraph, is supplemented with the following paragraph,
"Modified organisms not intended for release into the environment";

d) In Article 4, the words "within the framework of the established procedure for its state registration in accordance with", shall be replaced by the words, "in the manner prescribed";

e) Article 5, after the words "such organisms", will be supplemented with the words "including the said products imported into the territory of the Russian Federation";

f) Article 7 shall be reworded as follows:

7. Registration authorities issue certificates on state registration of genetically engineered organisms intended for release into the environment (if such organisms are subject to state registration), and of products obtained using such organisms, including the said products imported into the territory of the Russian Federation. The only exceptions are medicinal products and devices (hereinafter - a certificate of state registration of the modified organism and product). The validity of such certificate is determined based on conclusions provided in subparagraph "b" of Article 12 of these Rules, and may not exceed ten years.

The forms of these certificates are approved by the Ministry of Education and Science of the Russian

Federation;

g) Paragraph “f” of Article 11 after "plants and animals" supplements with, "(except for plants and animals containing genetically engineered material, the introduction of which cannot be the result of natural (inherent) processes)";

h) The second paragraph of clause “b” of Article 12 shall be supplemented with the words, "containing, among other information on the conformity of the genetic modification with natural (natural) processes";

i) Article 18 shall be added with the words, "if such organisms are subject to state registration";

j) Article 24 shall be supplemented with paragraph "g" of the following content:

"g) Information on the effects of modified organisms on humans and the environment is added by registration authorities.";

l) Paragraph 25 shall be supplemented with subparagraph "f" as follows:

"(f) Information on the effects of products on humans and the environment is added by registration authorities.";

m) The subparagraph "d" of Article 27 shall be supplemented with, "and control over the release of modified organisms into environment".

End unofficial translation