Required Report: Required - Public Distribution **Date:** February 18,2020

Report Number: RS2019-0021

Report Name: Agricultural Biotechnology Annual

Country: Russian Federation

Post: Moscow

Report Category: Biotechnology and Other New Production Technologies

Prepared By:

Approved By: Deanna Ayala

Report Highlights:

On January 29, 2018, the Government of the Russian Federation issued Resolution No. 81 “On Amending the Resolution of the Government of the Russian Federation No. 839 of September 23, 2013.” The amendment “grand-fathered” registrations of feeds that were launched prior to July 1, 2017, waiving prior registration of each GE organism for such feeds. Russia continues the ban on cultivation and breeding of genetically engineered (GE) plants and animals in the Russian Federation per Federal Law No. 358-FZ of July 3, 2016. While imports of registered 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:

The Russian Federation does not allow cultivation of GE crops. However, there is no ban on imports of GE commodities, food and feed. In order to import, 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-FZ stopped development of a mechanism for registration of GE crops for cultivation. Moreover, FL No. 358-FZ 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, 15 corn lines, nine 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 finalized its draft methodological guidelines (MUK) for registration of GE lines for feed and feed additives. The document is currently pending registration by the Ministry of Justice before it can come into force, but the timeline for the registration process is unclear. However, even after the guidelines are enacted, it will take some time – possibly 2 or 3 years -- for the GE lines to be registered or re-registered.

Feed use registrations are only granted for a period of five years, and the registration periods for only two soybean lines and four corn lines are still valid, the registrations for the remaining 13 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 comes into force, the registration renewal process and timeline are unclear.

There is no information on research in the field of GE animals and cloning in Russia. Federal Law No. 358-FZ 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.)

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

a) PRODUCT DEVELOPMENT:

There is no publicly available information on the development of GE crops in Russia. Before the 2016 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, government and private sector 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. Russia prohibits cultivation of GE plants or breeding of GE animals on the territory of the Russian Federation. (For more information, see section REGULATORY FRAMEWORK in PART B of this report)

c) EXPORTS:

Russia's conventional soybean production has been steadily increasing, and the output of soybeans is expected to beat the record 4.03 Million Metric Tons (MMT) of the current marketing year (MY) to reach 4.30 MMT in MY 2019/2020. However, exports of soybeans fell by over 25 percent by volume in January-August 2019, compared to the same period of 2018, due to the drop of their production in the Far East region that is the major exporter of this item from Russia to the Chinese market. 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 2018, Russia exported 4.8 MMT, or nearly eight percent less than in calendar year (CY) 2017. In the first eight months of CY 2019 (January – August), Russia exported 1.8 MMT of corn, compared to 3.9 MMT in the same period in 2018. However, Russian corn exports are forecast to be up in MY19/20 due to a rebound in production in the main exporting regions. 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 parts of the south, Russia hopes to increase exports of soybeans in the future.

Table 1. Russia: Exports of corn, soybeans and soybean meal, CY 2014-2017 and January-August 2019 compared with January-August 2018

	2014	2015	2016	2017	2018	Jan-Aug 2018	Jan.-Aug 2019
Metric Tons							
Corn (HS[1] Number 1005)	3,418,920	3,699,473	5,334,018	5,193,641	4,787,807	3,895,877	1,832,639
Soybeans (HS Number 1201)	78,732	383,517	422,492	519,601	967,950	642,121	477,834
Soybean meal (HS number 2304)	548,037	458,247	450,814	300,486	412,618	291,232	248,980
1,000 U.S. Dollars							
Corn (HS Number 1005)	688,082	601,076	861,798	845,555	853,829	681,377	394,166
Soybeans (HS Number 1201)	23,761	119,673	133,156	168,523	292,704	199,060	149,111
Soybean meal (HS number 2304)	315,915	226,321	201,713	142,158	206,363	145,644	114,768

Source: Federal Customs Service of Russia

d) 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 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 and are "non-viable" (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 June 24, 2019, President Putin signed decree No. 293 extending Russia's ban on the import of agricultural products from the countries that applied economic sanctions against Russia, including the

[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 may be sourced from GE soybeans.

United States, until the end of 2020. The Government issued decree No. 806 of June 25, 2019, 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 and other details, please refer to GAIN report *RS1907 Russia Extended Food Import Ban through End 2020* (to download the report, please, proceed to https://gain.fas.usda.gov).

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 2014-2018 and January-August 2019 compared with January-August 2018, metric tons (MT)

	2014	2015	2016	2017	2018	Jan-Aug 2018	Jan-Aug 2019
Metric Tons							
Corn (1005)	52,728	43,844	41,124	52,640	44,182	34,685	27,520
- from the U.S.	3,986	3,435	370	0	0	0	0
Corn Groats and Meal (1103 13)	5,350	232	82	139	225	132	462
- from the U.S.	0	0	0	0	0	0	0
Corn Starch (1108 12)	18,032	13,253	14,258	11,375	4,548	2,799	2,713
- from the U.S.	0	0	1	0	1	1	0
Soybeans (1201)	2,028,163	2,179,998	2,283,314	2,236,745	2,240,089	1,471,002	1,392,903
- from the U.S.	390,008	526,171	216,018	0	0	0	0
Soybean flour (1208 10)	344	277	194	140	224	120	252
- from the U.S.	0	2	0	0	0	0	0
Soybean Meal (2304)	532,933	532,684	229,139	70,147	178,155	124,907	139,738
- from the U.S.	24,171	7,898	2,833	0	0	0	0
Soybean Isolates (from 3504)							
Total group 3504	58,711	46,245	43,485	42,199	41,785	25,985	27,947
- from the U.S.	485	120	126	168	136	88	46
1,000 U.S. Dollars							
Corn (1005)	221,429	146,812	141,308	186,285	156,318	126,646	93,740
- from the U.S.	4,071	3,202	343	0	0	0	0
Corn Groats and Meal (1103 13)	2,115	188	64	109	156	93	266
- from the U.S.	0	0	0	0	0	0	0
Corn Starch (1108 12)	11,495	7,242	6,629	6,543	4,679	3,089	3,946
- from the U.S.	1	4	6	5	11	6	0
Soybeans (1201)	1,150,758	941,890	977,489	966,059	992,624	656,608	543,362

- from the U.S.	215,294	219,849	81,541	0	0	0	0
Soybean flour (1208 10)	383	252	164	119	207	113	222
- from the U.S.	0	2	0	0	0	0	0
Soybean Meal (2304)	334,379	257,610	97,666	32,766	88,263	61,142	63,001
- from the U.S.	15,673	4,418	1,030	0	0	0	0
Soybean Isolates (from 3504)	0	0	0	0			
Total group 3504	165,381	128,136	103,990	113,068	108,315	68,889	67,734
- from the U.S.	4,618	676	764	1,124	910	574	453

Source: Federal Customs Service of Russia

e) 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.

f) 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:

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 No. 839, "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." Subsequently, the implementation of this Resolution was postponed to July 1, 2017 but was pre-empted on July 3, 2016, with adoption of FL No. 358-FZ 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 amended Russia's framework of rules for the registration of GE organisms and products derived or containing such organisms to bring Resolution No. 839 in compliance with Federal Law No. 358-FZ of July 3, 2016. For more information, please refer to the following Post GAIN reports:

- *RS1743 GOR Resolution 770 Amends Rules for Registration of GE Organisms* (to download the report, please proceed to https://gain.fas.usda.gov)
- *RS1634 Russia Bans Cultivation and Breeding of GE Crops and Animals*
- *RS1833 Russian Federation Agricultural Biotechnology Annual 2018* (to download the report, please proceed to https://gain.fas.usda.gov)

The Federal Service for Surveillance of Consumer Rights Protection and Human Welfare (Rospotrebnadzor) 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 for 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 Ministry of Agriculture and 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 a MUK for registration. As a result, a total of 13 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.

It was not until October 2019 that the Russian Ministry of Agriculture finalized its draft methodological guidelines (MUK) for registration of GE lines for feed and feed additives that it had been drafting since 2017. The document is currently pending registration by the Ministry of Justice before it can come into force, but the timeline for the registration process is unclear. However, even after the guidelines are enacted, it will take some time – possibly two or three years -- for the GE lines to be registered or re-registered.

Overall, while the guidelines were drafted in consultation with industry, it does not appear that any of the further recommended changes that were proposed following the public comment period, including by the U.S. Government, were adopted. In particular, the requirements to provide "information on the non-viability of GMOs of plant origin" and to conduct "a study on the viability of GMOs of plant origin" remained in place. Toxicological studies and reproductive toxicity studies shall be carried out on two generations (F0, F1), but in case of findings of any negative effect, the studies will be continued on generation F3. The guidelines also state that all studies in Russia "shall be carried out by an organization (testing laboratory) accredited in the national accreditation system, with the scope of accreditation corresponding to the studies specified in this methodology," however, the list of such organizations is not provided. It is unclear whether studies performed by the Institute for Nutrition for food registrations will be accepted for feed registrations.

When approved, the draft MUK will have a great impact on the development of Russian agricultural biotechnology and on trade in agricultural products as 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.

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: 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: in Russian) participates in the development of agricultural biotechnology policy together with Ministry of Economic Development and the Ministry of Science and Higher 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 No. 839 of September 2013, as currently amended (among other things, in compliance with Federal Law No. 358-FZ 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: 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 No. 839 of September 2013 (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 Government Resolution No. 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 Science and Higher Education, 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.

The Ministry of Industry and Trade of the Russian Federation (website: 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 (TR) in the EAEU, formerly known as the Customs Union (CU);

The Ministry of Economic Development of the Russian Federation (website: 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 *RS1239 Program on Development of Biotechnology in Russia through 2020;* to download the report, please, proceed to https://gain.fas.usda.gov);

The Russian Academy of Sciences (RAN) (website: 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. Between 2013 and 2018, these institutes were subordinated to the Federal Agency of Scientific Organizations (FANO), which was established as a result of the 2013 reorganization described above. However, the FANO ceased to exist in May 2018 when the Ministry of Education and Science was split into the Ministry of Science and Higher Education and the Ministry of Education (in charge of high school and other types of education except for higher education), and the head of FANO was appointed Minister of Science and Higher Education.

The Ministry Science and Higher Education (website: in Russian) is in charge of financing research in research institutes formerly being part of the three reorganized academies of sciences, to include the following institutes that conducted research in the field of agricultural biotechnology before any 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 *RS1545 Russian Federation Agricultural Biotechnology Annual 2015* (to download the report, please proceed to https://gain.fas.usda.gov.)

The Eurasian Economic Union (EAEU) (website: in Russian) 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

At present agricultural biotech policy is regulated by the EAEU Decisions – so called "technical regulations" of the CU/EAEU, Russian federal laws, government resolutions and orders of the heads of the Russian 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 (to download the reports that are not linked below, please proceed to https://gain.fas.usda.gov):

- *RS1036 Custom Union Update July 2010*
- *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*

in force as of January 1, 2019:

- *RS1752 EAEU Technical Regulation on Packaged Water*

Note: "GMO" Registration for food is carried out in compliance with the EAEU Regulation which prevails any regulations approved on the national level, for example Government Resolution No. 839.

However, "GMO" Registration for feed is implemented in compliance with Government Resolution No. 839.

The technical regulations of the EAEU are mandatory for all members of the EAEU. The summary of the EAEU technical regulations is provided in *RS1760 Russian Federation Agricultural Biotechnology Annual 2017* (to download the report, please proceed to https://gain.fas.usda.gov.)

Federal Laws of the Russian Federation

- **Federal Law No. 358-FZ of July 3, 2016** (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 No. 358-FZ 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 No. 358-FZ amends Federal Law No. 86-FZ of July 5, 1996, Federal Law No. 149-FZ of December 17, 1997, Russian Federal Code of Administrative offences, and Federal Law No. 7-FZ of January 10, 2002. (For more information on FL No. 358-FZ see FAS/Moscow GAIN report *RS1634 Russia Bans Cultivation and Breeding of GE Crops and Animals*). 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 (from around $157 to $783). The penalties for violations by judicial persons will be from 100,000 rubles to 500,000 rubles (from around $1,567 to $7,833). Federal Law No. 358-FZ has come in force in its entirety as of July 1, 2017. This law makes an exception for the cultivation and breeding of plants and animals required for scientific expertise 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.
- **Federal Law No. 86-FZ of July 5, 1996** (in Russian) "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 No. 358-FZ 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** (in Russian) "On the Sanitary-Epidemiological Well-being of the Population" (as amended);
- **Federal Law No. 29-FZ of January 2, 2000** (in Russian) "On the Quality and Safety of Food Products with amendments made in 2001 – 2008" (as amended);

- **Federal Law No. 2300-1 of February 7, 1992** (in Russian) "On the Protection of Consumer Rights" (as amended.) The amendment of October 25, 2007 set 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** (in Russian) "On Protection of the Environment" (as amended.) Amendment made by FL No. 358-FZ of July 2016, to Article 50.1 added 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 No. 149-FZ of December 17, 1997** (in Russian) "On Seed Industry" (as amended.) In particular, FL No. 358-FZ of July 3, 2016, amended the law to ban 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**, No. 195-FZ of December 30, 2001 (in Russian) (as amended.) In particular, FL No. 358-FZ amended the Code to add Article 6.3.1: "Violation of the legislation of the Russian Federation in the Area of Genetic Engineering Activity," as follows: " 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 by FL 521-FZ of December 31, 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 rubles (from $313 to $783), and for legal entities are from 100,000 to 300,000 rubles (from $1,567 to $4,700). The law also provides Rospotrebnadzor with the authority to draw up protocols on administrative violations in such cases and submit these cases for consideration of the court.

Resolutions of the Russian Government

- Resolution of the Government of the Russian Federation No. 866 of August 28, 2012 "On the Federal Executive Body Authorized to Carry out State Registration of Goods, and Repealing

Certain Acts of the Government of the Russian Federation on Issues of State Registration of Certain Types of Products" (in Russian.) The resolution authorized Rospotrebnadzor to carry out state registration of GE foods in accordance with the CU/EAEU legislation, and revoked Resolution of the Government of the Russian Federation No. 988 of December 21, 2000, which previously regulated the issue;

- Resolution of the Russian Government No. 717 of July 14, 2012 (in Russian) "On the State Program for Development of Agriculture and Regulation of Agricultural and Food Markets in 2013-2020" (as amended.) 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 (in Russian) "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" (as amended.) 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 *RS1366 Government Resolution on GMO Registration for Environmental Release* (to download the report, please, proceed to https://gain.fas.usda.gov);
- Resolution of the Russian Government No. 548 of June 16, 2014 (in Russian) "On Amendments to the Resolution No. 839 of September 23, 2013" postponed the implementation of Resolution No. 839 from July 1, 2014 to July 1, 2017. Please see GAIN Report *RS1442 GMO Registration for Cultivation Postponed* (to download the report, please proceed to https://gain.fas.usda.gov).
- Resolution of the Russian Government No. 770 of June 29, 2017 (in Russian) "On Amending the Resolution of the Government of the Russian Federation No. 839 of September 23, 2013" amended 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-FZ 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 *RS1743 GOR Resolution 770 Amends Rules for Registration of GE Organisms* (to download the report, please proceed to https://gain.fas.usda.gov.)
- Resolution of the Russian Government No. 81 of January 29, 2018 (in Russian) "On Amending the Resolution of the Government of the Russian Federation No. 839 of September 23, 2013" "grand-fathered" registrations of feed and food products, e.g. soybean meal (i.e. not "events", which are registered in Russia by the owner of the technology, e.g. MON87701) that were launched prior to July 1, 2017 (date of entry into force of Resolution No. 839). In particular, prior registration of each GE organism used in a product is not required if registration of that product was launched before July 1, 2017, provided that the registration process of the GE event (line) including molecular-genetic testing, medical and biological evaluation, sanitary and epidemiological assessment and biological safety testing was also launched before that date. As a result, the stack line MON87701xMON89788 is eligible for import.
- The second and related Resolution is, "On Amendments to GOR Resolution No. 839 dated September 23, 2013 and is essentially is an addendum to Resolution No. 839 (Rules of State registration RS1366 Government Resolution on GMO Registration for Environmental Release). Under this provision, Monsanto was able to register soybean line MON89788 and 87701 and soy line 40-3-2, two of which are used in the stacked soybean meal line MON87701xMON89788 for

feed use. 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 expired in the beginning of 2018. The certificate for GE soybean meal registered by VPSS is valid until February 12, 2023.

- 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 Provisions 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." .

Normative acts of government bodies

- Resolution of the Chief Sanitary Doctor of the Russian Federation (No 14 of November 8, 2000), 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. 366 dated July 26, 2017 on approval of regulations for VPSS on the State Registration of Genetically-Engineered-Modified Organisms Used for the Production of Feed and Feed Additives for Animals; Genetically-Engineered-Modified Organisms Used for the Production of Medicines for Veterinary Use, as well as Feed and Feed Additives for Animals Obtained Using Genetically-Engineered-Modified Organisms or Containing such Organisms. The document can be viewed here in Russian.
- Draft order of the Ministry of Agriculture approving Methodology Guidelines for Assessing the Biological Safety of GE Organisms for the Production of Feeds and Feed Additives (in Russian) that would establish a mechanism for the registration of GE feeds.

iii. GE CROPS/LINES REGISTRATION FOR FOOD AND FEED USE

Registration 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 Government Resolution No. 839. Rospotrebnadzor has developed MUK that conforms to requirements of Government Resolution No. 839. These guidelines are published on the Rospotrebnadzor website in Russian.

The registration process for food remains the same as was stated in the Annual Biotechnology GAIN reports for 2011 through 2014 (*RS1545 Russian Federation Agricultural Biotechnology Annual 2015* (to download the report, please proceed to https://gain.fas.usda.gov):

- 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 (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: 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."

Registration for Feed Use

Registration for feed use has been effectively suspended since the adoption of FL No. 358-FZ in July 2016, due to lack of a regulatory mechanism for registration of GE feeds which is yet to be finalized.

The responsibilities of VPSS in feed registration were confirmed by Order No. 366 of the Russian Ministry of Agriculture on July 26, 2017 (in Russian) "On Approving Administrative Regulation of Federal Veterinary and Phytosanitary Service for Providing Services on State Registration of Genetically-Engineered-Modified Organisms, Used for the Production of Feed and Feed Additives for Animals; 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."

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, which 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: in Russian. The List of Registered GE feed is provided here (in Russian).

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 the 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 to 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 plus customs clearance and other fees, but averages around 6.3 million rubles (approximately $99,000) 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 ($313).

For registration of biotech events for feed use, VPSS usually registers an event only after it has been approved for food-use. On average, the past charges for examination and a five-year event registration for feed use was 4.5 million rubles (approximately $70,500). The charge for re-registration of the event every five years was 3.8 million rubles (approximately $59,500). Fees will be updated under the new Methodological Guidance. Companies that import formula feed with registered biotech components also need to register this feed as GE feed. The registration is given to the company that imports this feed and VPSS requires that each feed containing a registered GE event must also be registered.

iv. 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 Government Resolution No. 839 and its amendments. While Rospotrebnadzor has developed regulatory mechanisms for registration and monitoring of GE plants, products for food use, the Ministry of Agriculture is yet to finalize its regulatory mechanism within the current framework for feed registration.

b) APPROVALS:

Table 3. Russia: Approved and Registered Biotech Crops, 1999-2019 (As of October 2019)[2]

	Crop/line/event/trait	Applicant	Year and period of Registration	
			For Food Use[3]	For Feed Use
1	Bt corn MON 810, resistant to European corn borer *Ostrinia nubilalis*	Legacy Monsanto	2000 – 2003, 2003 – 2008 ar. 2009 – for unlimited period	2003 – 2008 Sep. 2008 – Aug. 2013 Aug. 2013 – Sep. 2018
2	Roundup Ready® corn NK 603, tolerant to glyphosate	Legacy 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 (*Diabrotica spp.)*	Legacy Monsanto	2003 – 2008 Aug. 2008 – for unlimited period	Was registered 2003-2013
4*	Corn Bt 11, tolerant to gluphosinate and resistant to corn borer Ostrinia nubilalis	Syngenta	2003 – 2008 Sep. 2008 – for unlimited period	Dec. 2006 – Dec. 2011, Dec. 2011 – Dec. 2016 Jan. 2017 – Jan. 2022
5*	LL Corn T25, tolerant to gluphosinate	Legacy 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	Syngenta	2007 – for unlimited period	Nov. 2007 – Nov. 2012; Nov. 2012 – Nov. 2017

[2] Crop/lines marked with asterisk (*) are currently registered.
[3] The food registrations are valid in the "Customs Union of the Republic of Belarus, Republic of Kazakhstan and the Russian Federation".

	glyphosate*			
7	Corn MIR 604, resistant to corn root worm (Diabrotica 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 (*Diabrotica spp.*)	Legacy Mo19nsanto	May 2007 – for unlimited period	Sep. 2008 – Aug. 2013; Sep. 2013 – Sep. 2018
10	Corn MON 89034, resistant to Lepidoptera pest	Legacy 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 1212 – March 2017 Jan. 2017 - Jan. 2022
12	Corn 5307, resistant to corn root worm (*Diabrotica II*, *Coleoptera*)	Syngenta	Apr. 2014 – for unlimited period	Apr. 2014 – Apr. 2019
13	Roundup Ready® soybeans 40-3-2, tolerant to glyphosate	Legacy Monsanto	1999 – 2002, 2002 – 2007, Dec. 2007 - for unlimited period	2003 – 2008, May 2008 – May 2013 May 2013 – May 2018
14	Bt soybeans, MON 87701, resistant to Lepidoptera pests	Legacy Monsanto	May 2013 – for unlimited period	Jul. 2013 – Jul. 2018
15*	Soybean MON 89788 (RRS2Y), tolerant to glyphosate + yield gain	Legacy Monsanto	Jan. 2010 – for unlimited period	May 2010 – May 2015 Oct. 2015 – Oct. 2020
16	Liberty Link® Soybeans A2704-12, tolerant to gluphosinate	Legacy Bayer Crop Sciences	2002 – 2007 Feb. 2008 – for unlimited period	Nov. 2007 – Nov. 2012 Nov. 2012 – Nov. 2017
17	Liberty Link® Soybeans A5547-127, tolerant to gluphosinate ammonium	Legacy Bayer Crop Sciences	2002 – 2007 Feb. 2008 – for unlimited period	Nov. 2007 – Nov. 2012 Nov. 2012 – Nov. 2017
18*	Soybeans FG72, tolerant to isoxaflutole and glyphosate	Legacy 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
20	Soybeans SYHT0H2,	Syngenta	Jan. 2016 – for	Apr. 2013 – Apr. 2019

	herbiside HPPD* + glufosinate	(Producers Syngenta /Bayer)	unlimited period	
21	Rice LL62, tolerant to gluphosinate ammonium	Legacy Bayer Crop Sciences	2003 – 2008 Jan. 2009 – for unlimited period	X
22	Roundup Ready ® Sugar beet H7-1, tolerant to glyphosate	Legacy 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 87708 (Dicamba)	AO Bayer	July 2019 – for unlimited period	Submission upon resumption of registrations for feed
26	Corn MZHG0JG Tolerant to glyphosate and glufosinate ammonium	Syngenta	March 2018 – for unlimited period	Not submitted
27	Corn MZIR098 Resistance to Diabrotica and tolerance to glufosinate ammonium	Syngenta	Under review. Submitted in 2015	Not submitted
28	Corn 1507 resistance to certain Lepidoptera pests and tolerance to glufosinate	Pioneer Hi-Bred Interntational & Dow AgroSciences	March 2018 – for unlimited period	Not submitted
29	Corn DAS 40278-9 tolerant to herbicide 2,4 D	Dow AgroSciences	March 2019 – for unlimited period	Not submitted
30	Soybeans MON 87701 x MON 87708 (Intacta), tolerant to glyphosate and lepidopteran pests	AO Bayer	July 2019 – for unlimited period	Submission upon resumption of registrations for feed

*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

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 No. 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. The proposed Methodological Guidance does not include a process for registering a "stack" and therefore in practice each individual event would need to be registered and the stack itself would need to be registered for feed use.

It is worth noting that the Russian importer 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, registration for soybean meal with this line was granted;

2) Soybeans genetically modified with the line 40-3-2, glyphosate resistant.

Currently draft methodological guidelines for GE crops/lines for feed use have 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 No. 358-FZ 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 (from around $157 to $783) for individual entrepreneurs, and from 100,000 rubles to 300,000 rubles (from around $1,567 to $7,833) 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. 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 Eurasian Economic Union, above.

In 2017, the EAEU amended Technical Regulation of the CU "On Food Products Labeling" (TR TS 022/2011) to specify 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. The EAEU established an 18 months transition period for the amendment allowing companies during this transition period 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. The transition period is set to expire by mid-2020.

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 Eurasian Economic Union, 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 section Responsible Government Ministries in Part B, Regulatory Framework, 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, in Russian) 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 section Responsible Government Ministries above). Thus, this GE testing requirement for planting seeds may hinder the process of registration of new varieties of planting seeds in Russia, which already takes at least 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 that 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 or feed additives based on 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/EAEU 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.[4] 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 No. 358-FZ 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.

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:

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 lack of consumer awareness and understanding of GE technology 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. Further, GE commodities used for feed do not face the same end-use consumer considerations.

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

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

that domestic production is cleaner than some imported products. However, there has not been any regulatory frame for developing organic industry. On August 3, 2018, 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. Currently, only one certifying body is accredited[5]. Also, rules governing certification of imported organic products need further clarification.

b) 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 few years there has been no information on the continuation of this research.

Since 2002, Russia has reportedly been involved in a bilateral partnership project with Belarus raising transgenic goats as a step in the development of medicines exploiting the antibiotic qualities of lactoferrin, a protein found in women's milk, which can be added to goat's milk through genetic modification of the goat. From the Russian side, the Institute of Gene Biology of the Russian Academy of Sciences was in charge of the joint project, financed by the Union State of Russia and Belarus via "BelRosTransgen" and "BelRosTransgen-2" programs in 2003-2006 and 2009-2013, respectively. In late 2007, the first two male goats with the human lactoferrin gene incorporated into their DNA were born on a biotechnological farm in Belarus. By early 2010, transgene goats produced milk with the same – or higher – amounts of lactoferrin than found naturally in human breast milk. After Union State financing stopped in 2013, further

5

research and development of lactoferrin products was carried out in Russia by a private company of the same team of researchers who were originally involved in the bilateral project. In Belarus, further research and development has been financed by the government. Since late 2016, an experimental facility to make human lactoferrin out of milk produced by transgenic goats has been operating in the Microbiology Institute of the National Academy of Sciences of Belarus in Minsk. Most recently, press reports indicated that Russia and Belarus were currently developing the concept of the "BelRosTransgen-3" program with the goal of marketing products based on lactoferrin from transgenic goats.

Given the public policy prohibiting production of GE plants in Russia, additional 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 - 2020 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.

MARKET ACCEPTANCE/STUDIES: Not applicable

Attachments:

No Attachments