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Global Agricultural Information Network

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Approved By:

Deanna Ayala

Prepared By:

FAS/Moscow Staff

Report Highlights:

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.” The Resolution serves to continue the ban on cultivation and breeding of genetically engineered (GE) plants and animals in the Russian Federation per Federal Law No 358 of July 3, 2016. While imports of GE products are permitted, currently there are no methodological guidelines for registering GE events for feed use as well as for stacked events, making it impossible for those events to be registered and in some cases preventing their import. There is a mechanism for registration of GE products for food use.

Executive Summary:

There is no ban on imports of GE commodities, food and feed. However, the Government of Russia (GOR) requires that GE lines present in food, feed and commodities be registered in Russia. The registration of food and feed that contain these registered GE lines is also required. The procedures for registration of food and feed are each separate and administered by two different GOR entities. Intended registration of GE crops for cultivation and the actual registration of GE crops for feed use have been under the authority of the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS). The changes made by Federal Law (FL) No.358 stopped development of a mechanism for registration of GE crops for cultivation. Moreover, Federal Law No. 358 resulted in a de-facto suspension of registration of new GE lines for feed use.

With respect to GE products for food use, the Federal Service for Surveillance of Consumer Rights Protection and Human Welfare (Rospotrebnadzor) has guidelines in place for the registration of GE organisms for food. Currently, 14 corn lines, eight soybean lines, one rice line, one sugar beet line and two potato lines are registered for food use in Russia and in the Eurasian Economic Union (EAEU).

Meanwhile, the Ministry of Agriculture has not yet approved regulatory documents for GE organisms for feeds, feed additives and veterinary pharmaceuticals. Currently the Ministry of Agriculture is working with the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS) to come to mutual agreement on methodological guidance (MUK) for registration of GE lines for feed and feed additives, however, according to sources the timeline for agreement on MUK is unclear.

Feed use registrations have only been granted for a period of five years, and the registration periods for only three soybean lines and five corn lines are still valid, the registrations for the remaining 17 corn and soybean lines began to expire in 2017 and continue according to each event's expiration date (please see table 3, below). Despite efforts to re-register the lines, until a regulatory mechanism for registration of GE feeds is approved, the registration renewal process and timeline are unclear.

On December 7, 2018, the Ministry of Agriculture published the second version of a new set of proposed guidelines for review (for more information please refer to Policy section of this report). The first version of the guidelines were drafted in consultation with industry and the December version removes one hurdle but the other (scope of testing) remains intact. Even if the guidelines are passed, it will take some time – possibly up to two years -- for the GE lines to be re-registered.

There is no information on research in the field of GE animals and cloning in Russia. Federal Law No.358 prohibits breeding of GE animals in the Russian Federation.

(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.)

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

a) PRODUCT DEVELOPMENT:

There is no information on the development of GE crops in Russia. Before the ban on cultivation of GE crops, Russian scientists conducted some laboratory research on GE crops, but the research had not yet reached the stage of field trials. Although field trials are not technically prohibited, they need special permission from the Variety Testing Commission at the Ministry of Agriculture and approval from Interagency GMO Commission, which are typically not granted.

Given the seeming disinterest in cultivating or using GE crops in Russia coupled with the current economic situation in Russia and government initiatives to develop organic agriculture, as well as the lack of an implementation mechanism to register GE lines for feed, financing of research for development of Russian GE crops in the near term is unlikely.

b) COMMERCIAL PRODUCTION:

Russia does not cultivate any GE crops, including GE seeds.

A de-facto ban on cultivation of GE crops in Russia existed previously because the legislative mechanism for approval of GE crops for cultivation did not exist. At the end of 2013, the Russian Government adopted Resolution 839, “on development of a mechanism for the registration of GE crops for cultivation by July 1, 2014.” Subsequently, the implementation of this Resolution was postponed to July 1, 2017 but was pre-empted on July 3, 2016, when the Federation Assembly, Russian’s major legislative body, adopted FL 358 that prohibits cultivation of GE plants and breeding of GE animals on the territory of the Russian Federation. 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. For more details please refer to [FAS GAIN Report 1743](#).

a) EXPORTS:

Russia’s soybean production has been steadily increasing while imports have gone down. For example, exports were up 40 percent, to 272 thousand metric tons in January-July 2018 versus the same period in 2017. All soybeans are considered non-GE but lack any certification to this effect. Soybean meal made from crushed, imported beans and re-exported may contain GE lines. With respect to corn, in calendar

year 2017, Russia exported 5.2 million metric tons (MMT) or nearly two percent less than in calendar year (CY) 2016. In the first seven months of CY 2018 (January – July), Russia exported 3.8 MMT of corn, compared to 3.2 MMT in the same period in 2017. Despite the slight increase in exports of corn in the first seven months of 2018, unfavorable weather conditions in summer and autumn resulted in lower yields in the main corn producing federal districts. As a result, a smaller corn crop will likely translate into lower export numbers. Since there are no approved methods and/or laboratories for certification of GE-free production of corn and soybeans in Russia, producers and exporters cannot register their crops as GE-free, and exporters are not paid premiums for GE-free crops. Along with the growth of soybean production in the Far East and some territories in the south, Russia hopes to increase exports of soybeans in the future.

Table 1. Russia: Exports of corn, soybeans and soybean meal, CY 2013-2017 and Jan-July 2018 compared with Jan-July 2017

	2013	2014	2015	2016	2017	Jan- July 2017	Jan.- July 2018
Metric Tons							
Corn (HS* ¹ Number 1005)	2,599,288	3,418,920	3,698,768	5,334	5,194	3,210	3,790
Soybeans (HS Number 1201)	83,553	78,732	382,490	422,000	519,601	247,403	621,659
Soybean meal (HS number 2304)	210,306	548,037	458,247	450,814	300,486	193,119	271,929
1,000 U.S. Dollars							
Corn (HS Number 1005)	590,073	688,082	600,939	861,798	845,554	535,600	662,300
Soybeans (HS Number 1201)	26,202	23,761	119,177	133,156	168,523	78,515	191,625
Soybean meal (HS number 2304)	126,540	315,915	226,321	201,713	142,157	91,533	134,811

Source: Global Trade Atlas

b) IMPORTS

Russia does not permit the importation of GE planting seeds. Therefore, U.S. exports of GE planting seeds to Russia are not allowed, and registration of GE lines in imports for processing into food and feed has become more and more difficult. This is partially due to increased regulatory scrutiny. With no finalized regulatory documents for biosafety or for the registration of GE feeds, feed additives and veterinary

¹ HS is the Harmonized Item Description and Coding System an international standard maintained by the World Customs Organization. NOTE: Since Russia does not cultivate GE crops, it is assumed that exports of corn and soybeans in the table above are all non-GE, although these products are not certified as non-GE. Soybean meal that is produced in whole or in part from imported soybeans that may be sourced from GE soybeans.

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 the situation will continue to have a serious impact on the trade of these products, specifically in bulk crops, such as soybeans, corn, and other crops that may be GE, as well as processed products made with GE components.

Russia allows the importation of GE crops, and processed products containing GE ingredients if these crops/products have been tested and registered in Russia for food and/or feed use (See paragraph APPROVALS in PART B of the report).

Russian Customs data does not separate GE products from non-GE products. However, most corn and soybeans imported into Russia, as well as products produced from imported corn and soybeans, may contain GE crops and GE ingredients in amounts that do not exceed Russian and the EAEU GE presence requirements (For more information see section LEGISLATION AND REGULATIONS and paragraph LOW LEVEL PRESENCE (LLP) POLICY in PART B of this report).

On July 12, 2018, President Putin signed decree No. 420 extending Russia’s ban on the import of agricultural products from the countries that applied economic sanctions against Russia, including the United States, until the end of 2019 ([FAS GAIN Report](#)). The Government issued decree No. 816 of July 12, 2018, implementing the decree of the President without any changes to the lists of covered countries or products. Soybeans, soybean meal, and corn are not on the list of banned products. For the current list of banned products, please see [RS1754 Russia Expands Food Import Ban to Swine and By-Products](#).

While imports of corn, soybeans, or products thereof, are not covered by this ban, since February 15, 2016, Russia temporarily banned imports of corn (HS code 1005), planting seeds of sweet corn (HS code 071290 110 0) and soybeans (HS code 1201) from the United States based on reported findings of regulated weeds in these imported crops. In fall 2016, imports of soybeans nearly came to a halt. (More in paragraph STACKED or PYRAMID EVENT APPROVALS in PART B of this report).

Table 2. Russia: Imports of products that may contain GE ingredients, CY 2013-2017 and Jan.-July 2018 compared with Jan.-July 2017, metric tons (MT)

	2013	2014	2015	2016	2017	Jan- July 2017	Jan.- July 2018
Metric Tons							
Corn (1005)	55,271	52,728	43,844	41,124	52,640	38,735	34,513
- from the U.S.	6,210	3,986	3,435	370	0	0	0
Corn Groats and Meal (1103 13)	14,343	5,350	232	82	139	76	110
- from the U.S.	0	0	0	0	0	0	0
Corn Starch (1108 12)	15,941	18,032	13,253	14,258	11,375	6,918	2,283
- from the U.S.	6	0	0	1	1	0	0

Soybeans (1201)	1,145,155	2,028,163	2,179,719	2,283	2,236	1,290	1,304
- from the U.S.	208,274	390,008	526,171	216,018	0	0	0
Soybean flour (1208 10)	873	344	277	194	140	120	100
- from the U.S.	0	0	2		0	0	0
Soybean Meal (2304)	630,557	532,933	532,684	229,139	70	54,748	115,017
- from the U.S.	7,257	24,171	7,898	2,833		0	0
Soybean Isolates (from 3504)							
Total group 3504	54,559	58,711	46,245	43,485	42,199	22,632	23,099
- from the U.S.	190	485	120	126	168	91	67
1,000 U.S. Dollars							
Corn (1005)	161,299	221,429	146,367	141,308	185,285	137,170	126,564
- from the U.S.	6,294	4,071	3,202	343	0	0	0
Corn Groats and Meal (1103 13)	6,464	2,115	188	64	109,180	57,964	78,294
- from the U.S.	0	0	0	18	0	0	0
Corn Starch (1108 12)	12,107	11,495	7,243	6,628	6,542	3,529	2,551
- from the U.S.	36	1	4	6	5	2	3
Soybeans (1201)	675,783	1,150,758	941,790	977,488	966,058	559,290	585,953
- from the U.S.	121,985	215,294	219,849	81,541	0	0	0
Soybean flour (1208 10)	968	383	252	164	119	100	95
- from the U.S.	0	0	2	0	0	0	0
Soybean Meal (2304)	403,840	334,379	257,610	97,665	32,765	15,114	32,410
- from the U.S.	4,801	15,673	4,418	1,029		0	0
Soybean Isolates (from 3504)	0	0	0	0	0	0	0
Total group 3504	149,459	165,381	128,136	103,989	113,067	59,083	60,547
- from the U.S.	1,203	4,618	676	764	1,124	551	461

Source: Global Trade Atlas

c) FOOD AID:

Russia provides in-kind food aid of grain, flour, vegetable oil, and grain and oilseeds products to some countries, such as Syria. Presumably, since Russia does not cultivate GE crops, their food aid does not contain any GE products. Russia is not a recipient of food aid.

d) TRADE BARRIERS:

Russia bans the cultivation of GE crops, and this impedes U.S. exports of planting seeds of crops, such as soybeans, rapeseed, sugar beets and corn. Russia's demand for efficient, drought-resistant varieties and hybrids of planting seeds of these crops is very high, but there is no open market for these seeds.

PART B: Policy

a) REGULATORY FRAMEWORK:

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 serves to continue the ban on cultivation and breeding of GE plants and animals in the Russian Federation per Federal Law No 358 of July 3, 2016. For more information please refer to Post GAIN report [Russia Bans Cultivation and Breeding of GE Crops and Animals 7-12-2016.pdf](#) and [RS1760 Biotechnology Annual Report 2017](#).

In June 2017, the Russian Ministry of Agriculture together with VPSS drafted regulatory documents for the safety assessment and testing of GE ingredients for feeds, feed additives, veterinary pharmaceuticals, GE animals, and GE microorganisms. However, none of these drafts received final approval thus, there have not been any guidelines in place for registration of feeds and feed additives obtained with GE organisms for over a year although two drafts have been circulated (please see below). As a result, a total of 11 corn and soybean lines’ feed registrations have expired, thereby impeding imports of those products. Among those are Roundup Ready soybeans, Bt soybeans and LL soybeans.

On July 3, 2018, the Ministry of Agriculture published the first draft of a set of proposed methodological guidelines for review. These guidelines were drafted in consultation with industry and with some modest recommended changes would have allowed companies to re-register their products. Many Russian entities (e.g. National Meat Association) and businesses have formally expressed their support for the new guidelines and the U.S. Government has officially submitted comments. However, according to industry sources none of the proposed comments were taken into consideration.

The July draft was superseded by a December 7, 2018 version of “Methodological Guidelines for Assessing the Biological Safety of GE Organisms for the Production of Feeds and Feed Additives” published on Russia’s government portal at <http://regulation.gov.ru/projects#npa=81934>. This document is key to resuming new and extending current registration of GE lines for feeds and additives. It resolves one major hurdle but keeps another intact. That is, the December version of the Methodological Guidance (MG) specifies that repro studies shall be conducted on two generations of laboratory animals; this is the procedure followed by Rospotrebnadzor for registering GE lines for food and what would be ideal for registration for feed. Previous drafts had up to five generations so if this change remains it would be a significant improvement.

On the other hand, the MG doesn't authorize Federal Research Center of Nutrition, Biotechnology and Food Safety (former the Institute of Nutrition (ION) to conduct safety assessments. ION reports to the Rospotrebnadzor and was used in the past for registration of GE lines for food and feed. The only difference between the two studies is that ION analyzes the results with regard to the value for humans, and VGNKI analyzes the same results with regard to the value for animals. Nevertheless, companies would be required to repeat the entire scope of studies. The period for studies is reported to be approximately 14 months, and the cost roughly \$ 130,000 minimum per GE product. It is unclear

whether this cost in dollar and duration terms will deter any of the tech companies from registering their lines.

The proposal is open for public comment but it has not been notified to the WTO in any of its iterations including this one. Closing date for comments is December 19.

i. RESPONSIBLE GOVERNMENT MINISTRIES

The following government ministries and agencies are responsible for regulation of GE plants (food, feed, seed, and environmental safety issues):

Federal Service for Surveillance of Consumer Rights Protection and Human Welfare (Rospotrebnadzor) (website: <http://rospotrebnadzor.ru/about/> - in Russian). Rospotrebnadzor has the following functions:

- Conducts state registration of new GE lines for food use and new food products containing GE organisms, including those that are imported into Russia for the first time;
- Conducts surveys and control of turnover of GE food products in accordance with Russian and EAEU legislation;
- Develops legislation on GE food products; and
- Monitors the influence of GE crops and products on people and the environment.

The Ministry of Agriculture of the Russian Federation (website: www.mcx.ru – in Russian) participates in the development of agricultural biotechnology policy together with Ministry of Economic Development and the Ministry of Science and Education of the Russian Federation. Its functions include the following:

Overall policy development for the use of GE crops and organisms in agriculture. In accordance with Government Resolution 839 of September 2013, amended in June 2017 (which 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); and

- Overall legal regulation of veterinary and phytosanitary conditions of agricultural production and the use of agricultural products, including legal regulation aimed at mitigation of any negative effects of GE crops and organisms on agricultural animals, plants, the environment, agricultural raw products, and processed food products.

The Federal Service for Veterinary and Phytosanitary Surveillance (VPSS) is subordinated to the Ministry of Agriculture of the Russian Federation (website: <http://www.fsvps.ru/> in Russian). VPSS has the following functions:

- Conducts state registration of new GE lines for feed use and new feed containing GE organisms, including those that are imported into Russia for the first time;
- Issues certificates of registration for GE feed;
- Surveys the safety of feed and feed additives derived from GE crops at all stages of production and turnover;
- In accordance with Government Resolution 839 of September 2013, amended in June 2017 (together

with the Ministry of Agriculture), VPSS is currently in the process of developing regulations for the use and monitoring of GE crops, including for cultivation, and GE animals; and
- Together with the Federal Service for Surveillance of Consumer Rights Protection and Human Welfare, monitors the influence of GE crops, animals and products on people and the environment.

According to GOR#839, VPSS and Rospotrebnadzor are required to forward the information on state registration to Consolidated Register, maintained by the Ministry of Health.

The Consolidated Register is maintained by the Ministry of Health of the Russian Federation in electronic form in compliance with the requirements established by legislation of the Russian Federation on information, information technologies and protection of information. The relevant information is entered into the Consolidated Register by the registration authorities in compliance with the order established by the Ministry of Health of the Russian Federation in concurrence with the Ministry of Mass Communications, the Ministry of Education and Science, the Ministry of Agriculture, and the Rospotrebnadzor. The Consolidated Register includes a Register of modified organisms and a Register of products. The information in the consolidated Register is open and publicly available for individual and legal entities and posted on the official site of the Ministry of Health.

www.rosminzdrav.ru

The Ministry of Industry and Trade of the Russian Federation (website: <http://www.minpromtorg.gov.ru> – in Russian) participates in the development of national standards and TRs which set requirements for the biological safety of regulated items. This Ministry participates in the development of technical regulations in the EAEU, formerly known as the Customs Union (CU);

The Ministry of Economic Development of the Russian Federation (website: www.economy.gov.ru – in Russian) since 2012 monitors the implementation of the Comprehensive Program on Development of Biotechnology in the Russian Federation through 2020 (more on the Program see FAS/Moscow GAIN report [Program on Development of Biotechnology in Russia through 2020](#));

The Russian Academy of Sciences (RAN) (website: www.ras.ru – in Russian). On September 27, 2013, the Russian President signed the Federal Law “On the Russian Academy of Sciences, Reorganization of the State Academies of Sciences and on Amendments to Some Legal Acts” (Federal Law No. 253-FZ) with immediate effect. This law envisaged that the formerly independent Russian Academy of Sciences, Russian Academy of Medical Sciences and Russian Academy of Agricultural Sciences would merge into the Russian Academy of Sciences. These academies finally united by the end of 2016. The main function of the new Academy is to coordinate fundamental science and research and expertise on science-related programs and projects, including in the field of agricultural biotechnology. So far there is no information on the unified strategy of RAN in development of programs and projects in the field of agricultural biotechnology. The applied research in the field of agricultural biotechnology is still conducted by research institutes, which were under the authority of the three formerly independent academies. Now these institutes are subordinated to the Federal Agency of Science Organizations.

The Federal Agency of Scientific Organizations (FANO) (website: www.fano.gov.ru – in Russian) was organized in 2013 after the merger in 2013 of three former independent Russian Science Academies (Russian Academy of Sciences, Russian Academy of Medical Sciences and Russian Academy of

Agricultural Sciences) into the Russian Academy of Sciences. The FANO owns and operates the property of all these three Academies, including the property of their institutes. FANO also is assigned to finance research in these institutes, to include institutes that conducted research in the field of agricultural biotechnology before the reorganization: Institute of Agricultural Biotechnology, Center for Quality and Standardization of Veterinary Drugs and Feed, Institute of Nutrition, Center of Bioengineering. For more information on the functions of these institutes before the reorganization, see FAS/Moscow GAIN report [Agricultural Biotechnology Annual 7-9-2015.pdf](#).

The Eurasian Economic Union (EAEU) (website: www.eaeunion.org) unites Kazakhstan, Russia, Belarus, Armenia, and Kyrgyzstan. The EAEU develops and adopts common customs and technical regulations for all member countries.

Since the creation of the unified economic space within the CU on January 1, 2012, now the EAEU, certificates and permits for the use of biotech food and biotech food ingredients that were issued for circulation within the territory of the EAEU are valid.

ii, LEGISLATION AND REGULATIONS

The Federal Service for Surveillance of Consumer Rights Protection and Human Welfare (Rosпотребнадзор) developed regulatory documents for registration of GE organisms for food by July 1, 2017 and the mechanism is working for registration of GE organisms for food. Overall the registration procedure for GE food has not changed since Post's last report and registration once granted is given an unlimited term (compared to registrations for feed use that are granted for the period of five years. The regulatory documents approved by the EAEU take precedence over the regulatory documents issued for registration of GE organisms for food on the national level. However, the regulatory documents for registration of GE organisms for feeds, feed additives and veterinary drugs were not developed by July 1, 2017 by the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS). Moreover, the EAEU does not have any regulatory documents that refer to registration of GE organisms for feed use. Therefore, any applications submitted after July 1, 2017 for GE line registration for feed use have been rejected by VPSS based on the lack of MUK for registration.

At present agricultural biotech policy is being regulated by the Decisions of the EAEU – so called “technical regulations” of the CU, Russian federal laws, government resolutions and orders of the heads of the Russian regulation ministries, agencies, and services.

Decisions of the Eurasian Economic Union (EAEU)

Since July 2010, the EAEU has adopted several technical regulations that have influenced agricultural and food biotechnology. These technical regulations came into force on July 1, 2013, and all regulations require marking the presence of “GMOs” on labels and informing consumers in cases when food products are processed from or with the use of a “GMO,” even if there is no DNA or proteins of “GMO” components in the marketed food products. For the unofficial translations of the CU technical regulations that cover food safety and labeling issues and that came into force on July 1, 2013, please see GAIN reports:

- RS 1036 Customs Union [Update](#) No.299 dated May 28, 2010 On Applying Sanitary Measures in EAEU

- [RS1233 Customs Union Technical Regulation on Food Safety;](#)
- [RS1250 Customs Union Technical Regulation on Safety of Grain;](#)
- [RSATO1211 Customs Union Technical Regulations on Food Products Labeling;](#)
- [RS1326 Customs Union Technical Regulation on Fat and Oil Products;](#)
- [RS1334 Customs Union Technical Regulation on Juice.](#)
- [RS1340 Customs Union Technical Regulation on Specialized Foods](#)
- [RS1338 Customs Union Technical Regulation on Food Additives](#)

in force since May 1, 2014:

[RS1382 Customs Union Technical Regulation on Milk and Dairy Products](#)

[RS1384 Customs Union Technical Regulation on Meat](#)

in force as of September 1, 2017:

[RS1734 Technical Regulation on Safety of Fish and Fish Products](#)

will come into force as of January 1, 2019:

[RS1752 EAEU Technical Regulation on Packaged Water](#)

Note: “GMO” Registration for food is carried out in compliance of the CU Regulation which prevails any regulations approved on the national level, for example GOR #839. However, “GMO” Registration for feed is implemented in compliance with GOR #839.

The technical regulations (TR) of the EAEU are mandatory for all members of the EAEU. The summary of the CU technical regulations is provided in [RS1760 Biotechnology Annual Report 2017](#).

Federal Laws of the Russian Federation

- **Federal Law No. 358 of July 3, 2016** ([FL 358](#) - in Russian) “On amendments to certain legislative acts of the Russian Federation concerning the improvement of state regulation in the sphere of genetic-engineering activities.” FL 358 bans the cultivation of GE crops, formalizing the previous de-facto ban resulting from the lack of a regulatory framework (see previous Biotechnology Annuals) to a specific, legal ban. FL 358 amends Federal Law No. 86 of July 5, 1996, Federal Law No. 149 of December 17, 1997, Russian Federal Code of Administrative offences, and Federal Law No. 7 of January 10, 2002. (For more information on FL 358 see FAS/Moscow GAIN report [Russia Bans Cultivation and Breeding of GE Crops and Animals 7-12-2016.pdf](#)). These amendments specifically prohibit the cultivation of GE plants and the breeding of GE animals on the territory of the Russian Federation, except for the cultivation and breeding of plants and animals required for scientific expertise or research. The penalties for violating officials will be from 10,000 rubles to 50,000 rubles. The penalties for violations by judicial persons will be from 100,000 rubles to 500,000 rubles.² Federal Law 358 will come into force on the date of its official publication (July 4, 2016), except the article pertaining to penalties in cases of violations, which will come into force on July 1, 2017. This law makes an exception for "the cultivation and breeding of plants and animals required for scientific expertise

² At the time of signing the FL 358 of July 3, 2016, the exchange rate was 64 rubles per \$1.

or research." Based on monitoring of the effect of "GMO," or products derived from/or containing "GMOs," on humans and the environment, the Government shall have the right to ban imports into Russia of "GMOs" intended for environmental release and (or) products derived from or containing such organisms."³

- **Federal Law No. 86-FZ of June 5, 1996**, On the State Regulation in the Sphere of Genetic Engineering Activities" with amendments made in 2000 and in 2010. This is a foundational federal law on genetic engineering in Russia, but the law does not provide instruments for implementation. There were several amendments to this federal law, including the last one, made by FL 358 of July 3, 2016, which emphasized the role of state control over the release of GE organisms into the environment, state monitoring of the effects of such release on the environment and also on the health of human beings. The amendments add the responsibility of control and monitoring, as well as registration, of GE organisms and products, including imported goods, to the state. The amendments broaden the meaning of "safety control in the sphere of genetic engineering," and emphasize that, based on the results of monitoring the effects of GE organisms and products on the environment and on human health; the authorized bodies of the executive power can ban imports of GE organisms and/or products derived from GE organisms into Russia.
- **Federal Law No 52-FZ of March 30, 1999**, On the Sanitary-Epidemiological Well-being of the Population;
- **Federal Law No. 29-FZ of January 2, 2000**, On the Quality and Safety of Food Products with amendments made in 2001 – 2008;
- **Federal Law No. 2300-1 of February 7, 1992**, On the Protection of Consumer Rights with amendments. The amendment of October 25, 2007 sets the threshold for mandatory labeling of food ingredients made from biotech material at 0.9 percent. Prior to this amendment, trace amounts of biotech food ingredients required labeling;
- **The Federal Law No. 7-FZ of January 10, 2002**, "On Protection of the Environment" with amendments made in 2011 and in 2016. Amendment made by FL 358 of July 2016, to Article 50.1 adds the following text: "it is prohibited to grow or breed plants and animals whose genetics have been modified by using genetic-engineering methods and which contain genetic-engineering materials that cannot be introduced as a result of natural (spontaneous) processes, with exception of growing and breeding such plants and animals in the course of expert examination and research activities."
- **Federal Law of December 17, 1997**, No. 149-FZ "On Seed Industry" as amended by FL 358 of July 3, 2016, bans imports of GE planting seeds into Russia, except for sowing (planting) such seeds for research activities." "It is prohibited to import into the Russian Federation territory, or to use for sowing (planting), the seeds of plants which have modified genetics through the application of gene-engineering methods and which contain GE material that cannot be introduced as a result of natural (spontaneous) processes, with the exception of sowing (planting) such seeds in the course of expert examination and research activities."
- **Russian Federation Code of Administrative Violations**, as amended by FL 358, under Article 6.3. Article 6.3 "Violation of the legislation of the Russian Federation in the Area of Genetic

³ http://www.gazeta.ru/science/news/2016/06/24/n_8804021.shtml (in Russian)

Engineering Activity.” “ A violation of the legislation of the Russian Federation in the Area of Genetic Engineering Activity consisting of the use of genetically modified organisms and/or products, derived with the use of such organisms or containing such organisms, that have not been registered with the state in cases where state registration is required by said legislation, or where the period of validity of the certificate on state registration has expired, or in the case where genetically modified organisms are not used in conformity with the purpose(s) for which they were registered, or where there is failure to comply with genetically modified organisms stipulated special use conditions are not complied with, e.g. in the manufacture of specific type of products, will involve imposition of a penalty on officials in the amount ranging from Ten Thousand to Fifty Thousand Rubles; on legal entities – from 100,000 to 500,000 Rubles.” The previous amendments to the Code of Administrative Violations (made in December 2014) set fines for violations of mandatory requirements for labeling food products derived from GE organisms (referred to as “GMO” in the Russian documents) or containing such organisms. The [fines](#) (in Russian) for individual entrepreneurs are from 20,000 to 50,000 rubles⁴ (from \$364 to \$909), and for legal entities are from 100,000 to 300,000 rubles (from \$1,818 to \$5,455). The law also provides Rospotrebnadzor with the authority to draw up protocols on administrative violations in such cases and submit these cases to the consideration of the court.

Resolutions of the Russian Government

- Resolution of the Government of the Russian Federation No. 988 of December 21, 2000, On State Registration of New Food Products, Materials, and Goods with amendments. The resolution authorizes registration of GE foods;
 - Resolution of the Russian Government No. 717 of July 14, 2012, “On the State Program for Development of Agriculture and Regulation of Agricultural and Food Markets in 2013-2020.” The program outlines the main directions of development of agricultural science, including biotechnology, although agricultural biotechnology is not a priority;
 - Resolution of the Russian Government No. 839 of September 23, 2013, “On the State Registration of Genetically-Engineered-Modified Organisms Intended for Release into the Environment as well as Products Derived from the Use of Such Organisms or Containing Such Organisms.” The Resolution approved the rules of registration of GE organisms and orders Ministries and federal bodies to update or develop procedures for the beginning of registration FAS/Moscow reported on Resolution No. 839 in the [GAIN Report](#); and
 - Resolution of the Russian Government No. 548 of June 16, 2014, “On the Amendments to the Resolution No. 839 of September 23, 2013” postpones the implementation of Resolution 839 from July 1, 2014 to July 1, 2017.
 - 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. For more details, please refer to FAS GAIN Report.
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- ii. In February 2018, the Government of Russia approved two official documents related to biotech feed registrations. The title of the first one is, “On Suspension of Several Provision of the Rules for State Registration of Genetically-Engineered-Modified Organisms Intended for Release into the Environment as well as Products Derived from the Use of Such Organisms or Containing Such Organisms, including Above-Mentioned Products Shipped (Imported) into the Territory of the Russian Federation; and the Approval the Rules for State Registration of Feeds, Derived from Genetically-Engineered-Modified Organisms or Containing Such Organisms.”

The second Resolution is, “On Amendments to GOR Resolution # 839 dated September 23, 2013.”

This essentially is an addendum to Resolution #839 (Rules of State registration RS1366 Government Resolution on GMO Registration for Environmental Release). The Russian importer Sodrugestvo initiated both Resolutions and they apply only to Sodrugestvo in order to finalize registration of the stacked soybean meal line MON87701xMON89788 for feed use, soybean line MON89788 and 87701 and soy line 40-3-2. The registration of soybean line MON89799 is set to expire in October 2020. The registrations of soy line 87701 and soy line 40-3-2 have already expired in the beginning of 2018. The developers (Monsanto [now owned by Bayer], Syngenta and Bayer CropScience AG) appealed to the government to put in place a more systematic approach to the procedure for registering GE lines registration and to amend the initial drafts, proposed by Sodrugestvo, with an extension period to the expiration date of all currently approved/registered biotech feed lines, which have expiration dates between July 1, 2017 and July 1, 2018. However, to date only Sodrugestvo was granted the right to import three soybean lines and produce stacked soybean meal line. The certificate for GE soybean meal registered by VPSS is valid until February 12, 2023.

In January 2017, the developer (Monsanto) submitted papers to Rospotrebnadzor for food registration of the MON 87708 (Dicamba) Soybean, and it is undergoing registration according to the Regulation #839 rules for food use. However, its further registration for feed use cannot be implemented before methodological guidance is approved by the Ministry of Agriculture.

Normative acts of government bodies

- Resolution of the Chief Sanitary Doctor of the Russian Federation (No 14 of November 8, 2011), On the Procedures of Sanitary-Epidemiological Expertise of Food Products from Genetically Modified Sources;
- Methodological directives on norms and methods for testing, identification and analyses of genetically modified foods, organisms and microorganisms. State standards for food products. These methods and standards may be developed by different organizations, but are usually approved by the Federal Agency on Technical Regulation and Metrology of the Ministry of Industry and Trade of the Russian Federation; and
- Order of the Ministry of Agriculture No. 466 of October 6, 2009 on approval of regulations for VPSS on the State Registration of Feed Derived from Genetically-Engineered-Modified Organisms was repealed as of September 3, 2017, as Order of the Ministry of Agriculture No. 366 dated July 26, 2017 came into force, The document can be viewed here <http://www.garant.ru/products/ipo/prime/doc/71651236/> (in Russian)

iii. RECENT DRAFTS GUIDELINES PENDING APPROVAL

In June 2017, the Russian Ministry of Agriculture together with Rosselkhoznadzor (VPSS) drafted nine regulatory documents for the safety assessment and testing of GE ingredients for feeds, feed additives, veterinary pharmaceuticals, GE animals, and GE microorganisms. However, none of these drafts received final approval. As a result, there have not been any guidelines in place for registration of feeds and feed additives obtained with GE organisms for over a year. Note: none of these draft regulations were notified to the WTO. (Please see GAIN RS1739 attached).

These drafts have been under review for some time and on July 3, 2018, the Russian Federation's government document portal (www.regulation.gov.ru) published texts of three revised drafts containing methodology guidelines for assessment of biological safety and for molecular studies of GE organisms in feeds, feed additives and veterinary pharmaceuticals. All three of these regulatory documents were drafted by the Russian Ministry of Agriculture (i.e. without direct support from VPSS). These new drafts have also not been notified to the WTO, but public comments were submitted by the U.S. side in July 2018.

These documents, as stated, were drafted in accordance with the Government Resolution No. 839 of September 23, 2013 that required the Ministry of Agriculture to develop a mechanism for the registration of GE feeds. If approved, the 2018 draft documents will have a great impact on the development of Russian agricultural biotechnology and on trade in agricultural products and veterinary pharmaceuticals. According to industry contacts, the key document with respect to trade in GE products is Methodology Guidelines for Assessing the Biological Safety of GE Organisms for the Production of Feeds and Feed Additives (<http://regulation.gov.ru/projects#npa=81934> in Russian), which may influence the order for accreditation of GE organisms for the production of feeds. If approved, technology companies will be able to resume registration of GE lines for feeds and feed additives (which have been held up since July 1, 2017). As noted above, the current draft documents were developed by the Ministry of Agriculture and has not been approved by VPSS. Without VPSS' approval, the document will not be enacted. Industry sources report that there are two key issues where VPSS and the Ministry of Agriculture disagree: 1) the current draft requires testing on two generations, however, VPSS insists on testing on three generations; 2) the current draft also states that any accredited institution would be authorized to perform testing for safety of GE organisms for production of feeds. By comparison, the June 2017 drafts only authorized the Center for Quality and Standardization of Veterinary Drugs and Feed (VGNKI), which is an organization that reports to VPSS. VPSS insists that only VGNKI be named as an eligible institution to provide accreditation for conducting testing of biological safety for GE organisms to produce feed and feed additives. Whereas, all past research for GE organisms for feed have reportedly been conducted by the Federal Research Center of Nutrition, Biotechnology and Food Safety (former Institute of Nutrition or ION). So, if VPSS does not support ION as another accredited institution to conduct testing for GE organisms for production of feeds, then technology companies will have to initiate all research work with VGNKI. It is unclear at this time where VPSS stands on this current draft and how likely it is to be approved. Industry sent comments supporting the current version of the draft.

GE CROPS/LINES REGISTRATION FOR FOOD AND FEED USE

iv. REGISTRATON FOR FOOD USE (procedure)

Rospotrebnadzor registers biotech crops and ingredients for food use for Russia and for the EAEU. Decisions of EAEU prevail over Government of Russia regulation for GE crops/lines registration for food use. The registration for food use is implemented in compliance with Decision of EAEU No.299 dated July 26, 2010, while registration for feed use must comply with GOR # 839. Rospotrebnadzor has developed MUK that conforms to requirements of Government Resolution # 839. This guidance is published on the website in Russian

[.http://rospotrebnadzor.ru/documents/details.php?ELEMENT_ID=7871.](http://rospotrebnadzor.ru/documents/details.php?ELEMENT_ID=7871)

The registration process for food remains the same as was stated in the Annual Biotechnology GAIN reports for 2011 through 2014 ([Agricultural Biotechnology Annual 7-9-2015.pdf](#)):

- The applicant submits an application and dossier to Rospotrebnadzor;
- Rospotrebnadzor assigns a safety assessment study to the Federal Research Center of Nutrition, Biotechnology and Food Safety or former Federal State Budget Enterprise “Science and Research Institute of Nutrition,” which may coordinate with other Russian science institutes and laboratories in the field of biotechnology and microbiology;
- The applicant concludes an agreement for the food safety assessment with this Center; and
- Based on the Institute’s assessment, Rospotrebnadzor issues a certificate of registration and registers the product. Rospotrebnadzor grants registration for food use for unlimited period as stated in EAEU Decision. Information about registration of biotech crops and ingredients for food use should be forwarded to the Consolidated Register (www.rosminzdrav.ru in Russian) maintained by the Ministry of Health.

Laboratory tests required for the safety assessment take approximately twelve months to conduct and an additional two to three months are needed to organize and prepare documents for the new GE crops. Registering food products and ingredients requires less time. However, registration is only granted if the biotech product contains biotech events that have already been registered. Since 2006, Rospotrebnadzor has registered food-use crops for an unlimited time-period. Information on GE crops registered for food-use for food products or an ingredient containing registered biotech ingredients is available on Rospotrebnadzor’s website: <http://fp.crc.ru/gosregfr/> (in Russian). The list of registered products contains all new food products, not only biotech products or products with biotech ingredients. There are several hundred different products and names. To find permitted food products for a specific crop, search for the name of the crop and the words “genetically modified.”

v. REGISTRATION FOR FEED USE

Registration for feed use has been effectively suspended since the adoption of FL 358 in July 2016, largely due to the reorganization of the research institute that was previously subordinated to VPSS.

However, according to the amendments to GOR # 839 that came into force starting July 1, 2017, the procedure for registration of GE crops for feed use has changed. The responsibilities of VPSS in feed registration were confirmed by Order No. 366 of the Russian Ministry of Agriculture on July 26, 2017 “On Approving Administrative Regulation of Federal Veterinary and Phytosanitary Service for Providing Services on State Registration of Genetically-Engineered-Modified Organisms, Used for Production of Pharmaceuticals for Veterinary Use, as well as Feeds and Feed Additives for Animals, Received from Genetically-Engineered-Modified Organisms or Containing such Organisms.”

<http://www.garant.ru/products/ipo/prime/doc/71651236/>

Order 366 states that the registration is issued for the period from one up to 10 years. The regulation covers “products of plant, animal and microbiological origin, and their components, used for feeding animals, and which contain animal health non-harmful digestible nutrients.” The Order does not allow the registration of several types of GE feed under one name, or the registration of the same GE feed several times under one name or under several different names. The applicant must submit the following documents:

- application for the state registration of GE feed;
- information on the origin of GE feed, evaluation of the potential danger of use of GE feed (compared with the initial basic feed), and recommendation of the applicant on risk reduction, information on the supposed use of the GE feed, and on the registration and use of this feed abroad; information about the technology of growing the modified variety of the plant that is used for production of GE feed, data on the technology of production of GE feed, draft of the instruction on the use of GE feed; and
- if the modified plant variety that is used for feed is viable and is meant for biomass or fodder growing, the certificate from the Russian State Register of Selection Achievements must be attached.

The Russian Federal Center of Quality and Standardization of Veterinary Pharmaceuticals and Feed (VGNKI) subordinate to VPSS is authorized to conduct safety assessment and studies for GE crop/line registration for feed use.

All documents shall be in Russian or shall have a certified translation into Russian. Copies of documents shall be certified by a notary. VPSS will make a decision on the registration of a GE feed based on the Conclusion of the Experts Council on the safety (non-safety) of the GE feed. The procedures and necessary documents for registration of feed containing “GMOs” is provided on VPSS’s website: <http://www.fsvps.ru/fsvps/regLicensing/gmo/index.html> (in Russian). The List of Registered GE feed, before July 15, 2015, is provided [here](#) (in Russian). The List of Registered GE feed after July 15, 2015, is available at the site: <https://galen.vetrif.ru/#/registry/gmo/registry?page=1>.

Plant-origin feed imports no longer require a veterinary certificate but still require a letter stating that the feed is biotech free. Feed may be classified as biotech-free if presence of each non-registered biotech line in feed does not exceed 0.5 percent and if the presence of each registered biotech line in the feed does not exceed 0.9 percent. In this case, “registered” refers to products registered in Russia and “non-registered” refers to products not registered in Russia. The presence of genetic alterations in feed components is calculated separately and not comprehensively. For example, if two registered components in feed contain 0.6 percent of genetic alterations in each, then the feed is considered to be non-biotech, although together the sum is 1.2 percent. The pre-export identification of feed as “non-GMO” is not required. It is up to the producer/exporter to declare the feed as “non-GMO,” but regardless, VPSS examines the products for the presence of GE components.

If the feed contains GE ingredients, and is not declared as biotech free, the shipment must include a copy of the certificate indicating that the biotech components in the feed are registered with VPSS. The imports must also have a phytosanitary certificate, although this requirement is unrelated to biotechnology. Any biotech components in feed must be appropriately registered. Presence of each non-registered biotech line shall not exceed 0.5 percent. The EAEU’s Technical Regulation on Feed has not been adopted yet, but the draft has the same 0.5 percent maximum for non-registered biotech lines, as in current Russian regulations. However, the adopted Technical Regulation on Safety of Grain stipulates that feed (grain/oilseed) is considered “non-GMO” if the presence of each non-registered biotech lines does not exceed 0.9 percent. The Technical Regulation on Safety of Grain came into force on July 1, 2013.

Fees for registration of biotech events (all fees are set in rubles)

Rospotrebnadzor’s charges for all examinations and related services, including comprehensive studies required to register biotech events for food use. The fee varies, depending on the range of examinations and studies, but averages around 4.5 million rubles (approximately \$76,300) for the approval of new events for an unlimited period. The option to register for an unlimited period began in 2006.

Registration of food products that contain a previously registered biotech event is 20,000 rubles (\$338).

Currently there are no guidelines for registration fees of biotech events for feed use. Under previous guidelines the charge for examination and a five-year event registration for feed use was 4.5 million rubles (approximately \$76,300). The charge for re-registration of the event every five years was 3.8 million rubles (approximately \$64,400). Companies that imported formula feed with registered biotech components also needed to register these feed as biotech feed. The registration was given to the company that imported this feed and VPSS required that each feed containing a registered GE event must also be registered.

vi. RECENT ACTIVITIES OF RUSSIAN AUTHORITIES IN REGARDS TO GE CROPS

Ministries and institutes, including institutes subordinate to the Ministry of Science and Education, Ministry of Health, Rospotrebnadzor and VPSS, that are involved in the development of regulatory mechanisms for registration and monitoring of GE plants, products and ingredients continue working on regulations considering new approaches to Russian GE policy declared by GOR #839 and its amendments. While Rospotrebnadzor has developed regulatory mechanisms for registration and monitoring of GE plants, products for food use, VPSS has not developed the system within the current framework for feed registration, since it does not have a clear understanding of the goal, interest, and authorities in the registration process.

b) APPROVALS:

Table 3. Russia: Approved and Registered Biotech Crops, 1999-2018 (As of October 2018)

	Crop/line/event/trait	Applicant	Year and period of Registration	
			For Food Use	For Feed Use
1	Bt corn MON 810, resistant to European corn borer <i>Ostrinia nubilalis</i>	Monsanto	2000 – 2003, 2003 – 2008 Mar. 2009 – for unlimited period	2003 – 2008 Sep. 2008 – Aug. 2013 Aug. 2013 – Sep. 2018
2	Roundup Ready® corn NK 603, tolerant to glyphosate	Monsanto	2002 – 2007; Feb. 2008 – for unlimited period	2003 – 2008 Sep. 2008 – Aug. 2013 Aug. 2013 – Sep. 2018
3	Bt corn MON 863, resistant to corn root worm (<i>Diabrotica spp.</i>)	Monsanto	2003 – 2008 Aug. 2008 – for unlimited	Was registered 2003-2013

			period	
4	Corn Bt 11, tolerant to gluphosinate and resistant to corn borer <i>Ostrinia nubilalis</i>	Syngenta	2003 – 2008 Sep. 2008 – for unlimited period	Dec. 2006 – Dec. 2011, Dec. 2011 – Dec. 2016 Oct. 2016 submitted for re- registration
5	LL Corn T25, tolerant to gluphosinate	Bayer Crop Sciences	2001 – 2006, Feb. 2007 – for unlimited period	Dec. 2006 – Dec. 2011; Dec. 2011 – Dec. 2016 03.10.2017 – 03.10.22
6	Roundup Ready ® corn GA 21, tolerant to glyphosate*	Syngenta	2007 – for unlimited period	Nov. 2007 – Nov. 2012; Nov. 2012 – Nov. 2017 Re-registration suspended
7	Corn MIR 604, resistant to corn root worm (<i>Diabrotica</i> spp.)	Syngenta	Jul. 2007 – for unlimited period	May 2008 – May 2013; May 2013 – May 2018
8	Corn 3272 with α -amylase enzyme to break starch during ethanol production	Syngenta	April 2010 – for unlimited period	Oct. 2010 – Oct. 2015 March 2016 – March 2021
9	Corn MON 88017 (CCR), tolerant to glyphosate and resistant to corn root worm (<i>Diabrotica</i> spp.)	Monsanto	May 2007 – for unlimited period	Sep. 2008 – Aug. 2013; Sep. 2013 – Sep. 2018
10	Corn MON 89034, resistant to Lepidoptera pest	Monsanto	December 2014 – for unlimited period	Mar. 2013 – Mar. 2018
11	Corn MIR162, resistant to Broad Lepidoptera spp.	Syngenta	Apr. 2011 - for unlimited period	March 2012 – March 2017 Jan. 2017 - Jan. 2022
12	Corn 5307, resistant to corn root worm (<i>Diabrotica II</i> , <i>Coleoptera</i>)	Syngenta	Apr. 2014 – for unlimited period	Apr. 2014 – Apr. 2019
13	Roundup Ready® soybeans 40-3-2, tolerant to glyphosate	Monsanto	1999 – 2002, 2002 – 2007, Dec. 2007 - for unlimited	2003 – 2008, May 2008 – May 2013 May 2013 – May

			period	2018
14	Bt soybeans, MON 87701, resistant to Lepidoptera pests	Monsanto	May 2013 – for unlimited period	Jul. 2013 – Jul. 2018
15	Soybean MON 89788 (RRS2Y), tolerant to glyphosate + yield gain	Monsanto	Jan. 2010 – for unlimited period	May 2010 – May 2015 Oct. 2015 – Oct. 2020
16	Liberty Link® Soybeans A2704-12, tolerant to glyphosate	Bayer Crop Sciences	2002 – 2007 Feb. 2008 – for unlimited period	Nov. 2007 – Nov. 2012 Nov. 2012 – Nov. 2017 Re-registration suspended
17	Liberty Link® Soybeans A5547-127, tolerant to glyphosate ammonium	Bayer Crop Sciences	2002 – 2007 Feb. 2008 – for unlimited period	Nov. 2007 – Nov. 2012 Nov. 2012 – Nov. 2017 Re-registration suspended
18	Soybeans FG72, tolerant to isoxaflutole and glyphosate	Bayer	Dec. 2015 – for unlimited period	Apr. 2014 – Apr. 2020
19	Soybeans BPS-CV-127-9, imidazolinone	BASF	Dec. 2012 – for unlimited period	Sep. 2012 – Sep. 2017 Re-registration suspended
20	Soybeans SYHT0H2, herbicide HPPD* + glufosinate	Syngenta (Producers Syngenta/Bayer)	Jan. 2016 – for unlimited period	Apr. 2013 – Apr. 2019
21	Rice LL62, tolerant to glyphosate ammonium	Bayer Crop Sciences	2003 – 2008 Jan. 2009 – for unlimited period	X
22	Roundup Ready ® Sugar beet H7-1, tolerant to glyphosate	Monsanto/KWS	May 2006 – for unlimited period	X
23	Bt potato “Elizaveta” (resistant to Colorado potato beetle)	Center “Bio-engineering”, Russia	Dec. 2005 – for unlimited period**	X
24	Bt potato “Lugovskoy” (resistant to Colorado potato beetle)	Center “Bio-engineering”	Jul. 2006 – for unlimited period**	X
25	Soybeans MON	Monsanto	Submitted	Submission

	87708 (Dicamba)		January 2017	upon receipt Registration for food		
26	Corn MZHG0JG Tolerant to glyphosate and glufosinate ammonium	Syngenta	Submitted Nov 2015 expected Dec 2017	Submission upon receipt food registration		
27	Corn MZIR098 Resistance to Diabrotica and tolerance to glufosinate ammonium	Syngenta	Submitted Jan.2017	Re-registration suspended		
28	Corn 1507 resistance to certain Lepidoptera pests and tolerance to glufosinate	Pioneer Hi-Bred International & Dow AgroSciences	March 23, 2017 (unlimited)	Not submitted		
29	Corn DAS 40278-9 tolerant to herbicide 2,4 D	Dow AgroSciences	Submitted Feb.2017	Not submitted		
<table border="1" style="width: 100%;"> <tr> <td>*HPPD – herbicides that inhibit the enzyme hydroxy-phenyl-pyruvate-dioxygenase</td> </tr> <tr> <td>**Bt potato “Elizaveta” and “Lugovskoy” are registered for food use only for Russia, because these two potato varieties were not registered for the EAEU</td> </tr> </table>					*HPPD – herbicides that inhibit the enzyme hydroxy-phenyl-pyruvate-dioxygenase	**Bt potato “Elizaveta” and “Lugovskoy” are registered for food use only for Russia, because these two potato varieties were not registered for the EAEU
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The above information is based on information received from certain applicants willing to share their registration information. However, Post believes other registration activities have been initiated (but not, yet approved), but information related to these possible registration requests is not available.

c) STACKED OR PYRAMID EVENT APPROVALS

Government Resolution #839 as amended, implemented from July 1, 2017, does not contain any reference to rules or procedures for stacked event registration. So far, Rospotrebnadzor has developed some recommendations on the registration (for food) of stacked events (breeding stacks), which are similar to the rules adopted by the European Union. However, these recommendations have not been adopted by VPSS. Since 2016, VPSS intensified thorough testing of feed produced from imported soybeans, and regularly started finding traces of stacked events not registered in Russia. The situation resulted in de facto suspension of imports of soybeans and soybean meal to Russia as the importer could not be reasonably assured the imported product would not contain an unregistered event. It is worth noting that Sodrugestvo received an approved registration of a stacked event for food use, which theoretically permits the importation of stacked soybeans (with the approved event), but only for food.

Currently, only Sodrugestvo is permitted to import the following GE soybeans: 1) genetically modified soybeans with the line MON87701 x MON89788, resistant to lepidopteran pests and resistant to

glyphosate; Sodrugestvo registered this stacked line in 2016 with Rospotrebnadzor for food use and with VPSS in February 2018 for feed use. The registration of stacked lines was possible since Monsanto had registered individual lines earlier. After registration of the GE soybeans, Sodrugestvo received registration for soybean meal with this line; 2) soybeans genetically modified with the line 40-3-2, glyphosate resistant.

The currently draft methodological guidance for GE crops/lines for feed use has no reference to a mechanism for stacked line registration. At this point, it is unclear what a mechanism for stacked line registration would look like and when it could be approved.

d) FIELD TESTING

Since cultivation is banned, Russian researchers do not conduct wide scale field tests of GE crops, although the FL 358 does not ban imports of planting seeds of GE crops for laboratory tests and experiments.

e) INNOVATIVE BIOTECHNOLOGIES:

There is no information on the development of innovative plant biotechnologies. According to available information, Russian research in biotechnology is limited to biological means of plant protection, growth stimulators, and microbiological fertilizer.

f) COEXISTANCE:

Not applicable since there is no mechanism and legislation for cultivation of GE crops.

g) LABELING

Labeling and information for consumers on the presence of GE ingredients in food products is regulated by the technical regulations of the EAEU on safety and labeling of food products. These regulations require that in any of the EAEU member states, products must be labeled if the presence of GE lines is over 0.9 percent. According to amendments to the Russian Code of Administrative Violations made in December 2014 (see section Federal Laws of the current report), penalties for violations in labeling of GE food have strengthened. In Russia, fees for violating this labeling requirement range from 20,000 rubles to 50,000 rubles for individual entrepreneurs, and from 100,000 rubles to 300,000 rubles for legal entities. The EAEU technical regulation for feed has not yet been adopted. Feed sold in Russia does not require labeling. However, registration of GE lines for use in feed is required if the presence of registered lines is over 0.9 percent and the presence of non-registered lines is over 0.5 percent

Food Labeling: In accordance with the Technical Regulations of the EAEU that came into force on July 1, 2013, all organizations that import, produce, or trade food products to/in member countries of the EAEU must inform consumers about the presence of biotech components in food products if each individual biotech event does not exceed 0.9 percent. In 2015, Armenia and Kyrgyzstan became members of the EAEU. These two members must also follow the EAEU technical regulations/ including technical regulations on labeling food products, after a transitional period. The methods that should be used to test for biotech presence in food are also specified in the Attachments to the EAEU Technical Regulations on Food Safety and Food Labeling and are the same that were used in Russia by

Rospotrebnadzor before the EAEU Technical Regulations on Food labeling and Food Safety came into force.

For food products imported into Russia, Rospotrebnadzor has the right to conduct sample tests to detect the presence of biotech components. In order to verify the biotech-free claim, the producer or exporter may conduct its own tests at independent laboratories), but the results of these tests are not accepted by Rospotrebnadzor. These pre-export tests are voluntary for producers and exporters. If a producer/exporter claims that its products are not genetically altered, Rospotrebnadzor still has the right to examine these products. Furthermore, if the presence of genetic alteration in the products is more than 0.9 percent, a claim for fraud may be lodged against that company. Usually Rospotrebnadzor pays special attention to products containing soybean or corn ingredients. For more information on the EAEU's food labeling requirements please see section Decisions of the CU, above.

In 2016, the EAEU notified the WTO of the draft amendments to the TR on Food Labeling (“GMO” text on the food label shall be of the same size and be placed next to the Unified mark of products circulating in markets of EAEU member states). In December 2017, Eurasian Economic Commission (EEC) by its [EEC Council Decision No. 90](#) amended Technical Regulation of the CU “On Food Products Labeling” (TR TS 022/2011) – (see the original in [Russian](#)). The amendment specifies that for products obtained with the use of “GMOs” the inscription “GMO” should be marked next to the unified mark of products circulating on the market of the EAEU Member States and the inscription should be similar to the unified mark in form and size. Initially, the decision was set to come into force on December 26, 2018. However, in May 2018, [EEC Collegium Decision No. 72](#) “On the Procedure of Implementation of Amendments to the Technical Regulation of the CU “On Food Products Labeling”” (TR TS 022/2011) (see original in [Russian](#)) established an 18 months transition period for the most recent amendments to the EAEU TR “On Food Products Labeling” specifying labeling requirements for products obtained with the use of “GMOs,” reported in the GAIN report [RS1807 Eurasian Economic Union Ag Times No. 1 of 2018](#). In particular, during this transition period companies will be allowed to produce and release into circulation products in accordance with the previous requirements of the EAEU TR “On Food Products Labeling,” while sale of such products shall be allowed within their shelf life.

Feed labeling: Information on the composition of feed, including the presence of biotech components is provided on the shipping documents, but so far Russia has not required labeling of presence of “GMOs” in feed on consumer packs of feed. The EAEU Technical Regulation on Feed is still under discussion and has not been adopted. Requirements for information on “GMO” in shipping documents for grain and oilseeds, and their products, are in the EAEU's Technical Regulation on Safety of Grain. For more information please see section Decisions of the CU, above.

Rospotrebnadzor before the EAEU Technical Regulations on Food labeling and Food Safety came into force.

For food products imported into Russia, Rospotrebnadzor has the right to conduct sample tests to detect the presence of biotech components. In order to verify the biotech-free claim, the producer or exporter may conduct its own tests at independent laboratories), but the results of these tests are not accepted by Rospotrebnadzor. These pre-export tests are voluntary for producers and exporters. If a producer/exporter claims that its products are not genetically altered, Rospotrebnadzor still has the right to examine these products. Furthermore, if the presence of genetic alteration in the products is more

than 0.9 percent, a claim for fraud may be lodged against that company. Usually Rospotrebnadzor pays special attention to products containing soybean or corn ingredients. For more information on the EAEU's food labeling requirements please see section Decisions of the CU, above.

In 2016, the EAEU notified the WTO of the draft amendments to the TR on Food Labeling ("GMO" text on the food label shall be of the same size and be placed next to the Unified mark of products circulating in markets of EAEU member states). In December 2017, Eurasian Economic Commission (EEC) by its [EEC Council Decision No. 90](#) amended Technical Regulation of the CU "On Food Products Labeling" (TR TS 022/2011) – (see the original in [Russian](#)). The amendment specifies that for products obtained with the use of "GMOs" the inscription "GMO" should be marked next to the unified mark of products circulating on the market of the EAEU Member States and the inscription should be similar to the unified mark in form and size. Initially, the decision was set to come into force on December 26, 2018. However, in May 2018, [EEC Collegium Decision No. 72](#) "On the Procedure of Implementation of Amendments to the Technical Regulation of the CU "On Food Products Labeling"" (TR TS 022/2011) (see original in [Russian](#)) established an 18 months transition period for the most recent amendments to the EAEU TR "On Food Products Labeling" specifying labeling requirements for products obtained with the use of "GMOs," reported in the GAIN report [RS1807 Eurasian Economic Union Ag Times No. 1 of 2018](#). In particular, during this transition period companies will be allowed to produce and release into circulation products in accordance with the previous requirements of the EAEU TR "On Food Products Labeling," while sale of such products shall be allowed within their shelf life.

Feed labeling: Information on the composition of feed, including the presence of biotech components is provided on the shipping documents, but so far Russia has not required labeling of presence of "GMOs" in feed on consumer packs of feed. The EAEU Technical Regulation on Feed is still under discussion and has not been adopted. Requirements for information on "GMO" in shipping documents for grain and oilseeds, and their products, are in the EAEU's Technical Regulation on Safety of Grain. For more information please see section Decisions of the CU, above.

h) MONITORING AND TESTING:

In Russia, Rospotrebnadzor monitors/tests GE food products and VPSS monitors/tests grains, oilseeds for animal consumption, feed additives, and ingredients (for more information see paragraph above on the role of different ministries and agencies). The Ministry of Agriculture authorizes its subordinate State Commission for Testing and Protection of Selection Achievements (Gossortcommission - http://gossort.com/gk_documents.html#1481282222420-7dd10f37-7d05) to conduct testing on the presence of GE constructions in planting seeds submitted for registration in the Russian Federation. Industry analysts report that the Commission itself does not have any equipment for such tests, and that the tests will be conducted by the former Institute of Agricultural Biotechnology, which underwent the process of reorganization (see part on regulatory institutions). Thus, this GE testing requirement for planting seeds may hinder the process of registration of new varieties of planting seeds in Russia, which, without adding this, takes no less than two years. There are no approved methods and/or laboratories for certification of GE-free production of corn and soybeans in Russia.

i) LOW LEVEL PRESENCE (LLP) POLICY:

In accordance with Russian and EAEU legislation, imported food products are considered non-GE if the presence of GEs does not exceed levels determined by Russian and EAEU legislation: not more than 0.9 percent of registered or non-registered GE lines in food products or ingredients, and not more than 0.9

percent of registered GE lines and not more than 0.5 percent of non-registered GE lines in feed or feed ingredients. However, in 2016 the attention of Russia's feed surveillance authorities to the presence of non-registered lines in feed and the absence of information on the registered lines increased. In several cases, VPSS, the watchdog for control of GE in feed, temporarily suspended imports of feed on the basis of finding non-registered GE ingredients. However, these threshold levels do not mean that Russia has adopted or follows any coordinated LLP policy. (For more information, please see the section of this report on CU Technical Regulations.)

Russian scientists have participated in international workshops on LLP policy, but Russia has not officially acceded to the LLP international initiatives.

j) ADDITIONAL REGULATORY REQUIREMENTS: Not Applicable.

k) INTELLECTUAL PROPERTY RIGHTS (IPR):

Not applicable since there is no official information on the presence of GE crops in the fields of Russian farmers. However, this may become a serious issue if the illegal presence of GE crops is detected in Russian fields.

l) CARTAGENA PROTOCOL RATIFICATION:

Russian scientists understand the necessity to monitor biotechnology at the international level, including through measures envisaged by the Cartagena protocol. However, Russia has not ratified this protocol, and is not a party to the Protocol. In January 2015, the Russian Ministry of Health suggested a draft FL to join the Cartagena protocol.⁵ The draft envisaged a FL coming into force on July 1, 2017 but was not approved. This is the same date as deadline established in the postponed GOR Resolution No. 839 (on development of mechanism for GE cultivation) for development of a registration mechanism. However, FL 358 of July 3, 2016, banned cultivation of GE crops in Russia, and forced the biotechnology scientific community to re-consider many draft regulatory documents in the field of biotechnology. Thus, as of November 2016, the FL to accede to the Cartagena protocol has not been adopted.

m) INTERNATIONAL TREATIES/FORUMS:

Russia participates in the Asia-Pacific Economic Cooperation High Level Policy Dialogue on Agricultural Biotechnology, in the meetings of the Codex Alimentarius, and in the meetings of the International Plant Protection Convention (IPPC). Russia participated in the Global LLP Initiative in Rosario, Brazil, in September 2012 and in some LLP events in 2013. FAS/Moscow is not aware of the positions on biotech related issues by the GOR at these forums.

n) RELATED ISSUES: Not applicable

PART C: Marketing:

a) PUBLIC/PRIVATE OPINIONS:

⁵ <http://www.fedlab.ru/minzdrav/proekt-federalnogo-zakona-o-vnesenii-izmeneniya-v-chast-vtoruyu-nalogovogo-kodeksa-rossiyskoy-federa/> (in Russian)

There are no active pro-GE (agricultural biotechnology) organizations, with the exception of a few select farmers' organizations and unions that are interested in increasing Russia's grain and oilseeds production. In general, the feed trade does not reflect any strong pro- or anti-biotech bias. Also recently there have not been any significant public or government campaigns lobbying against the use of GE plant and production.

The "anti-GMO" preference of Russian consumers can still influence imports of corn and soybeans and their products, especially soybeans and soybean products. Public opinion in general reflects a negative attitude toward plant biotechnology. However, this negative opinion is seldom reflected in purchasing priorities of the Russian population, which are based on the price of products. Moreover, the current economic environment has increased consumer demands for cheaper products, meaning consumers are not necessarily willing to pay extra for non-GE products.

For the last five years, the Russian government has been actively promoting the idea of producing organic or "environmentally clean" agricultural production, cementing the idea with the Russian public that domestic production is cleaner than some imported products. However, there has not been any regulatory frame for developing organic industry. On August 3, President Putin signed the Federal Law No.280-FZ "On Organic Products and Amendments to Certain Legislative Acts of the Russian Federation" (the Law). The Law regulates manufacturing, storage, transportation, labeling, and marketing of organic products and comes into force on January 1, 2020. According to industry experts, the Law provides legal support for further development of the organic industry but does not have a mechanism for implementation, such as certification procedures.

a) MARKET ACCEPTANCE/STUDIES:

Post is not aware of any recent market acceptance studies. Journalists in Russia often report of consumer concerns with GE products. However, since the recent passage of the new legislation, such press reports have decreased.

It is worth noting that labeling requirements increase the price of food containing GE ingredients. The price of examining products for the presence (or absence) of biotech components is high because the approved methods of testing are expensive. It is rare to find a "GMO" label in Russia, though non-GE labels still can be seen on dairy, eggs, and poultry products. In 2012, the Moscow city government stopped requiring non-GE labeling and many food processors in Moscow discontinued these special tests to determine the absence of GE ingredients. However, some products are still sold with the special "Does not contain GMO" label. This is a voluntary, promotional label because Russia does not have standards for "organic" foods. Some food processors still prefer purchasing non-GE products, especially soybeans and soybean products. However, price is the main concern now for both food processors and consumers.

CHAPTER 2: ANIMAL BIOTECHNOLOGY:

PART D: Production and Trade

- a. PRODUCT DEVELOPMENT: Research on GE animals was conducted in Russia under the guidance of Professor Lev Ernst, Academician of the Russian Academy of Sciences, and the

Russian Academy of Agricultural Sciences (he died in April 2012). His research focused on the cloning and the genetic modification of animals' immune response to infectious diseases. However, during the last three years there has been no information on the continuation of this research.

Given the seeming disinterest in using GE animals in Russia coupled with the current economic situation in Russia, financing of research for development of Russian GE animals in the near term is unlikely.

- b. **COMMERCIAL PRODUCTION:** Increased cattle production is one of the priorities of the Russian Government and the GOR supports low interest rate loans to livestock producers, including loans for importing pedigree breeding animals, semen and embryos. This support does not include any research on GE animals or clones.
- c. **EXPORTS:** Russia does not export any GE animals or livestock clones.
- d. **IMPORTS:** There is no information on any official restrictions on imports of GE animals or livestock clones. There are no known facts of any imports of such products, even for research.
- e. **TRADE BARRIERS:** Not Applicable.

PART E: Policy

- a. **REGULATORY FRAMEWORK:** Russia's Program BIO 2020, the road map for the development of biotechnology in Russia is still valid. Although agricultural biotechnology is not a priority of Program BIO 2020, it is defined as a section of biotechnology dealing with issues of theory, methodology, and implementation of its achievements in plant and animal production. Moreover, in the State Program for Development of Russian agriculture in 2013 the development of biotechnology in animal and feed production envisages development of bio-additives for improvement of quality of feed – amino-acids, feed protein, ferments, and vitamin probiotics. However, the State Program includes no mention of GE animals or cloning. Since many of the regulation on GE plants also reference animals, see PART B of this report.
- b. **APPROVALS:** Russia has no GE animal approvals.
- c. **INOVATIVE BIOTECHNOLOGIES:** No animal related initiatives.
- d. **LABELING AND TRACEABILITY:** Not applicable.
- e. **INTELLECTUAL PROPERTY RIGHTS:** Not applicable.
- f. **INTERNATIONAL TREATIES/FORUMS:** Not applicable.
- g. **RELATED ISSUES:** Not applicable.

PART F: Marketing

- a. **PUBLIC/PRIVATE OPINIONS:** Not applicable.
- b. **MARKET ACCEPTANCE/STUDIES:** Not applicable.

